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Feasibility and assessment of outcome measures for yoga as self-care for minorities with arthritis: a pilot study

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Abstract

Background: While there is a growing interest in the therapeutic benefits of yoga, minority populations with arthritis tend to be under-represented in the research. Additionally, there is an absence of guidance in the literature regarding the use of multicultural teams and sociocultural health beliefs, when designing yoga studies for a racially diverse population with arthritis. This pilot study examined the feasibility of offering yoga as a self-care modality to an urban, bilingual, minority population with osteoarthritis (OA) or rheumatoid arthritis (RA), in the Washington, DC area.

Methods: The primary objective of the study was to assess the feasibility of offering an 8-week, bilingual yoga intervention adapted for arthritis to a convenience sample of primarily Hispanic and Black/African-American adults. A racially diverse interdisciplinary research team was assembled to design a study to facilitate recruitment and retention. The second objective identified outcome measures to operationalize potential facilitators and barriers to self-care and self-efficacy. The third objective determined the feasibility of using computer-assisted self-interview (CASI) for data collection.

Results: Enrolled participants (*n* = 30) were mostly female (93%), Spanish speaking (69%), and diagnosed with RA (88. 5%). Feasibility was evaluated using practicality, acceptability, adaptation, and expansion of an arthritis-adapted yoga intervention, modified for this population. Recruitment (51%) and participation (60%) rates were similar to previous research and clinical experience with the study population. Of those enrolled, 18 started the intervention. For adherence, 12 out of 18 (67%) participants completed the intervention. All (100%), who completed the intervention, continued to practice yoga 3 months after completing the study. Using nonparametric tests, selected outcome measures showed a measurable change post-intervention suggesting appropriate use in future studies. An in-person computerized questionnaire was determined to be a feasible method of data collection.

Conclusions: Findings from this pilot study confirm the feasibility of offering yoga to this racially/ethnically diverse population with arthritis. This article provides recruitment/retention rates, outcome measures with error rates, and data collection recommendations for a previously under-represented population. Suggestions include allocating resources for translation and using a multicultural design to facilitate recruitment and retention.

Trial registration: ClinicalTrials.gov, NCT01617421

Keywords: Yoga, Minority, Osteoarthritis, Rheumatoid arthritis, Feasibility study

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Background

While there is a growing interest in the therapeutic benefits of yoga for the prevention and alleviation of symptoms related to disease [1], there is a need for more evaluation of its effectiveness, especially among minority populations. Lifetime yoga practitioners are more likely female, non-Hispanic white, and college educated [2]; however, Hispanic and non-Hispanic Blacks are increasingly using yoga in the USA [3]. This pilot study investigates the feasibility of offering a yoga intervention to an urban, bilingual, minority population receiving rheumatology care.

A feasibility study [4] was indicated due to the underrepresentation of minority and non-English speaking populations in yoga research, a lack of researched guidance into sociocultural health beliefs, and a lack of diverse research teams. The few studies in the literature which speak to the experiences of minorities who have access to yoga practices are not specifically related to arthritis diagnoses [5-7]. This pilot study was undertaken using a yoga intervention shown to have a positive effect on patients with arthritis [8], by a racially diverse interdisciplinary team of clinicians familiar with the study population [9], and researchers who studied the health behaviors and beliefs of this population [10, 11]. This paper discusses the findings obtained from implementing the intervention as proposed in the original protocol [9].

Methods

Participants and setting

Research participants were recruited from English- and Spanish-speaking patients receiving care from the National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS) Community Health Clinic (CHC) rheumatology practice located in a racially diverse area within the Washington, DC metro region. All enrolled patients met the eligibility criteria: 18 years of age or older, enrolled in the NIAMS Natural History of Rheumatic Disease in Minority Communities study (ClinicalTrials.gov# NCT00024479), and a diagnosis of either osteoarthritis (OA) or rheumatoid arthritis (RA). Exclusion criteria included recent or planned joint surgery, use of assistive ambulatory devices, hypermobility, or unstable disease that could compromise participation in the study. Detailed eligibility criteria can be found in the protocol article [9]. Informed consent and baseline questionnaires were completed at the rheumatology clinic by trained bilingual interviewers.

Intervention

This study used Hatha yoga (influenced by Integral, Iyengar, and Kripalu yoga) which includes postures (asanas), breathing techniques (pranayama), and meditation [9]. Biweekly,

60-min, bilingual yoga classes were offered for 8 weeks at a yoga studio in Washington, DC. Classes were kept small (3–10 participants) to allow for pose modifications as needed for each participant. The same instructor taught all classes with occasional substitution from the principal investigator (PI)/yoga instructor (approximately 2–3 times per cohort). The same 16-class manual was used from the previous randomized research study *Yoga for Arthritis*, conducted through Johns Hopkins University [8]. Participants were given instructions, bilingual manuals, and yoga equipment to encourage home practice. Participants were asked to keep journals to document the frequency and duration of home practice and their experience while on the study. After the last class, a yoga DVD and a list of local yoga studios were given to encourage continued practice.

Objectives

The objectives of the pilot study were to determine: (1) the feasibility of adapting a previously studied arthritisbased yoga intervention for a bilingual ethnic minority patient group, (2) the appropriateness of specific physical function and patient-reported outcome measures, and (3) the feasibility of using computer-assisted self-interview (CASI) for data collection [9].

Sample size and ethical aspects

Since there were no references for this specific population using a yoga intervention, an accrual ceiling of 20 participants (determined by those attending at least one class) was selected based upon discussions with NIAMS clinical staff, previous research with the population [11], and attrition rates from the previous yoga for arthritis study [8]. Approval to conduct the study was obtained through the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)/NIAMS intramural institutional review board (IRB).

Feasibility criteria

This paper addresses the feasibility which includes the practicality, acceptability, adaptation, and expansion of implementing the pilot study protocol [4]. Practicality was evaluated to the extent that intervention could be implemented within the constrained resources, time, commitment, etc. Acceptability was evaluated primarily through participant journal entries and exit interviews comments, outlined in a previously published article [12]. Adaptation and expansion were evaluated using specific rates (recruitment, adherence, and completion), selected outcome measures, exit interviews, and field notes. Data collected about the intervention included class attendance, home practice, and the continuation of yoga practice. This study expands and adapts the Hopkins study, highlighting changes needed for a bilingual minority population and offering the intervention

in a community location. The previous *Yoga for Arthritis* study was not specifically designed to address minority participation. While the study had a diverse participant pool, there were few Spanish speakers, and the strongest predictor of attrition was minority race [8]. The feasibility of using a CASI data collection method was based on the amount of assistance needed, interviewer comments, technical issues, and exit interview comments.

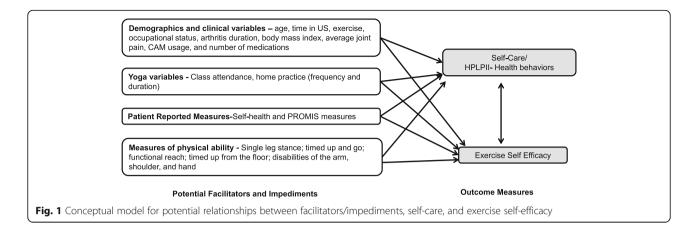
Outcome measures

Due to the lack of standard global measures to test the impact of the yoga intervention, a secondary objective was added to assess patient-reported outcome (PRO) measures and physical assessments (Table 1) across the two time points (baseline and final). Detailed information regarding the decision to use the selected measures were outlined in the original protocol article [9]. The two main outcomes, self-care and exercise self-efficacy (Fig. 1), were operationalized using the Health-Promoting Lifestyle Profile II (HPLP-II) [13] and the Chronic Disease Self-Efficacy-Exercise Regularly Scale [14]. Bandura's social cognitive theory was used as a theoretical framework in determining paths of influence believed to be relevant for this study [15]. Social cognitive theory suggests that self-efficacy plays an important role in motivating behavior change. Self-efficacy is defined as the confidence in one's ability to perform a task [15]. Self-efficacy beliefs shape the outcomes people expect their efforts to produce, also how obstacles and impediments are viewed. Those of high efficacy stay the course in the face of difficulties. Ways to influence self-efficacy include learning a new behavior, seeing people similar to oneself succeed, social persuasion, reducing negative emotional states, and correcting misinterpretations of physical ability [15].

The following additional measures were selected to operationalize potential facilitators or barriers for this population. Self-reported health [16] was selected as an attribute of overall well-being. The Patient-Reported Outcomes Measurement System (PROMIS) 29-profile [17] was selected to evaluate eight domains (Table 1) related to physical, mental, and social health while using fewer questions to reduce participant burden. Physical measures were selected and completed by the physiatrist, physical therapist, and occupational therapist on the study. Global physical measures (Table 1) were selected to evaluate domains of balance (single leg stance (SLS) [18], functional reach test [19]) and functional mobility (timed "Up and Go" test (TUG) [20]) that may be responsive to change with an exercise intervention. The timed floor transfer test [21] was used to evaluate strength, flexibility, function, and problem solving needed to transfer from standing to

Table 1 Patient-reported outcome and physical function measures

| Measures | No. of items | Spanish translation | Reliability/validity tests in the literature |
|---|-----------------|------------------------|---|
| Self-Efficacy Exercise Regularly—Likert scale: 1 (not at all confident) to 10 (totally confident) | 3 | Y | (n = 478) mean 6.3 (SD 2.70). Internal consistency reliability 0.83. Test-retest reliability 0.86 |
| Health Promoting Lifestyle Profile (HPLP II)—Likert-type scales (1—never to 4—routinely). Subscales: spiritual growth, interpersonal relations, nutrition, physical activity, health responsibility, and stress management. | 52 | Y | Alpha reliability coefficient for the total scale is .922. Alpha coefficients for the subscales range from .702 to .904. |
| Self-Rated Health—"Would you say your health in general is excellent, very good, good, fair, or poor?" | 1 | Y | (n = 51) Mean 3.29 (SD 0.91). Test-retest reliability- 0.92 |
| PROMIS-29—8 domains include: anxiety, depression, fatigue, pain (interference and intensity), physical function, sleep disturbance, and satisfaction with social participation | 29 | Y | |
| Single Leg Stand (SLS)—determines if the patient can stand on one leg for 10 s. | | N/A | Mean criterion-related validity was high (Pearson's $r = 0.84$). Inter-observer reliability (ICC (2,1) = 0.81 (t1) and 0.82 (t2). Intra-observer reliability was on average ICC (2,1) = 0.88; Pearson's $r = 0.90$ |
| Functional Reach—measures the difference between a person's arm length and maximal forward reach. | | N/A | The Pearson correlation coefficient was .71 and the R2 using linear regression was .51; Test-retest reliability of the three postural control measures: intraclass correlation coefficient (ICC 1, 3) for center of pressure excursion (COPE) was .52, functional reach .81, and "yardstick" reach .92. |
| Timed Up and Go Test (TUG)—measures the time to stand up, walk 3 m, turn, walk back to the chair, and sit down. | | N/A | Inter-rater reliability- ICC ranged from 0.99–0.992. Intra-session, test-retest reliability, ICC (2, 1) was 0.978 |
| Timed Up from the Floor Test | | N/A | The interrater reliability between various pairs of testers ($r = .99$) |
| The Disability of the Arm, Shoulder, and Hand (DASH)—measures generalized upper limb functional ability. | | Υ | DASH was found to correlate with other measures ($r > 0.69$) with a test-retest reliability of (ICC = 0.96) |



the floor and to return to standing. The Disabilities of the Arm, Shoulder, And Hand (DASH) [22] was selected to assess upper limb functional ability.

Statistical methods

Descriptive statistics were used to report demographic and clinical measures. Spearman's rho (for continuous variables) and Kruskal-Wallis test (for categorical variables) were used to test the relationships among demographic and clinical measures. The Wilcoxon signed-rank test was used to compare the difference from baseline to final time points for PROs and physical measures, for those completing the study (n = 12). "Change" variables were calculated using the difference (final minus baseline) across time. Linear mixed models were also used to evaluate change across the two time points using all available data for enrolled participants. Absolute values of correlation coefficients were used as estimates of effect sizes [23] using Cohen's definitions for correlation coefficients: small (.10), medium (.30), and large (.50) [24]. Missing data were managed according to the measure recommendations. SPSS 21 statistical software was used for data analyses.

Results

Recruitment and participant flow

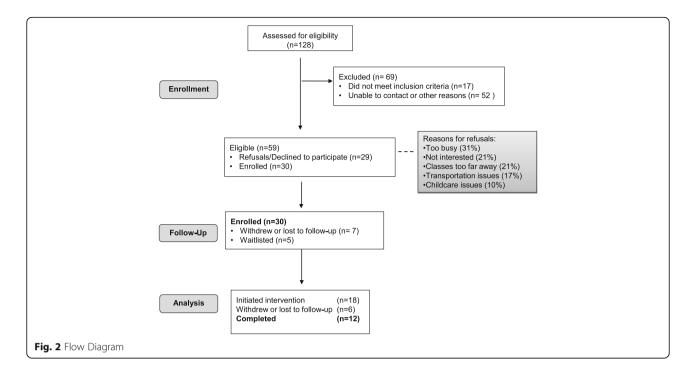
The principal investigator and bilingual research assistants attended the weekly outpatient clinic from 2012 through 2015. Patients were primarily referred by the NIAMS clinicians after completing their regular rheumatology appointment. Additional referrals from rehabilitation medicine clinicians were cleared by NIAMS clinicians prior to enrollment. The first participant was enrolled October 2012, and the first class started in March 2013. Initial classes were formed using only clinician referrals of frequently seen patients; however, after 18 months, direct referrals decreased. A list of less frequently seen, but potentially eligible referrals, was then provided for recruitment. Potential respondents were called directly, or "cold called," using this list. This change in approach increased enrollment; however, without the initial discussion with a trusted clinician, refusals and ineligibles increased. After screening 128 patients, 51% of the 59 eligible patients were enrolled (Fig. 2). Reasons for refusals included the following: too busy, not interested, classes too far away, transportation issues, and childcare issues.

Once enrolled, participants completed a rehabilitation assessment and then were waitlisted until a cohort was formed. The yoga classes were offered as a group intervention, therefore scheduling was driven by the ability to create a cohort who could attend classes during the same times. Participants remained on a waiting list until a suitable cohort was formed. During the course of the study, six patients withdrew, including one for religious reasons [25]; additionally, seven patients were lost to follow-up. The start of the intervention was determined by attending the first yoga class; 60% of those enrolled met these criteria. Of the 18 participants who started the intervention, 12 completed (Fig. 2). Those who completed on average attended 10 out of 16 classes. Home practice averaged 2-3 days a week for approximately 20 min each day.

Selected demographic variables were evaluated for the difference between those enrolled and those who refused; crosstab chi-square values showed no significant different between the two groups. However, it was observed that of the two Hispanic interviewers on the study, one self-identified as "White" and the other as "Other." Some participants appeared to choose a race category based on the interviewer's interpretation, which may have been biased the selection of a race category. Additionally, there was no way to determine how this decision was made for refusal data taken from the medical record, as discussed further by Magaña López et al. [26].



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Study population

Data used to characterize the study population (Table 2) show enrolled participants (n = 30) were mostly female, Hispanic, with the predominant diagnosis of RA (90%). Most participants were foreign-born, with the largest percentage from El Salvador (36.7%). Acculturation was measured using the length of time in the USA (median 19.0 years) and a self-reported measure of English language proficiency which showed only 13.3% did not speak any English [27]. As opposed to previous yoga research with sedentary adults [8], as many as 83.3% participants reported engaging in some form of exercise, and half were employed. Using the Inventory of Complementary and Alternative Medicine Practices (ICAMP) [11], total counts of CAM usage showed a mean value of 6.3 (95% CI 4.9-7.6) per participant, with 23.3% reporting a "movement activity specifically for arthritis or joint symptoms." Functional ability varied from those who walked twice a day for exercise, to those who needed a chair for yoga, and included some already receiving regular physical therapy for strength and flexibility. Group averages of painful joints using a response scale (0 = none thru 3 = severe)show approximately 50% reported no pain and as many as 6% reported severe pain at the time of enrollment (data not shown).

Evaluation of outcome measures

Table 3 shows baseline values for patient-reported outcomes and physical measurements for those enrolled, along with baseline, final, and mean change values for those who completed the study. The average overall HPLP-II score showed a significant increase to 2.8 (2.5, 3.1) at the final time point. Using the corresponding labels (1 = never, 2 = sometimes, 3 = often, 4 =routinely), the average results for the six HPLP-II subscales (Fig. 3) show most baseline responses were below 2.5 at baseline, but increased closer to 3 after the intervention. Sixty-four percent (7 out of 11) of cases had an increased exercise self-efficacy score from baseline. Selected physical measures (Table 3) showed a significant change: SLS-left increased by 4.6 points and functional reach increased by 0.90 points indicating improved balance. DASH decreased by 14 points showing an improvement for this measure. Exploratory models using all available data showed an increase in self-efficacy (p = 0.008) and a decrease in self-rated health (p < 0.001) and DASH (p = 0.004) across time points.

Average PROMIS-29 T scores were all within 1 SD of the US general population. T score distributions are standardized to compare to the average US population mean of 50 (SD—10 points) [17]. T score and standard error (SE) values (Table 4) were not directly calculated from the pilot sample but obtained from a Short Form Conversion Table based on raw scores from the pilot sample. While results for both time points are shown, the PROMIS-29 does not currently evaluate minimally clinically important differences and is not able to detect change related to the intervention. Only baseline measures were used in correlation evaluation.

Table 2 Descriptive statistics (n = 30)

| | Number | Percent |
|--|--------|---------|
| Gender | | |
| Male | 2 | 6.7 |
| Female | 28 | 93.3 |
| Ethnicity | | |
| Hispanic | 21 | 70.0 |
| Non-Hispanic or unknown | 9 | 30.0 |
| Race | | |
| Black/African American | 5 | 16.7 |
| White | 15 | 50.0 |
| Other | 5 | 16.7 |
| Unknown | 5 | 16.7 |
| Place of origin | | |
| North/East Africa, India, or Pakistan | 4 | 13.3 |
| Central America—Other countries | 4 | 13.3 |
| Central America—El Salvador | 11 | 36.7 |
| Mexico | 3 | 10.0 |
| South America | 4 | 13.3 |
| USA | 4 | 13.3 |
| English ability | | |
| Very well | 4 | 13.3 |
| Well | 10 | 33.3 |
| Not well | 12 | 40.0 |
| Not at all | 4 | 13.3 |
| Health literacy | | |
| SAHLSA ($n = 20$) | | |
| Inadequate health literacy | 9 | 45.0 |
| Adequate health literacy | 11 | 55.0 |
| REALM-SF/grade equivalent ($n = 10$) | | |
| (4–6)/seventh to eighth grade | 2 | 20.0 |
| (7)/high school | 8 | 80.0 |
| Diagnosis | | |
| Osteoarthritis | 3 | 10.0 |
| Rheumatoid arthritis | 27 | 90.0 |
| Types of CAM** | | |
| Health providers | 4 | 13.3 |
| Special diet | 13 | 46.7 |
| Vitamins or minerals | 25 | 93.3 |
| Herbs or supplements | 13 | 43.3 |
| Rubs or lotions | 15 | 53.3 |
| Other body treatments | 6 | 20.0 |
| Movement activity | 7 | 23.3 |
| Spiritual practice | 19 | 6.0 |
| BMI categories | | |
| Underweight or normal (< 18.5–24.9) | 6 | 20.0 |
| | | |

| , , | |
|-----------|--|
| 12 | 40.0 |
| 12 | 40.0 |
| | |
| 5 | 16.7 |
| 7 | 23.3 |
| 16 | 53.3 |
| 2 | 6.7 |
| | |
| 7 | 23.3 |
| 8 | 26.7 |
| 9 | 30.0 |
| 6 | 20.0 |
| Range | Median (IQR) |
| 32–69 | 49.5 (41.8–60.0) |
| 4–65 | 19.0 (10.0–27.5) |
| 1–40 | 7.0 (4.0–15.0) |
| 18.4–51.7 | 28.2 (26.1–33.4) |
| | |
| 4–16 | 10.5 (7.3–15.0) |
| 2–7 | 2.5 (2.3–4.8) |
| 7–39 | 22.4 (14.8–31.4) |
| | 12 5 7 16 2 7 8 9 6 Range 32–69 4–65 1–40 18.4–51.7 |

**Respondents could select more than one category; percent do not total to 100

Correlations

There were no significant correlations between any of the selected variables when compared to the change in HPLP-II. Significant correlations with the change in exercise self-efficacy are shown in (Fig. 4). Large effect sizes were found ranging from 0.604 (pain-interference) to 0.736 (self-health). There was an increased change in exercise self-efficacy for those with high reports of pain interference and fatigue at baseline. There was less change in exercise self-efficacy for older participants and those with longer disease duration. Increased exercise self-efficacy was correlated with improved self-rated health (from "fair" towards "very good" and "excellent").

Computer-assisted self-interview (CASI) data collection

All participants (n = 30) used the CASI instrument during the original enrollment process. On average, it took respondents 30 min with moderate assistance to complete the online questionnaire. Approximately, one third required 100% assistance; these participants typically also scored lower on the health literacy scales (Rapid Estimate of Adult Literacy in Medicine—Short Form (REALM-SF) and Short Assessment of Health Literacy for Spanish Adults (SAHLSA-50) [28]). Exit interviews indicated that respondents were "very comfortable/

Table 2 Descriptive statistics (n = 30) (Continued)

| Physical measures | | Baseline enrolled (n = 26) Mean (95% CI) | Baseline (<i>n</i> = 12) Mean (95% Cl) | Final (<i>n</i> = 12) Mean (95% Cl) | Mean change * (12 pairs) |
|---|-----------------|--|---|--|-----------------------------|
| Single leg stance (s) | Left | 15.0 (11.2,18.7) | 12.2 (6.1,18.4) | 16.9 (8.4,25.3) | - 4.61 |
| | Right | 16.5 (12.4,20.6) | 16.9 (10.6,23.2) | 17.6 (8.9,26.4) | - 0.75 |
| Functional reach (in.) | | 12.5 (11.7,13.3) | 12.2 (10.9,13.5) | 13.1 (11.7,14.6) | - 0.90 |
| Timed up and go (s) | | 8.1 (7.4,8.8) | 8.5 (7.7,9.3) | 8.1 (6.8,9.4) | 0.40 |
| Timed Up from the Floor (s) ^a | | 7.7 (4.5,10.9) | 9.6 (2.4,16.7) | 6.0 (3.3,8.7) | 3.58 |
| Disabilities of the Arm, Shoul | der, and Hand** | 34.8 (26.4,43.1) | 33.1 (20.9,45.3) | 18.9 (11.9,25.8) | 14.23 |
| Patient-reported outcome m | easures | Baseline enrolled (n = 30) Mean (95% CI) | Baseline (<i>n</i> = 11) Mean (95% Cl) | Final (<i>n</i> = 11) Mean (95% Cl) | Mean change (11 pairs) |
| Self-rated health | | 3.4 (3.0,3.7) | 3.0 (2.3,3.7) | 2.1 (1.6,2.6) | 0.91 |
| Self-efficacy exercise | | 5.9 (4.9,6.9) | 6.1 (4.0,8.1) | 7.5 (6.8,8.1) | - 1.42 |
| Health-Promoting Lifestyle Profile II score | | 2.4 (2.2,2.5) | 2.3 (2.0,2.6) | 2.8 (2.5,3.1) | - 0.49 |

Table 3 Physical measures and patient-reported outcome measures

*Wilcoxon signed-rank test. Italicized items are significant at p < 0.05

**For the DASH, lower scores equal less difficulty

^aFinal mean for Time Up from the Floor (n = 11), mean change calculated with 11 pairs

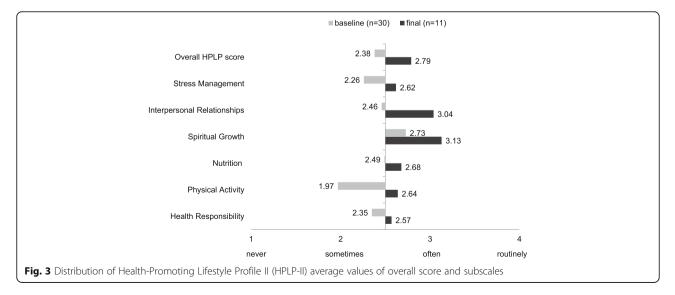
comfortable" (94%) using the CASI instrument and 100% would recommend its continued use.

Exit interviews and 3-month follow-up

A semi-structured exit interview [9] was created to elicit participant feedback on the study design. For those participating in the intervention, exit interviews (n = 16) were completed in the yoga studio following the last class. An attempt was also made to complete the interview by phone for those who withdrew from the study after attending the first class. Most (94%) respondents indicated they were satisfied with the yoga classes and the studio and agreed yoga classes should be bilingual. Half agreed that they feel more comfortable taking classes from teachers with diverse racial/ethnic backgrounds; 85% agreed the yoga poses work well for people with arthritis; and 63% preferred taking classes with others who have arthritis. Follow-up results 3 months after the intervention found all (100%) of those who completed the study were still practicing yoga, for approximately 2-3 times per week.

Side effects/adverse events

There was one report of increased fatigue after starting yoga classes. Further investigation determined the participant was carrying yoga equipment and walking a great distance to save money. The solution was to obtain a reduced fare bus pass and use the studio equipment for class. There was one report of joint pain after practicing a modified reverse table pose that resolved by the next day. Participant was advised not to attempt the pose again.



| PROMIS-29 profile (<i>T</i> scores) | Baseline enrolled (<i>n</i> = 30) Mean (SE) | Baseline (<i>n</i> = 11) Mean (SE) | Final (<i>n</i> = 11) Mean (SE) | Mean change * (11 pairs) |
|--------------------------------------|--|---|--|-----------------------------|
| Physical function | 45.3 (3.6) | 46.0 (3.5) | 47.4 (3.7) | - 1.37 |
| Anxiety | 54.5 (3.5) | 51.7 (3.6) | 49.1 (4.3) | 2.68 |
| Depression | 53.5 (3.3) | 49.7 (3.7) | 50 (4.1) | - 0.30 |
| Fatigue | 50 (2.8) | 48.4 (2.9) | 49.7 (2.6) | - 1.32 |
| Sleep disturbance | 49.7 (3.7) | 51.6 (3.8) | 47.2 (3.6) | 4.37 |
| Satisfaction with social roles | 48.3 (2.5) | 47.4 (2.8) | 50.6 (2.7) | - 3.22 |
| Pain interference | 56.9 (2.5) | 55.5 (2.6) | 49.7 (3.8) | 5.81 |
| Pain intensity (mean) | 4.8 | 4.5 | 3.9 | 0.68 |

 Table 4 Patient-reported outcome measures—PROMIS Profile-29

Pain intensity is a single item scored on a 0–10 scale; derived T score and SE values are not available

*Wilcoxon signed-rank test. Italicized item is significant at p < 0.05

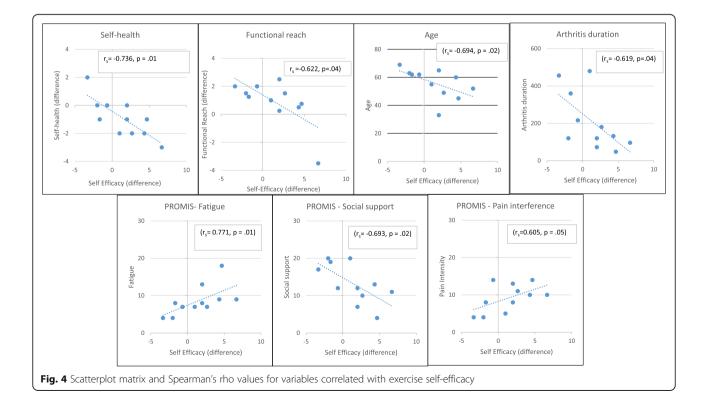
Discussion

This feasibility study was undertaken to evaluate the implementation of the intervention as proposed in the original protocol design. The discussion below summarizes findings related to feasibility including practicality, adaptation, and expansion to facilitate recruitment and retention, suggested future modifications, and a discussion of the study objectives.

Adaptations for bilingual study population

The study team included bilingual researchers and clinicians from Central/South America, Mexico, and Puerto Rico. Two native "bicultural translators," hired as research assistants, were involved from recruitment through data analysis. Their cultural familiarity assisted in establishing rapport, negotiating cultural understandings, and maintaining research integrity [29].

Several translation methods [30] were used. Team translation was used for Spanish journal entries and exit interview responses. Previously validated measures were most often translated using Spanish spoken in Mexico and Puerto Rico, instead of the Central American Spanish reflected within the study population. Professional translations were obtained for all remaining documents.



When reviewed by native Spanish speakers, some changes were made to use less formal or non-anglicized wording. For example:

English: Touch and am touched by people I care about.

Spanish: Toco y soy tocado(a) por las personas que me importan.

While translated verbatim, the Spanish wording implies inappropriate physical touch. The phrase was translated as feeling "loved or connected to others" by the interpreter when administering the questionnaire. As documented in cross-cultural research [31], translating documents significantly increased cost. Using interpreters during data collection and yoga classes increased the amount of time needed to complete these phases of the study.

Expansion for an urban, multicultural population

As discussed in the previous acceptability article [12], considerable time was spent designing a study with a "cultural infrastructure" to overcome potential barriers seen in the clinical setting and known from previous research with this population. Research team concerns with introducing yoga to this population included the lack of images of fullfigured people or minorities doing yoga, the lack of familiarity with yoga, and few yoga studios directly within their communities. A daylong photoshoot was held to obtain culturally relevant images for the recruitment materials. Several of the study researchers and clinicians came to the yoga studio to assist with exit interviews which added to the connection between the yoga intervention and their clinical/medical care.

Based on previous experience with this study population, clinicians on the study expressed potential concerns about meeting required time points, which were found to be valid during implementation. There were several occurrences of rescheduling missed appointments due to inability to take time off from work, difficulty in obtaining childcare, or needing to provide family support. For some, frequent calls were initiated to inquire about missed classes and encourage continued participation.

Comparable to the previous *Yoga for Arthritis* study [9], attrition was highest prior to the first class (while waiting for a cohort to form). The majority of classes were held mid-day and early afternoon, with one weekend offering. Classes were not held during the winter months (December–March). Barriers most frequently identified by participants were the studio location was too far away and difficulty working class times into their work schedule. Some participants traveled as much as 1–2 h to get to the studio. Suggestions for future studies would be to offer

travel vouchers, provide more evening/weekend classes, and on-site childcare to facilitate adherence while on the study. As stated earlier, clinician referral appeared to positively influence willingness to participate in the study. Calling from a list of potential participants increased access to a greater number of potential respondents but also increased refusals and ineligibles. It is suggested that both methods be employed in future studies.

Appropriateness of selected measures and data collection methods

The values for self-care (HPLP) as well as physical measures of balance, functional reach, and upper body function showed a significant change after the intervention and should be considered in future studies. For this study, it was necessary to schedule separate appointments for questionnaire completion and physical assessment. It is possible that time needed schedule appointments may have been a barrier to participation or acceptability for some participants. This may be alleviated by combining assessments in future studies.

Exercise self-efficacy did not show a significant statistical difference. While not available when this study was created, the new Yoga Self-Efficacy Scale (YSES) [32] may provide improved results over the exercise selfefficacy scale used in this study. Age, fatigue, arthritis duration, and social support showed large effect sizes and significant statistical correlation with exercise selfefficacy in this population and should continue to be assessed in future studies. Some PROMIS measures, such as satisfaction with social support, did not correlate as expected. For example, the change in exercise selfefficacy decreased for those with increased satisfaction with social roles (Fig. 4). This runs counter to the importance of social support found in the previous health behavior study [33] and warrants further evaluation.

More precise measures of home practice are needed to determine a potential "yoga dosage." Paper journals were used to decrease satisficing (which refers to a respondent providing a satisfactory answer instead of optimally answering a survey question that would require substantial cognitive effort) [34] and social desirability (inflating reports to be positively perceived) [35] of reported home practice. However, some respondents did not complete journals daily and may have reported weekly estimates of practice. Future research may consider the use of electronic diaries with an objective activity tracker (i.e., Fitbit®). Participants shared more about their experience, while in class with others, than in their journals as was expected. While collected in written field notes, future studies should consider audio-recordings.

Using the in-person web-based CASI questionnaires proved successful, especially after changing from a

laptop to a tablet. The acquisition of a tablet (iPad) required less space in the busy clinic, and participants were more willing to use the touch screen. Additionally, a Wi-Fi hotspot was obtained due to unreliable internet connectivity. It is suggested that in-person CASI, via tablet administration, be used for future data collection.

Generalizability

Due to the sample size limitations, results may not be generalizable; however, when appropriate, estimates are shown with confidence intervals which can be used to inform future sample size calculations [23]. Recommendations within this article offer suggestions for both expanding the current study design for a larger trial and for modifying other future yoga studies focusing on a bilingual minority population living with arthritis.

Conclusions

Results of this pilot study determined that it is feasible to proceed to a larger study with suggested modifications. Recruitment and adherence rates were as expected based on previous experience with this population, and the previous Yoga for Arthritis study. Measures of balance, functional reach, upper body function, and health behavior showed change after completing the intervention. It is recommended that similar measures be included in future studies. Specific suggestions include using electronic diaries with an activity tracker, using the Yoga Self-Efficacy Scale, and providing identified options (i.e., childcare, transportation vouchers, and offering evening/weekend options) within the study design. In-person web-based CASI via tablet administration proved to be a feasible method for data collection. Three-month follow-up found all who completed the study were still practicing yoga. Overall suggestions include allocating additional time and resources for translation/interpretation for bilingual populations, as well as creating a multicultural interdisciplinary research team with previous clinical experience with the study population to facilitate recruitment and retention. This study provides recruitment and retention rates for a previously underrepresented population. Results for selected measures are shown with error calculations for use in future sample size calculations.

Abbreviations

CAM: Complementary and alternative medicine; CASI: Computer-assisted selfinterview; CHC: Community Health Clinic; DASH: Disabilities of the Arm, Shoulder, and Hand; DC: District of Columbia; HPLP-II: Health-Promoting Lifestyle Profile II; ICAMP: Inventory of complementary and alternative medicine practices; IRB: Institutional review board; NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Disease; NIDDK: National Institute of Diabetes and Digestive and Kidney Disease; NIH: National Institutes of Health; OA: Osteoarthritis; PI: Principal investigator; PROMIS: Patient-Reported Outcomes Measurement System; RA: Rheumatoid arthritis; REALM-SF: Rapid Estimate of Adult Literacy in Medicine—Short Form; SAHLSA-50: Short Assessment of Health Literacy for Spanish Adults—50; SLS: Single leg stance; SRH: Self-rated health; TUG: Timed "Up and Go" test

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Availability of data and materials

The datasets used and/or analyzed during the study are available from the corresponding author on reasonable request.

Authors' contributions

All authors contributed to the writing of this manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Approval to conduct the study was obtained through the National Institute of Diabetes and Digestive and Kidney Disease/ National Institute of Arthritis and Musculoskeletal and Skin Disease's intramural institutional review board.

Consent for publication

The following language is included in the informed consent signed by each participant, "Data analyses will occur and results will be reported for presentation and/or publication".

Competing interests

SHM reports consulting fees from NIH during the conduct of the study and provides arthritis-related continuing education for yoga professionals. All remaining authors declare that there is no competing of interests.

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