# <u>original research</u>

# Matching Exercise Volume in Active Control Groups for Yoga Interventions

Heather J Leach, MS, PhD, ACSM CEP, CET; Mary C Hidde, MS, PhD, ACSM CEP; Jennifer D Portz, MSW, PhD; Marieke Van Puymbroeck, PhD, CTRS, FDRT; Julia L Sharp, PhD; Aimee L Fox, PhD; Arlene A Schmid, PhD, OTR, FAOTA; Christine A Fruhauf, PhD

#### ABSTRACT

**Context** • The selection of a control group should foremost be determined by the study's primary intended outcome and trial design. When examining the effects of the physical movements that comprise yoga postures, an active control group, with physical exercise as the control, is often recommended.

**Objective** • The current study aimed to define an active control group that participates in physical exercise, emphasizing the importance of matching the exercise's volume to that of an intervention group's yoga, and to provide a tangible example from a federally funded, recently completed, randomized controlled trial.

**Design** • The research team designed a control group, providing a case study as a example of it.

Setting • The study took place at Colorado State University.

Heather J Leach, MS, PhD, ACSM CEP, CET, Associate Professor, Department of Health and Exercise Science; Julia L Sharp, PhD, Associate Professor, Department of Statistics; Arlene A Schmid, PhD, OTR, FAOTA, Professor, Department of Occupational Therapy; and Christine A Fruhauf, PhD, Professor, Department of Human Development and Family Studies, Colorado State University, Fort Collins, Colorado, USA. Mary C Hidde, MS, PhD, ACSM CEP, Postdoctoral Fellow, Division of Cardiovascular Medicine and Division of Hematology and Oncology, Medical College of Wisconsin, Milwaukee, Wisconsin, USA. Jennifer D Portz, MSW, PhD, Assistant Professor, Division of General of Internal Medicine, University of Colorado School of Medicine, Aurora, Colorado, USA. Marieke Van Puymbroeck, PhD, CTRS, FDRT, Professor, Department of Parks, Recreation, and Tourism Management, and Associate Dean, Graduate Studies, Clemson University, Clemson, South Carolina, USA. Aimee L Fox, PhD, Assistant Professor, Center on Aging, Kansas State University, Manhattan, Kansas, USA.

Corresponding author: Heather J Leach, MS, PhD, ACSM CEP, CET E-mail: heather.leach@colostate.edu **Intervention** • The exercise component for the control group included 60 minutes of low-intensity exercise, matched with 60 minutes of Hatha yoga for the intervention group. Because the intervention included chronic pain self-management in addition to the exercise component, the education component for the control group included 45 minutes of group-based, general health-and-wellness education and discussion.

**Conclusions** • Future randomized trials for yoga and other complementary or integrative health interventions should continue to use appropriate active control groups, which will serve to enhance the scientific rigor of conclusions that can be drawn with respect to the effectiveness of these interventions. (*Altern Ther Health Med.* 2023;29(6):237-241).

Yoga is an aspect of complementary and integrative health. The efficacy of yoga in improving various health outcomes is increasingly being tested in randomized controlled trials.<sup>1</sup> When examining the effects of the physical movements that comprise yoga postures, an active control group, with physical exercise as the control, is often recommended.<sup>2,3</sup> Previous reviews have identified the challenges, gaps, and limitations in designing and implementing control groups for yoga and other complementary or integrative health interventions.<sup>1-4</sup>

Sherman recommends that the selection of a control group should foremost be determined by the study's primary intended outcome and trial design, such as mechanistic vs pragmatic.<sup>4</sup> Common controls include physical exercise, relaxation or meditation, and education.<sup>3</sup>

One strategy to define a control group is to analyze the intervention to narrow down and identify the specific aspects to be controlled.<sup>2</sup> For example, if the researchers are focusing on the physical movements of yoga postures, the control should involve physical exercise.<sup>2,3</sup> However, to draw conclusions regarding the effectiveness of yoga in comparison to different exercise programs, the control must match the

exercise volume or energy expenditure of the intervention, calculated based on exercise intensity and duration, because that characteristic may have a large impact on several outcomes of interest for yoga researchers, such as physical function, physical fitness, fatigue, quality of life, or mental health.

Exercise volume is used to estimate the total amount of energy expended during a bout of exercise and can be expressed as kilocalories or a metabolic equivalent of task (MET) minutes.<sup>5</sup> When developing an exercise-based, active control group for a yoga intervention, accounting for exercise volume is critical due to the known dose-response effects of exercise on a multitude of health outcomes.<sup>6</sup> Thus, without matching the exercise volumes of the yoga intervention and the physical-exercise control, a confounding effect could occur in terms of whether the effects are due to the intervention or simply increased or decreased energy expenditure.

The current study aimed to define an active control group that participates in physical exercise, emphasizing the importance of matching the exercise's volume to that of an intervention group's yoga, and to provide a tangible example from a federally funded, recently completed, randomized controlled trial.

## METHODS

The case study provides an example of an active control that matches the exercise volume of a yoga intervention. The trial's objective was to determine the preliminary efficacy and feasibility of a combined program of yoga and self-management education for caregiving dyads, such as a caregiver and care receiver with chronic pain.<sup>7</sup>

### Procedures

When designing the control group for the study, the research team considered several options, including a wait-list control or treatment-as-usual control group. However, the team determined that those types of control groups weren't appropriate when it was already known that both interventions, yoga and self-management, can improve pain outcomes.<sup>8,9</sup>

 Table 2. Example of Control Group's Exercise Session

- 1. Welcome and exercise-circuit demonstration, approximately 10 minutes
- 2. Ten-minute warm-up, such as arm rotations, stepping in place, shoulder rolls, and static stretching
- 3. Exercise circuit approximately 30 minutes, including rest
- 4. Exercises shown below, one-minute per exercise. Complete the entire circuit 3 times. Rest for 2 minutes after each circuit.
- 5. Ten-minute cool-down, such as arm rotations, shoulder rolls, or static stretching

No.	Exercise	Equipment	Directions	Safety cues	Harder Modification	Picture
1	Chest compressions	None	<ul> <li>With your arms at chest height, clasp your palms tightly together.</li> <li>Hold for 5 seconds; then rest for 5 seconds.</li> </ul>	<ul> <li>Don't squeeze to the point of discomfort.</li> <li>Keep arms straight out in front of the body, parallel to the ground.</li> </ul>	Squeeze your hands together in a set of pulses, with only one- second rest between each squeeze.	

#### Intervention

The team elected to use a low-intensity exercise and health-and-wellness education control group—an attention and placebo control group—that had the same amount of contact hours and attention from the practitioner as did the intervention group, about 2 hours twice a week for 8 weeks, for 32 hours in total (Table 1). The exercise component for the control group included 60 minutes of low-intensity exercise, matched with 60 minutes of Hatha yoga for the intervention group.<sup>10</sup> Each group's participants exercised as a group, and the caregiving dyads participated together in both groups.

Exercise was determined to be an appropriate comparison for yoga because it would match the estimated metabolic cost of hatha yoga, 2.5 METs.<sup>11</sup> The specific control-group exercises included a warm-up and three sets of eight exercises performed in a circuit-based format, such as walking in place, resistance bands, bodyweight exercises, and core work followed by a cool-down. Table 2 shows an example of an exercise session.

**Table 1.** Research Protocols for Intervention and ControlGroups

	Intervention: Merging Yoga and Self-management Skills (MY-skills)	Physical Exercise Comparison Group
Group format	Yes	Yes
Attention from practitioner	~32 hours	~32 hours
Contact	16 sessions	16 sessions
Caregiving dyad	Together	Together
Physical activity	Hatha yoga	Low-intensity exercise
Group education	Chronic pain self- management	General health and wellness

## Table 2. (continued)

No.	Exercise	Equipment	Directions	Safety cues	Harder Modification	Picture
2	Bicycle crunch	Chair	<ul> <li>Begin seated in a chair with good posture, with your feet flat on the floor and knees at 90-degree angles.</li> <li>Alternate lifting one knee and crunching it up toward your cheek while keeping your back straight.</li> </ul>	<ul> <li>If placing your hands behind your head, don't pull on your neck.</li> <li>Breathe deeply during the exercise.</li> <li>Exhale during the crunch phase and inhale during the relaxed phase.</li> </ul>	Perform the exercise on the floor for added intensity.	
3	Seated leg extensions	Chair, resistance band, or ankle weight	<ul> <li>Begin seated in a chair with good posture, with both feet flat on the floor and knees at 90-degree angles.</li> <li>Extend one leg straight out from your hip while squeezing the quad muscle.</li> <li>Lower your foot to the floor and repeat with the other leg.</li> </ul>	<ul> <li>Keep your back straight.</li> <li>Don't lock your knee; end with a slight knee- bend.</li> <li>Keep your core engaged.</li> </ul>	<ul> <li>Begin seated in a chair with good posture, with both feet flat on the floor and knees at 90-degree angles.</li> <li>Anchor a resistance band around each ankle.</li> <li>Extend one leg straight out from your hip while squeezing the quad muscle.</li> <li>Lower your foot to the floor and repeat with the other leg.</li> </ul>	
4	Standing side bends	None or small dumbbells	<ul> <li>Stand with feet shoulder-width apart, toes pointing straight ahead, with a small dumbbell in each hand.</li> <li>Slowly bend to one side, allowing the dumbbell to reach mid- thigh.</li> <li>Hold for 5 seconds and slowly raise back up to a straight posture.</li> <li>Slowly bend to the opposite side and repeat.</li> </ul>	Breathe deeply and return to a straight- back position between side bends.	Use heavier dumbbells for side bends.	
5	Lateral raises	Dumbbell or resistance band	<ul> <li>Stand with feet shoulder-width apart.</li> <li>Raise one arm straight out to the side up to shoulder level; do not go any higher.</li> <li>Slowly lower the arm to the side.</li> <li>Repeat.</li> </ul>	<ul> <li>Keep both your arms and back straight.</li> <li>Don't bring your arm above parallel to the ground.</li> </ul>	<ul> <li>Stand with feet shoulder-width apart, one hand holding one end of an elastic band and the other end of the band under the foot on the same side as the grasping hand.</li> <li>Raise it straight out to the side, up to shoulder level; don't go any higher.</li> <li>Slowly lower the arm to your side.</li> <li>Repeat.</li> </ul>	

No.	Exercise	Equipment	Directions	Safety cues	Harder Modification	Picture
6	Single-leg deadlift	None or dumbbells	<ul> <li>Stand on one leg with good posture.</li> <li>Bend at the waist and extend your right leg behind you.</li> <li>Inhale as you slowly continue bending at the waist and lowering your shoulders toward the ground until you feel a slight tension in the hamstrings of your supporting leg.</li> <li>Exhale as you push through your supporting leg, using the back and hamstring muscles to raise your body back to the starting position.</li> </ul>	<ul> <li>Keep the knee of the supporting leg bent throughout the exercise.</li> <li>Keep your back flat, hips, and shoulders pushed back and core tight.</li> <li>Keep your neck relaxed and let your gaze follow your movement.</li> </ul>	<ul> <li>Add dumbbells or another weight to your hands.</li> <li>Stand on an uneven surface.</li> </ul>	
7	Calf raises	Stair step	<ul> <li>Begin standing close to a wall, for support, or seated with feet hip- width apart.</li> <li>Slowly rise onto your toes and hold.</li> <li>Lower heels to starting position.</li> </ul>	<ul> <li>Position arms wide on the wall, if needed, for support or balance.</li> <li>Engage core and look straight ahead.</li> </ul>	<ul> <li>Begin standing on a step with your heels hanging off the edge.</li> <li>Slowly push up onto your toes and hold.</li> <li>Slowly lower heels back down slightly beyond the stair to get further resistance.</li> </ul>	
8	Bicep curls	Dumbbells or resistance band	<ul> <li>Stand with feet shoulder-width apart, a resistance band under each foot. Grasp one end of the band in each hand. Your arms should be at your side. Curl your arms towards your shoulders. Lower your arms back to your side and repeat.</li> </ul>	• Don't lock your knees.	<ul> <li>Stand with feet shoulder-width apart, a more- difficult resistance band under each foot.</li> <li>Grasp one end of the band in each hand. Your arms should be at your side.</li> <li>Curl your arms toward your shoulders.</li> <li>Lower your arms back to your side and repeat.</li> </ul>	

The control group's exercises were prescribed to be between 2.0 and 3.0 METs, equating to a relative intensity of 30%–40% of the heart-rate reserve. Heart-rate zones were calculated for the participants, who each wore a heart-rate monitor during exercise to ensure compliance with the exercise' intensity. Because the intervention included chronic pain self-management in addition to the exercise component, the education component for the control group included 45 minutes of group-based, general health-and-wellness education and discussion.

Fidelity checks were completed immediately following each session by the control group's leader, who was separate from the yoga and self-management practitioner, to ensure that participants were within the target heart-rate zone and that the control group's sessions didn't include any education about pain or pain management and the exercises didn't include breathwork or other aspects of the yoga practice, such as mantras or postures.

#### CONCLUSIONS

Given the challenges of designing and implementing control or comparison groups in yoga (and other complementary/integrative health) interventions,<sup>4</sup> the aims of this paper were to (a) highlight the importance of matching exercise volume between a physical exercise comparison group and yoga intervention (or other mindbody intervention with a physical movement component), and (b) provide a tangible example from a federally funded study. Future randomized trials for yoga and other complementary or integrative health interventions should continue to use appropriate active control groups, which will serve to enhance the scientific rigor of conclusions that can be drawn with respect to the effectiveness of these interventions.

#### AUTHORS' DISCLOSURE STATEMENT

This work was supported by the National Center for Complementary and Integrative Health (NCCIH), NCCIH 1 R34 AT009688-01 (PI's Schmid & Fruhauf), Clinical Trials Identifier: NCT03440320

#### REFERENCES

- Sivaramakrishnan D, et al. The effects of yoga compared to active and inactive controls on physical function and health related quality of life in older adults: Systematic review and metaanalysis of randomized controlled trials. Int J Behav Nutr Phys Act. 2019; 16(1):33.
- Kinser, PA and JL Robins. Control group design: Enhancing rigor in research of mind-body therapies for depression. *Evid Based Complement Alternat Med.* 2013; 2013:140467.
   Park CL, et al. Comparison groups in yoog research: A systematic review and critical evaluation
- Park CL, et al. Comparison groups in yoga research: A systematic review and critical evaluation of the literature. *Complement Ther Med.* 2014; 22(5):920-9.
- Sherman KJ. The trials and tribulations of selecting comparison groups in randomized trials of nonpharmacological complementary and integrative health interventions. J Altern Complement Med. 2020; 26(6):449-55.
- American College of Sports Medicine. ACSM's Guidelines for Exercise Testing and Prescription, 10th ed. Philadelphia, PA: Wolters Kluwer Health; 2017.
- US Department of Health and Human Services. Physical Activity Guidelines for Americans. United States of America; 2018.
- Schmid AA, Fruhauf CA, Fox AL, Sharp JL, Portz J, Van Puymbroeck M, and Leach HJ. Merging yoga and self-management skills (MY-Skills): A feasibility and pilot study. Under review. 2022. https://www.clinicaltrials.gov/, NCT03440320.
- Bussing A, et al. Yoga as a therapeutic intervention. Evid Based Complement Alternat Med. 2012; 174291.
- Mann EG, Lefort S, and Vandenkerkhof EG. Self-management interventions for chronic pain. Pain Manag. 2013; 3(3):211-22.
   Gibson BA, et al. Yosa for caregiving dyads experiencing chronic pain: protocol development for
- Gibson BA, et al. Yoga for caregiving dyads experiencing chronic pain: protocol development for merging yoga and self-management to develop skills intervention. Int J Yoga, 2021; 14(3):256-60.
   Ainsworth BE, et al. 2011 Compendium of bylosical activities: A second undate of codes and
- Ainsworth BE, et al. 2011 Compendium of physical activities: A second update of codes and MET values. *Med Sci Sports Exerc.* 2011; 43(8):1575-81.