Specific Aims

Together, diabetes and cardiovascular disease cost the U.S. economy a staggering $557.6 billion annually and are the leading chronic diseases of Black Americans. Maintaining a healthy body weight by being physically active and eating a healthy diet are the best means of reducing cardio-metabolic risk factors. Despite decades of behavioral research, however, lifestyle interventions targeting activity and diet have made little progress in effecting widespread and enduring health behavior changes in the populations most at risk for developing these conditions. We argue that addressing the role of habits, defined as behavior patterns operating below conscious awareness that are acquired through context-dependent repetition, would significantly improve the effectiveness of lifestyle interventions. Most simply, habits develop when repetition of a behavior (e.g., walking for 10 minutes) occurs in connection with a stable situational cue that supports the behavior (e.g., while on a lunch break). Once established, habits are cued by the characteristics of a specified recurring situation rather than by intentions. Recent research suggests that habit development may prevent relapse and aid maintenance of behavior changes beyond the duration of the intervention because the performance of habitual behaviors is less vulnerable to changes in motivation, mood, or extraneous circumstances. Emerging evidence also suggests that habit-development strategies are effective across a range of behaviors (e.g., dental flossing, physical activity, and dietary behaviors) and a range of settings to target the development of healthful physical activity and dietary habits. 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 short-term objective of the proposed research is to test the feasibility of of 80 Black American adults ages 40 and older with metabolic syndrome (MetS). We hypothesize that a habit- focused approach will be feasible to implement and acceptable to intervention recipients. We will pursue the following specific aims.

1. To evaluate intervention feasibility and acceptability. Determine if the intervention used in the proposed project is feasible. By tracking time, effort, costs, adherence to recommendations, participant recruitment and retention rates, and intervention satisfaction, we expect to be able to provide data that both support the feasibility of the intervention and help us improve it for a subsequent study.

2. To estimate intervention effect sizes for the primary outcome measures of habit development. Habit development and anthropometry will be measured using the four-item Self-Reported Behavioral Automaticity Index (Gardner et al., 2012) at baseline and Week 20.

Significance

Because individuals with MetS are twice as likely to develop heart disease and five times as likely to develop diabetes than those without MetS (NHLBI, 2011), the condition poses a serious threat to the already strained U.S. healthcare system. Its impact on minority communities, especially Black Americans, is even more significant. Intensive lifestyle interventions have that modest weight loss achieved through modifying dietary and physical activity behaviors positively impacts the five components of MetS and can significantly reduce or delay the onset of cardiovascular disease (CVD) and diabetes in high-risk individuals (Yamoko & Tango, 2012; UKPDS Group, 1996). However, the time and resource demands needed to derive such benefits limits the feasibility of this approach in resource-restricted settings and its appeal to individuals unable or unwilling to commit to such intensive intervention (Dale Grave et al., 2005). Results of efforts to scale down interventions to be amenable to real-world settings while still producing sustainable improvements in health outcomes have been mixed (Dunkley et al., 2012). Thus, there remains an urgent need to develop efficacious lifestyle behavior change programs that are both scalable to real-world conditions and accessible and

acceptable to a range of populations at risk of MetS and CVD.

A promising and novel approach to fostering health-promoting lifestyle changes is targeting the development of physical activity and dietary habits as part of behavioral interventions. While theory and empirical evidence supports the role of two pathways in behavior change—an intentional pathway based on deliberative thought and action and an automatic (habitual) route enacted in response to contextual cues (Evans, 2008)—interventions to date have focused on intentional processes and neglected habit development. Recently conducted habit-focused behavioral trials, however, demonstrate that habit-development strategies are positively correlated with key health outcomes (e.g., weight loss and maintenance and healthy dietary intake) (Carels et al., 2014; McGowan et al., 2013). The proposed habit-focused intervention promises similar results for participants with MetS and to enhance occupational therapy's contribution to solving pressing societal needs vis-à-vis developing a broader range of interventions for use in other populations with chronic health conditions and underserved populations.

We propose to implement a habit-based approach in a high-risk subgroup recruited from the emergency department (ED) of a safety-net institution located in Detroit, MI (whose 2014 population was 82% African- American). By focusing on the effect of habit development in physical activity and dietary behavior and its relevance to key health outcomes in an at-risk population, this project will set the stage for a broader study of a habit-based approach with more diverse patient groups and disease states. Should the habit-development approach be feasible and prove to be successful across a range of circumstances, our research's long-term impact on cardio-metabolic risk and related health outcomes would be immense.

C. Approach

Trial Setting:

Enrollment for this study will occur in the emergency department (ED) 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 ED for primary care is commonplace and access to lifestyle behavior change programming is limited. Once enrolled, study participants will complete data collection visits in the Wayne State University (WSU) Clinical Research Service Center (CRSC), also located in Detroit, approximately two miles from the DRH ED in the newly built WSU Integrated Biomedical Research building. Both sites are under the directorship of Dr. Phillip Levy, a co-investigator on this proposal, ensuring a seamless transition.

Sampling and Recruitment: Recruitment will occur on-site in the DRH ED through active screening by Dr. Levy's team 24 hours a day, 365 days a year using the same highly successful approach employed in his other ED-based studies. Dr. Levy has a highly trained research staff, including more than 50 paid and voluntary screeners who work on multiple studies at the same time (> 20 at the time of this grant submission). His team has extensive experience recruiting in this setting. 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.

We will recruit a sample of 80 subjects with MetS aged 40 and above, targeting equal numbers of men and women. We will use a modified MetS screening criteria that will allow us to identify potential participants at the point of care in the ED. The criteria include two or more of the following three cardio-metabolic risk factors: waistline > 40 inches for men and > 35 inches for women; blood pressure > 130/85; and HbA1c of 5.7%-6.4%. 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. Participants must have at least two of the three risk factors confirmed via documentation in their medical record. For this pilot study, we will restrict enrollment to English-speaking subjects who will

be discharged to home from the ED. Pregnant patients and those with any history of the following will also be excluded: previous diagnosis of resistant HTN; steroid-dependent asthma or emphysema; cirrhosis or hepatic failure; a cardiac event within the last 30 days; chronic kidney disease on renal replacement therapy; cancer (terminal or undergoing active chemotherapeutic or radiation therapy); taking medications for weight reduction or already being involved in a weight reduction program. Patients with other serious medical conditions (e.g., stroke, dementia) that may affect their ability to complete study activities also will be excluded.

Trial Procedures:

Once enrolled (Week -2), participants will be scheduled for a return visit in two weeks at the CRSC (Week 0), where baseline data collection will occur and participants will be randomized into one of the two study arms. Based on Dr. Levy's ongoing NIH-funded study of uncontrolled HTN (5R01MD005849-05), we anticipate attrition to be greatest between ED recruitment and the first follow-up visit (25.3%). Thus, delaying randomization until after this 2-week run-in period will reduce the likelihood of loss to follow-up. In Week 0, participants complete baseline measures and are randomized in equal numbers to one of two arms: Arm 1: Usual Care or Arm 2: Habit-focused Intervention. Usual care participants will receive freely available informational brochures containing information about making healthful dietary and physical activity changes but will receive no further intervention. Usual Care participants will be asked to return to the CSRC in Week 20 for the follow-up data collection visit.

C.5.1. Habit-Focused Arm. The intervention will be delivered by Dr. Fritz (PI), a licensed occupational therapist and certified health coach trained in Motivational Interviewing. The habit-focused arm utilizes a "low and slow" approach to behavior change whereby simple changes in habits are hypothesized to accumulate over time to impact health outcomes. Participants will be asked to commit to developing two new low-complexity habits (one dietary management habit and one physical activity habit) every 2 weeks over the 8-week intervention period (8 habits total). The intervention approach is based upon the following assumptions: (a) simple behaviors are more likely to become habits than more complex behaviors (Lally, Jaarsveld, Potts, & Wardle, 2010); (b) less-intensive approaches to lifestyle behavior changes may be easier to maintain long term (Hagobian & Phelan, 2013); and (c) significant changes in habit development can be seen in as little as 2 weeks (McGowan et al., 2013). Introducing two new health habits every 2 weeks is hypothesized to allow the previously selected habits to sufficiently develop before additional habits are pursued.

The intervention components (see Table 2) are designed to target the relationships among intentions, performance patterns, and performance contexts that affect habit development. Intervention participants will be asked to participate in five health-coaching sessions and to return to the CRSC in Week 20 for follow-up data collection. The initial face-to-face coaching session is expected to last approximately 60 minutes with subsequent telephone sessions lasting approximately 30 minutes. Coaching sessions will be augmented with the use of the Habit Recorder workbook (Appendix A), an informational workbook that contains information about MetS, healthy lifestyle behaviors, and the principles of habit development along with worksheets to guide the construction of context modifications and implementation intentions. Each session, participants select two new habits to develop and carry forward. Targeting two new habits every 2 weeks is hypothesized to reduce the burden of developing multiple new habits during the intervention period.

Participants will be asked to record their intentions and modifications in the Recorder, and those data will be used to individually tailor study text messages. For example, for the intention "I will walk for 10 minutes every evening before dinner," the message would include the specific intention and be delivered at a participant- identified time that coincides with the intended behavioral performance. We will use Movisens XS, a customizable ambulatory momentary assessment platform that allows the research team to administer assessments and deliver tailored text notifications.

Trial Participant Retention. We will use previously successful retention strategies to encourage participation for the full trial, including routinely obtaining contact information for the participants and up to three friends/relatives who could help locate them. We anticipate that the regularly scheduled coaching sessions will help foster participant retention in the intervention arm. To reduce the

likelihood of participant attrition in the control arm, we will contact participants at Week 8 of the study to express our appreciation for their involvement in the study, update contact information if needed, and to remind the participant of the Week 20 follow-up data collection visit. All participants will also receive the study coordinator's cell phone number. We will also incentivize data collection by providing $25 for completing each component of the study (total incentive of up to $150/participant).

Trial Measures and Data Collection.

Acceptability of the Intervention: After receipt of the intervention, participants will be asked to participate in a structured interview to better understand the users' experience of the intervention and to elicit suggestions for intervention improvements. We will target intervention completers, non-completers, and refusers to develop a more holistic understanding of participants' intervention experiences and reasons for non-participation. Individuals will receive $25 for their participation in the interview.

Process Assessment: Following the example of Tickle-Dengnen (2013), we will track multiple indicators of trial feasibility, including the following:

We will also assess the primary outcome of Habit Development: Habit development will be measured using the four-item Self-Reported Behavioral Automaticity Index (SRBAI) (Gardner et al., 2012) at baseline and Week 20. The SRBAI contains stem statements that can be adapted to address desired behavioral domains (e.g., physical activity, dietary behaviors). Every participant will complete the global SRBAI created for the study (Appendix C). Intervention participants will also complete the SRBAI questions that are tailored to the specific habits that they selected to develop (Appendix D).

Covariates will be measured at baseline (Week 0) and include the seven-item Rapid Estimate of Adult Literacy in Medicine: Short Form (REALM-SF) (Nevarez, Alvarez, Tzuang, & Gallagher-Thompson, 2011) and a socio-demographic factors using a socio-demographic survey.

Data Analysis:

Descriptive statistics (proportions, rates) will be used to assess quantitative process component measures (Aim 1, section D.5.3.b) and to determine *M*, *SD*, and effect sizes (Cohen's d) for outcome variables to inform power analyses for the subsequent study (Aim 2). We will analyze the interview data using qualitative thematic analysis (Boyatzis, 1998). To maintain rigor, we will also work to minimize threats to validity using a five-step qualitative analysis training model (Luborsky, 2001). A systematic approach to data coding is expected to enhance coding reliability and overall quality of study results.