



## Physical activity counseling in overweight and obese primary care patients: Outcomes of the VA-STRIDE randomized controlled trial

Shasha Gao<sup>a</sup>, Roslyn A. Stone<sup>a</sup>, Linda J. Hough<sup>a</sup>, Jeffrey P. Haibach<sup>a</sup>, Bess H. Marcus<sup>b</sup>, Joseph T. Ciccolo<sup>c</sup>, Andrea M. Kriska<sup>d</sup>, Kelly H. Burkitt<sup>a</sup>, Ann R. Steenkiste<sup>a</sup>, Marie A. Berger<sup>a</sup>, Mary A. Sevick<sup>e,\*</sup>

<sup>a</sup> Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System, Pittsburgh, PA, United States

<sup>b</sup> Department of Family Medicine and Public Health, University of California San Diego, La Jolla, CA, United States

<sup>c</sup> Department of Biobehavioral Sciences, Columbia University Teachers College, New York, NY, United States

<sup>d</sup> Department of Epidemiology, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA, United States

<sup>e</sup> Department of Population Health, New York University School of Medicine, New York, NY, United States

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### ABSTRACT

The purpose of this 2-arm randomized clinical trial was to evaluate the effectiveness of a 12-month, expert system-based, print-delivered physical activity intervention in a primary care Veteran population in Pittsburgh, Pennsylvania.

Participants were not excluded for many health conditions that typically are exclusionary criteria in physical activity trials. The primary outcome measures were physical activity reported using the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire and an accelerometer-based activity assessment at baseline, 6, and 12 months.

Of the 232 Veterans enrolled in the study, 208 (89.7%) were retained at the 6-month follow-up and 203 (87.5%) were retained at 12 months. Compared to the attention control, intervention participants had significantly increased odds of meeting the U.S. recommended guideline of  $\geq 150$  min/week of at least moderate-intensity physical activity at 12 months for the modified CHAMPS (odds ratio [OR] = 2.86; 95% CI: 1.03–7.96;  $p = 0.04$ ) but not at 6 months (OR = 1.54; 95% CI: 0.56–4.23;  $p = 0.40$ ). Based on accelerometer data, intervention participants had significantly increased odds of meeting  $\geq 150$  min/week of moderate-equivalent physical activity at 6 months (OR = 6.26; 95% CI: 1.26–31.22;  $p = 0.03$ ) and borderline significantly increased odds at 12 months (OR = 4.73; 95% CI: 0.98–22.76;  $p = 0.053$ ).

An expert system physical activity counseling intervention can increase or sustain the proportion of Veterans in primary care meeting current recommendations for moderate-intensity physical activity.

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### Introduction

The 1995 Centers for Disease Control and Prevention and the American College of Sports Medicine joint summary statement on the health benefits of physical activity recommended at least 30 min of moderate to vigorous intensity aerobic physical activity on most days of the week (Pate et al., 1995). In 2000, the U.S. Department of Health and Human Services (DHHS) identified increasing the proportion of adults who meet this physical activity recommendation as a Healthy People 2010 goal (United States Department of Health Human Services,

2000). In 2008, DHHS released the national Physical Activity Guidelines (United States Department of Health and Human Services, 2008) that recommended at least 150 min per week of moderate to vigorous intensity aerobic physical activity.

Despite consistent attention and recommendations since the 1990s, a majority of U.S. adults persistently fail to meet the recommended levels of physical activity (Blackwell et al., 2014; Centers for Disease Control and Prevention (U.S.), 2007; Centers for Disease Control and Prevention (U.S.), 2001). Among Veterans, an analysis of 2000 Behavioral Risk Factor Surveillance System data showed Veterans to be as sedentary as the general population, with 44% being overweight and 25% obese; among obese Veterans, 59% were inactive and only 16% adhered to recommended levels of physical activity (Wang et al., 2005).

Numerous studies have shown face-to-face physical activity interventions to be efficacious for engaging participants in a more active

\* Corresponding author at: Department of Population Health, New York University School of Medicine, 227 East 30th Street, New York, NY 10016, United States. Fax: +1 212 263 4201.

E-mail address: [mary.sevick@nyumc.org](mailto:mary.sevick@nyumc.org) (M.A. Sevick).

lifestyle. However, practical barriers (e.g., time, cost, and the need to travel to a central location) limit the reach of such interventions and reduce their public health impact. Literature reviews have shown that home-based interventions may be more effective than center-based interventions (Hillsdon & Thorogood, 1996) and that interventions not requiring face-to-face contact have larger effect sizes (Dishman & Buckworth, 1996). Based on these findings, Marcus and colleagues developed an expert system that generates theory-based motivationally tailored physical activity counseling messages (Marcus et al., 1998; Bock et al., 2001; King et al., 1991, 1995). Using that system, these investigators evaluated the efficacy of two counseling delivery approaches (print messages sent via postal mail versus messages discussed via telephone) to engage healthy adults in a home-based program of physical activity in Project STRIDE (Marcus et al., 2007a, b). Compared to participants randomized to an attention control arm, both intervention arms demonstrated significant increases in physical activity at 6 months. At 12 months, physical activity declined in the telephone arm but continued to increase in the print-mail arm. The print intervention also was more cost-effective than the telephone approach (Sevick et al., 2007).

In the VA-STRIDE study, we evaluated the effectiveness of the Project STRIDE print intervention among Veterans recruited from a primary care setting. The primary hypothesis of VA-STRIDE is that participants randomized to the print intervention arm would be more likely than attention control arm participants to meet the U.S. recommended physical activity target of at least 150 min per week of moderate-intensity physical activity.

## Methods

### Design

VA-STRIDE was a randomized controlled trial among Veterans receiving routine care through the VA Pittsburgh Healthcare System (VAPHS) University Drive Campus (UD) Primary Care Clinic. Veterans enrolled in the study were randomized to either a physical activity intervention arm or an attention control arm. Measurements occurred at baseline, 6 months, and 12 months. The study was reviewed and approved by the VAPHS Institutional Review Board.

### Sample

To be eligible for the study, participants were required to: (1) have had at least one primary care visit at the VAPHS UD clinic in the 12 months prior to screening, (2) be at least 18 years old at the time of enrollment, and (3) be overweight or obese (i.e., body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>) at the most recent primary care visit. Excluded from the study were Veterans with existing ICD-9 codes for psychoses (codes 290–299), alcohol or drug dependence (codes 303 and 304), intellectual disability (codes 317–319), unstable angina (code 411.1), pulmonary hypertension (codes 416.0 and 416.8), spinal cord injuries (codes 806 and 952), lack of housing (code V60.0), long-term oxygen therapy (code V46.2), or wheelchairs (code V53.8). Additional exclusion criteria included need of an assistive walking device (e.g., cane or walker), inability to walk at least 120 yards unassisted, being non-English-speaking, reading below the 7th grade level, living in an institutional setting, planning to move out of the VAPHS service area in the next 12 months, employment by VAPHS, or unwillingness to adhere to the study protocol.

An electronic sampling frame was developed using the Veterans Health Information Systems and Technology Architecture (VistA) data files, which include clinical information abstracted from the computerized medical records of Veterans receiving primary care at VAPHS UD. Subject-specific ICD-9 codes were used to identify potentially eligible participants who had an upcoming visit with their primary care provider (PCP). During that scheduled visit, the PCP evaluated each potentially eligible Veteran for their ability to safely participate in unsupervised

moderate-intensity physical activity, specified any required exercise precautions, and requested the Veteran's permission to be contacted by study staff to discuss possible enrollment (Hawkins et al., 2014).

Remaining eligibility and safety criteria were evaluated during a subsequent telephone screen conducted by study staff. Baseline physical activity was ascertained using a 2-part question. Veterans were asked if, during a typical week, they engaged in any moderate-intensity aerobic physical activity of at least 10-min duration and if so, whether they engaged in such activity for at least 60 min/week; those who responded affirmatively were ineligible. We also excluded Veterans participating in other clinical studies that would be expected to impact the primary VA-STRIDE study outcome of physical activity.

MOVE! is a national weight management program supported by the VA's National Center for Health Promotion and Disease Prevention. Veterans are screened annually for obesity and referred to MOVE! programs that vary by VA facility. At the time of the VA-STRIDE study MOVE! program options within the VAPHS included weekly group meetings, and teleconferencing. While physical activity is addressed in MOVE! the primary goal of the program is weight management. MOVE! participants were not excluded from the study as the program is considered standard care within the VA Healthcare System. Additional details on the recruitment and enrollment process for this study are provided elsewhere (Hawkins et al., 2014).

### Procedures

#### Baseline assessment

Signed informed consent was obtained from eligible Veterans during their baseline study visit, at which time demographic, clinical, and self-reported physical activity data were collected. Physical activity also was measured using accelerometers during the week following the baseline visit, after which participants were randomized. Participants were given \$25.00 for the time and travel expenses associated with this baseline visit.

#### Randomization and orientation

Participants attended a 60-min orientation session about one week after their baseline assessment, at which time they were informed of their randomized treatment assignment and received initial counseling relevant to their treatment arm.

Those randomized to the intervention arm received individually tailored physical activity counseling based on medical conditions identified in their medical record and their baseline assessment. This session included guided goal setting to gradually increase moderate-intensity aerobic physical activity to at least 150 min/week. For those randomized to the attention control, the orientation session involved generalized healthy lifestyle counseling that included recommendations regarding cancer screening, cholesterol, nutrition, balancing calorie intake and energy expenditure, alcohol consumption, stress and relaxation, and sleep. To minimize cross-over effects, orientation sessions were delivered by two different study staff. Participants in both arms were given \$15.00 for the time and expense associated with their orientation session.

#### Intervention

Subsequent to the initial orientation session, the intervention group received 12 months of expert system feedback counseling, delivered via postal mail, in parallel with 12 months of routine primary care. Using the same approach as Project STRIDE (Marcus et al., 2007a), participants were mailed a Physical Activity Questionnaire (PAQ) monthly during months 1–6 and bimonthly during months 7–12. PAQs were completed, returned, and scanned into an expert system to produce theory-based individualized feedback reports. Printed feedback reports were mailed back to participants, along with physical activity self-help booklets matched to the Veteran's stage of motivational readiness and newsletters with suggestions for increasing physical activity. Fourteen feedback mailings were sent to participants on the following schedule: weekly

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