Examination of Psychological Tools and Tracking in an Online Intervention for Type 2 Diabetes

NCT03037528

Document Date: 01-26-17

Protocol, analysis plan, and consent form

Nutritional management is one of the cornerstones of type 2 diabetes treatment, as dietary changes can lead to glycemic control and the reduced need for anti-glycemic medications [1]. Several dietary approaches are recommended for type 2 diabetes, including a very-low carbohydrate (VLC) diet. For example, a recent report by the ADA's Nutrition Review Committee noted the benefits of a reduced-carbohydrate diet and updated the policy guidelines to recommend that for people with type 2 diabetes "…not meeting glycemic targets or where reducing anti-glycemic medications is a priority, reducing overall carbohydrate intake with a low- or VLC eating plan is a viable approach" [2]. Physiologically, carbohydrate intake raises blood glucose levels, which in turn increases insulin secretion from the pancreas. Insulin then inhibits lipolysis and the subsequent release of fatty acids from cells [3]. Numerous studies indicate that a reduced-carbohydrate diet is particularly effective at improving glycemic control, reducing the need for glucose-lowering medications, increasing weight loss, and bringing about other positive health outcomes in type 2 diabetes [4-7].

However, long term adherence to any diet can be challenging, and it is not clear which strategies could help people maintain dietary changes. In this trial, as we screened three potentially effective strategies using a full-factorial design. This was informed by the Multiphase Optimization Strategy (MOST) framework [8]. This approach suggests that before conducting clinical trials of multi-component interventions, particular components of the intervention should be tested, especially those which might be costly, burdensome, or simply have not been previously tested enough to be clearly appropriate for a particular intervention. Such an approach is becoming more common in intervention development, e.g., in the areas of weight loss [9], physical activity promotion [10], and in our previous pilot study of VLC diet for type 2 diabetes [11]. In this case, we tested three low-cost strategies that varied in their burdensomeness and level of previous testing in this intervention [12].

In the current trial, we examined three supplemental strategies that we expected may improve glucose control over a 12-month period. The first was dietary self-monitoring, varying whether participants were encouraged to keep track of what they were eating every day versus monthly (in bursts of three days every 4 weeks). Weight loss trials involving dietary changes typically encourage daily dietary self-monitoring, as this can help people to become more aware of their dietary adherence, and it tends to be associated with weight loss [13]. However, participants commonly dislike daily monitoring and their adherence to it tends to fade over time [14, 15]. Thus, we compared encouragement to self-monitor diet daily vs. less often, which may still be able to help participants self-regulate, but to do so in a less burdensome manner.

The second strategy we included was mindfulness, varying whether or not we taught participants how to increase their experience of mindfulness and mindful eating. We included exercises to increase awareness of the physical, cognitive, and emotional triggers of overeating; the awareness of internal cues that signal hunger, fullness, and taste satisfaction; "surfing" the urges to reduce emotional eating; and the cultivation of healthier alternatives [16, 17]. These approaches aim to help participants become more aware of their hunger-related bodily sensations, food cravings, and eating triggers, so that they can choose to respond more deliberately. Previous research shows that mindful eating helps reduce emotional eating, an important barrier for dietary adherence [18, 19]; increased mindful eating was correlated with decreased fasting glucose levels in participants of a mindful eating weight loss intervention [20]; and mindful eating was a mediator of the effect of a mindful eating intervention for weight loss [19]. However, mindfulness strategies can backfire, sometimes leading to greater anxiety and

depression [21], and the strategies require extra time and attention, which could be burdensome.

The third strategy was positive affect skills training, aiming to increase the frequency that participants experienced positive emotions, such as focusing on gratitude, using one's personal strengths, conducting acts of kindness, and savoring positive experiences [22]. To adhere to a behavioral intervention, participants need to effectively cope with inevitable stressors. According to the revised Stress and Coping Theory [23, 24], positive affect can serve as a psychological "time-out" from stress and increase adaptive coping [25-27], and interventions that help increase the experience of positive affect have been able to reduce depressive symptoms [28]. Additionally, hedonic theories of behavior propose that people do more of what they enjoy [29], possibly because positive emotional responses to behaviors increase the motivation and nonconscious desire to engage in those behaviors [30, 31]. For example, previous research has found an association between higher eating plan satisfaction rates and adherence [32, 33]. However, positive affect skill interventions may have small to little impact on outcomes [34], and they take time to implement, which could be burdensome.

The primary aim of this study was to assess whether several supplementary strategies (daily versus monthly dietary self-monitoring, mindfulness skills, and positive affect skills) could improve outcomes in this VLC intervention with adults with type 2 diabetes.

Procedure

The institutional review board at the University of Michigan approved the study materials (HUM00115537). We registered this study with clinicaltrials.gov (NCT03037528). We placed advertisements or notices of the research online (including Craigslist, University of Michigan's web-based portal for clinical trials, and ResearchMatch) and sent invitation letters to potentially eligible participants identified from health plan records at Michigan Medicine. Interested participants were directed to the study website, which contained the University of Michigan logo, pertinent study information, and a link to an online self-report screening survey (Qualtrics.com). Those who were eligible for further screening based on their survey responses were asked to provide online electronic consent for the trial and subsequently to undergo a second online survey (Qualtrics) which included the eight-item Patient Health Questionnaire (PHQ-8) to measure depressive symptoms [35]; a self-administered glycated hemoglobin (HbA1c) test from DTI Laboratories, Inc; and 3 days of dietary tracking on MyFitnessPal. We also mailed these individuals a body weight scale that connects to its own cellular network (BodyTrace) and automatically reports weights to the study team. Those who met all entry criteria (below) were invited to participate in the trial.

Participants were eligible to participate if they were aged 21 to 70 years, had a baseline HbA1c of 6.5% or higher, had a BMI of 25-45 kg/m^2 (based on self-reported height and measured weight from the study-provided scale), had regular access to the internet, were willing to check their email at least once a week, were comfortable reading and writing in English, had no potentially serious comorbidities, such as liver or kidney failure, were planning on living in the United States for the duration of the trial, were not vegetarian or vegan, and were not on weight-loss medications, and were not taking warfarin, Coumadin, or lithium. We also excluded people who were pregnant or breastfeeding, had an untreated thyroid condition, had an untreated mental health condition, had had weight loss surgery in previous year, or were undergoing cancer treatments. Given that this study was conducted remotely, to mitigate the risk of hypoglycemia, we excluded participants who reported taking any glucose-lowering medication other than metformin.

This 2x2x2 full factorial experimental design examined the impact of three experimental, 2-level components. Once all baseline measurements had been completed, study staff randomized participants to one of the eight experimental conditions (see Table 1) using a computer program to reveal the next assignment. The order was created using block randomization procedures, with blocks randomly allocated to size 8 or 16 and with the seed numbers of 64655102233242, 64655183677600 from the website Sealed Envelope (Sealed Envelope Ltd. 2015. Create a blocked randomization list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 14 Jan 2017]). We stratified randomization by gender.

All tested combinations of the three intervention enhancement strategies.

	Experimental components		
Combination	**Tracking frequency**	**Mindfulness**	**Positive affect**
1	Daily	Yes	Yes
2	Daily	Yes	No
3	Daily	No	Yes
4	Daily	No	No
5	Monthly	Yes	Yes
6	Monthly	Yes	No
7	Monthly	No	Yes
8	Monthly	No	No

The Basic Intervention

Once participants were assigned to one of eight groups, they were e-mailed links to online intervention materials throughout the 12-month intervention, weekly for the first 4 months and then biweekly for the remaining 8 months, for a total of 32 emails. Each of the 32 batches of materials focused on a different topic related to following a VLC diet. Emailed links connected participants to a) a short survey to assess intervention-related dietary adherence and any health concerns, b) a short, embedded video teaching class topics (such as managing their diet during holidays or shifting particular meals to be VLC, etc.), c) downloadable handouts to accompany the video, and d) links to external online resources supporting class topics. Transcripts of the embedded videos were also provided.

The basic intervention included several components that all participants received, regardless of assignment. We taught participants to eat a VLC diet per our previous protocol [11], reducing carbohydrate intake to between 20-35 non-fiber grams of carbohydrates a day with the goal of achieving nutritional ketosis, defined as a positive urine dipstick (Bayer Ketostix), which measures ketone acetoacetate. A VLC diet consists of meats, cheeses, eggs, healthy fats, nuts, seeds, and low-carbohydrate vegetables, eliminating starchy and sugary foods. Participants also had email access to a diet coach whenever they had questions and would receive prompt replies with support and resources and who emailed participants a minimum of every two weeks. Coaches have generally been found to be effective additions to behavioral interventions [36]. Participants received a scale at the start of the intervention and were asked participants to track their body weight regularly. Coaches used this information to monitor participant success and tailor support. Beginning in week 6 of the intervention, we provided goals for physical activity and sleep. Using the Diabetes Prevention Program [37] as a guide, participants were encouraged be physically active for at least 150 minutes a week. Participants were also encouraged to practice sleep hygiene with the target of 7-9 hours total sleep per day. To encourage the adoption and maintenance of the new intervention-related behaviors, participants

were sent text messages up to 5 times a week about the targeted behaviors and skills, depending on which group they had been assigned to, as reminders about targeted behaviors are tied to greater behavioral adherence [38]. To help participants change their dietary patterns and increase their self-efficacy around preparing and eating new foods, we mailed cookbooks to participants: *Keto Living 3 Cookbook: Lose Weight with 101 All New Delicious and Low Carb Ketogenic Recipes* [39] at baseline, *Bacon & Butter, the Ultimate Ketogenic Diet Cookbook* [40] at month 3, *The Wicked Good Ketogenic Diet Cookbook: Easy, Whole Food Keto Recipes for Any Budget* [41] at month 6, and *The Everyday Ketogenic Kitchen With More Than 150 Inspirational Low-Carb, High-Fat Recipes to Maximize Your Health* [42] at month 10.

Experimental Components

In addition to the core intervention, we randomized participants to one of eight possible combinations of the three supplemental components; tracking frequency, positive affect, and/or mindfulness. For each, the program materials were altered, including different content added to the videos, handouts, and text messages. Each factor was selected for its potential to improve participants' ability and interest in adhering to the assigned diet over 12 months.

1) Daily vs. monthly self-monitoring of dietary intake. We asked participants to track their diet using the free web-based and/or mobile application MyFitnessPal [43], which has a wide variety of foods in its database that are common to the diet assigned in this trial (reducing participant burden and increasing accuracy). Half of participants were asked to track their diet daily and the other half were asked to track their diet monthly (for 3 days every 4 weeks).

2) Training vs. no training in mindfulness. Half of participants were taught mindfulness, including mindful eating, how to practice it in everyday life, research behind the skills, how the skills are expected to help, and targeted suggestions for practicing the skills until the next lesson. We asked participants to focus on consciously savoring their food, eating more slowly, and noticing the textures, flavors, and aromas of their food more carefully. For example, they were asked to practice slowly savoring their food with a snack and were then encouraged to practice this skill with at least one meal a day over the next week.

3) Training vs. no training in positive affect skills. Half of participants were taught diet-focused positive affect skills, how to practice them in everyday life, the supporting research, how and why the skills are expected to help, and targeted suggestions for practicing the skills. We taught participants ways to feel more positive affect, for example, by focusing on gratitude, thinking about and applying their personal strengths, applying their personal strengths.

Assessments

We measured outcomes at baseline and at 4, 8, and 12 months after baseline. As an incentive for continued participation, we paid participants US $25 for completing their outcome measurements at 4 months, US $25 at 8 months, and US $50 at 12 months. At each period, we measured glycemic control with an at-home kit, body weight using the scale we had mailed to participants (participants were asked to stand on the scale twice in five minutes and we used the average weight), and depressive symptoms using the PHQ-8 [35].

Statistical analysis

We conducted two-sided *t*-tests to assess statistical significance and effect size (Cohen's d).

References

1. Forouhi, N.G., et al., *Dietary and nutritional approaches for prevention and management of type 2 diabetes.* BMJ, 2018. **361**: p. k2234.

2. Evert, A.B., et al., *Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report.* Diabetes Care, 2019. **42**(5): p. 731.
3. Hite, A.H., V.G. Berkowitz, and K. Berkowitz, *Low-carbohydrate diet review: shifting the paradigm.* Nutr Clin Pract, 2011. **26**(3): p. 300-8.
4. Kirk, J.K., et al., *Restricted-carbohydrate diets in patients with type 2 diabetes: a meta-analysis.* Journal of the American Dietetic Association, 2008. **108**(1): p. 91-100.
5. Nielsen, J.V. and E. Joensson, *Low-carbohydrate diet in type 2 diabetes. Stable improvement of bodyweight and glycemic control during 22 months follow-up.* Nutr Metab (Lond), 2006. **3**(1): p. 22.
6. Accurso, A., et al., *Dietary carbohydrate restriction in type 2 diabetes mellitus and metabolic syndrome: time for a critical appraisal.* Nutrition & metabolism, 2008. **5**(1): p. 9.
7. Santos, F., et al., *Systematic review and meta-analysis of clinical trials of the effects of low carbohydrate diets on cardiovascular risk factors.* obesity reviews, 2012.
8. Collins, L.M., *Optimization of behavioral, biobehavioral, and biomedical interventions*. 2018: Springer.
9. Spring, B., et al., *A Factorial Experiment to Optimize Remotely Delivered Behavioral Treatment for Obesity: Results of the Opt-IN Study.* Obesity (Silver Spring, Md.), 2020. **28**(9): p. 1652-1662.
10. Phillips, S.M., et al., *Optimization of a technology-supported physical activity promotion intervention for breast cancer survivors: Results from Fit2Thrive.* Cancer, 2021.
11. Saslow, L.R., et al., *Intervention Enhancement Strategies Among Adults With Type 2 Diabetes in a Very Low-Carbohydrate Web-Based Program: Evaluating the Impact With a Randomized Trial.* JMIR Diabetes, 2020. **5**(3): p. e15835.
12. Collins, L.M., et al., *Factorial experiments: efficient tools for evaluation of intervention components.* Am J Prev Med, 2014. **47**(4): p. 498-504.
13. Raber, M., et al., *A systematic review of the use of dietary self-monitoring in behavioural weight loss interventions: delivery, intensity and effectiveness.* Public Health Nutr, 2021. **24**(17): p. 5885-5913.
14. Burke, L.E., et al., *Using mHealth technology to enhance self-monitoring for weight loss: a randomized trial.* American journal of preventive medicine, 2012. **43**(1): p. 20-26.
15. Yon, B.A., et al., *Personal digital assistants are comparable to traditional diaries for dietary self-monitoring during a weight loss program.* Journal of behavioral medicine, 2007. **30**(2): p. 165-175.
16. Forman, E.M., et al., *Acceptance-based versus standard behavioral treatment for obesity: Results from the mind your health randomized controlled trial.* Obesity (Silver Spring, Md.), 2016. **24**(10): p. 2050-2056.
17. Forman, E.M. and M.L. Butryn, *A new look at the science of weight control: how acceptance and commitment strategies can address the challenge of self-regulation.* Appetite, 2015. **84**: p. 171-180.
18. Mason, A.E., et al., *Acute responses to opioidergic blockade as a biomarker of hedonic eating among obese women enrolled in a mindfulness-based weight loss intervention trial.* Appetite, 2015. **91**: p. 311-320.
19. Mason, A.E., et al., *Reduced reward-driven eating accounts for the impact of a mindfulness-based diet and exercise intervention on weight loss: Data from the SHINE randomized controlled trial.* Appetite, 2016. **100**: p. 86-93.
20. Mason, A.E., et al., *Effects of a mindfulness-based intervention on mindful eating, sweets consumption, and fasting glucose levels in obese adults: data from the SHINE randomized controlled trial.* Journal of behavioral medicine, 2016. **39**(2): p. 201-213.
21. Farias, M., et al., *Adverse events in meditation practices and meditation-based therapies: a systematic review.* Acta Psychiatr Scand, 2020. **142**(5): p. 374-393.

22. Cohn, M.A., et al., *An online positive affect skills intervention reduces depression in adults with type 2 diabetes.* The journal of positive psychology, 2014. **9**(6): p. 523-534.
23. Folkman, S., *Positive psychological states and coping with severe stress.* Social Science and Medicine, 1997. **45**: p. 1207-1221.
24. Folkman, S., *The case for positive emotions in the stress process.* Anxiety, Stress & Coping, 2008. **21**: p. 3-14.
25. Lazarus, R.S., A.D. Kanner, and S. Folkman, *Emotions: A cognitive-phenomenological analysis*, in *Theories of emotion*, R. Plutchik and H. Kellerman, Editors. 1980, Academic Press: New York. p. 189-217.
26. Fredrickson, B.L. and T. Joiner, *Positive emotions trigger upward spirals toward emotional well-being.* Psychological Science, 2002. **13**(2): p. 172-175.
27. Moskowitz, J.T., et al., *Coping and mood during AIDS-related caregiving and bereavement.* Annals of Behavioral Medicine, 1996. **18**(1): p. 49-57.
28. Sin, N.L. and S. Lyubomirsky, *Enhancing well-being and alleviating depressive symptoms with positive psychology intervention: A practice-friendly meta-analysis.* Journal of Clinical Psychology, 2009. **65**: p. 467-487.
29. Williams, D.M., *Exercise, affect, and adherence: an integrated model and a case for self-paced exercise.* Journal of sport & exercise psychology, 2008. **30**(5): p. 471.
30. Fredrickson, B.L., *Positive emotions broaden and build.* Advances in experimental social psychology, 2013. **47**(1): p. 53.
31. Van Cappellen, P., et al., *Positive affective processes underlie positive health behaviour change.* Psychology & Health, 2017: p. 1-21.
32. Coyne, T., et al., *Dietary satisfaction correlated with adherence in the Modification of Diet in Renal Disease Study.* Journal of the American Dietetic Association, 1995. **95**(11): p. 1301-1306.
33. Ahlgren, S., et al., *Development of a preliminary diabetes dietary satisfaction and outcomes measure for patients with type 2 diabetes.* Quality of Life Research, 2004. **13**(4): p. 819-832.
34. White, C.A., B. Uttl, and M.D. Holder, *Meta-analyses of positive psychology interventions: The effects are much smaller than previously reported.* PLoS One, 2019. **14**(5): p. e0216588.
35. Kroenke, K., et al., *The PHQ-8 as a measure of current depression in the general population.* J Affect Disord, 2009. **114**(1-3): p. 163-73.
36. Kivelä, K., et al., *The effects of health coaching on adult patients with chronic diseases: A systematic review.* Patient education and counseling, 2014. **97**(2): p. 147-157.
37. Orchard, T.J., et al., *The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial.* Annals of Internal Medicine, 2005. **142**(8): p. 611.
38. Fry, J.P. and R.A. Neff, *Periodic prompts and reminders in health promotion and health behavior interventions: systematic review.* Journal of medical Internet research, 2009. **11**(2).
39. Coleman, E., N. Burlington, and A. Moss, *Keto Living 3 -Color Cookbook: Lose Weight with 101 All New Delicious and Low Carb Ketogenic Recipes*. 2014: Visual Magic Productions.
40. Richoux, C., *Bacon & Butter: The Ultimate Ketogenic Diet Cookbook*. 2014: Callisto Media Incorporated.
41. Hughes, A.C., *The Wicked Good Ketogenic Diet Cookbook: Easy, Whole Food Keto Recipes for Any Budget*. 2016: Callisto Media Incorporated.
42. Ketchum, C., *The Everyday Ketogenic Kitchen: With More Than 150 Inspirational Low-Carb, High-Fat Recipes to Maximize Your Health*. 2017: Victory Belt Publishing.

43. Yusof, A.F. and N. Iahad. *Review on online and mobile weight loss management system for overcoming obesity*. in *Computer & Information Science (ICCIS), 2012 International Conference on*. 2012. IEEE.

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Examination Psychological Tools and Tracking in an Online Intervention for Type 2 Diabetes

1.2 Company or agency sponsoring the study: This research is sponsored by the National Institute of Health.

1.3 Names, degrees, and affiliations of the researchers conducting the study: Laura Saslow, Ph.D., Assistant Professor in the Department of Health Behavior and Biological Sciences in the School of Nursing, University of Michigan, Ann Arbor; Sarah Kim, M.D., Assistant Professor, School of Medicine, University of California, San Francisco; and James E. Aikens, Ph.D. Associate Professor Department of Family Medicine University of Michigan Medical School.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

This study is being done in order to better understand what the ideal diet and lifestyle recommendations are for individuals with type 2 diabetes and whether that information can be successfully taught over the internet.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may be eligible for this study if you are an adult (aged 21-70) living in the United States with type 2 diabetes (measured A1c level of 6.5% at the start), who is also overweight, taking either no drugs for their diabetes or just metformin, can read English, and has regular access to a personal computer and the internet.

3.2 How many people (subjects) are expected to take part in this study?

We expect 150 people to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Overview: If you are likely eligible for this study based on your initial web screening survey and/or phone call, you will have 4 weeks to do the following: track what you eat for 3 days with MyFitnessPal, a free online and mobile application; fill out another online survey (30-45 minutes) about you; and return a mail-away diagnostic test kit to measure your blood sugar levels (HbA1c; to confirm a current A1c level of 6.5% or higher). If you continue to be eligible, we will mail you a digital body weight scale, which we will ask you to use to measure your weight. You'll have 2 weeks to do this.

Next, you'll be randomly assigned (like tossing a coin) to 1 of 8 groups that may include a combination of the following three components:

Recommendations to track what you eat either daily or in 3-day bursts about every 4 weeks. You will be asked to track what you eat most days or you will be asked to track periodically, mostly about 3 days every 4 weeks or when you are curious to do so.

Recommendations to learn about a practice positive affect skills (yes or no). You may learn about positive affect skills, such as gratitude and positive reappraisal, in order to help you enjoy the program more and be able to stick with the program.

Recommendations to learn about mindfulness and mindful eating (yes or no). You may learn about mindfulness and mindful eating skills, such as ways to better pay attention to what you are feeling and your level of hunger, in order to help you enjoy the program more and be able to stick with the program.

All groups will have an online program to support you and help you lose weight and get your blood sugar under control.

Location: All measurements will take place online or in your home. Class sessions will take place online.

Study Classes. After all of the above baseline assessments are complete and you are eligible, you will complete a short online questionnaire to confirm your interest and availability for the study classes and follow-up assessments. You will be asked to follow a diet with little sugar or starch taught using weekly online classes over 12 months (online material, including online videos and handouts will be sent to you weekly or every 2 weeks). Each class will take about 15-60 minutes to complete. In the classes, you will learn how to implement the diet in a healthy way, tools to help you stick to the diet, and how to manage stress in your daily life. The total amount of out-of-class time will be about 2-5 hours a week.

Follow-up Assessment: You will have a follow-up assessment at 4, 8, and 12 months after classes start, including a repeat of the baseline surveys described above, the blood measurements, and the body weight assessment.

You will also be asked to provide feedback about the classes and study assessments. If you feel uncomfortable answering some of these questions, you may decline to answer them.

How will your study supplies be provided to you?
Some of your study materials will be shipped directly to you from vendors such as Amazon, DTILaboratories, and BodyTrace. By signing this consent form you are allowing the study team to provide the vendors with your name and address. This is in order for the materials be shipped to your home or office. Study materials include a digital body weight scale and urine ketone test strips mailed to you at the start of the study as well as any other gifts that you may receive as part of the study, such as diet-relevant books and food.

How will your blood samples be stored and used?
Your blood will be sent to a lab for immediate testing for HbA1c.

Will your blood be saved for future use?
No.

Will you receive your test results?
If you wish, you will receive these blood results from the study staff.

Can you stop being in the study?
Yes. You can decide to stop at any time. You will just tell the study researcher or staff person if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

4.2 How much of my time will be needed to take part in this study?
Your participation in the study will take about 12 months plus the time it takes for you to do the baseline measurements. Each assessment (at 0, 4, 8, and 12 months) may take several hours to do the A1c test, step on the scale, answer the self-report survey information, and track your diet. Participation in the diet and lifestyle program will take varying amounts of time, but the materials may take 1-2 hours to read and apply each week.

4.3 When will my participation in the study be over?
The study lasts 12 months long once you have been started on classes.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

1. *<u>Blood measurements:</u> We will be testing your blood using an FDA-approved non-fasting, finger stick, whole blood mail-in test. You will be asked to prick your finger (similar to when you might test yourself using a home glucose meter), collect a small amount of blood into a tiny tube, called a capillary, and then mail this away. The risks of pricking yourself for the self-test blood kit include temporary discomfort from the stick, localized bleeding, or localized infection. For more information about the test see: http://www.dtilaboratories.com/accubase-video.html*

2. *<u>Questionnaires:</u> Some of the questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to discontinue your participation at any time.*

3. *Diet: You may experience some side effects when you first reduce the amount of sugars and starches in your diet, such as constipation, headache, bad breath, and muscle cramps. These symptoms usually go away after the first couple weeks on the diet. If this happens, you can talk to the study staff. If your concerns or side effects are severe, you can speak to the study physician (Dr. Kim, from the University of California, San Francisco). She will be available on call if you have any urgent concerns.*

4. *Dietary changes: You could find it difficult to change your diet. Also, your friends or family may not support the changes you are making to your diet or lifestyle. If this happens, you can speak to study staff about this.*

5. *Home assignments: You may find it inconvenient to complete the home assignments for the class. Also, you could experience distressing emotions during some of the home assignments. If this happens, you can stop the exercise and speak to the study staff.*

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may receive possible benefits of taking part in this study. These may include improved diabetes control, , weight loss, reduced risk for diabetes complications, and decreased feelings of stress, but this cannot be guaranteed. The information that you provide may also provide benefit to other individuals with type 2 diabetes by helping health professionals better understand how to help people with type 2 diabetes improve their health, mood, and lower their risk for diabetes complications, although these benefits cannot be guaranteed.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

You are free to choose not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get care the way you usually do.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study (HbA1c test).

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will you be paid or given anything for taking part in this study?

You will receive $25 for completing the follow-up information at month 4, $25 for the same tasks at month 8, and $50 for these tasks at month 12. You will be paid in Amazon.com gift certificates that will

be e-mailed to you. In addition, you will be able to keep the digital body weight scale mailed to you at the start of the study as well as any other gifts that you may receive as part of the study.

8.3 Who could profit or financially benefit from the study results?
This research is done without a financial conflict of interest.

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect your privacy?
Your information will be stored on encrypted servers. We will mail class information weekly using e-mail. You may e-mail or call us about questions pertaining to the study or your health. Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Questionnaire responses are confidential and will not be shared with people outside the study. Your personal information may be given out if required by law.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease and/or other communicable disease status
- Genetic counseling/genetic testing records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- We will share your name and address with companies, such as Amazon, DTI Laboratories, and BodyTrace, so that we can send you study-related materials including an HbA1c test and a digital body weight scale. Where possible, companies have signed confidentiality agreements to not disclose your information to anyone besides the SUCCEED team. In the case of Amazon.com, so that we can e-mail you gift certificates, we may give them your e-mail address.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study

- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Laura Saslow
Mailing Address: Office 2178, 400 N Ingalls St, Ann Arbor, MI, 48109
Telephone: 734-764-7836

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document.

- Other (specify):_____

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with {Study Team Member Name/s}. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

In the website, please enter your legal name to consent to this research study.