Pilot RCT of Hatha Yoga for Chronic Low Back Pain in a Predominantly Low Income Minority Population

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BOSTON UNIVERSITY
YLBP
BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.
Chronic Low Back Pain (CLBP)

- Large cause of suffering and cost in society
- Minorities with CLBP receive less patient education, analgesics, rehabilitation, and CAM therapies
- Several studies in mostly white patients suggest yoga is helpful for CLBP
- Feasibility, safety and effectiveness of yoga for people from predominantly low income minority backgrounds with CLBP is unknown
Study Aims

1. Determine the feasibility of a RCT comparing yoga to a usual care wait-list control for predominantly lower income minorities with CLBP

2. Collect pilot data on pain, back-related dysfunction, medication use, and safety
Study Population

• Inclusion Criteria
  – 18 to 64 years old
  – Non-specific LBP ≥ 12 weeks
  – Average pain intensity of ≥ 4 on 11 point numerical rating scale
  – Ability to understand English

• Exclusion criteria
  – Yoga in previous 12 months
  – Pregnancy
  – Non-muscular causes of CLBP
  – Active substance abuse or suicidality
  – Ongoing litigation/claims
Recruitment

- Targeted 2 community health centers
- Flyers in clinics and neighborhood
- Educate providers
- MD letters
- Community newspaper and radio ads
- Honorarium

DO YOU SUFFER FROM
CHRONIC LOW BACK PAIN?

YOGA may help!

You may be able to receive 12 weeks of free yoga classes in a research study of yoga for low back pain at the Dorchester House Multi-Service Center, 1353 Dorchester Avenue. Adults of all backgrounds who have had low back pain for at least 12 weeks are encouraged to call.

For more information, please call (617) 414-6795 or email YogaBackPainStudy@bmc.org. Compensation will be provided.
Hatha Yoga Protocol

- Constituted diverse expert panel
- Systematic review of lay and scientific literature on yoga and LBP
- Designed protocol based upon professional experience and literature
- Consensus and iterative refinements
Protocol

- 12 weeks
- 1 class/wk
- 75 mins/class
- ≤8 people/class
- 2 teachers/class
- Variations
- World music
- Home practice
- Audio CD
- Handbook
- Yoga supplies
Data Collection

- Baseline, 6, 12, and 26 weeks
  - Paper questionnaires, assessor not masked

- Primary Outcomes – Feasibility
  - Time to recruit 30 subjects
  - % ethnic/racial minorities
  - Adherence

- Secondary Outcomes – Effectiveness/Safety
  - Pain (0-10)
  - Modified Roland Morris Disability Scale (0-23)
  - Pain medication use
  - Adverse events
Inquiries about study (n=234)

Assessed for potential eligibility (n=66)

Excluded (n=36)
  Did not meet inclusion criteria (n=33)*
  Declined to participate (n=3)

Recruitment ended before eligibility determined (n=168)

Randomized (n=30)

Allocated to yoga (n=15)
  Attended any classes (n=14)
  Received self-care book (n=15)

Allocated to wait list control (n=15)
  Received self-care book (n=15)
### Baseline Characteristics

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<table>
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<tbody>
<tr>
<td>Mean age, yrs</td>
<td>44</td>
</tr>
<tr>
<td>% female</td>
<td>83</td>
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<tr>
<td>Race, %</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>24</td>
</tr>
<tr>
<td>Black</td>
<td>70</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
<tr>
<td>% Hispanic</td>
<td>13</td>
</tr>
<tr>
<td>% Ethnic or racial minority</td>
<td>83</td>
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<tr>
<td>% Annual household income $ \leq $ 30,000</td>
<td>44</td>
</tr>
<tr>
<td>% No or public-funded health insurance</td>
<td>50</td>
</tr>
<tr>
<td>% High school grad</td>
<td>33</td>
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<tr>
<td>% LBP duration $&gt;1$ yr</td>
<td>80</td>
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<tr>
<td>Mean pain score</td>
<td>7.1</td>
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<tr>
<td>Mean Roland score</td>
<td>15.3</td>
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<tr>
<td>% Pain medication use</td>
<td>70</td>
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Many co-morbidities and few had previous yoga experience
Adherence and Safety

• Median classes attended: 8
• 14/15 attended ≥1 yoga class
• 13/15 practiced at home
  – Average 4 days/wk for 25 mins/day
• 1 pt with transient worsening of LBP
• The case of JP
Week
Pain Score
0 1 2 3 4 5 6 7 8 9 10
Usual care
Yoga

Pain Score

Week

p=.02
Back Related Dysfunction

Roland Disability Scale Score

Yoga
Usual Care

p = .28
Pain Medication Use in Last Week

- Any Pain Medicine
- NSAIDs
- Acetaminophen
- Opiates
- Muscle Relaxants
- Other

*Percent*

*Yoga*

*Usual Care*

*p<.05*
26 Week Follow-up

- **Yoga**
  - Maintained improvement
  - **But** 7/15 loss to follow-up and increase in non-study treatments

- **Usual Care**
  - Improved
  - 0/15 loss to follow-up
  - **But** non-study treatments increased to 87% at 26 weeks including 5 who did yoga
Limitations

- No control for attention and group effect
- Small sample size
- Long-term loss to follow up in yoga group
- Long-term high use of non-study treatments in control group
Conclusions

- An RCT of a standardized yoga program for CLBP in a predominantly lower income minority population is at least in the short-term feasible.
- Yoga is a promising therapy for CLBP in this population.
- Larger studies with methods to increase long-term adherence and follow-up are needed.
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Thank You

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Yoga for Low Back Pain