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## Original Research

# Clinically meaningful changes in functional performance resulting from self-directed interventions in individuals with arthritis<sup>☆</sup>

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## ABSTRACT

**Objectives:** To examine the clinical meaningfulness of changes observed in functional performance from two self-directed interventions targeting adults with arthritis.

**Study design:** Randomized controlled trial.

**Methods:** Participants ( $n = 312$ ) were randomized to a 12-week self-directed exercise or nutrition intervention. Objective measures of functional performance (6-minute walk, seated reach, grip strength, 30-second chair stand, gait speed, balance) were obtained at baseline, 12 weeks, and nine months. Minimally ( $\geq 0.20$  standard deviation) and substantially ( $\geq 0.50$ ) meaningful changes in functional performance were examined. Changes in the percent 'impaired' and at risk for losing independence using established standards, and associations between physical activity and impairment/risk status were also examined. Group  $\times$  Time interactions were not significant; therefore groups were combined in all analyses.

**Results:** Minimally (31–71%) and substantially (13–54%) meaningful changes in function were shown. There was a significant decrease in the percentage of participants 'impaired' on the 30-second chair stand (both time points) and gait speed (nine months). The percentage of participants at risk for losing independence significantly decreased for the 30-second chair stand (both time points) and the 6-minute walk (nine months). Those engaging in  $\geq 2$  h of leisure-time physical activity were significantly less likely to be impaired on the 6-minute walk, 30-second chair stand, and gait speed at 12 weeks, and the 6-minute walk at nine months.

**Conclusions:** Interventions that can slow functional declines, and ideally result in clinically meaningful improvements in functional performance among adults with arthritis are needed. Meaningful improvements in various indicators of functional performance can result from self-directed exercise and nutrition programs. These types of programs have the potential for wide-spread dissemination, and thus broad reach.

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## Introduction

Arthritis is one of the most common chronic health conditions, affecting nearly 50 million adults in the United States in 2007–2009.<sup>1</sup> The high prevalence of arthritis-associated disability,<sup>1</sup> in addition to the billions of dollars attributed to arthritis,<sup>2</sup> make it a major public health concern. Unfortunately, arthritis and its subsequent limitations are expected to continue to grow over the next 40 years due to the ageing population.<sup>3</sup> Among the many consequences of arthritis are decreased range of motion and reduced physical functioning,<sup>4</sup> likely leading to activity limitations. Limitations in activity due to arthritis are highly prevalent<sup>4</sup> and are also expected to grow by 2030.<sup>3</sup> Although functional limitations can vary significantly in how they are defined, studies have consistently shown a decline in function over time among individuals with arthritis.<sup>5,6</sup>

The high and growing prevalence<sup>1</sup> and disabling effects of arthritis<sup>7</sup> have prompted a number of governmental agencies to formulate plans and strategies aimed at combating the condition and its negative consequences.<sup>4,8,9</sup> For example, one objective of Healthy People 2020<sup>9</sup> is to reduce the proportion of adults with doctor-diagnosed arthritis who find it ‘very difficult’ to perform specific joint-related activities including walking a quarter of a mile; walking up 10 steps without resting; stooping, bending, or kneeling; and using fingers to grasp or handle small objectives.

Physical activity may be one means for slowing the progression and/or preventing functional declines among adults with arthritis. While a number of physical activity intervention studies have administered objective functional tests and examined change in function over time,<sup>10–15</sup> the meaningfulness of the changes has not been explored. Although examining whether a significant change in functional performance occurred is important, examining what that change means, and whether the change is meaningful, may be more valuable from a clinical standpoint.

STEPS to Health was a randomized, controlled trial that evaluated the effects of a 12-week, self-directed exercise

program (First Step to Active Health<sup>®</sup>) for people with arthritis. The primary outcomes paper<sup>16</sup> examined and reported changes in functional performance at 12 weeks and nine months. In general, results showed significant improvements in functional performance in both the intervention (exercise) and attention control (nutrition) groups at both follow-up time points. The purpose of this sub study was to further explore if the changes observed in functional performance were (1) clinically meaningful, (2) impacted the percentage of study participants classified as impaired, and (3) changed the percentage of participants at risk of losing functional independence.

## Methods

### Participant recruitment

A number of recruitment strategies were used, with the most common and most successful being emails to worksite listservs and newspaper advertisements. Because this study evaluated the effects of a public health intervention, a public health definition of arthritis, consistent with what is used in the National Health Interview Survey and the Behavioral Risk Factor Surveillance System,<sup>17</sup> was used. Participants responding ‘yes’ to the question, ‘have you ever been told by a doctor or other health care professional that you have some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?’ were eligible to take part in this study. Interested participants contacted the study office and completed a phone screen to assess eligibility status (Table 1).

### Procedure

Participants deemed eligible following the telephone screening were scheduled to take part in a measurement session at the University of South Carolina. Prior to the scheduled measurement session, participants were mailed a survey and an informed consent form.

**Table 1 – Eligibility criteria for steps to health.**

**Participants were eligible for the study if they:**

- Were told by a health care professional that they have some form of arthritis
- Reported at least one symptom of arthritis (joint pain, stiffness, tenderness, decreased range of motion, redness and warmth, deformity, crackling or grating, fatigue)
- Were  $\geq 18$  years of age
- Were the only one in their household participating in the study
- Were not planning to move out of the area in the next nine months
- Were able to read and write in English
- Were not participating in another research study (unless it was an observational study without and intervention or medication)

**Participants were ineligible for the study if they:**

- Endorsed an item on the PA Readiness Questionnaire (PAR-Q)<sup>46</sup>:
  - Note: participants were not excluded if they took medication for hypertension and their blood pressure was controlled
- Had a fall in the past year that required medical assistance
- Were pregnant, breastfeeding, or planning to become pregnant in the next year (women)
- Were diabetic and taking insulin
- Could not walk longer than 3 min without a rest
- Could not stand without assistance for more than 2 min
- Could not sit in chair without arms for more than 5 min
- Were already physically active (aerobic activities  $\geq 3$  days/week for  $\geq 30$  min/day or strength training  $\geq 2$  days/week for  $\geq 20$  min/day)

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