

A. Specific Aims

Chronic low back pain (CLBP) affects 5-10% of U.S. adults annually^{1,2} and costs over \$50 billion per year in direct health care expenditures.³ Individuals from low-income minority backgrounds are disproportionately impacted by CLBP due to disparities in access and treatment.³⁻⁷ Several recent studies suggest yoga may be effective for CLBP.⁸⁻¹³ Yoga may also have other relevant benefits for CLBP patients, such as improved mood, stress reduction, and lower cost.¹⁴ Multiple CLBP studies and meta-analyses strongly support a moderate benefit for exercise therapy individually-delivered by a physical therapist,¹⁵ a reimbursed well-established treatment to which physicians refer 22-38% of their low back pain patients.^{16,17} However, *no studies have directly compared yoga to physical therapy for CLBP in any population*—low-income minority or otherwise. To ultimately reduce disparities in CLBP for minority populations, patients, providers, and health insurers need to know how a complementary therapy such as yoga compares in effectiveness to a more well-established treatment such as physical therapy (PT).¹⁸ If yoga is more effective than PT and costs less with greater adherence, the potential therapeutic and economic implications would be substantial. Alternatively, demonstrating that yoga is inferior will help guide better treatment decisions and reduce unnecessary expenditures on ineffective treatments.

We propose a *comparative effectiveness* randomized controlled trial for people from predominantly low-income minority backgrounds with CLBP comparing three treatment groups: (1) A standardized 12-week yoga protocol delivered in a class format; (2) A standardized exercise therapy protocol based on evidence-based clinical guidelines individually delivered by a physical therapist; and (3) An education group that receives a book on self-care for CLBP. Our preliminary studies demonstrate that low-income minorities with CLBP can be readily recruited from urban community health centers to participate in a randomized controlled trial of a standardized yoga protocol versus usual care. Our pilot data suggest 12 weeks of yoga may decrease pain, improve back-related function, and lower pain medication use in this population.⁹ However, we also found yoga participants had difficulty with long-term adherence beyond the study due to lack of access to classes and other socioeconomic obstacles.⁹

For a “complementary” therapy such as yoga to become a well established “mainstream” treatment requires high-quality strong evidence for effectiveness, safety, and cost-effectiveness. To determine whether such evidence is present or not, we propose the following aims:

A.1. Primary Aim

A.1.1. Determine the comparative effectiveness of 12 weeks of yoga, PT, or education for adults with chronic low back pain (CLBP) from predominantly low-income minority communities.

Hypothesis 1: Pain relief for patients randomized to yoga will be clinically and statistically superior at 12 weeks to patients randomized to PT and patients randomized to education.

Hypothesis 2: Functional improvement for patients randomized to yoga will be clinically and statistically superior at 12 weeks to patients randomized to PT and patients randomized to education.

Hypothesis 3: Pain medication use in patients randomized to yoga will be clinically and statistically less at 12 weeks than in patients randomized to a PT intervention and patients randomized to education.

A.2. Secondary Aims

A.2.1. In adults with CLBP who have completed initial 12 week yoga or PT interventions, compare effectiveness outcomes (pain, functional improvement, pain medication use) between patients participating in a structured yoga maintenance program, a structured PT maintenance program, or no structured maintenance program.

Hypothesis 4: After completion of an initial 12 week yoga intervention, patients randomized to an ongoing 40-week structured yoga maintenance program will have superior effectiveness outcomes at 26 and 52 weeks compared to patients randomized to no yoga maintenance program.

Hypothesis 5: After completion of an initial 12 week PT intervention, patients randomized to an ongoing 40 week structured PT maintenance program will have superior effectiveness outcomes at 26 and 52 weeks compared to patients randomized to no PT maintenance program.

Hypothesis 6: Patients randomized to an ongoing 40 week structured yoga maintenance program will have superior effectiveness outcomes at 26 and 52 weeks compared to patients randomized to an ongoing 40 week structured PT maintenance program.

A.2.2. Determine the cost-effectiveness of yoga, PT, and education for adults with CLBP at 12 weeks, 6 months, and one year from three perspectives: society, third party payers, and the participant.

Hypothesis 7: Yoga for adults with CLBP will be more cost-effective than either PT or education at 12 weeks, 6 months, and one year from the perspective of society, third party payers, and the participant.