Contemporary Clinical Trials Communications 7 (2017) 166–171

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

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☆

Heather Fritz[a,b,*], Aaron Brody[c], Philip Levy[d]

[a] Eugene Applebaum College of Pharmacy and Health Sciences, Occupational Therapy Program, Wayne State University, Detroit, MI 48201, United States
[b] Institute of Gerontology, Wayne State University, Detroit, MI 48202, United States
[c] Department of Emergency Medicine, Wayne State University, Detroit, MI 48201, United States
[d] Department of Emergency Medicine and Assistant Vice President for Translational Science and Clinical Research Innovation, Wayne State University, Detroit, MI 48201, United States

ARTICLE INFO

Keywords:
Habits
Behavioral automaticity
Health behavior
Metabolic syndrome
Emergency department

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studies report that the effects of interventions targeting those factors are not maintained once interventions are withdrawn.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.

* Corresponding author. Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI 48201, United States.
E-mail address: Heather.fritz@wayne.edu (H. Fritz).

http://dx.doi.org/10.1016/j.conctc.2017.06.009
Received 27 January 2017; Received in revised form 9 June 2017; Accepted 21 June 2017
Available online 24 June 2017

of behaviors, effective in low doses, and deliverable via multiple formats, suggesting the feasibly 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 telecoaching) 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

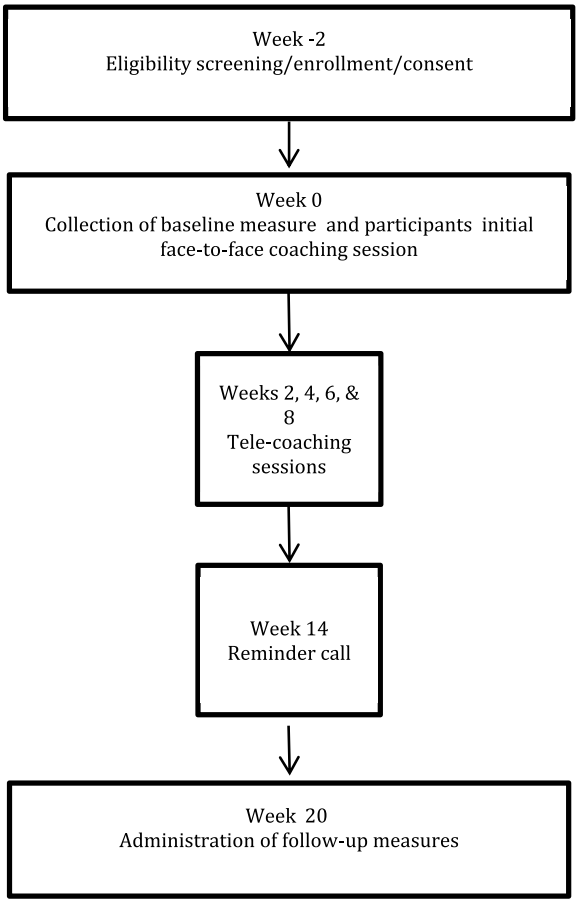

Fig. 1. Trial Procedures Flow Diagram

English-speaking subjects who will be discharged to home from the ED. We anticipate a high rate of multiple co-morbidity among our target population and will therefore, not exclude potential participants because of the presence of other chronic conditions (e.g., arthritis or chronic pain) as long as they are able to engage in their everyday activities under their own power. Pregnant patients and those with any history of the following will 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.

3.5. Intervention components and approach

The Pick Two to Stick To (P2S2) intervention will be delivered by occupational therapy professionals (coaches) under the direct supervision of the PI, a licensed occupational therapist and certified health coach. 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 for 8 habits total (see figure x). The intervention approach is based upon the following assumptions: (a) simple behaviors are more likely to become habits than more complex behaviors [29]; (b) environments can be purposively modified to promote habit development [29]; (c) less-intensive approaches to lifestyle behavior changes may be easier to maintain long term [30]; and (d) significant changes in behavioral automaticity can be seen in as little as 2 weeks [31].

Developing new habits requires individuals to identify behaviors that are simple enough to be initiated immediately and done every day without special accommodations (e.g., needing to first secure a gym membership or special tools or materials). Habit development also requires individuals to identify a recurring situation that will eventually serve as the cue for the habitual behavior (e.g., before making, dinner, while driving, after letting the dog out). In addition, it is useful to propose environmental modifications that will serve as reminders to engage in the behavior until performance becomes more automatic (when activation of the behavior is transferred to situational cues). Occupational therapists receive training in environmental modifications, task analysis, and activity grading, that makes them well suited to deliver the intervention content and address issues related to habit development [32].

The intervention consists of five coaching sessions. An initial face-to-face coaching session (expected to last 90 min) occurs at a University laboratory in week 0 followed by four telephone based health-coaching sessions (lasting approximately 30 min occurring at weeks 2, 4, 6, and 8). A follow up data collection visits will occur at week 20 (see Fig. 1 for trial flow).

The initial session will focus on building rapport with the participant, providing an over view of the program, and presenting educational material about MetS, lifestyle recommendations, and physical activity and dietary guidelines, and the principles of habit development and habit development strategies. The information provided during the initial session is included in the participant Habit Recorder workbook (described below) and can be referred to throughout the intervention as participant continue to make new dietary and physical activity habit development plans (see Table 1). Subsequent coaching sessions will focus on working with participants to: (1) identify additional behaviors to develop into habits, (2) apply habit development skills to behaviors that participants want to develop into habits (3) identify and propose modifications to the specific situations that will support the development of participants identified habits, and (4) review progress towards habit development goals and trouble shoot as needed. The P2S2's multiple phone coaching sessions are designed to provide participants

Table 1
Sequence of habit development.

	Week 0	Week 2	Week 4	Week 6	Week 8
Habits1&2	2				
Habits 3&4		2			
Habits 5&6			2		
Habits 7&8				2	

Table 2
Program content and sequence.

Session	Format	Curriculum
Session 1: Week 0	Face-to-face	Welcome to the P2S2 program Information overview: Metabolic syndrome, healthy diet, physical activity, Information and skills training: Principles of habit development. Habit development plan#1
Session 2: Week 2	Telephone	Review information (as needed) Assess progress Habit development plan#2
Session 3: Week 4	Telephone	Review information (as needed) Assess progress Habit development plan#3
Session 4: Week 6	Telephone	Review information (as needed) Assess progress Habit development plan#4
Session 5: Week 8	Telephone	Assess progress Guidelines for habit maintenance Closer of the program

repeated opportunities to practice the application of habit development in their daily life. In essence the structure of the program is designed to promote the 'habit of building new habits'. See Table 2 for an overview of intervention content. A manual has been drafted to guide the delivery of the intervention.

Coaching sessions will be augmented with use of the participant Habit Recorder workbook, which contains information on habit development principles along with worksheets to guide participants through constructing a habit-development plans and modifying their situational contexts to support their habit development efforts. Each session, participants record their plan and context modifications in the workbook. The workbook also includes self-monitoring sheets and informational handouts.

In addition to interaction with the interventionist participants will also receive tailored text messages that are specific to their habit development plans. Participants will receive one tailored text message for each of their habits equaling two text messages per day. Participants will have the option to receive their text messages daily or three times per week. For example, a participant wants to develop the habit of eating fruit in the car on the way home from work instead of sugary sweets and drives home from work at 3 p.m. each day. The corresponding text message could be sent daily at 3 p.m., and the message could read "eat fruit instead of chocolate on my way home."

To support program delivery, P2S2 incentive bags are provided to all participants. Bags include a meter length of medium resistance thera-band (for exercises) and informative handouts, a pedometer, a Habit Recorder workbook, a high fiber snack bar, a bottle of water, a "USDA My Plate" microwave and dishwasher safe plate, a pen and a pad of post it notes. Participation will also be incentivized by providing participants $25 after week 0, immediately post intervention at week 8, and at the week 20 data collection follow up visit.

To promote intervention fidelity all interventionist will complete training at the University laboratory with the (PI). Training will focus on familiarizing interventionist with the principles of habit development, motivational interviewing, the intervention manual, and the study's standard operating procedures. Interventionists will also complete a minimum of 3 'mock' coaching sessions under the supervision of the PI. The initial face-to-face sessions will be conducted in a room equipped with live video and audio steaming to facilitate behavioral observation. The PI will observe the initial 2 sessions for each interventionist and then will randomly observe subsequent sessions thereafter to ensure treatment fidelity. For each session, interventionists will document session length, attendance, and content, and any deviations from the protocol. Session content checklists will be used to allow sessions to be rated for fidelity in the delivery of intervention content. During implementation, the interventionists and study staff will also hold biweekly research meeting to discuss progress and any issues that may arise.

3.6. Adherence and follow up

The primary expected potential problem in the study is participant attrition given the length of the follow-up period and the participant population. From our previous studies we know that attrition before in initial face-to-face meeting is commonplace in the emergency department participant population. We will use multiple techniques to minimize attrition. We will provide taxi service to transport individuals to the University laboratory for the week 0 and week 20 data collection visits. Other strategies to promote adherence include advanced scheduling and multiple phone reminders. At the time of entry into the study, participants will complete a locator form that will be updated at each subsequent contact. If participants cannot be reached by phone, research staff will attempt to track participants through medical clinic visits and/or hospitalizations. In addition, participants will receive a study newsletter, which provides general information about healthy eating and physical activity.

Another expected problem is low participant engagement as measured by the number of phone sessions scheduled versus the number successfully conducted on schedule. If a participant does not answer the scheduled coaching call, study staff will call the participant every three days and use the other above mentioned strategies to makes contact with the participant and reschedule the session. Missed phone sessions will be rescheduled as soon as possible and subsequent phone sessions will be rescheduled to continue on a bi-weekly basis. We anticipate that many sessions will occur within a 3 day window of the scheduled call date. If despite all attempts study staff are unable to make contact with the participant after 3 weeks, we will consider the participant dropped from the active intervention. We will still make every attempt to contact the participant and encourage them to return to the laboratory for the final data collection. We will also ask the participant to participate in the study exit interview.

3.7. Trial measures and data collection

A trained research assistant will collect baseline data (primary and secondary outcomes, and covariates) from the study participants. With the exception of interview data, all data will be directly entered into EnCore clinical trial management software. Baseline data collection will occur at week 0. Because of the time that it takes to develop a habit it is not expected that significant changes in outcomes measures would be detected immediately post intervention. Thus follow up data collection will occur at week 20. The exception to this is the Self-Reported Behavioral Automaticity Index (SRBAI) (described below).

3.8. Intervention Satisfaction

At the 20 week data collection visit we will invite participants in the treatment condition to participate in a brief semi-structured interview expected to last approximately 30 min to better understand their perceptions of the intervention. Specifically, we will query participant satisfaction with the structure and dose of the intervention, the number of habits requested to be developed over the course of the study, the ease of interacting with study staff, and satisfaction with the content and quantity of text message supports. Follow up probes will elicit participants' recommendations for improving the program for further use.

3.9. Process Assessment

Following the example of Tickle-Dengnen (2013) [33] we will track multiple indicators of trial feasibility, including (See Table 3):

Table 3
Program components and method of measurement.

Process Component	Method
Recruitment, retention, satisfaction, and follow-up rates	Track recruitment and retention rates throughout the study period including reasons for refusal to participate. Interview participants for feedback on strategies to improve participation and retention rates.
Appropriateness of inclusion/exclusion criteria	Conduct a post-study review with our consulting physician to determine if further revision of the inclusion/exclusion criteria is needed.
Usability and feasibility of outcomes measures	Interview participants about their perceptions of the data collection procedures and evaluate the feasibility of collecting the primary, secondary, and covariate measures.

3.10. Primary Outcome

Behavioral automaticity will be measured using the four-item Self-Reported Behavioral Automaticity Index (SRBAI) [14]. The SRBAI measures self-reported perceptions of behavioral automaticity for an identified behavior and includes the following four response items: "I do automatically", "I do without having to consciously remember", "I do without thinking", and "I start doing before I realize I'm doing it". The response scale is anchored by agree/disagree. The SRBAI is composed of a subset of items from the gold standard habit measure, the Self-Reported Habit Index (SRHI). The SRBAI's validity is supported by comparison with the SRHI. The SRBAI is reported to be reliable. Of 45 reliability assessments of the SRBAI, 23 found α level of 0.05 within the range. 90–0.97, 17 found an alpha between 0.80 and 0.89, four, an alpha between 0.70 and 0.79, and one alpha of 0.68.

The SRBAI will be used two ways in the study. A global SRBAI will be administered to all participants. The global SRBAI stem will be tailored to behaviors recommended to either do or avoid as part of a healthy lifestyle. See below for an example of the global SRBAI used in the study. The SRBAI will also be used to track the development of participants' self-selected habits throughout the intervention. Though the time that it takes to develop a habit varies considerably, evidence suggests that changes in habit development can bee see within 2 weeks [31]. To track self-selected habits the SRBAI will be administered to the participant during every coaching session and the stem statement will be participants self-selected habit goals (one each for a dietary habit and a physical activity habit). The SRBAI will then be administered again (as a post measure) 2-weeks later at the next coaching session. For example, if a participants habit goal was to eat a piece of fruit one the way home from work every day, then the SRBAI stem statement would read, "eating a piece of fruit on my way home every day is something …" The exact same question would be administered 2-weeks later. See Table 4.

3.11. Secondary Outcomes

Blood pressure will be measured using the BPTru blood pressure device. Weight measurements will be taken with participants wearing lightweight clothing and without shoes using a calibrated beam balance scale. Measurements will be taken twice during each exam, and the average will be used in analyses. Waist circumference will be measured using a K-E anthropometric tape or equivalent in accordance with established anthropometry guidelines [34]. BMI will be calculated as weight in kilograms divided by the square of height in meters.

Table 4
Example of global self-reported behavioral automaticity index question.

	Strongly Disagree					Strongly Agree	
3. Selecting low-sodium foods is something …	1	2	3	4	5	6	7
I do automatically	□	□	□	□	□	□	□
I do without having to consciously remember	□	□	□	□	□	□	□
I do without thinking	□	□	□	□	□	□	□
I start doing before I realize I'm doing it	□	□	□	□	□	□	□

3.12. Descriptive Variables

Descriptive variables will be measured at baseline (Week 0) to better characterize the sample for a future trial and include the seven-item Rapid Estimate of Adult Literacy in Medicine: Short Form (REALM-SF) [35] and a socio-demographic survey to gather data on participant characteristics such as age, gender, race/ethnicity, members in household, income and education.

3.13. Covariates

Covariates will be measured at baseline (Week 0) and include a two-item, 5-point Likert scale assessing motivation for making lifestyle changes [36], and a 28 item Global Habit Self-Assessment based on the Self-Reported Behavioral Automaticity Index described above and created for use in this study. Participants will use the Global Habit Self-Assessment to report their level of behavioral automaticity regarding a range of lifestyle behaviors (e.g., using olive oil for cooking, using whole grains).

3.14. Data analysis

We will analyze data from baseline and follow up measures using descriptive statistics and general linear models. We will set significance at 0.05 and use SPSS for Macintosh version 22.0 for to conduct these analyses. A power calculation was not performed since this is a feasibility study. However, data from the SRBAI may be used to determine effect sizes for a subsequent pilot trial. We will analyze interview data gathered to assess intervention feasibility and satisfaction using qualitative content analysis. Other process component data including recruitment and retention data, program fidelity, and any adaptation made or challenges faced by the interventionist during program delivery will be analyzed as well. Participant feedback on the program will be used to determine if changes should be made to key features of the intervention structure. For example, if participants express disdain for the text message reminders, or state that having to develop two new habits every 2-weeks is too much effort, then we will consider modifying these elements prior to conducting subsequent study.

4. Conclusion

Development of automaticity as it relates to chronic disease management is critical, serving as the basis for subconscious adherence to important aspect of care. This is particularly true for conditions such as MetS where diet and lifestyle choices can have a profound impact on health outcomes. Whether interventions aimed at changing habits can influence this automaticity, particularly for high-risk, low resource communities where other barriers exist, is not known. This pilot study will thus fill an important gap, providing insight to inform subsequent, larger scale trials. We anticipate that the proposed study protocol will be feasible and that the program will be satisfactory to participants. We

acknowledge, however, that several issues may impact the successful completion of the trial. Participant retention is notoriously difficult among emergency department participant pools [37]. Even with our proposed multistep approach and a highly experienced group of emergency department based research staff, it is possible that we will face a higher than estimated rate of participant attrition.

We also know from our previous work with the emergency department patient population that many of our potential participants will have life circumstances (e.g., rotating shift work, multiple jobs, or sudden changes in employment or childcare status) or secondary health problems that will make it difficult to schedule or adhere to the bi-weekly phone session. Though results from the feasibility study will provide more insights into those issues, we have considered alternative approaches to improve feasibility, and specifically participant engagement. Such approaches could include providing participants the choice for home based versus laboratory data collection, and increasing the number of initial face to face sessions to from one to three to further build therapeutic rapport with participants. We have also considered a contingency management model [38] in which participants are provided a nominal, but increasing incentive (either monetary or a voucher system) with each subsequent study contact, a strategy that has been effective in increasing participant engagement among a range of populations. Despite these potential barriers, we believe that the innovative approach of the P2S2 will contribute important and much needed data in the area of habit-focused intervention development and the feasibility of working through emergency departments to interface with a population otherwise unlikely to access lifestyle behavior change programming.

Funding

This work was supported by funding from the Wayne State University Eugene College of Pharmacy and Health Care Sciences, Wayne State University, Detroit, MI.

References

[1] National Heart Lung and Blood Institute, Health: What is Metabolic Syndrome? (2011) Retrieved from http://www.nhlbi.nih.gov/health/health-topics/topics/ms.
[2] M. Takahara, I. Shimomura, Metabolic syndrome and lifestyle modification, Rev. Endocr. Metabolic Disord. 15 (4) (2014) 317–327, http://dx.doi.org/10.1007/s11154-014-9294-8.
[3] UKPDS Group, UK prospective diabetes study 17: a nine-year update of a randomized, controlled trial on the effect of improved metabolic control on complications in non-insulin-dependent diabetes mellitus, Ann. Intern. Med. 124 (1996) 136–145.
[4] M.J. Franz, J.J. VanWormer, A.L. Crain, J.L. Boucher, T. Histon, W. Caplan, N.P. Pronk, Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up, J. Am. Dietetic Assoc. 107 (10) (2007) 1755–1767, http://dx.doi.org/10.1016/j.jada.2007.07.017.
[5] S.L. Norris, J. Lau, S.J. Smith, C.H. Schmid, M.M. Engelgau, Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control, Diabetes Care 25 (7) (2002) 1159–1171, http://dx.doi.org/10.2337/diacare.25.7.1159.
[6] W. Nilsen, L. Haverkos, L. Nebeling, V. Taylor, Maintenance of long term behavior change, Am. J. Health Behav. 34 (6) (2010) 643–646.
[7] H. Fritz, M.P. Cutchin, Integrating the science of habit: opportunities for occupational therapy, OTJR Occup. Participation Health (2016), http://dx.doi.org/10.1177/1539449216643307.
[8] B. Gardner, A review and analysis of the use of 'habit' in understanding, predicting, and influencing health-related behavior, Health Psychol. Rev. (2014) 1–19, http://dx.doi.org/10.1080/17437199.2013.876238.
[9] P. Lally, B. Gardner, Promoting habit formation, Health Psychol. Rev. 7 (S1) (2013) S137–S158, http://dx.doi.org/10.1080/17437199.2011.603640.
[10] S. Orbell, B. Verplanken, The automatic component of habit in health behavior: habit as cue-contingent automaticity, Health Psychol. 29 (4) (2010) 374–383, http://dx.doi.org/10.1037/a0019596.
[11] R.A. Carels, J.M. Burmeister, A.M. Koball, M.W. Oehlhof, N. Hinman, M. LeRoy, A. Gumble, A randomized trial comparing two approaches to weight loss: differences in weight loss maintenance, J. Health Psychol. 19 (2) (2014) 296–311, http://dx.doi.org/10.1177/1359105312470156.
[12] L. McGowan, L. Cooke, B. Gardner, R. Beeken, H. Croker, J. Wardle, Healthy feeding habits: efficacy results from a cluster-randomized, controlled exploratory trial of a novel, habit-based intervention with parents, Am. J. Clin. Nutr. 98 (2013) 769–777, http://dx.doi.org/10.3945/ajcn.112.052159.
[13] B. Mullan, V. Allom, K. Fayn, I. Johnston, Building habit strength: a pilot intervention designed to improve food-safety behavior, Food Res. Int. 66 (2014) 274–278, http://dx.doi.org/10.1016/j.foodres.2014.09.027.
[14] P. Lally, A. Chipperfield, J. Wardle, Healthy habits: efficacy of simple advice on weight control based on a habit-formation model, Int. J. Obes. 32 (4) (2008) 700–707, http://dx.doi.org/10.1038/sj.ijo.0803771.
[15] B. Gardner, C. Abraham, P. Lally, G. de Bruijn, Towards parsimony in habit measurement: testing the convergent and predictive validity of an automaticity subscale of the self-report habit index, Int. J. Behav. Nutr. Phys. Activ. 9 (1) (2012) 102, http://dx.doi.org/10.1186/1479-5868-9-102.
[16] A.J. Rothman, P. Sheeran, W. Wood, Reflective and automatic processes in the initiation and maintenance of dietary change, Ann. Behav. Med. 38 (2009) S4–S17, http://dx.doi.org/10.1007/s12160-009-9118-3.
[17] G. De Bruijn, S.P.J. Kremers, E. De Vet, J. De Nooijer, W. Van Mechelen, J. Brug, Does habit strength moderate the intention-behaviour relationship in the theory of planned behaviour? The case of fruit consumption, Psychol. Health 22 (8) (2007) 899–916, http://dx.doi.org/10.1080/14768320601176113.
[18] E.J. Kothe, K. Sainsbury, L. Smith, B.A. Mullan, Explaining the intention-behaviour gap in gluten-free diet adherence: the moderating roles of habit and perceived behavioural control, J. Health Psychol. 20 (5) (2015) 580–591, http://dx.doi.org/10.1177/1359105315576606.
[19] L.A. Phillips, J. Cohen, E. Burns, J. Abrams, S. Renninger, Self-management of chronic illness: the role of "habit" versus reflective factors in exercise and medication adherence, J. Behav. Med. (2016), http://dx.doi.org/10.1007/s10865-016-9732-z.
[20] L.A. Phillips, H. Leventhal, E.A. Leventhal, Assessing theoretical predictors of long-term medication adherence: patients' treatment-related beliefs, experiential feedback and habit development, Psychol. Health 28 (10) (2013) 1135–1151, http://dx.doi.org/10.1080/08870446.2013.793798.
[21] B. Verplanken, O. Melkevik, Predicting habits: the case of physical exercise, Psychol. Sport Exerc. 9 (1) (2008) 15–26.
[22] S. Orbell, B. Verplanken, The automatic component of habit in health behavior: habit as cue-contingent automaticity, Health Psychol. 29 (4) (2010) 374–383, http://dx.doi.org/10.1037/a0019596.
[23] B. Mullan, V. Allom, K. Fayn, I. Johnston, Building habit strength: a pilot intervention designed to improve food-safety behavior, Food Res. Int. 66 (2014) 274–278, http://dx.doi.org/10.1016/j.foodres.2014.09.027.
[24] J.D. Fisher, W.A. Fisher, Changing AIDS-risk behavior, Psychol. Bull. 111 (1992) 447–455.
[25] U.S., Preventative Services Task Force, Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: recommendation statement, May 1, Am. Fam. Physician 91 (9) (2015) (online).
[26] G. Graham, Disparities in cardiovascular disease risk in the United States, Curr. Cardiol. Rev. 11 (3) (2015) 238–245.
[27] U.S. Department of Health and Human Services, Office of Minority Health, Black/african American Profile, (2014) Retrieved from http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=61.
[28] Strengthening the safety net in Detroit and Wayne County, Detroit Health Care Stabilization Workgroup, (2013) Retrieved from http://www.michigan.gov/documents/ag/18_319301_7.pdf.
[29] Wood, W., & Neal, D. T. (Unpublished – no date). Habit-based behavior change interventions. Los Angeles, CA: Department of Psychology. University of Southern California Catalyst Behavioral Sciences.
[30] T.A. Hagobian, S. Phelan, Lifestyle interventions to reduce obesity and diabetes, Am. J. Lifestyle Med. 7 (2) (2013) 84–98, http://dx.doi.org/10.1177/1559827612449600.
[31] P. Lally, C. Jaarsveld, H. Potts, J. Wardle, How are habits formed: modeling habit formation in the real world? Eur. J. Soc. Psychol. 40 (2010) 998–1009, http://dx.doi.org/10.1002/ejsp.674.
[32] H. Fritz, M.P. Cutchin, Integrating the science of habit: opportunities for occupational therapy, OTJR Occup. Participation Health (2016), http://dx.doi.org/10.1177/1539449216643307.
[33] L. Tickle-Dengnen, Nuts and bolts of conducting feasibility studies, Am. J. Occup. Ther. 67 (2) (2013) 171–176, http://dx.doi.org/10.5014/ajot.2013.006270.
[34] Centers for Disease Control and Prevention, Anthropometry Procedures Manual. (2007), (2007) Retrieved from http://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_an.pdf.
[35] J.E. Ware Jr., M. Kosinski, S.D. Keller, A 12 item short form health survey: construction of scales and preliminary tests of reliability and validity, Med. Care 34 (1996) 220–233.
[36] M.A. Adriaanse, P.M. Gollwitzer, D.T. de Ridder, J.B. de Wit, F.M. Kroese, Breaking habits with implementation intentions: a test of underlying processes, Pers. Soc. Psychol. Bull. 37 (4) (2011) 502–513, http://dx.doi.org/10.1177/0146167211399102.
[37] S.S. Cofield, R. Conwit, W. Barsan, J. Quinn, Recruitment and retention of patients into emergency medicine clinical trials, Acad. Emerg. Med. 17 (10) (2010) 1104–1112.
[38] S.T. Higgins, A.J. Budney, W.K. Bickel, F.E. Foerg, R. Donham, G.J. Badger, Incentives improve outcome in outpatient behavioral treatment of cocaine dependence, Arch. Gen. Psychiatr. 51 (7) (1994) 568–576.