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

> Robert Saper Larry Culpepper Paula Gardiner Diana Cullum-Dugan

Surya Karri Karen Sherman Roger Davis Russell Phillips







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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



- 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 \geq 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?



<u>YOGA</u> 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 <u>Voga.BackPainStudy@bmc.org</u> 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







Knee to chest

Knee to chest with twist

Cat and Dog Pose





Chair Pose Modified



Mountain Pose



Shoulder Opener

Chair Pose





Half Moon (Crescent)

Child's Pose

Cobra and variation



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









Bridge pose

Cat and Dog Pose Variation

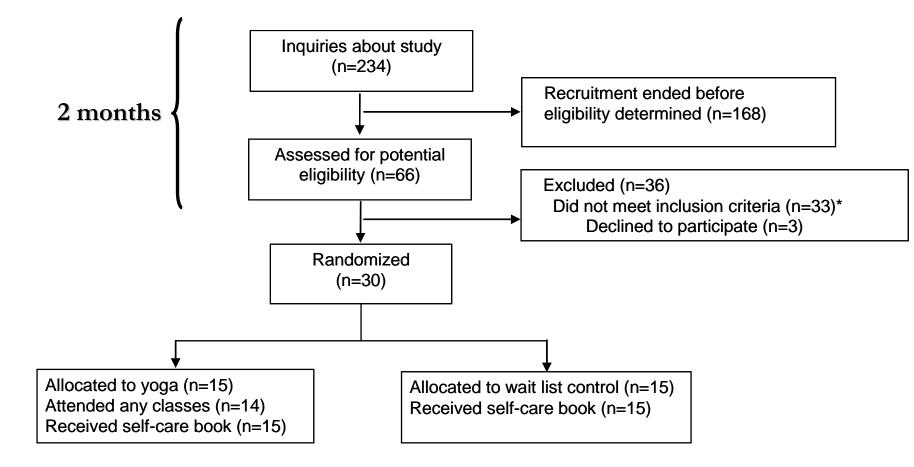
Table Top Leg Extension

Triangle at wall

Data Collection

- Baseline, 6, <u>12</u>, 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

Participant Flow Chart



Baseline Characteristics

Mean age, yrs	44
% female	83
Race, %	
White	24
Black	70
Other	6
% Hispanic	13
% Ethnic or racial minority	83

% Annual household income < \$30,000	44
% No or public-funded health insurance	50
% ≤ High school grad	33
% LBP duration >1 yr	80
Mean pain score	7.1
Mean Roland score	15.3
% Pain medication use	70

Many co-morbidities and few had previous yoga experience

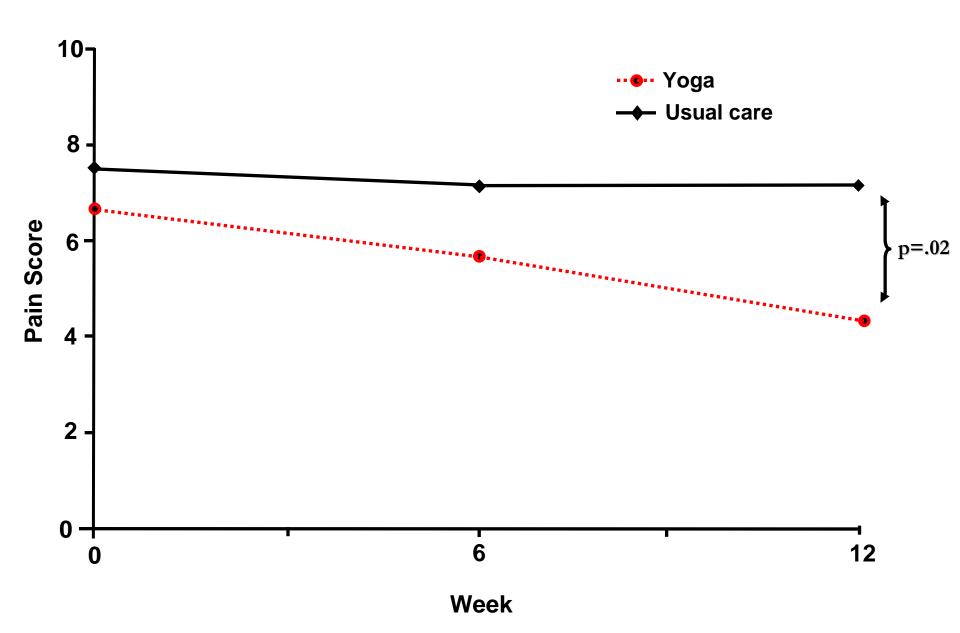
Adherence and Safety

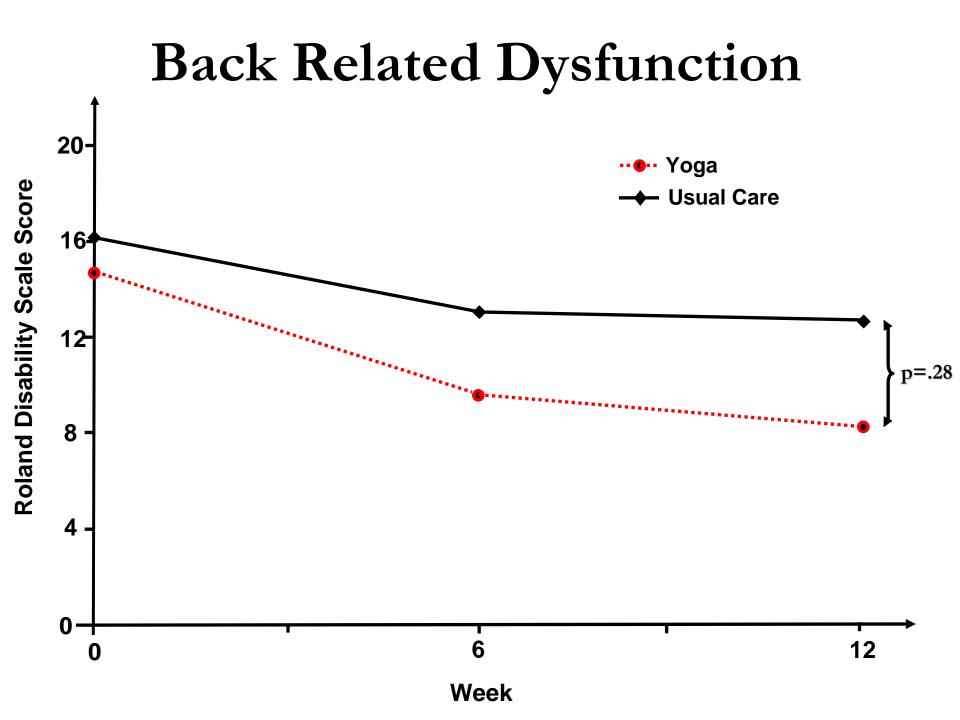
- Median classes attended: 8
- 14/15 attended ≥1 yoga class
- 13/15 practiced at home

- Average 4 days/wk for 25 mins/day

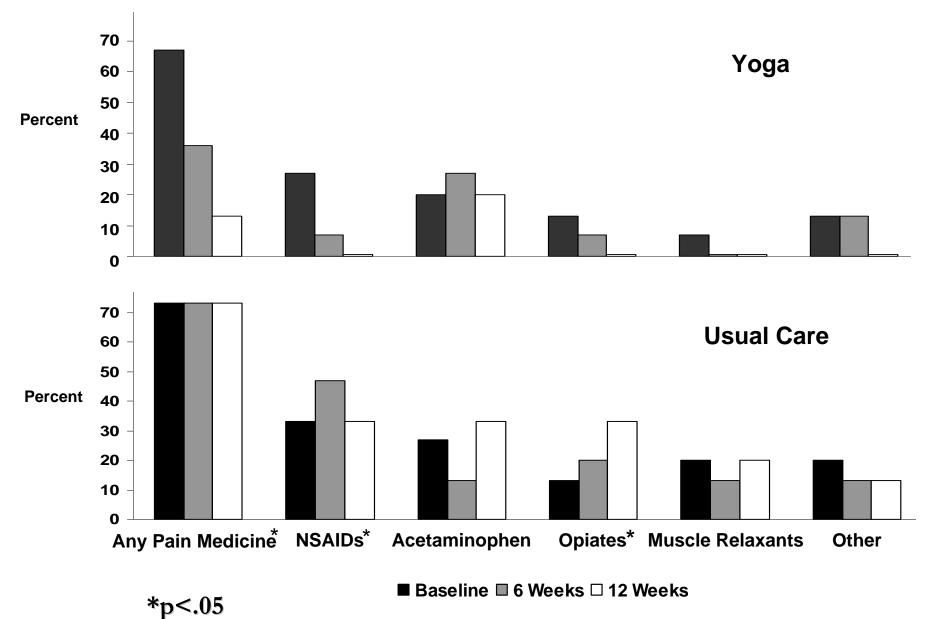
- 1 pt with transient worsening of LBP
- The case of JP

Pain





Pain Medication Use in Last Week



26 Week Follow-up

- Yoga
 - Maintained improvement
 - <u>But</u> 7/15 loss to follow-up and increase in non-study treatments
- Usual Care
 - Improved
 - -0/15 loss to follow-up

 <u>But</u> 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







