Assessing the Effectiveness of Non-Pharmacologic Interventions for Older Patients Experiencing Chronic Pain

The Harvard community has made this article openly available. Please share how this access benefits you. Your story matters

<table>
<thead>
<tr>
<th>Citation</th>
<th>Majzoub Perez, Katherine. 2016. Assessing the Effectiveness of Non-Pharmacologic Interventions for Older Patients Experiencing Chronic Pain. Doctoral dissertation, Harvard Medical School.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citable link</td>
<td><a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:40620278">http://nrs.harvard.edu/urn-3:HUL.InstRepos:40620278</a></td>
</tr>
<tr>
<td>Terms of Use</td>
<td>This article was downloaded from Harvard University’s DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA">http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA</a></td>
</tr>
</tbody>
</table>
Scholarly Report submitted in partial fulfillment of the MD Degree at Harvard Medical School

Date: 1 March 2016

Student Name: Katherine Majzoub Perez, MPP

Title: Assessing the Effectiveness of Non-pharmacologic Interventions for Older Patients Experiencing Chronic Pain

Mentor: Darshan Mehta, MD, MPH, Benson-Henry Institute for Mind Body Medicine, Massachusetts General Hospital

Collaborators: Kathleen Miller, RN, MA, PhD, AHN-BC, Massachusetts General Hospital Wellness Center at Revere Health Care Center, and Hui Zheng, PhD, Biostatistics Center at Massachusetts General Hospital
ABSTRACT

Title: Assessing the Effectiveness of Non-pharmacologic Interventions for Older Patients Experiencing Chronic Pain

Purpose: To review the literature regarding the effectiveness of opioids and non-pharmacologic interventions in alleviating chronic pain and to examine the effectiveness of a pilot program at a community health center that used a multimodal, non-pharmacologic strategy to manage pain experienced by low-income adults over the age of 50.

Methods: A review of the literature was conducted in February 2016 using the PubMed database. From September 2012 until May 2013, the Benson Henry Institute’s Wellness Center at MGH Revere HealthCare Center offered the Moving With Ease program, which provided low-cost, non-pharmacologic treatments for chronic pain, including massage, acupuncture, yoga, and relaxation training, to 25 low-income patients over the age of 50. Primary outcomes were self-reported pain, depression score, and self-perceived stress, as measured by the Brief Pain Inventory (BPI), the Patient Health Questionnaire (PHQ-2), and the Perceived Stress Scale (PSS). Differences between pre- and post-program scores were analyzed using paired t-tests with \( p < 0.05 \). In addition, semi-structured interviews were conducted to further understand participants’ experiences.

Results: The literature review found that there is insufficient evidence to evaluate the long-term efficacy of opioid and integrative treatments for chronic pain, especially in older adults, and that there are significant harms associated with opioid-based treatments. Pilot study data was collected from all 25 patients; 10 patients were interviewed about their experiences with the Moving With Ease program. Participant ages ranged from 52 to 88 years, with a mean age of 70 years; 16 of the 25 participants were women. Improvements were observed in some scores but there were not statistically significant improvements between participants’ pre- and post-program scores on the BPI, PHQ-2, or PSS. The analysis of the qualitative data suggests that patients’ perceived benefits from participating in the program are notable, and in several cases, life-changing.

Conclusions: There remains uncertainty about the efficacy of treatments for chronic pain and how to tailor them to individual patients. The quantitative results of the pilot study suggest that the intervention was effective in reducing pain, however the findings were non-significant. Participants’ qualitative descriptions of the benefits of the program further indicate that a multimodal integrative approach may be effective for older patients experiencing chronic pain. Limitations of the approach include its small sample size and possible response bias, since not all participants were available to be interviewed.
### Glossary of Abbreviations

- BHI: Benson-Henry Institute
- CAM: Complementary and Alternative Medicine
- CNCP: Chronic non-cancer pain
- RCT: Randomized controlled trial
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>2</td>
</tr>
<tr>
<td>GLOSSARY OF ABBREVIATIONS</td>
<td>3</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>5</td>
</tr>
<tr>
<td>LITERATURE REVIEW</td>
<td>6</td>
</tr>
<tr>
<td>Methods</td>
<td>6</td>
</tr>
<tr>
<td>Current Guidelines</td>
<td>6</td>
</tr>
<tr>
<td>Evaluating the Efficacy of Opioids for the Treatment of Chronic Pain</td>
<td>7</td>
</tr>
<tr>
<td>Efficacy of Opioids for the Treatment of Chronic Pain</td>
<td>7</td>
</tr>
<tr>
<td>Adverse Effects Associated with Opioid Treatments</td>
<td>9</td>
</tr>
<tr>
<td>Evaluating the Efficacy of Integrative Treatments for Chronic Pain</td>
<td>10</td>
</tr>
<tr>
<td>Efficacy of Selected Integrative Treatments for Chronic Pain</td>
<td>11</td>
</tr>
<tr>
<td>Placebo Effects and Chronic Pain</td>
<td>14</td>
</tr>
<tr>
<td>Conclusion</td>
<td>15</td>
</tr>
<tr>
<td>STUDENT ROLE</td>
<td>15</td>
</tr>
<tr>
<td>PILOT STUDY: MOVING WITH EASE</td>
<td>16</td>
</tr>
<tr>
<td>Methods</td>
<td>16</td>
</tr>
<tr>
<td>Results</td>
<td>18</td>
</tr>
<tr>
<td>Discussion</td>
<td>20</td>
</tr>
<tr>
<td>Limitations</td>
<td>21</td>
</tr>
<tr>
<td>Conclusion</td>
<td>21</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>22</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>23</td>
</tr>
<tr>
<td>TABLES AND FIGURES</td>
<td>27</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>41</td>
</tr>
<tr>
<td>APPENDIX A: Definitions of Substance Dependence and Substance Abuse</td>
<td>41</td>
</tr>
<tr>
<td>APPENDIX B: Guiding questions for semi-structured patient interviews</td>
<td>43</td>
</tr>
</tbody>
</table>
INTRODUCTION

The National Academy of Medicine’s Committee on Advancing Pain Research, Care and Education introduced a 2011 report with the statement, “…there is crisis in the impact of and response to pain in America.”(1) Indeed, low back pain is thought to be the main reason for disability adjusted life years worldwide(2) and 40-50% of adults over the age of 60 have at least one chronic pain condition.(3) Furthermore, a 2005 survey of over 100 primary care providers in the United States estimated that 37.5% of adult primary care visits are related to chronic pain.(4) In 2011, the National Academy of Medicine calculated that 100 million US adults experience chronic pain, costing the nation between $560 and $635 billion dollars per year.(1) Those figures are likely even higher today as the population continues to age.(1)

A common definition of chronic pain is, "pain without biological value that has persisted beyond the normal time and despite the usual customary efforts to diagnose and treat the original condition and injury."(5) By definition, therefore, chronic pain is an ailment that has failed treatment. Unsurprisingly, it frustrates both physicians and patients. A survey of over one thousand primary care physicians in Europe found that 84% of them consider non-cancer chronic pain to be one of the most difficult conditions to treat, and that it is largely under-addressed in primary care.(6) Similarly, chronic pain syndromes are commonly considered to be one of the conditions associated with “difficult” patients, i.e., clinical interactions that make a physician feel frustrated and unable to help a patient.(7)

Beginning in the mid-1980s, synthetic opioid medications seemed to offer a promising solution to the problem of chronic pain.(8)(9)(10) This trend was reinforced by a statement from the American Pain Society and the American Academy of Pain Medicine in 1996 that opioids had low potential for addiction and were appropriate for the treatment of chronic non-cancer pain.(8) As prescriptions for opioids increased, so too did rates of opioid diversion and overdose deaths.(11) In Massachusetts, for example, over 1,000 people died due to opioid-related causes in 2014, which is more than double that number ten years prior.(12) At the same time, the evidence for the use of opioids for chronic pain began to become less clear as RCTs produced negative and equivocal results regarding their long-term efficacy.(13)(2) Today, opioids are widely considered to be a mainstay of chronic pain treatment, despite limited evidence of their long-term efficacy, known adverse effects, and widespread concerns about growing rates of addiction and overdose deaths.(5)(8)(14)

Due to amplified awareness about the negative aspects of opioids, recent years have seen increased interest in exploring non-pharmacologic approaches to pain management, especially for older patients.(3)(15) This age group is of particular interest given its higher prevalence of chronic pain but less frequent treatment for it.(15,16) In addition, there are several challenges to treating older adults in pain. First, clinical trials are often limited to younger, healthier participants, so it can be unclear whether
published evidence is applicable to elderly patients. Secondly, older adults have increased sensitivity to the adverse effects of many drugs; they are both more likely to have compromised drug metabolism due to liver or kidney insufficiency, and also to have a higher risk of drug interactions due to polypharmacy.

This report begins by reviewing the literature describing common pharmacologic and non-pharmacologic approaches to chronic pain in the primary care setting. It then evaluates the effectiveness of a pilot program that offered a multidisciplinary, non-pharmacologic intervention to low-income patients over 50 years of age who were experiencing chronic pain.

LITERATURE REVIEW

Methods

A review of the English-language literature in the PubMed database was conducted in February 2016 using the MeSH Term “chronic pain” and Title/Abstract “opioid” “opiate” “non-pharmacologic” “CAM” “integrative” “acupuncture” “yoga” “massage” “tai chi” or “relaxation response.”

Current Guidelines

Recent guidelines on the management of chronic non-cancer pain (CNCP) include those produced by the American Academy of Pain Medicine (2009, 2013),(19)(20) the American Pain Society (2009),(20) the Scottish government (2013),(21) the Institute for Clinical Systems Improvement (2013),(5) and the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine (2010).(22) All guidelines highlight the importance of a multi-pronged approach, which might include using a biopsychosocial model to evaluate chronic pain and/or employing a multimodal approach to treat pain.(5)(19)(20)(21)(22) The high incidence of psychiatric comorbidities and chronic pain is highlighted by multiple guidelines, which emphasize that treating concomitant psychiatric conditions can improve pain outcomes.(5)(21) In addition, several guidelines emphasize that non-opioid pharmacologics such as gabapentin, tricyclic antidepressants, and NSAIDs should be tried in advance of opioids, in acknowledgement of the unclear benefits and proven harms associated with the use of opioids.(5)(14)(20) Several guidelines recommend combining complementary, interventional, and pharmacologic approaches that vary depending on the type of pain, i.e. neuropathic, musculoskeletal, inflammatory, or mechanical/compressive.(5)(22) Of the five guidelines that were reviewed, two emphasized that there is not adequate evidence to make definitive recommendations about the optimal treatment of chronic pain.(20)(21)
Evaluating the Efficacy of Opioids for the Treatment of Chronic Pain

As highlighted in the treatment guidelines produced by the Scottish government and the combined efforts of the American Academy of Pain Medicine and the American Pain Society, a significant challenge of treating chronic pain is the poor evidence base for the efficacy of most common interventions. (20)(21) This is in part due to the nature of chronic pain, which has different underlying mechanisms depending on the individual, and therefore will produce different responses to the same treatment. (21) In addition, there is debate about the proper endpoints with which to evaluate chronic pain treatment efficacy; often chronic pain itself cannot be eliminated, so perceived pain rating, quality of life and functional status have all been suggested as alternate measures of success. (23) The IMMPACT guidelines attempt to standardize outcomes used in studies assessing treatments for pain. They recommend considering six aspects when evaluating the efficacy of an intervention, including: (1) pain; (2) physical functioning; (3) emotional functioning; (4) participant ratings of improvement and satisfaction with treatment; (5) symptoms and adverse events; and (6) participant disposition. (23)

Another limiting factor is that most clinical trials evaluating opioids are limited to 6 weeks or less, making their results not as applicable to actual practice, where patients will often take medications for months, if not years. (14) Different types of study designs such as enriched enrollment, comparison with an active drug versus a placebo, and parallel versus crossover design also impact interpretation of outcomes and threaten generalizability of findings to clinical settings. (2) Finally, pain studies have high dropout rates due to both intolerable adverse effects and perceived lack of efficacy of treatments. (24) How study authors include these dropouts in their final analysis can affect perceived efficacy and the relevance of outcomes to clinical settings. (2)(9)(21)

Efficacy of Opioids for the Treatment of Chronic Pain

Given the limitations described above, there is heterogeneity in both methods and outcomes of studies that assess the effectiveness of opioids for chronic pain. One of the most recent and thorough assessments is a 2013 Cochrane Collaborative systematic review of the efficacy of opioids compared to other treatments or placebo for chronic low back pain when used for four weeks or longer. (2) Based on the fifteen RCTs that were included in the review, the authors conclude that there is very low to moderate quality evidence that opioids reduce pain and improve function when compared to placebos. (2) The authors note that the studies they assessed often included enriched enrollment, which under-report adverse effects. (2) In addition, the paper highlights that the studies universally assessed short-term opioid use (<15 weeks), and had high dropout rates (>20%), which threatened the validity of reported outcomes for two reasons: 1) the studies were at risk for being under-powered with fewer participants and 2) the authors felt
that the “intention to treat” calculations were performed incorrectly in several of the studies. (2) Other publications have pointed out that intention-to-treat analyses can bias results in favor of the intervention (i.e. opioid use) since the last observation is carried forward even if in reality the patient has dropped out and is not receiving pain relief. (24)

Clinical significance is arguably just as important as statistical significance when considering the results of RCTs. A 2005 analysis of published and unpublished RCTs examining the efficacy of opioids found that on average, the absolute improvement in pain rating for patients in the opioid group on a zero to ten scale was approximately one. (25) It is difficult to assess the clinical impact of a one-point change since it has different levels of importance to different people. (26) In addition, it has been suggested that a change from a rating of one to zero is of different importance than a change from ten to nine. (26) A review of three studies analyzing clinically significant changes in pain on the ten point scale suggest that a pain score decrease of one point (or percentage changes of 15-20%) represent “minimally important but perhaps not very important” improvements. (26)

Another factor that challenges the clinical significance of opioid RCTs is the endpoint that is used. Sullivan and Howe point out that in many trials, function is limited to a particular body part (e.g. grip strength), however in clinical practice, what often matters to patients is ability to perform daily activities or return to work. (8) They review seven prospective studies suggesting that injured workers who receive opioid treatment for pain are less likely to return to work than are workers with similar levels of initial pain who do not receive opioids. (8) Similar findings have been observed in the Women’s Health Initiative Observational Cohort study. (8)

Finally, the short duration of most opioid RCTs is not applicable to many situations in clinical practice: a 2015 review of the effectiveness of long-term opioid therapy for the treatment of chronic pain found that there has not been a study published evaluating the long-term (>1 year) effects of opioid therapy on measures such as pain, function, quality of life, opioid abuse, or addiction. (14)

**Opioid efficacy in older adults**

A meta-analysis of the safety, efficacy, safety, and abuse potential of opioids as treatment for chronic non-cancer pain in adults over the age of 60 found an improvement in pain rating and physical disability but a decline in mental health when opioids were used to treat chronic pain. (3) A median of 25% of patients discontinued opioid treatment due to adverse effects (range 3-52%). (3) Among the head-to-head comparisons included in the meta-analysis, none suggested superiority of opioids over non-opioid pharmaceuticals. (3)
Adverse Effects Associated with Opioid Treatments

Systematic reviews have noted high dropout rates in RCTs of opioids, however dropout rates are not often analyzed as an endpoint in themselves.(24) A 2011 meta-analysis specifically assessed dropout rates in clinical trials for the use of opioids for osteoarthritis analgesia and found that among 19 trials, 38% of people receiving placebos dropped out and an even greater percentage of people receiving opioid treatments dropped out (p<0.0001, OR=1.315, 95%CI 1.197–1.445).(24) Patients in the opioid group were far more likely to drop out due to adverse events than were patients in the placebo group (OR=3.958, 95%CI 3.433–4.564; p<0.0001), and studies with stronger opioids resulted in higher dropout rates.(24) On the other hand, patients receiving placebos were more likely to drop out due to insufficient analgesia (OR=0.398, 95%CI 0.347–0.456, p<0.0001).(24) While the authors calculated a statistically significant effect size of pain reduction with opioid use, they conclude that “opioids do not increase the wellbeing of osteoarthritis patients in general” due to the high burden of adverse effects and they recommend that in most cases opioids should not be used for pain relief in osteoarthritis.(24) Similarly, the Scottish Intercollegiate Guidelines Network points out that high dropout rates in opioid trials due to adverse effects suggests that these treatments will not translate smoothly into clinical practice.(21)

A 2015 review of the effectiveness of long-term opioid therapy for the treatment of chronic pain identified “fair-quality” observational studies that highlight many adverse effects associated with long-term opioid therapy, including increased risk for overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction.(14) The 2013 Cochrane review of opioid treatment for low back pain found that people taking opioid versus placebo pills had statistically significant higher incidences of nausea (10% increase), dizziness (8% increase), constipation (7% increase), vomiting (7% increase), somnolence (6% increase), and dry mouth (6% increase).(2) Other adverse effects that have been identified in the literature include headache, fatigue, lethargy, and urinary hesitancy/disturbance.(21)

The risks of adverse events is heightened for older adults since this population is often underrepresented (or excluded) from the RCTs that are used to evaluate the safety and efficacy of medications.(18) Furthermore, those older adults who are included in RCTs rarely represent the typical older adult with chronic pain, since study participants need to have limited comorbidities and be mobile enough follow study protocols.(27)

ADDITION/DEPENDENCE: The addictive potential of opioids is a serious adverse effect of opioid medications. A 2015 systematic review of the literature found poor quality evidence (10 uncontrolled studies and one cohort study) reporting variable rates of opioid abuse or dependence in the primary care setting, ranging from 0.6% to 8% rates of abuse and 3% to 26% rates of dependence (based on DSM IV criteria, see Appendix A).(14) Part of this variation might be explained by whether patients with a history
of substance use disorder or mental illness were included in trials, since both of these groups of patients are more susceptible to developing substance use disorders. (8) Epidemiologic trends suggest that the increased incidence of opioid prescribing has led to an increase in opioid addiction, however this does not prove a causal relationship. (11) Multiple retrospective and prospective studies have found that there is decreased risk of opioid misuse in patients over the age of 60. (3)

**OVERDOSE/RESPIRATORY DEPRESSION**: Respiratory depression and subsequent death are likely opioid prescribers’ most feared side effect. This concern is well-founded; a recent systematic review of the literature cites a retrospective cohort study reporting that recent opioid users have a notably increased risk for a serious overdose event when compared to opioid non-users (adjusted hazard ratio 8.4 [CI 2.5 to 28]). (14) Other analyses suggest that risk of overdose increases with increased dose of opioids. (14) This is in part because patients do not develop full tolerance to the respiratory effects of opioids, as well as due to other factors that compromise oxygenation such as concomitant alcohol or benzodiazepine use, or medical problems such as asthma or pneumonia. (19)

**FRACTURE**: A 2015 systematic review found “some evidence” that opioid use increases the risk of hip, humerus, or wrist fracture, (14) while a cohort study of over 2000 patients age 60 and older found that the risk of fracture doubled for patients on long-term opioid therapy of greater than 50 mg when compared to patients not taking opioids. (28) Fractures of the hip or pelvis were the most common type of fracture (34%), suggesting significant morbidity and mortality. (28) The authors postulated that fractures may be increased due to either falls that result from lightheadedness or because of direct effects of opioids on bone mineral density. (28) The authors acknowledged that the strength of their findings was limited due to inability to control for baseline bone mineral density, pain intensity, and gait of the patients they evaluated. (28)

**Evaluating the Efficacy of Integrative Treatments for Chronic Pain**

Non-pharmacologic treatments for chronic pain include exercise, psychological therapies, ultrasonography, laser therapy, spinal manipulation, heat therapy, transcutaneous electrical nerve stimulation (TENS) and modalities traditionally considered to be in the category of integrative medicine, including yoga, massage, tai chi, and acupuncture. (29)

This review will focus on interventions in this latter category, integrative medicine, which is sometimes also referred to as complementary and alternative medicine (CAM). The evidence for the efficacy of integrative medical interventions varies, in part due to challenges that arise when trying to assess non-pharmacologic modalities with methods that were designed to assess the efficacy of pharmaceuticals. (30) For example, many integrative medical therapies are difficult to “blind” since they
involve hands-on interventions, e.g. acupuncture and massage. (30) By necessity therefore many RCTs evaluating integrative medical interventions are comparative effectiveness studies rather than placebo-controlled. While non-traditional for biomedicine, these comparative inquiries may be more relevant to clinical practice since it is rare for a clinician to be deciding between treatment and no treatment; more often the question is which treatment. Another challenge of evaluating integrative medical therapies is that there is great heterogeneity within each category of therapy, for example Vinyasa, Iyengar, and Yin yoga are all very different forms of yoga with potentially different effects on chronic pain. (31) There can also be great variety in the skill and approach of practitioners of these modalities, which rely heavily, if not entirely, on the practitioner as the producer of the therapy itself, e.g. massage.

Despite these challenges, patients frequently use integrative approaches to address their pain, and there have therefore been many attempts to understand their efficacy. The 2007 National Health Interview Survey estimate that of the 38% of US adults who had used CAM in the past year, approximately 31.7% of them had done so to treat some type of pain (back, neck, joint, or arthritis). (32) CAM use may be even more prevalent among people who are actively taking opioids for chronic pain; a 2007 survey of 908 people in this population found that 44% of them had received a CAM intervention within the past year. (33) Among this group, educated women with higher incomes were more likely to have used CAM, and massage was the most popular modality (27.3%). (33) Ninety-one percent of people in this study who used massage, and more than 80% of people using yoga or chiropractic therapy found them to be helpful. (33) Another cross-sectional survey of more than 400 primary care patients with chronic pain found that 52% used CAM to manage their pain. Sixty-eight percent of these patients felt that the CAM intervention either relieved (14%) or helped (54%) their pain. (34)

Efficacy of Selected Integrative Treatments for Chronic Pain

This review will focus on the integrative modalities used in the Moving With Ease pilot study, including yoga, acupuncture, massage, the relaxation response, and tai chi. Studies that evaluated individual therapies as well as multimodal approaches will be reviewed.

Multimodal interventions

A 2013 prospective observational pilot study is one of a few studies of personalized, multimodal, integrative approaches to chronic pain treatment. (35) Sixty-six percent of participants completed the 24-week study, which took place at nine clinics across the United States. Therapies were chosen based upon individual presentations and preferences. Forty-seven percent of participants were treated with acupuncture, 21.0% with manual therapy, 11% with “mind-body” techniques, 10.3% with integrative medicine consults, 4.9% with exercise, and 2.5% with yoga. Participants were responsible for the financial
costs of these interventions. Outcomes were a 23% reduction in pain severity scores and a 28% reduction in pain interference scores (as measured by the Brief Pain Inventory; \( p<0.001 \) for both score reductions). Weaknesses of the study were that it did not describe these interventions in detail (and implies that they may have varied significantly between sites) and that there was not a control group. The authors postulated that the patients with the best responses were those with higher pain interference scores at baseline, fewer years of chronic pain, and non-Hispanic ethnicity.(35)

A 2014 pilot study of integrative medicine-focused group visits for low-income people experiencing chronic pain also had positive results. The study included 65 participants and found statistically significant improvements in pain intensity, depression, sleep quality, perceived stress.(36)

**Combined reviews**

A few manuscripts evaluate multiple types of integrative medical interventions within one systematic review.

A 2012 review of eleven studies of seven distinct types of interventions (including acupuncture, static magnets, meditation, autogenic training, healing therapy, tai chi and progressive muscle relaxation) for chronic pain due to rheumatoid arthritis concluded that the interventions did not improve pain better than did usual care, a sham intervention, or being on a waitlist.(37) These conclusions were limited by small sample sizes; only two of the seven modalities were evaluated by more than one study, and all studies consisted of fewer than 60 participants.(37)

An earlier review (2007) analyzed the effect of CAM interventions on patients with chronic pain who were 50 years old or greater. Based on the results of 20 studies that evaluated one or more interventions, the authors concluded that there was insufficient evidence to make conclusions about efficacy, and that CAM interventions could be modified to be feasible and safe for older adults.(38)

A review of the evidence for using non-pharmacologic therapies to reduce pain and disability in chronic low back pain that was commissioned by the American Pain Society and the American College of Physicians found that there is “good” evidence of the efficacy of exercise, cognitive behavioral therapy, spinal manipulation and interdisciplinary rehabilitation, and “fair” evidence for acupuncture, massage, and yoga. The authors also concluded that there was poor reporting of harms across studies and that it remains unclear how to best tailor therapies to individual patients.(29)

**Yoga**

In recent years yoga has been perceived as an increasingly acceptable intervention for the management of chronic pain. A 2013 systematic review and meta-analysis of the use of yoga for low back pain found that when combining the data of eight RCTs, yoga was found to have a significantly positive effect on back pain in both the short-term (effect size 0.48, \( p<0.01 \)) and the long-term (effect size 0.33,
p=0.01). (31) An RCT comparing yoga to usual care for recurrent low back pain found that the yoga group had significantly improved functionality and disability (RMDQ) scores, as well as higher levels of dropout due adverse effects (increased pain). (39) This latter finding highlights the importance of considering that non-pharmacologic treatments can also have adverse effects. Despite the growing evidence that yoga can benefit chronic pain, data is lacking about the efficacy, feasibility, and safety of yoga-based interventions for older adults. (16)

**Acupuncture**

The Institute for Clinical Systems Improvement’s (ICSI) 2013 guidelines for the management of chronic pain highlight that there is high quality evidence for the use of acupuncture for the treatment of fibromyalgia, but that evidence for other chronic pain conditions is less robust. (5) A 2010 systematic review of the evidence for using acupuncture to alleviate chronic pain summarized the results of eight meta-analyses published between 2003 and 2008 and concluded that there is evidence that in the long term (6-12 months), acupuncture was better than sham acupuncture for knee pain and tension headache, and that in the short term (less than 6 months), acupuncture was superior for knee pain, back pain, and headache. (40) While these findings were statistically significant, the effect sizes ranged from 0.13 for one of the knee pain studies to 0.61 for one of the back pain studies, suggesting variable clinical significance. (40) The largest RCT to date for the evaluation of acupuncture for low back pain (3000 participants) found that acupuncture significantly improves low back pain when compared to conventional treatment. (1) The Scottish Intercollegiate National Guidelines conclude that acupuncture should be considered for patients experiencing chronic low back pain or osteoarthritis given that it offers short term relief and leads to few adverse effects. (21)

**Massage**

The ICSI guidelines for the treatment of chronic pain note that there is moderate to high quality evidence that massage can lower pain scores for patients with low back pain, knee osteoarthritis, juvenile osteoarthritis, and fibromyalgia. (5) They point out that the optimal “dose” of massage remains unclear (5) and other authors highlight that there has not been a study evaluating the efficacy, feasibility, or safety of massage for older adults with chronic pain. (16)

**Tai chi**

A 2009 systematic review of the use of tai chi for chronic musculoskeletal pain conditions concluded that although there is very limited high quality data in this area, tai chi seems to offer a small positive effect on pain and disability in people with arthritis. (41) A Cochrane Review of tai chi for
rheumatoid arthritis that included four RCTs found that tai chi improved range of motion but did not have significant effect on activities of daily living, pain, and subjective global assessment of health.(42)

Relaxation training

Relaxation training is used in the literature to encompass stress-reduction, mindfulness, and progressive mental relaxation.(43) In the context of the pilot intervention described below, however, relaxation training more specifically represents teaching patients how to elicit the “relaxation response,” a mental and physical state defined by Herbert Benson in 1974 as the opposite of “fight-or-flight.”(44)

There have been very few studies assessing the efficacy of teaching the relaxation response for the alleviation of chronic pain. A 2010 RCT compared the efficacy of relaxation training, cognitive behavioral therapy (CBT), and patient education in reducing pain, improving function, and decreasing rates of anxiety and depression for patients with rheumatoid arthritis.(45) After 12 months, both the relaxation training and patient education groups had significant decreases in pain, and overall symptoms improved significantly for patients in the CBT and patient education groups.(45) Changes in all other measures, including anxiety and depression, were not significant.(45)

Placebo Effects and Chronic Pain

It is notable that RCTs that fail to demonstrate efficacy of both pharmacologic and non-pharmacologic interventions often fail not because the treatment has no absolute effect but rather because its relative effect when compared to placebo is not significant. In other words, patients in the placebo arms of these trials are experiencing relief from pain on par with the relief experienced by patients receiving the active treatment. For example, a 2015 metaanalysis of nine studies evaluating analgesics the treatment of chronic pain over 12 weeks found that the average placebo response (on a 0-10 scale of pain intensity) in trials of opioids was a reduction of 22.5 (CI: 17.5-27.4) points.(46) Factors which seemed to increase the placebo effect included the comparison against opioids (compared to other analgesics), greater number of planned face-to-face visits, higher baseline pain intensity, and older patient age.(46) Given this evidence that placebos may not actually offer a comparison to “no treatment” but rather can be therapeutic in themselves, comparative effectiveness between true clinical options (e.g. opioids and CAM interventions) would be preferable in future research. Furthermore, the Institute of Medicine/National Academy of Medicine suggests in its report Relieving Pain in America that placebo-based interventions for chronic pain are themselves worthy of further investigation.(1)
Conclusion

This review suggests that more research is needed to understand the risks and benefits associated with two categories of popular therapies for chronic pain, namely opioid medications and integrative medical interventions. Furthermore, community-based, comparative effectiveness studies that avoid excluding patients with mental illness and histories of substance use disorders are most likely to be relevant to clinical practice. Given the large proportion of older people with chronic pain and the paucity of data in this age group, there is a particular need for more studies of chronic pain treatments that focus on patients who are older than 50 years of age.

STUDENT ROLE

My role included:

- Writing and submitting the proposal that was approved by the Partners Institutional Review Board
- Performing and writing the literature review on treatments for chronic pain
- Collating survey results and importing them into REDCap
- Interpreting survey results and performing statistical analyses using JMP (with guidance from a member of the Biostatistics Center at MGH)
- Designing qualitative interview questions
- Performing one-on-one interviews with program participants
- Transcribing interview recordings
- Coding interview transcripts using NVivo
- Writing the manuscript that describes the pilot study and its results
PILOT STUDY: MOVING WITH EASE

Objective

To produce a mixed quantitative and qualitative evaluation of Moving with Ease, a non-pharmacologic intervention for low-income, older patients experiencing chronic pain, offered by the Benson-Henry Institute Wellness Center at MGH Revere Health Care Center from September 2012 to May 2013.

Background

The Wellness Center at MGH Revere Health Care Center was founded in 2007, making it one of the first wellness centers in Massachusetts to be located within a community health center. In October 2012, the Wellness Center officially partnered with the Benson-Henry Institute for Mind Body Medicine, thus providing its predominantly low-income patients with access to one of the world’s premier institutions for the study and practice of mind-body medicine. Moving With Ease is one of many programs offered by the Benson-Henry Institute (BHI) Wellness Center. The goal of the program was to provide low-cost, non-pharmacologic treatments for chronic pain, including massage, acupuncture, yoga, tai chi, and relaxation training, to 25 patients over the age of 50. The BHI Wellness Center was able to offer the Moving With Ease program from September 2012 until May 2013 with the support of a grant from the Tufts Health Plan Foundation.

Methods

Recruitment and Intervention

Most patients were already attending other programs at the BHI Wellness Center when Moving With Ease began, and were therefore recruited by BHI Wellness Center staff. The rest of the participants were either referred by their primary care physicians or via flyers placed in the clinic’s primary care waiting room.

To enter the program, patients had to meet with a nurse for an Integrative Medicine consult, during which the provider and patient collaboratively designed a care plan to address the patient’s pain. Acupuncture treatments were given by two Licensed Acupuncturists in both group and individual settings, and lasted approximately one hour. Likewise, massage treatments were provided by two licensed massage therapists and lasted one hour. A registered nurse with experience teaching yoga led the hour-long yoga
classes. A representative from the Benson-Henry Institute taught the Relaxation Response workshops. *Moving With Ease* participants paid discounted rates for these services, as described in Table 1. The proportions of patients participating in acupuncture, integrative medicine consults, and massage are presented in Table 2.

**Quantitative Analysis**

The quantitative evaluation of the program focused on patients’ pre- and post-program responses to several validated measurements of pain (Brief Pain Inventory (BPI)), quality of life (PROMIS-10), Perceived Stress Scale 10 (PSS-10) and depression (Patient Health Questionnaire (PHQ-2). Because only a small handful of the patients completed the PROMIS-10 follow up survey, this instrument was excluded from the analysis. Primary outcomes were therefore self-reported pain, depression score, and self-perceived stress.

The data of twenty-five patients was collected, entered into a REDCap database, and exported into the statistical software *JMP*. Using the paired t-test function with *p*<0.05, patients’ pre- and post-intervention responses to the questions in the BPI, PHQ-2 and PSS-10 were compared and effect sizes were calculated. The *BPI User Guide* guided the analysis of the BPI results.(47)

**Qualitative Analysis**

The qualitative analysis was based on semi-structured interviews with patients who had participated in the *Moving With Ease* program. Given that many of the patients had reduced mobility due to pain, interviews were scheduled for times that the patients also needed to be at the health center for other reasons. Interview invitations were made by telephone and in person.

In total, 10 participants were interviewed using a semi-structured interview guide (Appendix B). All interviews took place at MGH Revere HealthCare Center, and lasted between 12 and 25 minutes. Although we would have ideally interviewed all program participants, the descriptive statistics in Table 3 suggest that the interviewees were a representative sample of the larger group demographically. It is notable, however, that on average, interviewees received more services than did the entire group. The patient interviews were de-identified, transcribed, and uploaded into the qualitative analysis software QSR NVivo. The transcripts were then coded and grouped according to themes.

The Partners Institutional Review Board approved these methods.
Results

In total, 25 people over the age of 52-years old participated in the *Moving with Ease* program. The group was 64% female, on average 70.1 years old, and most were residents of Revere, a community of about 50,000 people located 5 miles north of Boston (*Table 3*). Approximately fifteen percent of Revere’s residents live below the poverty line.(48)

**Quantitative Results:**

**Brief Pain Inventory:** The data analysis suggested improvements in all measures except for “pain at its least in the past 24 hours,” but none of these findings were statistically significant. Effect sizes for the aggregate scores (Pain Severity and Pain Interference) were small (*Table 4*).

**Perceived Stress Scale-10:** The trend for this measure was negative (higher stress), however this change was not significant and the effect size was small (*Table 4*).

**Patient Health Questionnaire-2:** The trend for this measure was positive (fewer depressive symptoms), however the findings were not significant. The effect size suggested moderate effect (*Table 4*).

**Qualitative Results:**

Categories of themes that emerged from the ten participant interviews included patients’ pain narratives, outcomes related to pain, psychological outcomes, praise for the program, and recommendations for improvement (*Table 7*). More specific themes and the number of participants who mentioned them (n) are described below.

**Pain Narratives**

Patients’ sources of chronic pain included neck pain (4), back pain (3), osteoarthritis (2), rheumatoid arthritis (2), spinal compression fractures (1), herniated discs (1), spinal stenosis (1), Raynaud’s syndrome (1), shoulder pain (“frozen shoulder”) (1), and sciatica (1). Previous attempted treatments to manage chronic pain included physical therapy (5), cortisone injections (2), “pain medications” (3), NSAIDs (3), chiropractor (1), surgery (1), exercise (1), acetaminophen (1), and Reiki (1). Regarding expectations about the benefit of the *Moving with Ease* intervention, one patient was very confident that it would help to relieve pain, and two patients described uncertainty. Patients’ motivations for joining the *Moving with Ease* program reflected an internal drive for self-improvement, including “if you don’t move it you lose it…as long as I’m alive I want to live” and “I have a lot of things wrong but I
keep pushing myself and keep moving and doing everything” and “It was just like, I can't deal with this anymore.”

Outcomes related to pain

Five participants made general comments about the effects of the program, including improvements in their chronic pain (“I got better”… “it all went away and has never come back”… “I don’t have the pain I had before, so that’s a big relief”… “when I got up before it was hard to walk, now I can just get up and walk”).

Participants had both positive and negative responses to acupuncture. Positive comments came from seven patients, who described how pain resolved after acupuncture, how disability (using a cane) was independent of pain, how their range of motion improved, and that the beneficial effects of acupuncture sometimes took time to manifest.

Two participants reported that they weren’t helped by acupuncture, one due to a worsening co-morbidity. The other person explained, “Some people it doesn’t help. Some it does. It didn’t help me.”

Massage was described in positive terms by four people, in the sense that it relieved pain, increased flexibility, and for one participant, improved breathing.

Tai chi was discussed in positive terms by two patients, who commented on the novelty of it and how stretching was beneficial. One male patient described feeling self-conscious in front of the other participants, all of whom were women.

Four patients described benefits of yoga, including that it helped them to move, relax, and reduce their pain. One person commented on feeling inhibited given the other strangers in the room, “…especially since we’re all old.”

Psychological outcomes

Outcomes that were mentioned that were not directly related to pain were all positive and related to mental state and function. They included increased a sense of well-being/stress reduction (4), self-confidence (3), empowerment (3), a feeling of hope/purpose (3), and improved memory (1).

Praise for Moving with Ease

Participants commented on several aspects of the Moving with Ease program that were positive, including the wellness center staff (5), the community-based location (2), and the sense of camaraderie they felt being in a group of other older people (3). They also discussed recommending the BHI Wellness Center to their friends and family (10).
Suggestions for improving *Moving with Ease*

Patients mentioned financial barriers to receiving more services (9), other classes/offerings they would like in the future (2), and physical barriers to participating in classes (1).

Discussion

This pilot study of non-pharmacologic interventions for the treatment of chronic pain presents information about how older, low-income adults utilize wellness services as well as how those services affect their chronic pain levels and mental states. With regard to service utilization, acupuncture and massage were nearly twice as highly utilized (in terms of total visits) as were tai chi and yoga. There are several possible reasons for this difference. First, tai chi and yoga were offered as group classes, so people had to be able to accommodate a set class schedule, whereas acupuncture and massage could be scheduled as individual appointments. An alternative explanation is that yoga and tai chi require active participation, which may be challenging for people experiencing chronic pain, while massage and acupuncture are passive modalities that do not require effort on behalf of the participant, aside from showing up for the appointment (which in some cases is an enormous commitment in itself).

The quantitative results suggest trends that the *Moving With Ease* pilot program improved participants’ pain and mood, however these results were not significant, possibly due to the small sample size. The qualitative arm of the study suggests that patients’ perceived benefits from participating in the program are notable. In several cases, they are on the order of life-changing. For example, one participant who reported being able to stand up and walk easily after not being able to do so in years, and the other who described the psychological benefit of the program with the words, “I would be lost without it. I have been lost without it.”

Negative comments about the *Moving with Ease* experience reflected discomfort with participating in group physical activities (yoga and tai chi), as well as a perceived lack of benefit of acupuncture. One interviewee reflected upon how external events (a new cancer diagnosis) negatively affected her overall experience of the program.

Although the main focus of this analysis was pain outcomes, other positive effects are notable. Participants cited several psychological benefits, including a sense of purpose, renewed hope, and the feeling of camaraderie that resulted from being with a group of peers. Given the emphasis placed on the biopsychosocial model of pain, these additional benefits are worthy of further study.

Reflecting overall satisfaction with the program, all ten interviewees indicated that they would recommend the *Moving With Ease* program to their friends, and provided reasons explaining why. Positive self-reported outcomes far outnumbered negative self-reported outcomes, and suggestions for improvement were limited to expanding services offered by the BHI Wellness Center, not modifying
existing services. Patients’ satisfaction and self-described pain relief and other benefits from the Wellness Center’s programs are especially notable in light of patients’ descriptions of failed treatment attempts prior to entering *Moving With Ease*.

Nine out of ten patients emphasized how the grant provided by the Tufts Health Plan Foundation enabled them to access services at the Wellness Center that they wouldn’t otherwise be able to afford. Although patients indicated that they continue to receive treatments and attend classes even though the grant has ended, they acknowledged that the increased cost of these services means that they will not receive this care as frequently.

**Limitations**

The major limitations of this pilot study are its small sample size, the lack of a control group, and the incomplete response rate on all of the quantitative measures. There was also possible response bias, since not all participants were available to be interviewed. Because the wellness center was offering concurrent programs, many of which were attended by *Moving with Ease* participants, it is possible that some of the outcomes measured by this study were reflective of programs other than *Moving with Ease*. A matched control group of participants in another one of the Wellness Center’s programs would have been helpful to assess this overlap.

Another factor to consider when interpreting this data is that these measures were validated using populations who were younger than the study population, and therefore not experiencing the same rate of background physical decline. In addition, it has been suggested that visual assessment scales of pain such as the one used by the BPI are less accurate in older populations. Finally, the PHQ-2 is meant to be a tool for screening depression, not a measurement of depression severity, as it was applied in this study. This is in contrast to the PHQ-9, which is validated to both screen for depression and assess severity of depression.

**Conclusion**

In conclusion, interviewed participants described experiencing meaningful reductions in pain and notable improvements in quality of life as a result of the *Moving With Ease* program, although participants’ responses to standardized instruments did not indicate a significant change in pain or quality of life. The inconclusive quantitative findings and strongly positive qualitative remarks raises the question of what type of outcome is most important when evaluating outcomes of treatments for chronic pain: patients’ subjective scores on standardized instruments or their testimonies and behavior changes following the intervention. To answer this question, it may be beneficial to assess programs like *Moving With Ease* using behavioral outcomes that impact quality of life and health care costs, such as amount of pain medication...
taken, changes in ability to complete activities of daily living, or number of primary care visits motivated by a chief complaint of pain prior to, during, and after the intervention. In addition, it would be helpful to repeat this study with a larger sample size, matched controls, more appropriate psychometrics, and instruments that are validated for older adults.

**ACKNOWLEDGEMENTS**

I am grateful for the intellectual mentorship offered by Ted Kaptchuk, OMD, Department of Social Medicine, Harvard Medical School prior to, during, and beyond the production of this report; for the guidance and collaboration provided by Darshan Mehta, MD, MPH, Benson-Henry Institute for Mind Body Medicine, Massachusetts General Hospital, and Kathleen Miller, RN, MA, PhD, AHN-BC, Massachusetts General Hospital Wellness Center at Revere Health Care Center, who together designed and implemented the *Moving With Ease* pilot program; for the guiding oversight of Janet Mullington, PhD, Department of Neurology, Beth Israel Deaconness Medical Center; and for the financial support of the Arnold P. Gold Foundation and the Harvard Medical School Center for Primary Care.
REFERENCES


TABLES AND FIGURES

Table 1. Discounted rates paid by *Moving With Ease* participants.

<table>
<thead>
<tr>
<th>Wellness Center Programs</th>
<th>Regular Cost at Wellness Center</th>
<th>Cost with <em>Moving With Ease</em> grant program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture, initial consult</td>
<td>$35</td>
<td>$15</td>
</tr>
<tr>
<td>Acupuncture, follow-up visit</td>
<td>$30</td>
<td>$15</td>
</tr>
<tr>
<td>Acupuncture, group visit</td>
<td>$20</td>
<td>$10</td>
</tr>
<tr>
<td>Massage therapy</td>
<td>$45</td>
<td>$20</td>
</tr>
<tr>
<td>Yoga and Tai Chi</td>
<td>$24 for 6 classes</td>
<td>Free pass</td>
</tr>
</tbody>
</table>

Table 2. Proportion of patients participating in respective types of treatments.

<table>
<thead>
<tr>
<th></th>
<th>Number of patients participating</th>
<th>Percentage of patients participating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture</td>
<td>18 (mean of 7.4 treatments/patient)</td>
<td>72%</td>
</tr>
<tr>
<td>Integrative Medicine Consult</td>
<td>25</td>
<td>100%</td>
</tr>
<tr>
<td>Massage</td>
<td>19 (mean of 4.7 treatments/patient)</td>
<td>76%</td>
</tr>
<tr>
<td>Tai Chi</td>
<td>6 (mean of 11.3 classes/patient)</td>
<td>24%</td>
</tr>
<tr>
<td>Yoga</td>
<td>5 (mean of 9.4 classes/patient)</td>
<td>20%</td>
</tr>
</tbody>
</table>

Figure 1. Popularity of services used, as measured by total number of treatments (acupuncture, massage) or classes (yoga, tai chi).
Table 3. Descriptive statistics about *Moving With Ease* participants and interviewees.

<table>
<thead>
<tr>
<th></th>
<th>All <em>Moving With Ease</em> participants (n=25)</th>
<th>Interviewees (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td>52-88 years</td>
<td>57-85 years</td>
</tr>
<tr>
<td>Average age</td>
<td>70.1 years</td>
<td>70.6 years</td>
</tr>
<tr>
<td>Resident of Revere</td>
<td>16 (64%)</td>
<td>7 (70%)</td>
</tr>
<tr>
<td>College Graduate</td>
<td>6 (24%)</td>
<td>2 (20%)</td>
</tr>
<tr>
<td># Female</td>
<td>16 (64%)</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Received acupuncture</td>
<td>18 (72%)</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Received massage</td>
<td>19 (76%)</td>
<td>9 (90%)</td>
</tr>
<tr>
<td>Mean acupuncture sessions/patient</td>
<td>5.3</td>
<td>8.6</td>
</tr>
<tr>
<td>Mean massage sessions/patient</td>
<td>3.6</td>
<td>5.7</td>
</tr>
</tbody>
</table>

Table 4. BPI (n=23)*

<table>
<thead>
<tr>
<th>Prompt</th>
<th>Mean Difference (p-value)</th>
<th>Direction of Clinical Change</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pain severity measures</em>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pain at its worse in the last 24 hours</td>
<td>-0.68 (0.30)</td>
<td>Improvement</td>
<td></td>
</tr>
<tr>
<td>4. Pain at its least in the last 24 hours</td>
<td>+0.625 (0.24)</td>
<td>Worsening</td>
<td></td>
</tr>
<tr>
<td>5. Pain on average</td>
<td>-0.83 (0.06)</td>
<td>Improvement</td>
<td></td>
</tr>
<tr>
<td>6. Pain right now</td>
<td>-0.67 (0.31)</td>
<td>Improvement</td>
<td></td>
</tr>
<tr>
<td><em>Pain severity measures average score (questions 3-6)</em></td>
<td>-0.42 (0.37)</td>
<td>Improvement</td>
<td>0.153</td>
</tr>
<tr>
<td><em>Pain interference measures average score (questions A-G</em>**)*</td>
<td>-0.02 (0.91)</td>
<td>Improvement</td>
<td>0.060</td>
</tr>
</tbody>
</table>

*Excludes 2 patients who did not fill out both pre- and post-BPI. **Questions 1, 2, 7, and 8 of the BPI were not included in the analysis. They are: “1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?” 2) “On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.” (diagram of body provided) 7) “What treatments or medications are you receiving for your pain?” 8) “In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.” ***A. How much does pain interfere with general activity? B. How much does pain interfere with mood? C. How much does pain interfere with walking ability? D. How much does pain interfere with normal work? E. How much does pain interfere with relations with other people? F. How much does pain interfere with sleep? G. How much does pain interfere with enjoyment of life?
Table 5. PSS-10 aggregate score (n=22)*

<table>
<thead>
<tr>
<th>Mean Difference (p-value)</th>
<th>Direction of Clinical Change</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1.32 (0.29)</td>
<td>Worsening</td>
<td>0.124</td>
</tr>
</tbody>
</table>

*Excludes 3 patients who did not fill out both pre- and post-PSS-10.

Table 6. PHQ-2 Total Score (n=25)

<table>
<thead>
<tr>
<th>Mean Difference (p-value)</th>
<th>Direction of Clinical Change</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.35 (0.20)</td>
<td>Improvement</td>
<td>0.276</td>
</tr>
</tbody>
</table>

Table 7. Interview Results. The number of patients represented in each section is noted in the left-hand column.

<table>
<thead>
<tr>
<th>Pain Narratives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients’ health problems that brought them to the Wellness Center</strong></td>
</tr>
<tr>
<td>(9 patients represented)</td>
</tr>
<tr>
<td>&quot;I've had a lot of physical illnesses [including] severe osteoarthritis…it started mostly with my breathing, because I also have emphysema and then I have a couple of herniated discs and I have 6 compressed fractures in my back, plus the osteoporosis.”</td>
</tr>
<tr>
<td><strong>Interviewer:</strong> You were saying you had arthritis, was that the first thing that made you want to come here? <strong>Patient:</strong> Yes.</td>
</tr>
<tr>
<td>&quot;I have spinal stenosis and stuff like that, back problems…I couldn't even walk…I couldn't get up, I'd start to crawl.”</td>
</tr>
<tr>
<td>&quot;I had rheumatoid arthritis, and Reynauds in the fingers, and just neck pain, back pain, you name it, it's there.”</td>
</tr>
<tr>
<td>&quot;I came in for acupuncture initially because of my neck. I had broken my neck in a car accident. That was 13 years ago and it's still sore…I can't do work any more. That's the problem. I can't do any work because of my neck and back.”</td>
</tr>
<tr>
<td>&quot;I have a lot of pain in my neck and my lower back. And I had pain in my shoulder…”</td>
</tr>
<tr>
<td>&quot;I have sciatica. If you've had sciatica, you know how painful it is. You can't imagine how painful it really is, right up and down the leg. I could get in my car but I couldn't get</td>
</tr>
</tbody>
</table>
out it was so painful, it hurt so. And I used to have to lift my leg out over the thing (car) to get out, and I just couldn't stand the pain. And then I couldn't turn my neck to see when I was driving, so when I was going onto a highway I couldn't turn my neck that way. It was like playing Russian Roulette, I used to have to sneak out…and so I decided to try the acupuncture since someone told me how good it was.”

“I couldn't hold my hands up to comb my hair. And all of those things, you know. And it was a great thing for me.

<table>
<thead>
<tr>
<th>Previous treatment attempts</th>
<th>“Not shots. Medications…my doctor was very good trying to get me to take various things. I'm a recovering alcoholic of 37 years and I don't take any mood-altering drugs, so I would try different things.”</th>
</tr>
</thead>
<tbody>
<tr>
<td>(8 patients represented)</td>
<td>“I tried physical therapy for this but it didn't help me. It made it feel worse. She was pressing on my shoulder and pulling my arm. I said, ‘You're torturing me, what are you doing to me?’ she was trying to stretch it out but I said ‘Ooh, no.’ But she told me, you know, you have a choice, ‘If you don't think it's helping you, you don't have to come back.’ I tried it a few times but…and when I talked to the orthopedic doctor who gave me cortisone shots, he told me no, I don't recommend PT for that type of frozen shoulder it doesn't really make much difference.”</td>
</tr>
</tbody>
</table>

Interviewer: “So you've taken pain meds and have had the surgeries. Have you tried anything else for the pain?” Patient: “Not really. Physical therapy and stuff like that. I do feel better when I stick to exercising but it's kind of like another job.”

“Before I came here I was going to [another health care facility] and I was going to their physical therapists and then I came here, you know, especially when I moved closer here was closer for me and I came here.”

“I don't like taking anything strong, you know. I'd rather do the physical therapy and exercises. But if you have to take it you have to… I'm not crazy about pain medicines too much, you know? …I mean I'll take Tylenol, you know, my doctor gave me ibuprofen but I send away for a lot of things and just to look into what I'm taking and all that. My daughter-in-law was a pharmacist. I'm just like that. As a matter of fact I just got a booklet on how certain medicines interact with other things and you can die from it, you know.”
“Medications, I've tried medications. I went to pain management. They did, what do they call it, trigger point injections. I'll never do that again. It was more painful than the pain in the neck... They put me on... what's it called... the initial medication they put me on for my neck back in 2000 worked but it also had side effects, it was a pretty benign medication. I was on a maximum dose, something like 3800mg a day, it's a massive dose, but it also affected bodily functions, it affected thought process, and basically numbed things out. So after a year I weaned off of that. The neck was okay, it wasn't great but it was okay. Sleeping is a serious problem for me for two reasons, first because of the pain and secondly because my mind is running constantly so that's difficult. So I got off that medication for a long while, I got back onto it a year ago for a short period of time and then I got off it again. Meaning that I told them I wasn't interested in staying on it. They put me on Ibuprofen 2400mg a day and it's 8 in the morning, noontime, and evening and that's sort of subsides the pain.”

“Physical therapy a few years ago. That helped some... I take Celebrex for arthritis.”

“I tried physical therapy, I tried a chiropractor, and they didn't seem to do me much good. And I heard that acupuncture might help me, so I started to come to acupuncture and I found out that it did help me. So I continued to come.”

“...I had done Reiki years before...”

| Expectations when first starting treatment at the Wellness Center | Interviewer: “Did you think before you started that you were going to get better from the acupuncture and massage?” Patient: “Yes. I had done Reiki years before. I didn't walk for almost 5 years. So I used to go to the Cape once a week for Reiki and I felt that was unbelievable, so when they said they had the acupuncture I said you know what, I'm going for it, I did it years ago. And it really, really has helped immensely.”

“Well I wasn't sure but I wanted to give it a try.”

“I didn't know. I just took the chance that it would work.”

| Motivation for seeking | “If you don't move it you lose it... I don't want to become a couch potato... I'm going to...” |
| care at the Wellness Center | die someday but as long as I'm alive I want to live…I like life, I've had a very busy day today. And I have a lot of young people in my life, and they consider me wise.” |
| (3 patients represented) | “I have a lot of things wrong but I keep pushing myself and keep moving and doing everything.” |
| | “I had gastric bypass 3 years ago and that kind of gave me an incentive to where I was going. It was just like, I can't deal with this anymore.” |

| Outcomes related to pain |  |
| General | “Less pain…better balance” |
| (4 patients represented) | “I got better.” |
| | “I would stay home at night watching TV and I would get this wicked pain in my neck. It was brutal. And in my left shoulder blade and it all went away [after treatment at the Wellness Center] and it has never come back. I still have pain in my lower back, it's arthritis. And also before I started, when I got up in the morning I was bent over, it took awhile to straighten up. I haven't had that in awhile. It hurts a little but nothing like it was before…I can sit longer, get up and walk away instead of…bending over and waiting to straighten up again.” |
| | “I don't have the pain that I've had before, so that's a big relief, believe me…When you don't have pain…pain is tough. Like I said, I didn't believe in drugs to solve my problem.” |
| | “We [my group of friends] go to the coffee shop every morning and we solve all the problems of the world there in the morning. So you're there for an hour or something and when I got up before it was hard to walk, now I can just get up and walk.” |

| Acupuncture (positive) | “Pain was stopped by acupuncture. I used to have terrible, terrible headaches and neck aches and I do have a headache occasionally but nothing like I used to have. The back pain is helped but on a temporary basis…And at times it would wake me up and I’d be in pain but with the acupuncture it doesn't hurt at all... Some days I need a cane, some days I
don't. But the acupuncture is helping the pain. It also to my surprise helps my breathing.”

“I did the acupuncture and massage and I was in a lot of pain in my shoulder and my wrist, my hand, my elbow, so I noticed a big difference by doing that…[before] I could only move my left hand like that (reaching behind back), I couldn't even do that (with right arm).”

“I try to come once a week…I kind of acclimated to having it to keep me in tune. When I don't have it, you should ask me. Then I feel worse, I feel more pain, I'm not as agile…I feel like acupuncture gives me that extra well-being all over. I take a nap almost every time I have it…and I'm not a nap person but it relaxes me to the point, and that's what it really gives you: a mind-body feeling of wellness…It gives you a step in your life to walk on.”

“The acupuncture is good.”

“It took a little time. But you know, it works. I look forward to coming because I know if I have pain it's going to hit it. Two weeks ago I was here for the acupuncture and I was having a really bad time with my neck again, but the next day, I could tell it was already better, I could move it again. I couldn't move it, you know? SO I do believe in that stuff…It's very soothing to me.”

“The neck pain went away after the first acupuncture… The shoulder blade took a couple of treatments before that went away.”

“The acupuncture was the one that really worked good.”

<table>
<thead>
<tr>
<th>Acupuncture (negative) (2 patients represented)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“This session around worked very poorly because I had other physical issues that came about. I found out I had cancer…I went through a medical procedure and I was operated on for…cancer and that was physically and emotionally devastating. Things just fell apart…The first session did seem to help, it took some of the pressure off, it released some of the pain. This last time because of the cancer, it changed my psychological position and put me more toward the negative versus the positive and I struggled with that…I think part of the thing was I was relaxing with it because I wanted it to work so I just did exactly what I was told to do. This time around I had serious issues, you know, emotional issues that were interfering with my thought process so I was not able to relax...”</td>
</tr>
<tr>
<td>Treatment</td>
</tr>
<tr>
<td>------------------</td>
</tr>
</tbody>
</table>
| Massage (positive) | “Massage helps with breathing too, and I've never understood that, but it does. And the massage therapy loosens up things so that when I go into yoga I can move, I'm not all stiff.”  
“I did the acupuncture and massage and [before] I was in a lot of pain in my shoulder and my wrist, my hand, my elbow, so I noticed a big difference by doing that.”  
“The massage helped me to quite a degree.”  
“Massage…does help and she [the massage therapist] really works the muscles and she does a really, really good job. She's very sociable, really, really nice. And she'll sit before every massage, just talk things out, how are things going, is there anything bothering you, this that and the other, so she knows what areas to work on which is good.” |
| Tai Chi (positive) | “I never had done tai chi and I think that was really good. And I probably wouldn't have tried tai chi if it hadn't been for here.”  
“…the yoga and the tai chi was really good. It's a lot of stretching and it makes a big difference.” |
| Tai Chi (negative) | “It was all women in the class and I could never dance or anything like that and I couldn't move around like the other people…I didn't like it, I didn't follow up on it, which I probably should have.” |
| Yoga (positive) | “I like it because it helps me to move. I know that I could very easily become a couch potato. And I can move, when I say I can move, like I know I'm stiff. I can't do today what I was doing two and a half months ago because my muscles are now all atrophied, but she gets everything moving, my legs, and everything moving.” |
| Yoga (negative)
(1 patient represented) |
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“[You're] kind of inhibited when you're with strangers in the room. Especially since we're all old (laughing).”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Psychological Outcomes</th>
</tr>
</thead>
</table>
| **Self-confidence**
(3 patients represented) |
| “I have more confidence in myself.” |
| “I have more confidence...And I get along with everybody. I like to make people laugh, you know?” |
| “I have more self-confidence. I love being around people. I'm more, I do more outside activities, I mean I don't try to stay home. I don't want to waste my time sleeping because I'm going to be sleeping a long time once I close my eyes for good, so I don't have enough hours in the day anymore. But that's okay...I learned a lot from being here.” |

| Empowerment
(3 patients represented) |
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“You've got to try to help yourself.”</td>
</tr>
<tr>
<td>“You know, I've got to worry about me. I've got to me the number one person I worry about because no one's gonna make me better but myself. And if I worry about all the garbage and all the drama in everyone's life all around me, I'm never going to get better.”</td>
</tr>
<tr>
<td>“I don't focus on taking care of myself, I do other things. Everything's external to internal work, if that makes any sense.”</td>
</tr>
</tbody>
</table>
| Well-being | “I kept coming because it gives me purpose.”  
(4 patients represented) | “It [the Wellness Center] gives you a well-being feeling.”  
“I don't know about anybody else, but when I get stressed, things become overwhelming and I get very anxious, so these programs have made a big difference in my life when you feel less stressed and more healthy. You feel really good…it's helped a lot with the stress and stress level.”  
“Psychologically I felt as if this program is trying to help people. It's a ray of help.” |
| Improved memory | “It keeps your mind sharp too. You know I have trouble remembering names, those are the normal things when you're old.” |  
(1 patient represented) |
| Something to look forward to | “I kept coming because it gives me purpose…it gives me something to look forward to that's pleasurable as well as being helpful…it gets me out of the house…I would be lost without it. I have been lost without it.”  
“It’s a wonderful thing, it's something to do.”  
“I enjoy it because of the movements and everything else, stuff you don't normally do. You see if you're retired you're not doing much.” |  
(3 patients represented) |
| Praise for Moving with Ease | “The practitioners are wonderful. They're absolutely wonderful.” |  
Wellness Center staff  
(5 patients represented) | “She [staff member] is so sweet! And I'm trying to get like some of them, be sweet like them.”  
“…the care and the love and affection that everybody in this group [of staff] shows makes..."
**Location in community**

(2 patients represented)

> “It’s so close, I'm right next door there, I can just walk right over. And that makes it especially nice.”

> “I live in Revere. As a matter of a fact my coffee shop is across the street so I just walk over.”

**Sense of camaraderie with peers**

(3 patients represented)

> “It is nice to be with my peers…there are many people who do not get out if it were not for this program, who would not exercise…you make friends and [they're] good to have…I had a neighbor, she's gone now, and she would walk around my building. I live in housing for the elderly, and I'd say, how you doin' today and she'd say fine, she said, you know what's hard though, and I'd never thought of it, she said, “It's difficult not to have somebody that you can say, remember when…” And it's true. Like one of the guys [in a Wellness Center class] did a take on Jimmy Durante and not too many people your age know who Jimmy Durante is you know. And he had this big schnoz, they called him The Schnoz, and we were all laughing. I can say that to my kids and my grandkids and they'll all look at me like I have four heads. So I like this aspect of communing with my peers. It's important.”

> “We do things together, you know. They even used to have dancing, they had a class then they stopped it. I mean everybody to each his own enjoys different things, but it's nice with the group, everybody getting along and trying to do different things…I've made a lot of new friends…There are a lot of us of our age, you know, you mingle, you can talk better [than with younger people].”

> “The people are so nice, both the people that come to the group and the people that are the staff…I'm happy with these people.”
**Recommending to others**

(10 patients represented)

“I do recommend it to people but most of them have the primary care in Boston.”

“I'd say it makes a big difference and helps people physically and emotionally.”

Interviewer: Have you recommended this center to any of your friends? Patient: Oh many people.

“I say you should try acupuncture. People are afraid of needles or they've never tried it and what good does it do you, and I say, try it!”

“I tell them you'll be very relaxed, it calms you down…I think almost anybody could benefit from it. Really. I mean…young kids have problems with arthritis and stuff, and stuff like that I think it's really good for them to have that little quiet time. I fall asleep when I'm here and I wake myself up snoring, so how relaxed am I?”

“One of my friends had a heart replacement a couple of years ago. I talked to him about the care that you get here and he isn't coming yet but he's a very close friend of mine and I've talked to him about how this place operates. It's really, really nice, it's really nice.”

“I would tell them the people the programs are all of the highest quality, that they've helped me and I enjoy going there.”

“[I tell my friends] that I have much less pain and I can walk better. People are telling me you are walking better.”

“It works for me and possibly it will work for you.”

“[I tell them] I loved it, I thought it was great, it had a lot of good stuff going for it.”

<table>
<thead>
<tr>
<th><strong>Suggestions for improving Moving with Ease</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suggestions for classes/offerings</strong></td>
</tr>
<tr>
<td>(2 patients represented)</td>
</tr>
<tr>
<td>“I wish they would allow moxa but they don't let them have the moxa or cupping. Because they're limited to doing the needles. I feel like that whole scenario of the cupping and the massage with it and the needles together is far superior.”</td>
</tr>
<tr>
<td>Financial barriers</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>(9 patients represented)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Physical barriers</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>(1 patient represented)</td>
</tr>
</tbody>
</table>
APPENDICES

APPENDIX A: Definitions of Substance Dependence and Substance Abuse

DSM-IV Substance Dependence:(50)
A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month:

1. Tolerance, as defined by either of the following:
   a. A need for markedly increased amounts of the substance to achieve intoxication or desired effect
   or
   b. Markedly diminished effect with continued use of the same amount of the substance

2. Withdrawal, as manifested by either of the following:
   a. The characteristic withdrawal syndrome for the substance
   or
   b. The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms

3. The substance is often taken in larger amounts or over a longer period than was intended

4. There is a persistent desire or unsuccessful efforts to cut down or control substance use

5. A great deal of time is spent on activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects

6. Important social, occupational, or recreational activities are given up or reduced because of substance use

7. The substance use is continued despite knowledge of having a persistent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)
**DSM-IV Substance Abuse:**

A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following, occurring within a 12-month period:

- Recurrent substance use resulting in a failure to fulfil major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household)
- Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use)
- Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct)
- Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequence of intoxication, physical fights)

**DSM V (2013) Substance Use Disorder:**

A problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

1. The substance is often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful effort to cut down or control use of the substance.
3. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
4. Craving, or a strong desire or urge to use the substance.
5. Recurrent use of the substance resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued use of the substance despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of its use.
7. Important social, occupational, or recreational activities are given up or reduced because of use of the substance.
8. Recurrent use of the substance in situations in which it is physically hazardous.
9. Use of the substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following:
   a. A need for markedly increased amounts of the substance to achieve intoxication or desired effect.
b. A markedly diminished effect with continued use of the same amount of the substance.

11. Withdrawal, as manifested by either of the following:
   a. The characteristic withdrawal syndrome for that substance (as specified in the DSM-5 for each substance).
   b. The substance (or a closely related substance) is taken to relieve or avoid withdrawal symptoms.

APPENDIX B: Guiding questions for semi-structured patient interviews

1. Had you been to the Wellness Center before you joined Moving With Ease?
2. Who told you about Moving With Ease?
3. Why did you decide to participate in Moving With Ease?
4. Did you have any hesitations about participating? If so, what were they?
5. Did you notice any improvements in your health while or after participating in Moving With Ease? If so, what were they and were there programs that were particularly helpful?
6. Did you notice any worsening in your health while or after participating in Moving With Ease? If so, what were they and were there programs that were particularly harmful?
7. How has your life changed because of Moving With Ease?
8. Do you plan to continue to attend programs at the Wellness Center?
9. Do you face any barriers to attending programs at the Wellness Center? If so, what are they?
10. Would you recommend Moving With Ease to your friends? Why or why not?