The Latino Integrative Medical Group Visit (IMGV) as a model to reduce pain in underserved Spanish speakers: a pilot feasibility study

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THE LATINO INTEGRATIVE MEDICAL GROUP VISIT (IMGV) AS A MODEL TO REDUCE PAIN IN UNDERSERVED SPANISH SPEAKERS: A PILOT FEASIBILITY STUDY

by

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To my beautiful wife, Lisbeth, and my adorable daughters, Ariana, Lucia and Fiorella, whose unconditional love make achieving any dreams possible.
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OSCAR CORNELIO-FLORES

ABSTRACT

Background: Disparities in access to quality chronic pain treatment options disproportionately affect minorities. Although there is increasing evidence about the effectiveness of complementary and integrative medicine (CIM) to help in the treatment of pain, little is known about how low income minorities would benefit from having greater access to CIM. The Integrative Medical Group Visit (IMGV) model incorporates CIM in a medical group visit setting with the goal of increasing access to CIM.

Objective: The aims of this pilot study were to test 1) the feasibility of a Spanish language IMGV and 2) its effectiveness to reduce pain and improve function in Spanish speakers with chronic pain.

Methods: The study setting is the Family Medicine Clinic at Boston Medical Center. Adult Spanish speakers with chronic pain for at least 12 weeks were included; those pregnant, with psychosis, suicidal ideation or active substance abuse disorder were excluded. The intervention consisted of weekly, two-hour sessions for a total of 9 weeks. Main outcomes were pain level, pain interference, and physical and emotional function measured by the PROMIS 29 pre- and post-intervention, depression and stress, measured by PHQ-8 and PSS-10,
respectively. Focus group participants discussed the feasibility of the intervention. Analyses involved t-tests to examine our outcome data, and qualitative thematic analysis for focus group data.

**Results:** This open study recruited 11 subjects, 10 women, average age of 51.9 years; 50% of participants attended more than four sessions. The outcomes showed a trend toward reduced depression, pain, fatigue, and anxiety. Qualitative themes of reduced pain, increased knowledge for healthier living, and improved access to pain treatment using an appropriately adapted intervention were found.

**Conclusions:** It was feasible to implement the Latino IMGV model in the outpatient setting at BMC. Trends in reduction of pain and depression, as well as increased knowledge for healthier living and better access to CIM modalities were found. Future powered studies are needed to further implement this model.
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LIST OF ABBREVIATIONS

BMC    Boston Medical Center
CIM    Complementary and Integrative Medicine
EBNHC  East Boston Neighborhood Health Center
IMGV   Integrative Medical Group Visit
MBSR   Mindfulness Based Stress Reduction
PHQ    Patient Health Questionnaire
PROMIS Patient Reported Outcomes Measurement Information System
PSS    Perceived Stress Scale
1. Introduction

1.1 Problem Statement

Chronic pain is among one of the most common chronic medical conditions in the United States, affecting 100 million American adults and costing the nation as much as $630 billion annually (Pizzo et al., 2011). Chronic pain is associated with different medical problems that benefit from a multidisciplinary approach to improve patient’s outcomes. Current provision of medical services to reduce pain and improve function and quality of life is not offered equally to all the sectors of the US population, with minority groups among those with least amount of access to these services (Mossey, 2011). Indeed, section 4305 of the 2010 Patient Protection and Affordable Care Act, specifically outlines the need to support disparities research in pain treatment and management (Health Policy Alternatives, Inc. 2010)

As a consequence, minorities are at higher risk for suffering from chronic pain, but also from depression, which tends to be more prevalent in patients with chronic pain (McWilliams, Cox & Enns, 2003). Minorities are particularly underrepresented in terms of access to complementary and integrative medicine (CIM) services for chronic pain. For non-English speaking patients of low socioeconomic status, treatment options for chronic pain are limited and often provide only temporary relief. Disparities in access to care among this population further contribute to substantial negative impact on physical and emotional
functioning. In particular, underserved Spanish speaking patients are one of the most vulnerable populations given their socioeconomic characteristics, language barriers and immigration status, among others.

Latinos account for the largest growing minority in the United States, expected to reach 30% of the population by 2025 (Vega, Rodriguez & Gruskin, 2009). Considering their particular socio-cultural vulnerabilities (language barrier, immigration status, among others), this population could be at higher risk of suffering from chronic pain and related comorbidities.

Studies have shown a benefit of mindfulness-based stress reduction (MBSR) interventions to address chronic pain (Gardiner, 2014; Rosenzweig, 2009). However, little is known about the feasibility and effectiveness of using the concept of “group medical visits” with a focus on “integrative medicine modalities” to address the widespread problem of chronic pain in underserved Latinos.

The aims of this study are to explore the feasibility and effectiveness of this innovative and promising model of care for underserved Spanish speaking patients with chronic pain. This project will examine the feasibility and effectiveness of the Integrative Medicine Group Visits (IMGV) model for treating underserved Spanish speaking patients who have chronic pain. IMGVs are group medical visits (also referred to as Shared Medical Appointments), facilitated by a doctor, during which patients learn about mindfulness, stress reduction and wellness topics and techniques for nine consecutive weeks. IMGV is a holistic
model of care that emphasizes self-care skills and creates a sense of community among patients and their medical providers.

1.2 Chronic pain and its comorbidities: a significant public health problem

The number of US adults affected by chronic pain and the total costs associated with management of this condition results in a significant amount of expenses as mentioned earlier on this paper. Data from the “Relieving Pain in America” report revealed that the annual economic cost of chronic pain in the United States is at least $560–635 billion (Pizzo et al., 2011). This estimate combines the incremental cost of health care ($261–300 billion) and the cost of lost productivity ($297–336 billion) attributable to pain. This report also states that “effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions”.

Patients with chronic pain often present with multiple psychiatric comorbidities, particularly depression and anxiety (McWilliams et al., 2003). In a sample representative of the general US civilian population (N=55,877) obtained from the National Comorbidity Survey, the authors studied the association between chronic pain due to arthritis and common mental health disorders was studied and compared to the general population. Patients with arthritis were the focus of this study given the chronic and painful nature of this condition. They found the prevalence of depression was 20.2% in the chronic pain group vs 9.3%
in the general population; any anxiety disorder in the pain group was 35.1% vs 18.1% in the general population.

In order to address the problem of chronic pain, health care providers need to consider additionally psychosocial factors. Indeed, in a population-based prospective study from three primary care registers covering a socio-demographically mixed urban area in England, which included 3171 adults (25–65 years old), initially free of pain for more than 3 months, 324 developed "chronic widespread pain" at the 15 month follow surveillance (Gupta et al., 2007). The authors found that factors associated with development of chronic widespread pain were: somatization, health seeking behavior and poor sleep. They also noted that psychosocial distress has a strong etiological influence in the development of chronic pain. This important influence of psychosocial factors and how they can alter the pain experience and determine outcomes in patients with pain has been studied in patients with chronic pain attending an outpatient Rheumatology clinic (Rahman, Reed, Underwood, Shipley, & Omar, 2008).

Given the complex nature of chronic pain, this condition also affect the management of other chronic conditions like insomnia, obesity and/or hypertension, as patients need to take not only more medications on a daily basis, but they may have a higher probability for medications interactions and side effects, which adds to the burden and suffering of patients with chronic pain conditions.

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1.3 Disparities in the treatment of chronic pain

Traditional therapeutic options for pain control include pharmacological and non-pharmacological options. Pharmaceuticals include: over the counter non-steroidal anti-inflammatory medications, like ibuprofen, naproxen, or acetaminophen and prescribed stronger pain medications, in particular opioids. Among the non-pharmacological approaches, American College of Physicians and the American Pain Society recommend intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, yoga, and cognitive-behavioral therapy, as they have proven to be effective taking as example chronic low back pain (Gardiner, Dresner, Barnett, Sadikova, & Saper, 2014).

There are biological, social and psychological mechanism that play a role in these differences in pain response observed among diverse ethnic groups. Consequently, using the same approach in the management of chronic pain when working with diverse populations will not likely be very helpful, as one of the main components of pain improvement is first to understand what is the meaning of pain and how they process this under their socio-cultural perspective. Burton and Shaw argued that clinical and laboratory studies have reported ethnic differences in pain perception, with more pain response reported generally by African-American, Hispanic, American-Indian, Alaskan native, Chinese, Indian and Asian-American participants (Burton & Shaw, 2015).
Mossey (2011) did a systematic review of the literature about racial disparities and the treatment of chronic pain. The author started with a MEDLINE search for the combined key words: race, ethnic, disparities, and pain, as well as cumulative indexes of three pain journals: Pain, Pain Medicine and the Journal of Pain, from 1996–2011. She reviewed 70 articles, and concluded that racial/ethnic minorities consistently receive less adequate treatment for acute and chronic pain than non-Hispanic whites, even after controlling for age, gender, and pain intensity. Interestingly, pain intensity underreporting appears to be a major contribution of minority individuals to pain management disparities.

1.4 Effectiveness of Complementary and Integrative Medicine (CIM) therapies to treat chronic pain in minorities:

Many studies have proven the effectiveness of CIM therapies, especially when treating chronic complex health problems (Bronfort, 2004; Cevik, 2015; Erhard, 1994; Kizhakkeveetill, 2014; Rasmussen, 1979; Shekelle, 1992; Simpson, 2015; & Tan, 2007). Among the different CIM therapies, yoga, acupuncture, massage and mindfulness-based stress reduction have been proven effective in the treatment of chronic pain. Dale and Stacey (2016) argue that defining “effective treatment” for chronic pain is difficult, because it will almost never mean a complete remission of pain. The authors analyzed a collection of industry-sponsored chronic pain trials and found that a reduction of pain by 30% is clinically meaningful, because it is at this this level that patient ratings demonstrate a “much improved” pain experience. The same authors
mention that ongoing pain is multidimensional with physical, cognitive, psychological, and behavioral aspects. Given this complex nature of chronic pain and the goals for treating it, a multimodal treatment approach is often needed, which usually takes into consideration different CIM modalities, like massage, acupuncture, mind-body techniques (mindfulness based stress reduction) and/or the use of herbs and dietary modifications.

Findings from a study done by Thompson and Nichter (2011) showed that approximately 4% of the US population who lack health insurance use CIM as an alternative to conventional medical care. The author also noted that those using CIM are more likely to be poorer and in worse health than those forgoing both conventional and CIM. In fact, many patients use CIM modalities as a “substitute” for “conventional medical care” because the first is usually more accessible even if insurance does not cover. In addition to this, many patients prefer certain CIM therapies based on their own concept of health and illness from a cultural perspective, as mentioned earlier. This is particularly important in immigrants from countries where what we call “alternative therapies” in the US, are actually “mainstream treatments” in their countries of origin, like the use of acupuncture in people from Asian cultures, or the “Shaman”, “huesero” (bone healer) or “sobador” (bone settler) in many Hispanic backgrounds. One of the reasons of the popularity of these “traditional healers” is their “holistic approach” when seeing a “client”. In fact, much of what they do is not always specific to
where the ailment in the body resides, but how the whole person is being affected by that illness.

1.5 Mind and Body Medicine Effectiveness in Minorities

Another healing mind-body modality, yoga, has been increasingly offered in the US (Clarke, Black, Stussman, Barnes, & Nahin, 2015). Its effectiveness in the improvement of pain, particularly chronic low back, has been largely studied and shown reduction of pain after a 12-week program, time frame most commonly used in the literature. However, there is limited research when this intervention is applied to underserved or low-income minorities. Dr. Robert Saper and his group (2009) studied the feasibility of a 12-week yoga intervention on low-income minorities at 2 community health centers in Boston, MA. They found that yoga participants reported less use of analgesic medications compared to usual care patients (13 % vs. 73%, p < 0.003), less opiate use (0% vs. 33%, p = 0.04) and greater overall improvement (73% vs. 27%, p = 0.03).

Mindfulness, “the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment to moment” (Kabat-Zinn, 2003), a type of meditation, has been used to reduce stress and its negative consequences on health in many scenarios, from businesses and schools, to clinical practice. Research has shown the effectiveness of this intervention in the reduction of pain. Rosenzweig et al. (2010) found that Mindfulness Based Stress Reduction (MBSR) programs
improved different conditions associated with pain in 133 patients from an Integrative Medicine University-based Clinic. From all the patients groups with a diagnosis associated with pain, the group with the greatest improvement involved patients with arthritis. Nevertheless, the few studies conducted in minorities, including Latinos, focused on the effects of MBSR on well-being and reduction of anxiety, not specifically in improvement of chronic pain (Abercrombie, Zamora & Korn, 2007).

1.6 The Integrative Medical Group Visit (IMGV) Model

The medical group visit model (or shared medical appointments), despite its recent popularity, was actually conceived in 1974 as a model for well-child consultations (Jaber, Braksmajer, & Trilling, 2006). This model of group care has many advantages, such as the “group solving effect” and the ability to increase patients’ “self-efficacy” as a result of participating in a group. The group problem-solving effect reduces perceived barriers to behavior change, which in clinical practice is one of the most challenging attitudes to change towards health improvement. As argued by Jaber et al. (2006), group education reinforces the messages received in the individual medical visit, increases perceived benefits, and provides social persuasion and effective action cues. The other vital aspect of the medical group visit is the self-efficacy effect, where modeling, or seeing other participants accomplishing the desired behaviors and overcoming obstacles, has powerful effects on the other participants in the group. Wong and his group recently published a study about the benefits of group medical visits in
primary care settings (Wong, Browne, Lavoie, Macleod, Chongo, & Ulrich, 2015). They found evidence for the following themes: group visits can foster access to needed health services; expand opportunities for collaboration and team-based care; and improve patient and provider experiences. However, an emerging theme was about structural challenges in delivering this intervention. This is why this proposed Latino IMGV study could help us understand important aspects of implementing a needed and innovative model of care.

One of the main characteristics of this intervention is that everything was provided in Spanish, from the recruitment of patients over the phone, to the 9-week intervention, and the patient's materials (curricula and CD). Research has demonstrated that having a bicultural facilitator and material can have a positive effect on the study (Guzman, Richardson, Gesell, & Barkin, 2009). The authors showed that after using a bicultural, bilingual Case Manager in a program to enroll overweight/obese Latino children, the number of referrals to a Tertiary Care Center for weight loss, increased from 1 to 13 families.

In addition to this, among many immigrant minority groups, being around others who share common medical, socio-economic and cultural problems and concerns make delivery of health care via a group visit model a “safety network”. In this clinical setting, participants who are living far away from their native countries and probably do not have an immediate social and family network, find their new “group” or “new family”, which itself is healing.
Previous research has shown that the medical group visit has improved many important process and health outcomes, such as improved quality of care (Jaber et al., 2006), improved preventive recommendations for people with diabetes (Wagner, Grothaus, & Sandhu, 2001), better rates of influenza and pneumonia vaccination in older adults (Beck et al., 1997) and decreased use of emergency room visits, hospitalization stay and specialty care needed (Jaber et al., 2006). Besides chronic pain, this model has also been utilized for patients with heart failure. In 2015, the Ohio State University Wexner Medical Center’s Center for Integrative Health and Wellness has developed an IMGV setting using diet, exercise, medications, lab testing and mind-body approaches (MBSR in particular) to reduce hospital readmission rates in recently discharged patients who were hospitalized for acute decompensated heart failure (Singrey, Mehta, & Casper, 2015). Their preliminary results show that the IMGV on that setting is helping to integrate and make the team work more functional and also improve the patient’s experience.

1.7 The Origins of the IMGV in low income patients

Dr. Paula Gardiner, Associate Professor of Family Medicine at Boston Medical Center, developed a feasibility study using the Integrative Medical Group Visit model to reduce pain and depression in an underserved group of patients coming to the outpatient Family Medicine Clinic (see Figure 1). She surveyed patients before and after an 8-session IMGV program to evaluate changes in pain in the last week (0–10 point scale) and comorbid symptoms including
depression (Patient Health Questionnaire-8 [PHQ-8]), perceived stress (Perceived Stress Scale-PSS), and sleep quality (Pittsburgh Sleep Quality Index-PSQI). The study included 65 patients, 60% were African-American and 9% Hispanic, and 68% were female. She and her team found a mean reduction in pain level for all patients between baseline and 8 weeks of 0.7 (SD=2.0, p=.005). Mean reduction in the PHQ-8 depression score for patients with a baseline score $\geq5$ was 2.6 (SD=4.6, p<.001). Statistically significant improvements were also seen in sleep quality and perceived stress. (Gardiner et al., 2015). Dr. Gardiner’s IMGV feasibility study laid the groundwork for the basic structure of the proposed model for Latinos. However, the intervention was delivered for English speakers only. Therefore, a Latino IMGV feasibility study was the next logical step, involving adaptation of Dr. Gardiner’s IMGV curriculum for Spanish speakers and implementation of this adapted model to the underserved Latino community with chronic pain.

Chao, Abercrombie, Santana, and Duncan (2015) have also used integrative medicine modalities in a group visit setting among underserved women with chronic pelvic pain. They found that participants improved their physical and psychological well-being, with significant reductions in average number of unhealthy days in the past month, depressive symptoms as well as depression severity.
Figure 1. BMC IMGV Model
2. Conceptual Model

Given this proposed study aims not only to study the effectiveness of the Latino IMGV to reduce pain among participants, but especially to assess the feasibility of its implementation, two conceptual models were used to guide this intervention. On the one hand, the Proctor model help us understand the aspects of feasibility and how to link them to our proposed outcomes, and, on the other hand, Engel’s biopsychosocial model will help us to assess the myriad of psychosocial aspects of pain and their interplay with the physical aspects of it.

2.1 Proctor Model for Implementation

Enola Proctor and her team have developed a model to assess implementation outcomes, which has been widely used by researchers in the field (Proctor et al., 2011). The following implementation outcomes are part of this model: acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration and sustainability. As this study covers four specific outcomes from this model (acceptability, adoption, appropriateness and feasibility), data that were gathered during the focus group session, I will call it, “Modified Proctor model”.

Acceptability refers to the perception among participants that this intervention is agreeable, palatable or satisfactory (Proctor et al., 2011). Adoption is defined as the intention, initial decision or action to try or utilize the proposed intervention, something that can also be described as the “uptake”.


Appropriateness, although conceptually similar to acceptability, refers to the perceived fit, relevance or compatibility of the innovation (in this case, the Latino IMGV) to a specific population, and/or the perceived fit of such innovation to address a particular problem (chronic pain in this study). Feasibility refers to the extent to which a new intervention can be successfully carried out within a particular setting.

2.2 Engel's biopsychosocial model

The second aim of this study is to evaluate the problem of chronic pain. Engel's biopsychosocial model appears to serve as an important conceptual framework for this project, as it has been widely used to guide chronic pain interventions (Koenig, Kupper, Skidmore, & Murphy, 2014). This model conceptualizes chronic pain as having interrelated causes and manifestations in multiple dimensions: physical (e.g., deconditioning), psychological (e.g., depression, stress, fear and avoidance of movement, poor coping), and social (e.g., relationship problems, racial discrimination, pain behavior). As a consequence, pain is highly associated with a myriad of conditions such as depression, stress, somatization, maladaptive coping and catastrophizing, fatigue, sleep disorders, and from a broader perspective, related to function and quality of life. In particular, the social characteristics of underserved Latinos as well as the psychological manifestations of stress could help us understand how the IMGV would be feasible on this vulnerable population.
Figure 2. Conceptual Model. Adapted from modified Proctor model and Engel’s Biopsychosocial model

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3. Research Questions

This study includes two research questions: 1) Is it feasible and acceptable to use the IMGV among underserved Latinos with chronic pain in a primary care setting; and, 2) How does this intervention improve not only pain, but also depression and perceived stress in the population in study?

3.1 Hypothesis

The Latino IMGV will be accepted and adopted by Spanish speaking patients with chronic pain, and can help reduce pain, depression and stress in this population.

3.2 Specific Aims

AIM 1: To assess the feasibility of the IMGV model to reduce chronic pain and improve function in underserved Spanish-speaking patients.

AIM 2: To test the effectiveness of the IMGV to reduce pain and improve function in underserved Spanish speakers.

3.3 Data Source(s)

The Latino IMGV intervention was conducted at the outpatient Family Medicine Clinic at Boston Medical Center (BMC).

The data come from the chronic pain patients who completed Spanish language questionnaires pre- and post- IMGV sessions. We also conducted a focus group at the end of the intervention to ask patients about their motivations,
perceptions, and overall experience participating in the Latino IMGV. In particular, they were asked about the impact of these sessions on their health, group dynamics and materials used during the intervention. The focus group serves as the main source to gather data about the implementation outcomes described in Aim 1 (acceptability, adoption, appropriateness, and feasibility). In one of the participants, who was not able to be present for the focus group, we did an “in-depth interview”. See Appendix 1 for a detailed list of questions used during the in-depth interview and the focus group.
4. Methodology

4.1 Study design

This is a pilot feasibility study, which enrolled 11 patients from BMC between January and August 2015. Since the study is on-going at the second clinical site (EBNHC), data will be presented from the BMC group only. Patient demographics as part of the screening process were collected before starting the first session.

The Boston University Medical Center Institutional Review Board approved this study.

4.2 Setting

The two sites for this study are: BMC and EBNHC. BMC is a tertiary Academic Medical Center, the largest safety net Hospital in New England, with a population of approximately 75% of patients coming from underserved communities. The intervention was delivered in the outpatient Family Medicine Clinic at BMC, where a “group visit room” has the adequate space and facilities (board, computer) and a semi-private area to talk to the patients if needed on a one-to-one basis.

4.3 Patient recruitment

Medical providers from the Department of Family Medicine at BMC referred patients for this study. Patients were also referred from other clinicians.
within the BMC system and from different Community Health Clinics affiliated with BMC. The study was advertised using flyers, in both Spanish and English, during educational meetings within the Family Medicine Department at BMC.

4.4 Inclusion Criteria

We had two main inclusion criteria for participating in this study:

- Adult patients with chronic musculoskeletal pain (at least 12 weeks) greater or equal to 4 on a 0–10 scale were considered for this research proposal.

- Even though the study was designed for Spanish speakers, some of the patients could have been fluent in English too.

4.5 Exclusion Criteria

Additionally, there were six main exclusion criteria for participation:

- Pregnant, or planning to become pregnant within the next 3 months, due to the risk of the safety of the participant, and compliance to attend the sessions could be compromised.

- Patients with psychosis or suicidal ideation. Unstable mental health conditions pose a risk to the safety of the group, and also affect compliance with the intervention.

- Active substance abuse disorder, which also poses a risk to the safety of the participants.
- Patients with a significant medical condition, such as advance cancer or other “terminal” medical problem, where also excluded from the study, given the risk of non-compliance with attendance to all the sessions.

- Those who have already participated in an Integrative Medical Group Visit (IMGV) were excluded, since that could bias or confound the treatment effect.

- Finally, patients that have begun a new pain treatment in the past month or plan to begin a new pain treatments in the next 3 months, since this could also bias or confound the treatment effect.

4.6 The Latino IMGV intervention

As mentioned earlier, the IMGV intervention is conducted once a week over the course of nine weeks, with the first session mostly informative and involving the introduction of participants, and the doctor, and this is the sessions where the ground rules are presented. The clinician leading the sessions combines the concepts of Mindfulness-Based Stress Reduction (MBSR), along with other CIM modalities (such as acupressure, self-massage, nutrition counseling) which are developed over the 9-week intervention (see Table 1 for a more detailed description of the curricula).

Each session starts with a “facilitated discussion” of the topic of the week, following the curriculum. During the first 15–20 minutes of the session, the clinician facilitating the session opens the conversation and gives a brief
overview of the wellness topic, then let participants to express their opinion about
that topic. As argued by Gardiner et al. (2014), the use of motivational
interviewing and shared decision-making strategies, help the clinician and the
participants to find a common ground and a better perspective from the patient's
perspective, which translates into individualized strategies to address the
problem of chronic pain and its associated comorbidities (depression, anxiety,
and so forth).
Table 1. Components of the adapted Latino IMGV Curriculum

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<tr>
<td>1</td>
<td><strong>Group orientation</strong>: Introduction to mindfulness themes; Confidentiality agreement</td>
<td>Beginner's mind, awareness of breath</td>
<td>Use of “Atencion plena” instead of mindfulness</td>
</tr>
<tr>
<td>2</td>
<td><strong>Our reactions to stress</strong>: Stress and your body; Ways of responding to stress; Working with perceptions; Upstream downstream fable; Role of stress</td>
<td>Nine-dots exercise, Body scan</td>
<td>Mostly use of picture of human body and the different symptoms related to stress</td>
</tr>
<tr>
<td>3</td>
<td><strong>The importance of healthy sleep</strong>: Ways to establish a healthy sleeping pattern; Introduction to meditation; The mind/body connection</td>
<td>Body scan</td>
<td>Importance of home remedies used for sleep</td>
</tr>
<tr>
<td>4</td>
<td><strong>Food and movement as medicine</strong>: Nutrition labels; Serving sizes; Mid-term group evaluation</td>
<td>Chair-yoga sequence</td>
<td>“Gentle stretches” instead of “yoga”</td>
</tr>
<tr>
<td>5</td>
<td><strong>Our bodies' response to pain</strong>: Review of integrative approaches to pain; Breathing exercise (STOP)</td>
<td>Acupressure</td>
<td>“PARA” instead of “STOP” technique</td>
</tr>
<tr>
<td>6</td>
<td><strong>Our bodies and inflammation</strong>: Foods and inflammation, Omega 3 fatty acids, trans fats and simple carbohydrates</td>
<td>Awareness of breath meditation</td>
<td>Use of Hispanic recipes, or ingredients to understand the inflammation process</td>
</tr>
<tr>
<td>7</td>
<td><strong>Approaches to depression and challenging communications</strong>: Integrative approaches to depression</td>
<td>Loving-Kindness Meditation</td>
<td>Meditation in Spanish “Bondad Amorosa” Spanish poetry</td>
</tr>
<tr>
<td>8</td>
<td><strong>Understanding the role of food</strong>: Sugar, whole foods, fiber, and protein; Goal setting</td>
<td>Mindful eating</td>
<td>“Raisin exercise”, where participants learned how to eat mindfully</td>
</tr>
<tr>
<td></td>
<td><strong>Wellness Review</strong>: next steps and resources. Focus group discussion</td>
<td>Self-care massage</td>
<td>Focus group, led in Spanish, and focused on the appropriateness and adoption of the intervention</td>
</tr>
</tbody>
</table>

Adapted and modified from Gardiner et al. (2014)
In order to help the group develop self-management skills and provide participants with the opportunity for empowerment, during the first 2–3 sessions patients were trained on how to take and record their vital signs (weight, blood pressure, and heart rate). This process of “self-check in” was done before the start of every session.

In addition to this, the clinician was always available to meet on a one-on-one basis with any participant who may ask for this, and this brief meeting was done either before or after the group session. This time provided the doctor and the patients the possibility to discuss any changes in their condition, medication changes, or even recent emergency room visits or hospitalizations.

The overall structure of this intervention followed the successful program developed by Dr. Gardiner and her team at BMC, with the exception of making this intervention culturally adapted to low-income Spanish speaking patients. As part of the adaptation, our research team considered not only developing a translation of the patient’s curriculum into a low-literacy Spanish level, but also into one that could be easy to understand considering that the concept of mindfulness (core principle of the intervention) is new to many participants. The following section describes in more detail how the Spanish adaptation of the curriculum was developed.
4.7 Adaptation of the patients’ curricula and other materials

The adaptation was a collaborative effort of six members of the cultural adaptation review team, which included three doctors, one research coordinator (all within the Family Medicine Department) and two medical students from Boston University. All the members of the team had a high fluency/reading level in Spanish. The team met over the course of several weeks, where the translation of one or two of the total nine chapters of the curricula was assigned to each member for review and suggestions for adaptations. Once the initial draft of the adapted curricula was developed and shared with the team, we started a process of reading another’s translation (1–2 sessions per member), for purposes of clarity and understanding among the group. The countries of origin of the review team in charge of the translations were: Cuba, Colombia, Panama, Peru and the U.S. This reflects the rich diversity of the Latino culture among BMC Family Medicine and the resources brought to this IMGV cultural and linguistic adaptation process. Although being “Latino” and speaking the same Spanish language would be interpreted as a common understanding for all, regional differences in some words and their meaning speak for the nuances and richness of this language. For example, during the transcription of one of the “healthy recipes”, a member of the team translated “bean” as “poroto”, which was unknown by other team members, who call it “haba” or “vaina” in their countries of origin. Achieving a consensus in the translation, and being aware of the need to offer materials in Spanish that would be both easy to understand based on a
low literacy level and by participants from different countries, was a challenge.

Another important aspect of the curricula adaptation was the use of “usted” instead of “tu”. In the English language we can use “you” indistinctly for adults, seniors or children; however, in Spanish countries there is a difference in the meaning of “usted”, which is a more formal word than “tu”, and especially used with people we have never met before, the elderly, or just when we want to emphasize more respect to the person we are talking to. Consequently, we used the “usted” form to translate the material, and also during the intervention.

Considering that the majority of low-income Latino patients who seek care at BMC or EBNHC could potentially have a low literacy level, another important adaptation of the curricula was the use of more pictures and less written information. The curricula also included sharing Hispanic recipes at the end of most of the sessions. These were chosen based on two criteria: healthy oriented meals and those that represent what is typical for the different regions where participants come from. It is important to note that due to the diverse variation in traditional foods within the Latino culture, the chosen recipes had some ingredients from Mexico, Honduras, Dominican Republic and South America (stated as a whole continent given most countries share similar food traditions).

Poetry is another component of the English curricula, and for the adaptation, we chose Spanish poetry with themes related to mindfulness (see Appendix 2 for a sample of a poem used in the intervention).
Participants were also provided with a compact disc (CD) that contained the following meditations, in Spanish: “awareness of breath” (“conciencia de la respiracion”), “body scanning” (“recorrido del cuerpo”) and “loving-kindness meditation” (“meditacion de la bondad amorosa”). This Spanish meditation CD was created in BMC as part of the curricula/materials adaptation process, and was recorded by Dr. Oscar Cornelio-Flores.

4.8 Measures/Spanish Patients Questionnaires

The following questionnaires were chosen for the purposes of obtaining information about pain, depression, anxiety and stress, pre- and post-intervention: PROMIS-29 (short versions), PHQ-8 and PSS-10. For information about the characteristics of the questionnaires used as well as its psychometric properties, see Table 2. All these have been previously validated in Spanish (Diez-Quevedo, Rangil, Sanchez-Planell, Kroenke, & Spitzer, 2001; Remor, 2006).

4.9 Primary Outcomes

Specific Aims

AIM 1: To assess the feasibility of the IMGV model to reduce chronic pain and improve function in underserved Spanish speaking patients.

The study is guided by the modified Proctor model to assess feasibility and its related constructs of adoption, acceptability and appropriateness. How these
data were collected and measured are described below.

**Feasibility**: defined by Proctor et al. (2011) as the extent to which a new treatment, or innovation, can be successfully carried out within a given agency or setting. Among the most used strategies to measure how feasible an intervention could be, we rely on information about enrollment, retention and participation rates. Another factor to consider if the intervention is feasible, is related to the available resources (personnel, space) in the proposed setting. Information about feasibility was obtained during the screening and enrollment process and during the 9 weeks where attendance was followed. Participants were asked if they could commit to come once a week for a two hour-sessions, for a total of nine weeks. One focus group session at the end of the intervention also served as a data source to inform about this implementation outcome.

**Adoption**: defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice (Proctor et al., 2011). Another way to define this implementation outcome is the “uptake” of the proposed intervention among users. The Latino IMGV will provide an opportunity to review if participants are using or “adopting” the new CIM techniques taught every week. Indeed, as part of the learning and practicing process of the intervention, participants will be asked to practice yoga, or awareness of breath meditation, or how to read food labels (for instance) as “homework”. This not only reinforces what was learned, but specifically provides information on adoption of new
information. Information about this outcome will be obtained during the focus group.

**Acceptability**: defined as the perception among implementation stakeholders that a given treatment or service is agreeable or satisfactory (Proctor et al., 2011). This important outcome is directly linked to the knowledge or familiarity with the intervention in use. Particular attention needs to be paid when an intervention is novel or not familiar to the population using it. This study required understanding what specific MBSR, acupressure or nutritional information, for instance, needs to be presented in a way that is easy enough to be understood by a population that was not probably familiar with these topics. It may be challenging just learning the concept of “yoga”, which may not be accepted by different ethnic groups. Using terms such as “gentle body stretches” may be a way to make yoga more acceptable among our targeted Latino patients.

**Appropriateness**: perceived fit, relevance, or compatibility of the innovation or therapy for a given consumer; and/or the perceived fit of the innovation to address a particular issue or problem (Proctor et al., 2011). In our study, this particular outcome is likely to have cultural underpinnings, and even though appropriateness could be related to acceptability, an intervention could be acceptable but not appropriate, or vice versa. For example, patients may agree that practicing mindfulness meditation is acceptable for reducing their stress
levels and pain, but it may not be appropriate based on cultural, or even religious beliefs. Focus group discussion provided evidence for this outcome.

**AIM 2**: To test the effectiveness of the IMGV to reduce pain and improve function in underserved Spanish speakers.

Testing the effectiveness of IMGV on pain and functional outcomes required the use of quantitative measures assessed prior to and after the intervention, in a pre-post test design. Pain severity in a scale “0–10” will be assessed at each session.

**PROMIS 29** (Patient Reported Outcomes Measurement Information System): Our outcome regarding how this proposed intervention will reduce pain and improve function in underserved Spanish speaking patients with chronic pain will be assessed using the PROMIS 29. This National Institute of Health created instrument is validated in Spanish and widely used to assess chronic conditions. This patient self-administered questionnaire and includes the main “domains” associated with pain: physical function, emotional function, quality of life and sleep (“PROMIS” n.d.).

**4.10 Secondary Outcomes**

**PHQ-8 (Patient Health Questionnaire-8)**: This scale has been validated to screen depression in the general population (Kroenke et al., 2009). This scale has also been validated in Spain among a large group of inpatients (N=1003), and when compared to the outpatient English version of the PHQ, the authors
found the Spanish version to have diagnostic validity to screen for depression (Diez-Quevedo et al., 2001).

**PSS-10 (Perceived Stress Scale):** This scale is also validated in Spanish, and provides important information about the toll stress causes on chronic pain, and the relationship among these two variables in the patients’ quality of life. Remor (2006) studied the psychometric properties of this scale among 440 adults Spanish in Europe, and found this Spanish PSS-10 version had adequate reliability (alpha = .82, test-retest, r = .77), validity, and sensitivity.
<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Measures</th>
<th>Description of Scale</th>
<th>Reliability /validity</th>
<th>Asked During</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent of successful carried out on this clinical setting</td>
<td></td>
<td></td>
<td>Screening enrollment retention Focus group</td>
</tr>
<tr>
<td>Adoption</td>
<td>“Uptake” or intention to use the therapy</td>
<td></td>
<td></td>
<td>Focus group</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Will patients accept this intervention?</td>
<td></td>
<td></td>
<td>Focus group</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perceived fit or relevance of the intervention for this population</td>
<td></td>
<td></td>
<td>Focus group</td>
</tr>
<tr>
<td><strong>Specific aim 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specific aim 2</strong></td>
<td>Patient Reported Outcomes Measurement Information System (PROMIS 29)-short version</td>
<td>Assesses pain severity, interference and physical function</td>
<td>Pain severity measured as a composite score of 4 items each with a 0–10 scale. Pain interference measured as a composite score of 7 items each with a 0–10 scale. Higher scores indicate higher levels of pain</td>
<td>0.91 construct, content</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Health Questionnaire (PHQ)</td>
<td>Measures severity of depression</td>
<td>Sum of 8 items each with a 0–3 scale. Higher scores indicate higher levels of depression</td>
<td>0.82 construct</td>
<td>Baseline and week #9</td>
</tr>
<tr>
<td>Perceived Stress Scale (PSS)</td>
<td>Measures the perception of stress</td>
<td>Sum of 10 items each with a 0–4 scale. Items 4, 5, 7 and 8 are reverse scored. Higher scores indicate higher levels of perceived stress</td>
<td>0.82 construct</td>
<td>Baseline and week #9</td>
</tr>
<tr>
<td><strong>Baseline Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Socio-demographics</td>
<td>Age, sex, ethnicity, language, education, work status, income, previous use of CIM</td>
<td></td>
<td></td>
<td>Screening, Baseline</td>
</tr>
</tbody>
</table>
4.11 Analysis Plan

The questionnaires mentioned above will be used pre- and post-intervention (at week 9), and statistical analysis using mean differences in pain and depression will be used. A focus group will be conducted at the end of the 9-week session, and will collect data about acceptability, and changes to make to the current curricula for future groups.

Quantitative Analysis

Weekly group attendance will be measured. Recruitment, retention and survey data will be analyzed using descriptive analysis: means, medians and standard deviation for continuous variables, and frequencies for categorical variables. The primary analysis will be made using "t"- test statistics to assess the difference in pain severity ("0–10" scale), and the PROMIS 29 at baseline and at the end of the study. The other PROMIS measures related to depression, fatigue and functional status will be measured as well. The analysis will be performed using SAS software version 9.1.

Qualitative Analysis

During the last week of the intervention, we conducted a focus group with participants to receive feedback on the following domains: perceptions, acceptability and uptake from the visits, their overall experience with the intervention and group dynamics, as well as challenges to attend the sessions. During this qualitative analysis, we asked for recommendations from participants
to make the group visits more culturally sensitive (See Appendix 1: Interview Guide for Focus Group). It is important to note that the focus group was conducted in Spanish by a member of our research team who is a native Spanish speaker, and not the doctor who delivered the intervention, to avoid the possibility of data collection bias. Given that one participant was not able to be present at session #9, we conducted an in-depth interview for this specific case, asking the same open-ended questions from the focus group. The focus group with four participants and the in-depth interview with one participant were audio recorded and transcribed verbatim.

For this qualitative approach, we used grounded thematic analysis (Miles, Huberman & Saldana, 2014), derived from a grounded theory approach (Charmaz, 2014), where initial codes are developed and used to create higher order categories in a cumulative manner. Following the coding process by two members of the team, emerging themes were coded using an iterative process until agreement had been reached between researchers. Data from the focus groups were coded by two researchers independently, with a third member reviewing the coded data (triangulation) to ensure inter-rater reliability through a consensual discussion method.
5. Results

Feasibility outcome results (specific aim 1) - A total of 38 patients were referred to the Latino IMGV between January and August 2015. Twenty patients could not be reached for eligibility screening, after several attempts of contacting them by phone. Eighteen patients were screened by phone, and 11 (61%) showed up for the first session and were therefore surveyed. The mean attendance rate across the 9-week intervention was 57%, with the highest attendance rate of 100% for the first session to 28% at the last session. Between weeks 4–8, the attendance rate was 40–60% (see Figure 3). In a study using group medical visits in underserved Latinos from the area of Lawrence, MA, the authors found that about 40% of the patients were lost-to-follow-up during the one-year long intervention (Geller, Orkaby & Cleghorn, 2010). The main reasons why patients were unable to attend, among those who were initially referred and contacted, were transportation and childcare issues.

Demographic results - The majority of the participants in the study were females (91%), and the mean age of the patients was 51.9 years (see Table 3). Among the countries of origin, most of them were from the Dominican Republic and El Salvador, however, there was representation from Guatemala, Colombia, Puerto Rico, Mexico and Peru.
This study is similar to other previous studies with group visits models, which have also showed that females constitute the majority of participants (Gardiner et al., 2014; Geller et al., 2010).

The main pain level score (scale from 0–10) at the first week of the intervention was 7.18. Regarding their educational level, only 1 participant had a College degree (10%), while most of them had completed High School.

When patients were asked about the previous use of any CIM therapy, most of them had tried at least one of the following: Massage therapy,
Chiropractic and/or Acupuncture. Only one patient had practiced yoga before this intervention. The proportion of patients using exclusively one CIM modality was not established given that some of them had used more than one therapy.

Table 3. Patients’ baseline characteristics

<table>
<thead>
<tr>
<th>N = 11</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) mean, sd</td>
<td>51.9 (11.9)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (91)</td>
</tr>
<tr>
<td>Male</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Consider Hispanic</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11 (100)</td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Country of origin</td>
<td></td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>3 (27)</td>
</tr>
<tr>
<td>El Salvador</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Guatemala</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Colombia</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Mexico</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Peru</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Mean pain level at first session (0–10)</td>
<td>7.18</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>Elementary</td>
<td>3 (30)</td>
</tr>
<tr>
<td>High School/GED</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Professional degree</td>
<td>3 (30)</td>
</tr>
<tr>
<td>College</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Previous CIM use</td>
<td></td>
</tr>
<tr>
<td>Massage</td>
<td>4</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>3</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>3</td>
</tr>
<tr>
<td>Yoga</td>
<td>1</td>
</tr>
</tbody>
</table>
Primary Outcome results (specific aim 2) - Table 4 shows the difference in mean of pain, depression, fatigue, stress and function between the first session (baseline) and the last one (9-weeks). The pain intensity decreased 1.60 units at the end of the intervention. The PROMIS-29 also showed a reduction of 3.20 units in pain when compared to baseline. The other PROMIS components also showed a reduction in fatigue, depression and anxiety (5.00, 1.20 and 2.00 units, respectively). Physical function improved 0.40 as well. It is important, however, to note that all of these findings did not reach statistical significance (p<0.05). The change in depression was also measured using the PHQ-8 scale, which showed a reduction of 3.25 units at the end of the Latino IMGV intervention. The Perceived Stress Scale (PSS) showed an increase of 3.80 at 9-weeks, respect to the baseline values.

Table 4. Differences in mean pain, depression, fatigue, stress and function

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean change score (“t-test”) (sd)</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity</td>
<td>-1.60 (2.70)</td>
<td>-4.95, -1.75</td>
<td>0.26</td>
</tr>
<tr>
<td>PROMIS-29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>-3.20 (8.23)</td>
<td>-13.42 to 7.02</td>
<td>0.43</td>
</tr>
<tr>
<td>Fatigue</td>
<td>-5.00 (5.70)</td>
<td>-12.08 to 2.08</td>
<td>0.12</td>
</tr>
<tr>
<td>Physical function</td>
<td>0.40 (3.36)</td>
<td>-3.77 to 4.57</td>
<td>0.80</td>
</tr>
<tr>
<td>Depression</td>
<td>-1.20 (1.30)</td>
<td>-2.82 to 0.42</td>
<td>0.11</td>
</tr>
<tr>
<td>Anxiety</td>
<td>-2.00 (3.37)</td>
<td>-7.36 to 3.36</td>
<td>0.32</td>
</tr>
<tr>
<td>PHQ-8</td>
<td>-3.25(5.68)</td>
<td>-12.29–5.79</td>
<td>0.34</td>
</tr>
<tr>
<td>PSS-10</td>
<td>3.80(6.22)</td>
<td>-3.92–11.52</td>
<td>0.24</td>
</tr>
</tbody>
</table>
Qualitative data analysis

Participants during the focus group session (four participants) and the in-depth interview (one participant) provided information which centered on the following themes: great experience; improved nutrition habits; group sessions are preferred; decreased pain, group solving effect and very helpful in Spanish. These themes, along others that were also mentioned by the patients are summarized in Table 5, along with our main outcomes linked to the modified Proctor Model of implementation.

Great experience

Participants expressed their gratitude and felt motivated by participating in the Latino IMGV, and they thought it was a great experience (examples of how they considered it a great experience are provided below). Participants also hoped they had the chance to be part of this kind of intervention more often.

“It has been a very nice experience, I could actually say a wonderful one, it has helped me, and I am leaving to Peru soon with the idea of sharing all this with my brothers down there”

“Before the group, I did not use to go out, now I talk to others, before I used to be just with myself, especially when I used to have pain, I cried alone, the stress was killing me, but now, I go out, and when I wake up I pray to God, and thank God…and go out, and I feel different, because I
feel this has helped me, it has help me spiritually and in my health…it has helped me a lot”

“I would recommend it to so many people to come, and the truth is that it has helped me, it really worked. I could show my experience to others, it worked with me.”

Group solving

As previously studied, the “group solving effect” theme is well described in the literature, and was one of the main themes emerging from participants of the Latino IMGV.

“You have shared, you have made new friends, we have shared our pain with others, we have learned we are not alone with this problem. You feel supported by the doctor and by your peers in the group. This is why these groups are important, I do not know why I did not do it earlier, it is important”

“When something happens to someone, or to yourself, the person collapses, feels bad, feels awful; then you are in the group and hear what others are going through is much worse than your own problems, and you asked yourself, how can I be complaining if this other person is still alive…and smiling? I am dying just being anxious, when this other person has much worse problems than me”
Preference of group visit to individual visit

The theme round the preference of the group visit versus the traditional one-to-one doctor-patient encounter focused on two main aspects: perception of having more time with your doctor, and the collaborative relationship among participants to learn new skills or knowledge about different health topics.

“Well, it is very different, the visits with your doctor are about fifteen minutes, you do not have much time to explain where you hurt, however, in the group is very different because you have two hours and you have time to explain to the doctor or you could explain him individually what your problem is, in detail, and look for a solution other than pills, alternative medicine instead… it is very important”

“The importance of being in the group is that everyone gives their own opinion and everyone talks. For example, if we are talking about what we do to relax, every person said something different. So, you say “Ah, that works for me too”. If we are talking about sleep, everyone says “I do this... or the other”, and that works for me as well. So, that is the importance of being in a group, that you share many ideas, so if more people are in the group... better, because you have more ideas, because all have a different therapy. I have my own therapy, and I shared it with everybody”
Decreased pain

Participants expressed their feeling of physical improvement regarding to their chronic pain. Indeed, some of them mentioned they were taking less pain medications than before joining the group, and even though they recognize pain was still there, they argued their pain was better controlled.

“I take my time and relax, I am taking less medicines and the chronic pain I used to have for long time has improved a lot. The pain has not gone away, I still have it, and with today’s weather, cold…there are some days you wake up with back pain, pain in the joints, but what used to have improved a lot with the medicines the doctor prescribed. I used to have a lot of pain in my hips and knees, and that has improved…thanks God”

“So, I think this helped me relax a lot, for my pain, that severe pain I always have, I would recommend to others to come to this Spanish group, so they can take advantage as we did, at least it helped me a lot…”

Better nutrition

Another theme that was very common was around food, its nutritional values, how the way we eat is important and the influence food can have on their bodies, particularly how it affects pain.
“...it was around the importance of food, how important is food, one may think ‘let’s eat’ but now one thinks let’s eat not automatically, instead one have to eat nutritious food that doesn't worsen the pain we have. So, this is what you learn, to eat mindfully, to learn to chew. I myself did not use to chew the food, just swallowed it, fast, so many things I have learned in such a short time, and that now will stick in my mind for all my life, because that will not be forgotten”

“If we talk about amount of food, we know those portions now, an apple or a piece of papaya has to be the right one, same with bread, fruits, like everything, also that integral foods are much better, healthier, have less sugar, no? I have learned all of that, and it is very good information because now I am aware of it, and probably at some point someone told me about it, but in the practice is different, I have learned that. Now, I have a picture, put a paper on my fridge, I say to myself...‘yesterday I ate this, today I will have this that has the same equivalent of proteins and carbohydrates’, so I think we all should learn a little bit of that, no?...it has helped me a lot”

Group visit and written materials very helpful in Spanish

When asked about their thoughts of the intervention being delivered completely in Spanish, from the curriculum, to the CD and the sessions, they all
expressed their gratitude for being able to communicate and interact with the provider and their peers in their native language.

“To me it was excellent to know this was in the same language we speak. When he, the doctor, told me that it was in Spanish, I asked him: is that in Spanish?…and he said ‘yes, everything will be in Spanish’, I felt so happy, because sometimes because of the language you feel isolated and say no, I won’t be able to participate, how I am going to express myself?, but thanks God, expressing in your own language is very nice”

“I understand is the same with the difference of the language, but because I am Hispanic, my mother tongue is Spanish…I think it helps many more people. We feel very comfortable obviously this has been done in our language”

Add dancing

Participants also mentioned that adding a “dancing” piece into the program may bring good benefits to decrease their stress levels. They were not specific about the type of dance they wish to have incorporated, only argued that adding dancing could be of benefit too.
“It would be nice that for the next groups you could add something else…like if others come to the group with stress, like we did, having a dance could help…I’m asking for too much eh?…hahaha.”

“Well, I think that if the next group would agree, they should have a dance session. It would be nice, and I would have liked us to have dancing as part of the program, because I think that helps you a lot with the stress”.

Among other less-common themes, participants commented on the following: “very good patient manual (curriculum)”, “therapy was relaxing”, and “weight loss”

**Linkages of qualitative themes to the Proctor Implementation outcomes**

Table 5 shows the main themes emerging from the qualitative analysis linked to the Proctor outcomes of implementation. One or more themes were associated with the outcomes in an effort to understand and interpret our qualitative data.
**Table 5. Qualitative themes linked to implementation outcomes**

<table>
<thead>
<tr>
<th>Themes</th>
<th>Implementation Outcomes from (modified) Proctor Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Great experience</td>
<td>Feasibility</td>
</tr>
<tr>
<td>Improved nutrition habits</td>
<td>Adoption</td>
</tr>
<tr>
<td>Preference of group visits to individual visits</td>
<td>Acceptability</td>
</tr>
<tr>
<td>Group solving effect</td>
<td>Acceptability</td>
</tr>
<tr>
<td>Decreased pain</td>
<td>Appropriateness</td>
</tr>
<tr>
<td>Very helpful in Spanish</td>
<td>Appropriateness</td>
</tr>
<tr>
<td>Add dancing</td>
<td>Appropriateness</td>
</tr>
</tbody>
</table>
6. Discussion

This pilot study showed it is feasible to adapt and implement an IMGV model for low-income Spanish speaking patients with chronic pain in an outpatient medical setting. Our retention rate, 40–50% for most of the sessions, was acceptable and similar to the retention rates found by Geller et al. (2010), but slightly lower than the rates described by Gardiner et al. (2014). Our finding of predominantly female attendees is consistent with those reported in the literature (Gardiner et al. 2014; Geller et al. 2010).

The diverse Hispanic origin in our study is relevant to mention, as being Hispanic is not equal to speaking the same language, as already mentioned in our paper. Having participants from seven different countries provides a more robust perspective of intervention adaptation needs, which creates a new intervention that is both useful and understood by all. Having diverse country of origin demographics in this study is also discussed by Geller (2010), where his study included a participant majority from the Dominican Republic and Puerto Rico, but also included patients from South America.

Our results showed a trend towards reduction of pain, anxiety, depression, fatigue and improvement in physical function. These findings are consistent with reports from previous literature (Gardiner et al., 2014; Geller et al., 2010 & Chao et al., 2015). Geller (2010) found reduced depression for participants with high attendance to the group medical visits for Latino patients during one year.
compared to those with low attendance. Mean depression scores in those with high attendance, measured by the Zung Depression Scale, improved from 46.83 to 38.85 ($p < .001$). Another study using an IMGV model for females with chronic pain also showed improvement in pain and depression (Chao et al., 2015). Even though 76% were racially diverse women with low household income, only 28% were Latina.

Both pain intensity and pain assessed with the PROMIS-29 scale, showed a trend towards improvement after the intervention. The “decreased pain” theme from the qualitative data analysis correlates with the findings in the pain questionnaires. Indeed, participants recognized that they still had pain, but they were able to cope better with their chronic pain, had more control of it, and also manifested they were taking less pain medications. This is particularly important to note that based on the Engel’s biopsychosocial model of pain, there is a close relationship between chronic pain and psychosocial distress.

We found that perceived stress was higher after the current intervention, contrary to previous findings (Gardiner et al., 2014). A possibility for this may include participants’ newly-found knowledge of the different manifestations of stress, which created more awareness of “what is perceived as stressful”. Latinos in particular may assimilate and manifest their stressful experiences in different ways in respect to other cultures (Burton & Shaw, 2015), and even though no statistical significance was found, these results warrant further investigation in larger implementation studies.
Considering that this study was the adaptation into Spanish from the successful English IMGV intervention created and conducted at BMC, other emerging themes from our qualitative data deserves our attention. Besides the themes shown in previous research, like “group solving effect”, or “preference of group visits over traditional visits” (Gardiner et al., 2014 & Jaber et al., 2006), our unique findings of gratitude from the patient’s perspective to have the intervention in Spanish was a very important theme that emerged from the focus group. These themes are related to the “feasibility” and “acceptability” outcomes of the modified Proctor model, where participants were able to consistently attend many of the weekly visits, and were open to this new intervention in Spanish.

As argued by Gardiner et al. (2014), there were many referrals for Spanish-speaking patients in their pilot study, but the intervention was held only in English. The importance of delivering a medical program in a culturally sensitive manner is a critical piece for the adaptation of a successful program into a new population, in this case, low-income Latinos with chronic pain. Along with the emerging theme of being grateful since the intervention was provided in Spanish, patients mentioned the fact that expressing themselves on their native language helps them to connect to others and do not feel “isolated”. This is particularly important when trying to improve access to healthcare and having a supporting system in a society new to some immigrant participants, who lack the social and familiar aid, and have a language barrier in addition to that.
Another important outcome to measure a successful implementation of a new program is regarding its “appropriateness”, which is defined as the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer (Proctor et al., 2011). As argued by the authors, there is sometimes an overlap in the literature between the concepts of acceptability and appropriateness; however, they establish a clear distinction that a proposed intervention may be perceived as appropriate but not acceptable, and vice versa. This study shows that the proposed Latino IMGV intervention for Spanish-speaking patients with chronic pain was considered both acceptable and also appropriate by the participants. Careful adaptation for a diverse Latino population needs to pay close attention to the differences in Spanish words used in one country but with a different meaning in another, or the type of food preferred. Based on this, the intervention was developed using words, foods and general examples that could be easily understood by all.

Finally, the adoption outcome, defined as the intention, initial decision or action to try to use a new practice (Proctor et al., 2011), was also clearly evident in this study. Participants, especially in regards to new knowledge about nutrition, commented that what they have learned it was used right after they learned about it, and they expressed the intention to keep doing it for a long time. This is particularly important to make an intervention sustainable, as the intention to use what was learned in a consistent manner, will help incorporating healthy habits.
into their daily routines of life. Indeed, participants expressed their willingness to use what they learned in the group, in especial the nutritional concepts, since they “will stick on my mind”.

An interesting recommendation from the participants was to consider a more active “movement/dance” component into the curriculum. The current Latino IMGV program has one session where participants learn and practice gentle yoga; however, they recommended to incorporate a “dancing” session, and taking into account the importance of dancing within the Latino culture, perhaps a session of “zumba” may be considered for future programs. This clearly resonates with the importance of delivering a content that is “culturally sensitive” and which engages patients in culturally-oriented dance as another alternative to improve health.

Besides the efforts focused on the adequate implementation of a novel intervention, this study has shown the importance of considering many cultural nuances of Latinos and the way how they cope with their stress and chronic pain, something that clearly aligns with the principles of the Engel’s biopsychosocial model. The complex interaction of language barriers, income limitations and lack of family/social support depicts important factors to keep into consideration when designing a new program for Latinos, as they may facilitate or prevent its successful implementation.
Limitations

This study has some limitations, such as having only the "intervention group", without a control cohort. Also, the fact that the sample was small did not allow us to have “power” and reach statistical significance in our quantitative analyses. In addition to this, the results presented in this paper are only from a small sample of low-income Spanish speakers living in inner city Boston, and may not be generalizable to other Latino population in the U.S.

On the other hand, this intervention has its strengths worth to consider, such as the successful adaptation of a 9-week IMGV curriculum for Spanish-speaking patients, who not only accepted it, but also expressed their intentions to keep using the new knowledge gained for a long time, because the components of the program were culturally sensitive and appropriate from their perspective. Indeed, this is the first integrative medicine group intervention of which we are aware that incorporates a full program (curriculum, materials and presentation/discussion) delivered in the patients’ native language. This aspect of the Latino IMGV intervention is critical, as providing access to quality healthcare for chronic pain to vulnerable populations in their language, could be a powerful tool to reduce disparities in health.
7. CONCLUSIONS AND FUTURE DIRECTIONS

The Latino IMGV is an innovative intervention that seems may play an important role in addressing the emotional, psychological and physical burden of chronic pain among vulnerable Latinos. The 9-week intervention at the Family Medicine Clinic from Boston Medical Center, was feasible, acceptable and appropriate to a low-income Latino sample who came from a diverse cultural background. Participants felt grateful for being part of this study, and even though the statistical analysis of reduction in pain and other numeric outcomes did not reach statistical significance, they all show a trend towards reduction of pain, anxiety, depression, fatigue and improvement in physical function. Emerging themes from participants also showed that most of them gained an important knowledge in nutrition, coping with stress, and benefits from being in a group setting. They especially valued having the intervention and materials in their native language.

The complex relationship among different cultural, social and economic factors (as described in the Engel’s model) affect how the implementation outcomes will be assessed (Proctor model), therefore, designing a successful intervention for a specific population needs to consider all these crucial aspects.

Given the promising preliminary results of this pilot study, future larger studies are needed to investigate this model of care, addressing besides a bigger sample to allow for “power” in the data analysis, the critical issue of
implementation interventions in primary care settings. Indeed, the proposal of successful implementation studies could shed some light in the common goal to reduce disparities in the access of chronic problems among vulnerable populations, and get us closer to a healthcare system that offers access, equity and good quality of care for all.
Appendix 1. Latino Integrative Medicine Group Visits-Participant Interview Guide (Focus Group)

Suggested Script: I would like to thank you for coming today to share your experiences, thoughts and opinions with us. We are looking for your feedback in order to improve our Integrative Medicine Group Visits Program. This is an open discussion and everything you share with me today is valuable. If there are any topics that we don’t touch on, but that you feel are relevant, please feel free to let me know at the end of the discussion. This discussion will be recorded; however we will make sure to keep this recording confidential and for use by our study staff only.

Motivations, Perceptions and Expectations

These questions explore participants’ ideas about integrative medicine and group care and assess their motivation for participating. Also assess patients’ experiences of having the complete intervention and materials in Spanish.

A. Please describe your reasons for participating in the integrative medicine group visits.

B. Please describe your experience with integrative medicine treatments before the IMGV.

C. If you were using any CAM therapies in the past (herbs, yoga, supplements, etc), did you share this with your Primary Care Physician? If not, any reasons for non-disclosing the use?

D. Please describe your experiences with group medical care before the IMGV.

E. Please describe what was the meaning for you to have the group visits in Spanish, as well as all the materials (binder, CD’s)

F. Participant Experience
These questions assess what changes participants may have experienced in physical, emotional, and mental health, and how group care may have affected these changes. Questions also examine other changes participants may have experienced (e.g., mindfulness).

A. Please describe your overall experience with the IMGV program.

Which aspects of the program were helpful? (Please provide an example).

Which aspects of the program were not helpful? (Please provide an example).

B. How has your health changed since being in the group? Think about your physical, emotional, social, and spiritual health. (Please provide an example). (What do you think led to this change?)

C. During the group did you have any urgent health problems? How did you deal with them?

a. How did the tools form the IMGV program help you deal with these problems?

b. What aspects of your health were you able to better manage?

c. How has your ability to cope with your health changed?

D. [Optional, if this material was not already discussed] What did you learn in group visits?

Possible follow-up questions:

1. What did you learn from doing Mindfulness-Based Stress Reduction?

2. (List other specific modalities, e.g. Self- massage and acupressure)
Group Dynamics

This section explores participants’ thoughts about the pros and cons of group care. Questions examine participants’ thoughts and opinions on group visits, benefits/disadvantages of group care, and other relevant concerns.

A. Please describe your experience being part of a group visit. What was positive? What was negative? Please provide examples.

B. How did the group care compare to individual time with your doctor?

C. How did having an integrative physician make a difference?

D. How important was being in a group to the program?

E. What did you learn from your fellow group members?

IMGV Logistics

These questions explore facilitators and barriers to participation in the 9-week program as well as thoughts on curriculum and instructors.

A. How challenging was it for you to attend the IMGV?

B. What things made it easier for you to attend weekly sessions?

C. What things made it difficult for you to attend weekly sessions?

D. How did you feel about the instructors? What did they do well? What could be improved?

1. MD

2. Meditation teacher
Recommendations and Exploratory Questions

These questions explore what recommendations participants have for the program and solicit their input on areas for improvement. Here participants have the opportunity to discuss what they liked and did not like about the program.

D. We are looking to improve the class materials and would like your feedback?

How were the class materials? (have binder available)

What worked? What did not work? Why?

1. CDs

2. Binder materials—home practice guides and doc talk sheets

3. Any other practice you consider should be included: prayer, exercise?

Conclusion

Suggested Script: I would like to thank you for coming today and sharing your experiences and, thoughts with us. This concludes our questions. Is there anything else you think is important that you would like to share with us that we have not covered?
Appendix 2. Spanish poem “El Tiempo” by Joan Brosa.

El tiempo

Este verso es el presente.
El verso que habéis leído es ya el pasado
-ha quedado atrás después de la lectura-.
El resto del poema es el futuro,
que existe fuera de vuestra percepción.
Las palabras están aquí, tanto si las leéis
como si no. Y ningún poder terrestre lo puede modificar.

Joan Brosa
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Vita

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Current Position (07/2014–present):
- Academic Fellow-Integrative Medicine and Health Care Disparities Program. Department of Family Medicine-Boston Medical Center (BMC). Boston, MA.
- Master of Science (MSc) on Health Services Research candidate (2016). Boston University School of Public Health. Boston, MA.

Education:

Post-Graduate Training:
8–9/2015: Resilience and Mindfulness Program for Clinicians: Bringing Intention, Attention and Reflection to Clinical Practice. Boston Medical Center.
10–11/2013: Mindfulness Based Stress Reduction (MBSR) 8-week course-University of North Carolina, Chapel Hill, NC.
05/2013: Functional Medicine – International Annual Conference. Dallas, TX.
04/2012–08/2012: Teaching Practice Faculty Development Course, University of North Carolina, NC.
07/2005–06/2008: Family Medicine Residency. Fairview Hospital-Cleveland Clinic Program. Cleveland, OH.
Licenses and Certification:
05/2014: Active Massachusetts Medical License.
12/2008: American Board of Family Medicine Certification.

Work History:
09/2012–06/2014: Adjunct Assistant Professor, University of North Carolina at Chapel Hill Medical School.
09/2011–06/2014: Attending, Prospect Hill Community Health Center, Prospect Hill, NC.
09/2008–09/2011: Medical Director, Columbus County Community Health Center, Whiteville, NC.
05/2001–03/2002: Medical Director- San Lucas Medical Center, Nueva Cajamarca, Peru.
05/2000–04/2001: Attending, Peruvian Air Force Hospital, Lima, Peru

Honors and Awards:
07/2015: Awarded Full Scholarship for 7th Annual Spirituality and Health Summer Institute-George Washington School of Medicine-Washington, DC.
07/2007: Prescriber’s Letter Natural Medicine Award (for strong interest in Integrative Medicine). Fairview Hospital-Cleveland Clinic Family Medicine Residency.
04/2000: Ranked upper tenth in Medical School Class.

Teaching Experience and Responsibilities:
09/2014–present: Teaching Boston University Family Medical Residents and Medical Students.
09/2009–09/2011: Teaching Family Medicine Residents and Medical Students from the University of North Carolina, NC.

Research Projects (ongoing studies):
“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”- Principal Investigator.

“Music Therapy versus Massage Therapy versus Usual Care in the Inpatient Setting: A Qualitative Analysis” – Co-investigator.
“Use of a Virtual Patient Advocate System-Gaby- in Group Medical Visits for Latinas and African American women with Diabetes”- Co-Investigator.

“Integrative Medicine Group Visits: A Randomized Controlled Trial”- Research Assistant.

**Presentations-Bibliography:**

12/2015: oral presentation to Clinical Leadership team at East Boston Neighborhood Health Center, Boston, MA:

“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”

11/2015: invited for oral presentation at the 143th Annual Meeting-American Public Health Association (APHA). Chicago, IL:

“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”

9/22/2015: Research in Progress presentation at Family Medicine – BMC, MA:

“Exploring the Experience of Hospitalized Patients Who Received Music and Massage Therapy: A Qualitative Analysis”.


8/2015: poster presentations at the Integrative Medicine for the Underserved (IM4US) Annual Conference. Boston, MA:

“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”

“Music Therapy vs. Massage Therapy vs. Usual Care in the Inpatient Setting: A Qualitative Analysis”.

6/2015: oral presentation at the II International Meeting on Mindfulness. San Paulo, Brazil:

“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”

04/2015: Poster Presentation at the Annual Meeting of the Society of Teachers of Family Medicine (STFM). Orlando, FL.

“Feasibility of the Latino Integrative Medical Group Visit (IMGV) to Reduce Pain and Improve Function in an Underserved Spanish Speaking Community”

04/2015: Presenter of webinar to the “Integrative Medicine Interest Group” from the American Medical Student Association:
“The Integrative Medicine Group Visit Model”
03/2015: Panelist for the 2015 Tufts University MAPS (Minority Association Pre-health Students)-Boston, MA:

“Symposium on Integrative Care: Exploring Diverse Approaches to Health”
01/2015: Research in Progress presentation at Harvard Integrative Medicine Fellowship Program,-Boston, MA:

“Integrative Medical Group Visits for underserved Latinos with chronic pain”
12/2014: Research in Progress presentation at the Department of Family Medicine – BMC:

“Feasibility of the Integrative Medical Group Visits Model to Improve Pain in Underserved Latinos”

**Languages Spoken:**

- Spanish: native speaker.
- English.
- Portuguese: basic conversational command.

**Medical Interests:**

Integrative Medicine, in particular mind-body techniques to reduce stress (Mindfulness Based Stress Reduction), Functional Medicine, nutritional interventions and Spirituality. My goal is to use these modalities to improve chronic disease management and maintain wellness, with a focus on underserved communities.

I consider Group Medical Visits (or Shared Medical Appointments) a very effective and efficient way to deliver care and improve patient’s outcomes. Besides practicing full spectrum Family Medicine, I also enjoy performing different outpatient procedures and be involved in teaching activities with medical students and residents.