



Assessing the feasibility, acceptability, and potential effectiveness of a behavioral-automaticity focused lifestyle intervention for African Americans with metabolic syndrome: The Pick two to Stick to protocol[☆]



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ABSTRACT

Background: Metabolic syndrome (MetS) significantly increases the risk of developing diabetes and cardiovascular disease. Being physically active and eating a healthy diet can reduce MetS risk factors. Too frequently, however, studies report that the effects of interventions targeting those factors are not maintained once interventions are withdrawn. A potential solution to the problem is targeting behavioral automaticity (habit-development) to aid in initiation and maintenance of health-behavior changes. The Pick two to Stick To (P2S2), is an 8-week, theory-based hybrid (face-to-face/telecoaching) habit focused lifestyle intervention designed to increase healthful physical activity and dietary behavioral automaticity. The purpose of this article is to describe the rationale and protocol for evaluating the P2S2 program's feasibility, acceptability and potential effectiveness. **Methods:** Using a prospective, non-comparative design, the P2S2 program will be implemented by trained occupational therapy 'coaches' to 40 African Americans aged 40 and above with MetS recruited from the emergency department. Semi-structured interviews with participants, bi-weekly research meetings with study staff, and observations of intervention delivery will provide data for a process evaluation. Estimates of effectiveness include weight, blood pressure, waist circumference, BMI, and behavioral automaticity measures that will be collected at baseline and week 20.

Conclusion: The P2S2 program could facilitate the development of healthful dietary and physical activity habits in an underserved population. Whether interventions aimed at changing habits can feasibly influence this automaticity, particularly for high-risk, low resource communities where other barriers exist, is not known. This pilot study, therefore, will fill an important gap, providing insight to inform subsequent trials.

1. Introduction

Metabolic syndrome (MetS) affects 34% of U.S. adults resulting in a two-fold likelihood of developing heart disease and a five-fold likelihood of developing diabetes compared to those without MetS [1]. Maintaining a healthy body weight by being physically active and eating a healthy diet are the best means of reducing MetS risk factors [2,3]. Too frequently, however, studies report that the effects of interventions targeting those factors are not maintained once interventions are withdrawn [4–6]. A promising and novel approach to fostering health-promoting lifestyle changes, and maintenance of those changes, is targeting the development of physical activity and dietary

habits [7]. Habits, defined as behavior patterns operating below conscious awareness and operationalized as behavioral automaticity, are acquired through context-dependent repetition [8,9]. Frequent repetition of a behavior (e.g., walking for 10 min) in connection with a stable situational cue that supports the behavior (e.g., while on a lunch break) results in the development of habitual behaviors that are cued by the characteristics of a specified recurring situation rather than by intentions, making them less vulnerable to changes in motivation, mood, or extraneous circumstances [10–12]. Recent research suggests that those characteristics of habit may prevent relapse and aid maintenance of behavior changes [11,12]. While a new area, emerging evidence also suggests that habit-development strategies are effective across a range

[☆] This enclosed work has been conducted in accordance with the Code of Ethics of the World Medical Association and has received Institutional Review Board approval.

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of behaviors, effective in low doses, and deliverable via multiple formats, suggesting the feasibility of implementing habit development strategies to target the development of healthful physical activity and dietary habits [10–13]. Nonetheless, these concepts and methods have yet to be fully tested to determine their feasibility as a treatment modality for promoting healthful lifestyle behavior changes.

The Pick two to Stick To (P2S2): Developing Habits for Healthy Living, is an 8-week, theory-based hybrid (face-to-face and tele-coaching) habit focused lifestyle behavior change intervention designed to increase the behavioral automaticity (habit development) of physical activity and dietary habits. Specifically, the P2S2 content is focused on facilitating the mastery and application of habit development skills in daily life. The intervention utilizes a “low and slow” approach to behavior change whereby simple changes in habits are hypothesized to accumulate over time to impact health outcomes. The over-arching aim of this study is to evaluate the feasibility of the P2S2 protocol when delivered by trained occupational therapy coaches to individuals with MetS recruited from the emergency department in a low resource setting as well as provide estimates of program effectiveness.

The purpose of this article is to describe the rationale and protocol for evaluating the P2S2 program's feasibility, acceptability, and potential effectiveness. Feasibility evaluations are a necessary precursor to conducting an RCT, especially in situation in which there is scant research to guide the design and implementation of the protocol elements. We are proposing an uncommon intervention approach, focusing on habit development, within a population not commonly included in lifestyle behavior change research. For those reasons an initial focus on feasibility is paramount to ensure that the combination of recruitment, data collection and tracking, interventionists training, and study management processes are satisfactory.

2. Theoretical framework

The P2S2 intervention is guided by a framework synthesized from theoretical and empirical literature on habit development [6–23] and the information-motivation-behavioral (IMB) model [24], which together address the mechanisms that affect the transition of behaviors across the continuum from highly intentional, to highly automatic. Important components of habit development include having frequently occurring opportunities for behavioral performance in contexts that support the development of the new habit. Habit development also involves having the behavioral skills to configure one's context to support habit development, and having the motivation to repeatedly perform behaviors until initiation is transferred to environmental cues. The IMB model is a validated behavioral change framework that hypothesizes that the prerequisites for health behavior changes include having condition-specific information about the value of behavior changes, intrinsic motivation for changes, and behavioral skills to change the target health behavior.

3. Methods

3.1. Study design

Using a prospective, non-comparative design, the P2S2 program will be implemented and evaluated in one site in Detroit Michigan, U.S.A. among a sample of 40 African Americans with MetS aged 40 and above. This study protocol was approved by the Institutional Review Board of the Wayne State University located in Detroit, USA. Baseline data collection will occur at week 0. Follow up data collection will occur at week 20.

3.2. Trial setting

Enrollment for this study will occur in the emergency department of Detroit Receiving Hospital (DRH) in Detroit, MI, which is part of the

eight-hospital Detroit Medical Center (DMC). In Detroit, where 59% of the population lives in a medically underserved area and in poverty (Detroit Health Care Stabilization Workgroup, 2007), reliance on the emergency department for primary care is commonplace. Lifestyle behavior counseling is now indicated in primary care encounters for adults ages 18 and older as a means of reducing risk for developing lifestyle related chronic conditions [25]. When individuals use the emergency department as their primary source of care they circumvent key avenues through which they could otherwise access lifestyle behavior counseling or referral to related programs. Recognizing the confluence of factors that lead to premature morbidity and mortality for African Americans in low resource setting, we seek to improve patient outcomes through recruiting at risk individuals from the ED and enrolling them in the P2S2 program.

3.3. Sampling and recruitment

Recruitment will occur on-site in the DRH emergency department through active screening by trained emergency department based research staff. The treating physician will introduce the study to potential participants, who will then be further screened for potential eligibility by trained study staff housed in the emergency department. A trained research assistant will meet the potential participant in the emergency department and discuss the purpose of the. If the potential participant expresses interest, the research assistant will then screen the potential participant for inclusion exclusion criteria. After reviewing basic study information, patients who are interested in participating will be provided with an in-depth review of the study consent form and a signed informed consent form will be obtained.

3.4. Participants

We will recruit a sample of 40 African Americans with MetS aged 40 and above, targeting equal numbers of men and women. The clinical criteria for MetS includes having at least three of the five following risk factors: A triglyceride level of 150 mg/dL or higher (or being on medicine to treat high triglycerides); An HDL cholesterol level of less than 50 mg/dL for women and less than 40 mg/dL for men (or being on medicine to treat low HDL cholesterol; waistline > 40 inches for men and > 35 inches for women; blood pressure > 130/85; and HbA1c of 5.7%–6.4%. However, because of the constraints of conducting point of care cholesterol and HbA1c testing in the emergency department, we will use a modified MetS screening criteria that will allow us to identify potential participants at the point of care. The criteria include two or more of the following three cardio-metabolic risk factors confirmed via point of care testing or documentation in their medical record: waistline > 40 inches for men and > 35 inches for women; blood pressure > 130/85; and HbA1c of 5.7%–6.4%.

We chose to deliver the intervention to adults ages 40 and older because MetS prevalence increases with age [26]. Recent estimates suggest the prevalence of MetS is 6.7% among 20 through 29 year olds and increases to 43.5% and 42.0% for participants aged 60 through 69 years and 70 years or older, respectively [26]. We chose to specifically target African Americans with MetS because while the total age-adjusted prevalence of MetS is slightly higher in Whites than African Americans (23.6% vs, 21.6% respectively), African Americans with cardiovascular and metabolic risk factors are more likely to experience early morbidity and mortality compared to Whites [26,27]. In addition, Detroit, MI. the proposed study site is one of the most medically underserved and economically challenged cities for African Americans in the United States. Health disparities are particularly evident in Detroit, where 83% of the 714,000 residents self-identify as African Americans, and 59% of the population lives in poverty [28].

Adults who present to the ED with non-life threatening conditions and who agree to receive text messages on their cell phones will be eligible for inclusion. For this pilot study, we will restrict enrollment to

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