

## ORIGINAL ARTICLE

# Preference and Expectation for Treatment Assignment in a Randomized Controlled Trial of Once- vs Twice-weekly Yoga for Chronic Low Back Pain

每周一次和两次瑜伽在控制慢性下腰痛方面随机对照试验的首选和期望

Preferencias y expectativas para la asignación de tratamiento en un ensayo controlado aleatorizado de yoga una vez a la semana frente a dos veces a la semana para dolor lumbar crónico

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## ABSTRACT

**Background:** In studies involving nonpharmacological complementary and alternative medicine interventions, participant blinding is very difficult. Participant expectations may affect perceived benefit of therapy. In studies of yoga as treatment for chronic low back pain, little is known about the relationship between patient expectations and preferences on outcomes. This study was designed to identify baseline predictors of preference and to determine if expectations and preferences for different doses of yoga affect back-related function and low back pain intensity.

**Methods:** This was a secondary data analysis of a 12-week randomized controlled trial comparing once-weekly vs twice-weekly yoga for treatment of chronic low back pain in 93 adults from a predominantly low-income minority population. At baseline, participants were asked about back function, back pain, treatment expectations, and treatment preferences. We created a variable “concordance” to describe the matching of participant preference to randomized treatment. Our outcome variables were change in back function and pain intensity after 12 weeks of yoga instruction. We performed logistic regression to identify predictors of preference for once- or twice-weekly yoga instruction. We created linear regression models to identify independent associations between expectations, preference, concordance, and outcomes.

**Results:** Worse back function at baseline was associated with 20% higher

odds of preferring twice-weekly yoga (OR 1.2, CI 1.1, 1.3). Individuals with higher expectation scores for twice-weekly yoga had 90% higher odds of preferring twice-weekly vs once-weekly yoga (OR 1.9, CI 1.3, 2.7). Individuals with higher expectation scores for once-weekly yoga had 40% less odds of preferring twice-weekly yoga (OR 0.6, CI 0.5, 0.9). After controlling for baseline characteristics, we found no statistically significant relationship between treatment outcomes, preference, expectation scores, or concordance.

**Conclusion:** In a population of predominantly low-income minority participants with chronic low back pain, worse back function was associated with preference for more frequent yoga classes. Those who preferred more yoga classes had higher expectations for those classes. Twelve-week change in back pain intensity and back function were not affected by dosing preference, expectation score, or concordance. More research is needed to better measure and quantify preference, expectations, and their relationship to outcomes in yoga research.

## 摘要

**背景:** 在涉及非药物的补充和替代医学干预措施的研究中, 采用参与者盲法非常困难。参与者的期望可能会影响感知的治疗益处。在瑜伽作为慢性下腰痛治疗的研究中, 患者期望和结果首选之间的关系知之甚少。这项研究的目的是找出首选的基线预测,

并确定不同强度瑜伽的期望和首选是否会影响背部相关功能及腰背疼痛强度。

**方法:** 这是一个为期 12 周的二次数据分析的随机对照试验, 93 例主要来自低收入少数民族人口的成年人参与了慢性腰痛的瑜伽治疗, 其中将每周一次和每周两次进行了对比。在基线水平, 受访者被问及背部功能、背部疼痛、治疗的期望和治疗的的首选。我们创建了一个变量“和谐”来描述参与者随机治疗首选的匹配度。我们的结果变量经过 12 周的瑜伽教学后背部功能和疼痛强度均有变化。我们进行逻辑回归分析, 以确定预测一周一次或两次瑜伽治疗的首选。我们创建了线性回归模型, 以确定期望、首选、一致性和结果之间的独立关系。

**结果:** 基线水平背部功能更差者宁愿一周两次瑜伽 (OR 1.2, CI 1.1, 1.3), 机率要高出 20%。相比一周一次瑜伽 (OR 1.9, CI 1.3, 2.7), 个人期望较高得分者一周两次瑜伽的有 90% 更高几率。相比每周两次瑜伽 (OR 0.6, CI 0.5, 0.9), 个人得分较高的期望者每周一次瑜伽的几率减少了 40%。控制基线特征之后, 我们发现治疗结果、首选、期望得分或一致性之间没有统计学意义的关系。

**结论:** 在主要是低收入的少数群体人口的患有慢性腰背痛参加者中, 背部功能更差和首选更频繁的瑜伽课程相关联。那些喜欢更多瑜伽课程的患者有更高的期望。为期 12 个星期后疼痛强度和背部功能的改变不受首选程度、期望得分或一致性的影响。需要更多的研究, 以更好地衡量和量化首选、期望以及和瑜伽研究成果的关系。

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## SINOPSIS

**Antecedentes:** En estudios que incluyen intervenciones complementarias no farmacológicas y de medicina alternativa es muy difícil realizar estas de manera ciega para los participantes. Las expectativas de los participantes pueden afectar el beneficio percibido de la terapia. En estudios del yoga como tratamiento del dolor lumbar crónico, se sabe poco de la relación entre las expectativas del paciente y las preferencias sobre los resultados. Este estudio se diseñó para identificar los predictores iniciales de preferencia y para determinar si las expectativas y preferencias para dosis diferentes de yoga afectaban la funcionalidad relativa a la espalda y la intensidad de dolor lumbar.

**Métodos:** Este fue un análisis de datos secundarios de un ensayo aleatorio controlado de 12 semanas que comparó yoga una vez a la semana frente a dos veces a la semana para el tratamiento del dolor lumbar crónico en 93 adultos de una población minoritaria predominantemente de ingresos bajos. En el momento ini-

cial, se les preguntó a los participantes sobre el dolor y la funcionalidad de sus espaldas, las expectativas del tratamiento y las preferencias del mismo. Creamos una “concordancia” variable para describir la correspondencia entre las preferencias del paciente y el tratamiento aleatorizado. Nuestras variables de resultados fueron el cambio de la funcionalidad de la espalda y la intensidad del dolor después de 12 semanas de sesiones de yoga. Realizamos una regresión logística para identificar los predictores de preferencias para las sesiones semanales o bisemanales de yoga. Creamos modelos de regresión lineal para identificar las asociaciones independientes entre expectativas, preferencias, concordancia y resultados.

**Resultados:** Una peor funcionalidad de la espalda en el inicio se asoció con un 20% de mayor probabilidad de preferir yoga dos veces a la semana (TP 1,2, IC 1,1, 1,3). Los individuos con mayores escalas de expectativas de yoga dos veces a la semana tuvieron un 90% más de probabilidades de preferir yoga dos veces a la semana que una vez a la semana (TP 1,9, IC

1,3, 2,7). Los individuos con mayores escalas de expectativas de yoga una vez a la semana tuvieron un 40% menos de probabilidades de preferir yoga dos veces a la semana (TP 0,6, IC 0,5, 0,9). Después de controlar las características iniciales, no hallamos relación estadísticamente significativa entre los resultados del tratamiento, preferencias, escalas de expectativas o concordancia.

**Conclusión:** En una población de participantes de minorías predominantemente con bajos ingresos con dolor lumbar crónico, se asoció una peor funcionalidad de la espalda con la preferencia por una mayor frecuencia de clases de yoga. Aquellos que prefirieron más clases de yoga tenían más expectativas para esas clases. El cambio de doce semanas en la intensidad del dolor de espalda y la funcionalidad de la misma no se vio afectado por la preferencia de dosis, escala de expectativas o concordancia. Se necesita realizar más investigaciones para medir mejor y cuantificar las preferencias, las expectativas y su relación con los resultados en la investigación del yoga.

## BACKGROUND

Low back pain has a global lifetime prevalence of about 39%<sup>1</sup> and is the greatest contributor to global disability.<sup>2</sup> The economic burden of back pain is also significant. In the United States, those with spine problems spend about \$86 billion more in healthcare dollars than those without spine problems.<sup>3</sup>

Concern that patient expectations can affect treatment outcomes is a large reason for participant blinding in clinical trials.<sup>4</sup> Blinding is particularly important in trials related to subjective outcomes such as pain. Clinical studies exist that explore the relationship between patient expectations and treatment outcomes, though few have been in the field of complementary and alternative medicine (CAM).<sup>5</sup> Within CAM, it is difficult or impossible to blind participants receiving nonpharmacological CAM interventions. Relatively few published CAM studies have addressed the association between patient expectations and outcomes.

It has been suggested that positive patient expectations regarding CAM therapies are responsible for treatment success.<sup>6</sup> Studies have been performed examining the effect of participant expectations regarding acupuncture,<sup>7-10</sup> massage,<sup>8</sup> and manual therapy<sup>11,12</sup> on outcomes for low back pain; however, these results have been inconsistent. Additionally, few studies have examined the effect of randomization into preferred

treatment group vs non-preferred treatment group on outcomes for various forms of CAM.<sup>7-13</sup> Little published data are available on the relationship between patient expectations and preferences of yoga on outcomes for low back pain. Tillbrook et al looked at yoga for chronic low back pain (cLBP) and found no association between yoga class preference and back function. However, they did not study the effect of expectations on back function or other outcomes.<sup>13</sup>

This is a secondary data analysis of a randomized controlled trial comparing once per week to twice per week yoga classes for treatment of cLBP.<sup>14</sup> Our primary publication found that there were no statistically significant differences in pain or back-related function between once- and twice-weekly yoga classes. However, within-group analysis showed statistically significant decreases in baseline pain and back-related function at 12 weeks in both once- and twice-weekly yoga classes. The purpose of the current analysis was to identify baseline predictors of preference and to determine if expectations and preferences for once- or twice-weekly yoga affected back-related function and low back pain intensity. Our hypotheses were that severity of back pain and impaired back function would be related to preference for more frequent yoga classes and that receiving the preferred treatment or having high expectations for treatment would be related to improved outcomes.

## METHODS

### Study Design

Data from Saper et al were analyzed in a secondary data analysis. The study was a two-armed randomized controlled trial comparing once-weekly yoga classes to twice-weekly yoga classes for treatment of cLBP in predominantly low-income, minority participants residing in Boston, Massachusetts. A full description of the methodology has been described previously.<sup>14</sup> Briefly, 95 adults aged 18 to 64 years participated in this study. Of these, 93 participants identified a preference for treatment group at baseline and were included in the analysis for this study. Inclusion criteria were current nonspecific low back pain persisting for 12 weeks or longer, mean low back pain intensity for the previous week of  $\geq 4$  on a 0 to 10 numerical rating scale, English fluency, active patient status at 1 of the 5 study sites, and willingness to provide contact information of at least 1 close friend or relative. We excluded participants if they had used yoga in the previous 6 months, had begun new cLBP treatment within the previous month, or anticipated starting a new treatment in the next 3 months; were pregnant; had back surgery in the previous 3 years; had specific cLBP pathologies (eg, spinal canal stenosis); had severe or progressive neurological deficits; had sciatica pain equal to or greater than their back pain; were involved in active workers compensation, disability, or personal injury claims; or had perceived religious conflict with yoga intervention. The Institutional Review Board of Boston University Medical Campus approved all study activities.

### Data Collection

At baseline, we collected sociodemographic, function, and back pain data. We assessed back function using the modified Roland Morris Disability Questionnaire (RMDQ),<sup>15</sup> a 23-item validated instrument measuring the number of activities of daily living limited due to back pain. Scores range from 0 to 23, with higher scores reflecting poorer back-related function. Average pain level for the previous week was assessed using an 11-point numeric scale (0=no pain to 10=worst pain).<sup>16</sup> Health-related quality of life was determined using the SF-36.<sup>17</sup> Expectation of helpfulness was assessed by asking, "How helpful do you expect yoga once a week would be for your back problems (0=not helpful at all to 10=very helpful)?" We then repeated the question for twice-weekly yoga. We categorized expectation scores using the median into high and low for once- and twice-weekly yoga.<sup>8</sup> Preference for treatment assignment was assessed by asking, "If you had a choice, which group would you prefer to be in: yoga once a week or yoga twice a week?" A participant was considered "concordant" if a his or her preference matched his or her randomization group. At 12 weeks, participants were surveyed once more to reassess back function and pain using the RMDQ and 11-point pain scale.

### Data Analysis

We summarized expectation scores, preferences, and sociodemographic data with descriptive statistics. We compared sociodemographic data, SF-36 scores, and back pain-related factors between those who preferred once-weekly yoga and those who preferred twice-weekly yoga. We performed bivariate analysis to identify possible associations using student *t*-test for continuous variables and chi-square test of independence for categorical and dichotomous variables. We used logistic regression to identify predictors of preference for once- or twice-weekly yoga instruction. We included variables that were associated with preference groups in bivariate analysis ( $P < .30$ ) and used a forward selection strategy to arrive at the final logistic regression model.

To determine if independent associations existed between expectations, preference, concordance, and outcomes, we first defined our primary outcomes of interest as change in back function and change in back pain. Change scores were calculated by subtracting baseline values from 12-week values. We created linear regression models using either change in RMDQ score or change in low back pain score as the dependent variable. We controlled for gender, age, ethnicity, language, income, education, religion, and employment, while examining preference for once- or twice-weekly yoga, expectation for once-weekly yoga, expectation for twice-weekly yoga, and concordance as predictors. A forward selection strategy was used to arrive at the final model. The analyses presented in Table 2 were planned secondary analyses. However, sample size was determined based on a power analysis for the primary analysis. All analyses used a 2-sided  $\alpha = 0.05$  for statistical significance. We used SAS version 9.3 (SAS Institute, Cary, North Carolina) for all statistical analyses.

## RESULTS

### Baseline Characteristics, Expectations, and Preference

Table 1 describes baseline sociodemographic and clinical characteristics of the 93 participants included in analyses stratified by preference for once- or twice-weekly yoga. Thirty-two percent of participants preferred once-weekly yoga, and 68% preferred twice-weekly yoga. Average age of all participants was 47.5 years, and the majority were female. Mean RMDQ and pain scores reflected moderate-to-severe chronic low back pain.

Table 1 also summarizes expectation scores. Among those who preferred once-weekly yoga, mean expectation scores for once-weekly yoga and twice-weekly yoga were similar (7.5 and 7.0 respectively,  $P = .46$ ). Among those who preferred twice-weekly yoga, mean expectation for twice-weekly yoga classes was greater than for once-weekly (9.0 and 6.5, respectively,  $P < .001$ ).

Expectation scores for weekly yoga were somewhat higher among those preferring once-weekly

**Table 1** Baseline Participant Characteristics by Preference

	Preference for Once-weekly Yoga (n=30)	Preference for Twice-weekly Yoga (n=63)	P value
<b>Age</b> Mean (SD)	48.6 (13)	47.0 (10)	.49
<b>Female</b> N (%)	22.0 (73)	48.0 (76)	.80
<b>Low Back Pain Intensity</b> Mean (SD)	6.5 (2)	7.0 (2)	.17
<b>Expectation Score for Once-weekly Yoga</b> Mean (SD)	7.5 (3)	6.5 (2)	.06
<b>Expectation Score of Twice-weekly Yoga</b> Mean (SD)	7.0 (3)	9.0 (2)	.003
<b>RMDQ</b> Mean (SD)	12.4 (6)	15.6 (5)	.007
<b>SF-36 Physical Component Score (PCS)</b> Mean (SD)	40.8 (8)	35.9 (7)	.003
<b>SF-36 Mental Component Score (MCS)</b> Mean (SD)	48.0 (13)	42.9 (12)	.07

Abbreviations: RMDQ, modified Roland Morris Disability Questionnaire; SD, standard deviation; SF-36, The Short Form-36 Health Survey.

yoga compared to those preferring twice-weekly classes (7.5 and 6.5 respectively,  $P=.06$ ). Expectations for twice-weekly yoga classes were significantly greater among those preferring twice-weekly classes compared to those who preferred once-weekly classes (9.0 and 7.0 respectively,  $P=.003$ ).

For individuals who preferred twice-weekly yoga, baseline RMDQ scores were significantly higher than those for participants preferring once-weekly yoga (15.6 and 12.4 respectively,  $P=.007$ ) and SF-36 Physical Component Scores were significantly lower (35.9 vs 40.8,  $P=.003$ ). SF-36 Mental Component Scores were also lower for the group preferring twice-weekly yoga, but this did not reach statistical significance (42.9 vs 48.0,  $P=.07$ ).

### Predictors of Preference for Once- vs Twice-weekly Yoga

We performed a logistic regression analysis to examine potential predictors of preference, including expectations (Table 2). We controlled for education, baseline RMDQ score, back pain score, and SF-36 Mental Component Scores. SF-36 Physical Component Scores were not included in the regression model due to high correlation to RMDQ scores (Pearson coefficient: 0.71,  $P<.001$ ). We found a statistically significant association between expectation and preference for twice-weekly yoga. Individuals with higher expectation scores for once-weekly yoga had 40% lower odds of preferring twice-weekly yoga (OR 0.6, CI 0.5, 0.9). Individuals with higher expectation scores for twice-weekly yoga had 90% higher odds of preferring twice-weekly vs once-weekly yoga (OR 1.9, CI 1.3, 2.7). There was also a statistically significant relationship between baseline RMDQ score and preference for twice-weekly yoga, with worse back function associated with 20% higher odds of preferring twice-weekly yoga (OR 1.2, CI 1.1, 1.3).

**Table 2** Predictors of Preference for Twice-weekly Yoga<sup>a</sup>

	Odds Ratio (95% Confidence Interval)
<b>Worse Back Function (RMDQ)</b>	1.2 (1.1, 1.3)
<b>Expectation Score for Once-weekly Yoga</b>	0.6 (0.5, 0.9)
<b>Expectation Score for Twice-weekly Yoga</b>	1.9 (1.3, 2.7)

<sup>a</sup> Adjusted for education, LBP pain score, and SF-36 Mental Component Score. Abbreviations: LBP, low back pain; RMDQ, modified Roland Morris Disability Questionnaire.

### Influence of Preference, Expectation and Concordance on Change in Back Pain and Function

Ninety-three participants identified a preference at baseline. Seventeen of 30 people (57%) who preferred once-weekly yoga were randomized into once-weekly yoga classes. Thirty-three of 63 people (52%) who preferred twice-weekly yoga were randomized into twice-weekly yoga classes. Fifty people (54%) were concordant, and 43 individuals (46%) were discordant.

Table 3 describes change in low back pain and RMDQ scores at the end of 12 weeks according to participant preference, expectation, and concordance. All groups had improved back pain and function after 12 weeks. However, we found no statistically significant or clinically meaningful differences when we stratified the data by preference, expectation, or concordance. We performed linear regression analysis to assess independent associations between change in RMDQ scores and preference, expectation, and concordance. After controlling for treatment arm, education, age, gender, baseline SF-36 Physical Component Score, and baseline RMDQ score, preference, expectations scores, or concordance were not independently predictive of outcome (data not shown). Similarly, regression

**Table 3** Influence of Preference, Expectation, and Concordance on Changes in Back Pain and Function

	Preference		P value	Expectation for Once-weekly Yoga Classes		P value	Expectation for Twice-weekly Classes		P value	Concordance of Preference With Treatment Assignment		P value
	Once-weekly	Twice-weekly		High	Low		High	Low		Yes	No	
<b>Change in LBP Intensity</b>												
Mean (SD)	2.0 (2)	2.4 (3)	.44	2.1 (3)	2.6 (3)	.34	2.2 (3)	2.4 (2)	.67	2.1 (3)	2.5 (3)	.42
<b>Change in RMDQ</b>												
Mean (SD)	4.6 (5)	5.6 (7)	.45	4.8 (7)	5.5 (6)	.59	4.6 (7)	5.7 (6)	.44	4.5 (5)	6.2 (7)	.22

Abbreviations: LBP, low back pain; RMDQ, modified Roland Morris Disability Questionnaire; SD, standard deviation.

models with change in low back pain intensity as the dependent variable also did not show any statistically significant associations. In both regression models, we did not see statistically significant interactions between preference and concordance or between preference and high or low expectations.

## DISCUSSION

In a population of low-income minority participants with cLBP, we found that worse back function was associated with preference for more frequent yoga classes. Participants who preferred more yoga classes had higher expectations for those classes. Despite this, our outcome measures of back pain intensity and change in RMDQ after 12 weeks did not appear to be affected by dosing preference or expectation score. In this study, being randomized into one's preferred treatment arm was not independently associated with outcome.

Little has been published about the effects of expectations and preferences of yoga on outcomes in cLBP.<sup>13</sup> The literature on expectations of CAM interventions on low back pain has had inconsistent conclusions. Three studies corroborate our findings. Myers et al asked expectation questions about usual care and usual care plus specific CAM interventions (chiropractic, acupuncture, or massage) of 444 patients with acute low back pain. Linear regression showed that expectations for specific therapy were not related to functional outcome as measured by the RMDQ at 5 weeks and 12 weeks.<sup>11</sup> Sherman et al assessed expectations and preferences regarding acupuncture for the treatment of cLBP in 477 patients. They found no significant predictors of short- or long-term improvement in back-related symptoms or function.<sup>7</sup> Bishop et al performed an adjusted logistic regression looking at the relationship between patient expectations for different manual therapies and successful outcomes in 112 patients. They found no statistically significant relationship between treatment expectations and outcome.<sup>18</sup> They included an "intervention-belief" interaction similar to our "concordance" variable, which also did not predict successful outcome at a statistically significant level.

In contrast to our findings, Kalauokalani et al assessed expectation for acupuncture, massage, and

self-care for treatment of chronic back pain in 135 patients. They found that patients with higher treatment expectations had more than a 3-point greater improvement on the RMDQ than did patients with lower treatment expectations.<sup>8</sup>

Our study has several limitations. All participants entering the study expected to receive a yoga intervention. We believe this caused relatively high expectation scores for all participants with little overall variance. This may explain why we did not observe a relationship between expectations and outcomes. Since our analysis of expectations and preference was performed on 2 doses of the same yoga intervention, we cannot generalize our findings to the comparison of different treatment modalities. We used a very general question about the "helpfulness" of yoga as the basis for our expectation rating. Though many studies have used similar constructs to assess expectations,<sup>7-9,11,18</sup> it is difficult to identify and encapsulate all the factors that influence expectation into a single number. For example, we do not know how an individual's expectations are affected by self-efficacy, prior knowledge, previous experience with yoga, and time. In addition, yoga, unlike some more passive treatments, requires a certain amount of motivation, activation, and participation for benefits. The high expectation scores may be related to increased self-efficacy and an increased willingness or motivation to engage in the practice of yoga. We could not account for these important factors in our analysis. Lastly, although the sample size for this study was not based on these planned secondary analyses, we had 89% to 96% power to detect a clinically significant difference in pain (2 points). However, there was less power (59% to 65% power) to detect a clinically significant difference in RMDQ (3 points).

## CONCLUSIONS

Clinically, our findings indicate that considering a patient's preference for yoga class frequency will likely not affect outcomes in cLBP as long as a minimally effective dose is received. Prior studies have demonstrated that for cLBP, benefits may accrue from 12 weeks of once-weekly yoga.<sup>13,14,19,20</sup> Our findings may have been different with more disparate interventions. Future research to improve our understand-

ing of the complexity of expectations on outcomes is needed. In particular, validating new multifaceted measures of expectation and understanding how expectation changes over time may prove useful.

### Authors' Contributions

RBS conceived of the study and participated in its design and coordination. HHT and JW performed the statistical analysis. HHT prepared the manuscript. All authors helped to draft the manuscript. All authors read and approved the final manuscript.

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