STUDY PROTOCOL

Diabetes Management

Healthy lifestyle intervention for adult clinic patients with type 2 diabetes mellitus

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ABSTRACT

Background: Diet and exercise therapy have been reported to be effective in improving blood glucose control and are an important part of treatment of type 2 diabetes mellitus. Objective: The goal of this study is to examine the efficacy of a healthy lifestyle intervention for adult clinic patients with type 2 diabetes mellitus, as measured by Hgb-A1c, cardiovascular indicators, physical activity, weight, and BMI. Also of interest are optimal strategies for subject recruitment, the number of intervention sessions attended, and participant use of the Fitbit watch to monitor their physical activity and track food and beverage consumption. Methods: A pre/post-test design will be used in this pilot study. Non-institutionalized adult patients (n=50) aged 18-65 years who have been seen at the Augusta Health outpatient clinics (General Internal Medicine or Family Medicine) for type 2 diabetes in the past 12 months, and who are interested in reducing their risk of disease recurrence through healthy lifestyle behaviors, will be eligible to participate. At orientation visit, eligible individuals will be asked to provide written informed consent. Consenting volunteers (n=50) will be asked to complete the baseline and 6-month follow-up questionnaire and to participate in 12 weekly group sessions of 90 min duration, involving physical activity and to meet with a dietitian (baseline, one month, 90 days) to receive individualized advice on diet and nutrition. The technology–based intervention will use wrist-worn Fitbit Blaze physical activity monitoring devices. Conclusions: This pilot study will provide important information about the feasibility and preliminary efficacy of a healthy lifestyle intervention for adult clinic patients with type 2 diabetes mellitus. The use of consumer-facing devices such as the Fitbit watch has the potential advantage over the use of research accelerometers, pedometers, or actigraphs in increasing the likelihood that the intervention will be sustainable after the study ends.

Introduction

Diabetes affects over 29 million Americans and is the sixth leading cause of death [1,2]. Diabetes is the leading cause of kidney failure, lower-limb amputations, and adult-onset blindness [2]. The total economic cost of diabetes in the U.S. was estimated to be between $245 billion and $322 billion in 2012 [3]. More than 20% of health care spending is for people with diagnosed diabetes. Although good glycemic control is associated with improved health outcomes and lower morbidity and premature mortality, almost half of patients with type 2 diabetes do not meet recommended targets for glycemic control, low density lipoprotein (LDL) cholesterol control, or blood pressure control [4]. Many patients with type 2 diabetes cared for in the community do not reach recommended

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KEYWORDS

- activity monitor
- diabetes mellitus
- diet
- nutrition
- physical activity
- quality of life

treatment goals even though there is evidence from randomized controlled trials of the efficacy of medical therapy for the disease [5].

Diet and exercise therapy have been reported to be effective in improving blood glucose control and are an important part of treatment of type 2 diabetes mellitus [6,7]. Exercise therapy has also been reported to be effective in improving quality of life in diabetic patients [8].

In 2013, the American Diabetes Association released new nutritional guidelines [9]. The guidelines calls for all adults diagnosed with diabetes to eat a variety of nutrient-dense foods in appropriate portion sizes as part of an eating plan that takes into account individual preferences, culture, religious beliefs, traditions and metabolic goals. A new section was included on eating patterns, e.g., Mediterranean, vegetarian, or lower-carbohydrate eating plan. In choosing an appropriate eating plan, people with diabetes should consider individual metabolic goals such as their glucose, lipid levels, and blood pressure [9].

Several studies designed to increase physical activity in diabetics have used activity monitors such as accelerometers, pedometers, or actigraphs in conjunction with counseling [6,10,11]. In a recent meta-analysis, activity monitor-based counseling resulted in a significantly greater improvement in physical activity compared to control intervention or usual care in type 2 diabetes. In addition, these interventions had a positive effect on hemoglobin-A1c (Hgb-A1c), systolic blood pressure, and body mass index (BMI) ($p<0.05$). Studies that utilize consumer wearable devices to promote physical activity in diabetic patients have not been reported. The use of consumer-facing devices such as the Fitbit watch has the potential advantage over the use of research accelerometers, pedometers, or actigraphs in increasing the likelihood that the intervention would be sustainable after the study ended. Consumer wearable devices that monitor physical activity are less expensive than a gym membership or many types of exercise equipment [12].

The goal of this study is to examine the efficacy of a healthy lifestyle intervention for adult clinic patients with type 2 diabetes mellitus, as measured by Hgb-A1c, cardiovascular indicators, physical activity, weight, and BMI. Also of interest are optimal strategies for subject recruitment, the number of intervention sessions attended, and participant use of the Fitbit watch to monitor their physical activity and track food and beverage consumption. We hypothesize that the physical activity and healthy diet and nutrition intervention will be associated with an improvement in Hgb-A1c, LDL-cholesterol, high density lipoprotein (HDL) cholesterol, triglycerides, systolic and diastolic blood pressure, physical activity, weight, and BMI between baseline and 6-month follow-up.

Methods

A pre/post-test design will be used in this pilot study.

Study population

Non-institutionalized adult patients (n=50) aged 18-65 years who have been seen at the Augusta Health outpatient clinics (General Internal Medicine or Family Medicine) for type 2 diabetes mellitus in the past 12 months, who live in the Central Savannah River Area and who are interested in reducing their risk of disease recurrence through healthy lifestyle behaviors, will be eligible to participate. Individuals will be excluded if clearance for their participation is not received from their physician, if they are pregnant or breastfeeding, or if they have a history of myocardial infarction, angina, coronary artery bypass graft surgery, coronary angioplasty, congestive heart failure; a condition that significantly limits their exercise such as peripheral arterial disease, severe orthopedic problems, or painful arthritis; or if they report a history of alcohol abuse, substance abuse, or major psychiatric illness. Patients will also be excluded if they are underweight (BMI<18.5), participating in a structured weight loss program or taking weight loss medication, or if they ever had weight loss surgery. The Physical Activity Readiness questionnaire developed by the Canadian Society for Exercise Physiology [13] will be used by a graduate research assistant to further screen patients for health conditions that may preclude them from participating in a moderate intensity exercise regimen. Patients who are already physically active or have a normal weight (BMI>18.5 to<29.5) will not be excluded.

Recruitment

Potential participants will be identified with the assistance of two of the coauthors who are primary care physicians (C.H, T.W). When the patients are seen for their routine follow-up visit, the physicians or their nurse will provide

the patients with information about the study and ask if they are interested in finding out more information about it or participating in the study. If they respond in the affirmative and sign a form consenting to the release of their name and contact information to the principal investigator (S.C.), the clinicians will forward this information. The principal investigator will then send a letter to potential participants describing the study and letting them know they will be contacted by telephone. Men and women who are interested in participating in the study will be screened by telephone by a graduate research assistant using questions about inclusion and exclusion criteria. Eligible patients will be invited to attend an orientation visit to learn more about the study. At orientation visit, the investigators will confirm eligibility and provide a detailed description of the study. Eligible individuals will be asked to provide written informed consent. Consenting volunteers (n=50) will be asked to complete the baseline and 6-month follow-up questionnaire and to participate in 12 weekly group sessions of 90 min duration, on physical activity and to meet with a dietitian to receive individualized advice on diet and nutrition.

■ Intervention

Registered dietitians will provide individualized nutrition counseling to patients enrolled in this study about healthy diet and nutrition for diabetics (e.g., the potential benefits of weight loss through healthy eating, glycemic control, limiting alcohol intake, and physical activity). The research participants will be asked to meet with a study dietitian shortly after the orientation visit, at one month follow-up, and at 90 days. Dietary information will be obtained using a 24 h food recall. The nutritional intervention will incorporate elements of social cognitive theory [14] including goal setting, self-assessment of dietary intake (food and beverage composition and caloric intake), and reinforcement of positive behaviors. Self-monitoring is strongly associated with behavior change [15]. The intervention will incorporate elements of the Health Belief Model (HBM) which posits that a person's beliefs about a health concern such as diabetes progression, their perceived benefits of an action (e.g., adopting a healthy diet, engaging in physical activity, avoiding alcohol and cigarette smoking), barriers to action, and self-efficacy explain engagement in health promoting behavior [16]. The HBM suggests that a stimulus or cue to action must be present to trigger health-promoting behavior. The intervention will provide several triggers to promote healthy behaviors **(Table 1)**. To increase self-efficacy, the intervention will provide information about practical steps that

Table 1. Summary of educational intervention.

Goal setting
Food diary
Physical activity record
Diabetes educational information
Time management (barriers to action)
Triggers/cues to action
Healthy recipes (barriers to action)
Menu suggestions
Meal planning
Food labels
Grocery shopping
Alcohol/smoking cessation (benefits to action)
Dietary information
Portion sizes
Eating out in social situations (barriers to action)
Health messaging on importance of healthy diet/physical activity (benefits to action)
Use of Fitbit watch to monitor physical activity

can be taken to lose weight or to maintain a healthy weight including menu suggestions. Other topics that will be discussed include portion sizes, meal planning, food labels, grocery shopping, eating out in social situations, and reducing sodium. The sessions will include instructions for setting individualized goals, tracking progress, and receiving feedback. The intervention will allow users to set a weight loss goal and to self-monitor daily food and beverage intake toward achieving that goal and serve as a cue for action. In addition to providing users with healthy recipes and menu suggestions, the intervention will provide information about the importance of consuming adequate amounts of fruit and vegetables, selecting whole grains and fat-free and low-fat dairy products, and avoiding red meat, saturated fats, added sugars, and refined grains. Dietary guidelines will be followed that were developed by the American Diabetes Association [9].

Education and skills development to increase physical activity will be adapted from intervention materials used in previous studies of patients with chronic illnesses. Participants will have opportunities for facilitated physical activities during the 12 weekly group sessions. The goal will be to provide fitness instruction and safe and appropriate opportunities for exercising. These sessions will include a warm-up, 25 min of dance fitness, 20 min of resistance training using body weight and elastic exercise bands, a cool-down, and stretching. The exercise routine and musical playlist will be modified based on participant feedback and instructor assessment. Participants will be provided with options for decreased intensity of physical activity to accommodate individual differences. Participants will be encouraged to try several of the exercises at home and to walk at least 90 min per week in between the weekly group sessions. Longer-term changes in everyday activities such as walking, jogging, swimming, and climbing stairs rather than taking elevators will also be encouraged.

Physical activity guidelines will be followed that were developed by the Department of Health and Human Services and the American College of Sports Medicine. The 2008 Physical Activity Guidelines for Americans emphasize that all adults should avoid inactivity [17]. Some physical activity is better than none, and adults who participate in any amount of physical activity gain some health benefits. For substantial health benefits, adults should do at least 150 min (2 h and 30 min) a week of moderate-intensity, or 75 min (1 h and 15 min) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Aerobic activity should be performed in episodes of at least 10 min, and preferably, it should be spread throughout the week [17]. The intervention developed and evaluated in this pilot study will focus on moderate intensity physical activity and will include health messages about the importance of routine physical activity for weight management and the potential health benefits.

Participants will receive a 12-week technology–based intervention that will use wrist-worn Fitbit Blaze physical activity monitoring devices (San Francisco, CA) paired with accompanying Fitbit app and web interface. Participants will be able to track min of physical activity per day and to receive instant feedback on their activity. Fitbit devices have the ability to measure a variety of activity-related outcomes including steps, distance, heart rate, active min, calories, and sleep. Additionally, users can access the app or web interface to track food intake, socialize with friends, and complete group challenges. Fitbit devices have shown high validity and reliability (ICC 0.71-1.00) [18-20] and a growing amount of research has successfully incorporated Fitbits into technology-based lifestyle interventions to increase physical activity, reduce overweight/obesity, and manage chronic conditions [6,10,11,21-23].

Participants will receive information about how to use the Fitbit watch and how to download the app onto their smartphone in order to monitor and track their physical activity and diet. They will also be instructed to wear Fitbit device on non-dominant hand. A Fitbit Wireless USB Dongle will be used to capture participant device data on a weekly basis during the weekly interfaces. For those that do not have smartphones to monitor Fitbit activity, the Dongle will ensure the information is captured during the weekly interface.

Participants will be encouraged to wear the Fitbit watch during waking h on a daily basis for the whole 12 week intervention period to record their daily steps and provide feedback and motivation to increase their physical activity participation. The Fitbit enhanced pedometer is designed to wirelessly synchronize with computer software to download stored

physical activity information. Participants will be encouraged to synchronize and download their data on a weekly basis. During the home visit to implement the intervention, participants will be taught how to use the Fitbit device and the associated internet based feedback and monitoring technology. The research team will have access to all de-identified participant Fitbit data and will monitor individual adherence with the intervention. If participants have not uploaded their Fitbit data to their computer or internet-connected tablet device in the past week, this information will be captured using a Dongle at the weekly interface.

On a daily basis, Fitbit users will log food items and beverages consumed in an electronic food diary. Users will also be able to track min of physical activity per day enabling them to receive feedback on their activity. Throughout the 6-month intervention period men and women enrolled in the trial will be contacted by a research assistant once a month, beginning one week after the baseline visit, in order to encourage them to continue using the Fitbit watch and to see if they are having any technical difficulties. The participants will also be able to call the study telephone number to receive technical assistance with use of the Fitbit watch.

■ Process measures

Process evaluation measures include the number of men and women who are invited to participate in the study along with the number who volunteer for the study, the number who meet the eligibility criteria, the number who meet with a dietician (initial visit, one month, 90 days), the number of physical activity intervention sessions attended, and the number who complete the 6-month follow-up questionnaire. Information about current medications for diabetes, hyperlipidemia, or cardiovascular disease prescribed as part of the participant's routine medical care will be abstracted by a resident or graduate research assistant.

■ Outcome measures

Since feasibility issues are of interest in this pilot study, the outcomes of interest include optimal strategies for subject recruitment, the number of intervention sessions attended, and participant use of the Fitbit watch to monitor their physical activity and track food and beverage consumption. Other outcomes include changes in weight (kg) and body mass index from baseline to 6 months, and increased physical activity (min per week). Other outcome measures include changes in systolic and diastolic blood pressure, fasting glucose, Hgb-A1c, high density lipoprotein cholesterol, low density lipoprotein cholesterol, triglycerides; and atherosclerotic cardiovascular disease risk score (http://www.cvriskcalculator.com/). Information about these clinical measurements performed as part of the participant's routine medical care for diabetes will be abstracted by a resident or graduate research assistant. Secondary outcomes include changes in consumption of healthy foods, decreased alcohol consumption, changes in quality of life, and changes in knowledge and attitudes about diabetes self-management through healthy lifestyle changes. We acknowledge that, in this pilot study, the number of participants may not be large enough to detect statistically significant differences in some of these outcomes.

As part of their routine medical care for diabetes, patients who attend an orientation visit and consent to take part in the study will be seen by an internal medicine or by a family medicine resident. These routine clinic visits are scheduled about every four months and include a review of medications and measurement of height, weight, systolic and diastolic blood pressure, fasting glucose, Hgb-A1c, and, less frequently, fasting insulin and lipids (high density lipoprotein cholesterol, low density lipoprotein cholesterol, triglycerides).

■ Measures

Dietary intake will be assessed at baseline and at 6 months using a 24 h food recall questionnaire [15, 24]. Physical activity will also be assessed using a validated questionnaire. Quality (of life will be assessed using the 20 item short form survey (SF-20) developed for the Medical Outcomes Study

(http://www.rand.org/health/surveys_tools/mos/20-item-short-form/survey-instrument.html). Health literacy will be measured at baseline using the Shortened Test of Functional Health Literacy in Adults (S-TOFHLA), which has been found to have good reliability and validity [25].

■ Dietary assessment

Nutrient and caloric intake will be analyzed using Nutritionist Pro (Version 7.0, First Data Bank Division, Hearst Corp, and San Bruno, CA).

■ Retention plan

Before obtaining the informed consent, we will thoroughly explain the study procedures, emphasize importance of follow-up. Other strategies to improve participant retention include sending birthday and holiday cards; encouragement to contact study staff to address any barrier to compliance with the study; reminder calls, and convenient times for visits. Participants will receive monetary incentives ($50 gift cards) to complete the baseline and 6-month follow-up assessments.

Participants will receive a $50 gift card for attending the baseline visit and a $50 gift card for completing the six-month follow-up questionnaire. Data will be collected from participants at the time of the baseline visit and at 6-months. Participants will be asked to complete a self-administered questionnaire at both time points. The questionnaires will be developed using behavioral survey items adapted from previous studies on diet, nutrition, physical activity, weight loss, and smartphone use. In addition to validated measures for assessing physical activity and 24 h dietary recall, questions will be included about age, race, education, annual income, and marital status, number of people in the household, and knowledge and attitudes about diabetes. The baseline and 6-month follow-up visit study questionnaires will be self-administered and take about 60 min to complete. The principal investigator and the graduate research assistant will be available to respond to any questions that the participants may have and to help ensure that each questionnaire is complete and has legible written responses.

All data collected as part of this study will be carefully monitored for completeness. The quality of the data will be maximized through pre-coded responses and computerized internal consistency checks and range checks of specified values. All information from study questionnaires and physiologic measures that is entered into computer databases will be checked for data entry errors and any discrepancies will be resolved. Data will be regularly backed up and stored in a secure location. Personally identifying information such as names and addresses will be kept separate from survey responses and will be kept under lock and key.

■ Data analyses

The general approach that will be taken for statistical analysis of the data is as follows. Initially, cross-tabulations of the data will be performed using SAS. Both chi-square and Fisher's exact tests will be used to examine the statistical significance of observed associations. Recruitment patterns will be examined by socioeconomic level (household income, education), age, and time since diagnosis of diabetes. The number of intervention sessions attended and meetings with a dietician (baseline, one month, 90-days) will be examined along with participant use of the Fitbit watch to monitor physical activity and track food and beverage consumption. After cross-tabulations and exploratory analyses of the survey data are completed, characteristics of the participants will be examined, including self-reported age, education, annual household income, marital status, number of people in the household, health literacy; weight, BMI, quality of life, self-reported behaviors (consumption of fruits, vegetables, whole grains, saturated fats, added sugars, and refined grains; alcohol consumption, time spent in past week in moderate-intensity and high-intensity physical activity), HgbA1c, fasting glucose, LDL-cholesterol, HDL-cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure, weight, BMI, atherosclerotic cardiovascular disease risk score, and medications prescribed for diabetes, hyperlipidemia and cardiovascular disease. Paired t-tests will be used to determine the statistical significance of changes in weight, BMI, quality of life; knowledge, attitudes, physiologic measures; and behavioral survey items between baseline and follow-up. Linear models will be used to compare changes in these variables between baseline and 6 months while controlling for potential confounding variables.

The targeted sample size for this pilot study was based upon our prior experience with similar studies and upon our review of the literature on similar studies that targeted diabetic patients. We acknowledge that the sample size may not be large enough to detect statistically significant differences in some of the outcomes of interest. The study will provide important information about the feasibility of subject recruitment and feasibility of a lifestyle intervention for adult diabetic clinic patients, and pave the way for a future larger-scale trial with a randomized design.

■ Limitations

Some inaccuracies in self-reported dietary information are likely. The 6-month

intervention/observation period will not allow for longer term changes in healthy behaviors to be assessed.

■ Human subjects

The study protocol has been submitted to the Augusta University Institutional Review Board for review and approval. Individuals will be excluded if clearance for their participation is not received from their physician, if they are currently pregnant or breastfeeding, or if they have a history of myocardial infarction, angina, coronary artery bypass graft surgery, coronary angioplasty, congestive heart failure; a condition that significantly limits their exercise such as peripheral arterial disease, severe orthopedic problems, or painful arthritis; or if they report a history of alcohol abuse, substance abuse, or major psychiatric illness. Men and women will also be excluded if they are participating in a structured weight loss program or taking weight loss medication, or if they ever had weight loss surgery.

Some participants may experience pain in their lower extremities due to physical activity such as walking. Such risks will be minimized by providing participants with additional options for physical activity such as swimming or stretching exercises. Further, the physical activity intervention will include a warm up and cool down and will be individualized to allow for decreased intensity. The possible benefits of the study are improved glycemic control and weight loss through healthy eating, consuming fewer calories, limiting alcohol intake, and physical activity. Practice of healthy lifestyle intervention could continue to provide benefits to the participant.

Conclusion

This pilot study will provide important information about the feasibility and preliminary efficacy of a healthy lifestyle intervention for adult clinic patients with type 2 diabetes mellitus. To our knowledge, this will be the first study to promote physical activity in diabetic patients that utilizes a consumer wearable device. The study will build upon prior studies that have used activity monitors such as accelerometers, pedometers, or actigraphs in conjunction with counseling to increase physical activity in diabetics have [6,11,24]. The use of consumer-facing devices such as the Fitbit watch has the potential advantage over the use of research accelerometers, pedometers, or actigraphs in increasing the likelihood that the intervention will be sustainable after the study ends.

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