

MTRIMM2 – Community Based Implementation Plan Summer 2016

OVERVIEW

The **MTRIMM2 – Community Based** Implementation Plan will be used to guide the delivery and progress of the intervention. It includes the overall management plan as well as individual roles and responsibilities.

KEY STUDY STAFF

- Principal Investigator:
 - o Lawrence Cheskin [contact information removed]
- Co-investigator:
 - o [names and contact information removed]
- Study Coordinator:
 - o [names and contact information removed]
- Data Manager:
 - o [names and contact information removed]
- Biostatistician:
 - o [names and contact information removed]
- REDCap Manager:
 - o [names and contact information removed]
- E-Mocha:
 - o [names and contact information removed]
- Data Collectors:
 - o [names and contact information removed]
- M-TRIMM Program Specialists:
 - o [names and contact information removed]

STAFF POSITION DESCRIPTIONS

- Study Coordinator: maintain all study activities and documents, organize study staff, schedule meetings, record meeting minutes, compose progress reports
- Data Manager: organize all data, maintain participant folders, maintain stock of enrollment and follow-up data forms, check data for errors; enter all data into REDCap data management and Excel spreadsheet. Data Collectors: recruit participants, administer consent and data forms
- Biostatistician: Conducts data analysis

TESTING

- The MTRIMM2 pilot will run from August 2016 through July 2018
- Beta testing for the REDCap data collection will be completed by August 2016

TEAM MEETINGS AND REPORTS

- Team members will meet bi-weekly, either in-person or via phone, unless circumstances call for more frequent meetings
 - o In-person meetings will take place at [address removed] offices, unless otherwise requested by PI
 - o Standard meeting length will be approximately 30 minutes
- Team members will report on progress such as:
 - o Current enrollment status

- Current follow-up status
- Challenges
- Troubleshooting
- Data entry status
- Concerns/questions
- Meeting minutes and reports will be written and distributed by the Study Coordinator via email within 48-hours of each meeting (Appendix A)
- Upon request, discussions at meetings will be formatted into progress reports by the Study Coordinator for use in discussions with the Monday Campaigns (funder)

RECRUITMENT

- Participant recruitment at The Brancati Center for the Advancement of Community Care - Walgreens Eager Park location [additional locations added later] will be conducted by data collectors
- Data collectors will arrive approximately 15 minutes prior to the start of assigned time at Center check-in with Center staff and set-up
- Access to Center clinic room door code: [removed]
- Data collectors will explain the study to study participants. Collectors will ensure:
 - That potential participant understands that study participation is voluntary
 - Potential participants have sufficient time to review consent forms and have any and all questions regarding the study and the forms answered
 - Study Coordinator completes the MTRIMM2 Screening Evaluation form (REDCap) to assess for Determination of Eligibility
 - Potential participants understand that their agreement to participate in the text messaging program will be based on randomization at enrollment and their provision of their cell phone number. Participants receive understandable explanation of the compensation structure (gift cards to be used at Walgreens at the completion of Visit 1: Enrollment/Baseline (\$10.00); Visit 2; 8 weeks (\$20.00), Visit 3: 16 weeks (\$20.00) and Visit 4: 42 weeks (\$40.00). A total of \$90.00 will be paid for completing the study.
- Materials needed for the Baseline meeting include required consent forms (Appendix C), What You Need to Know (Appendix B), Tips for Texting (Appendix M), Participant Study Instructions (Appendix N), Appointment Schedule (Appendix O), iPad(s), BMI Record label, and Educational/Lifestyle Materials (Baseline 0-8), (Appendix E), Written Text Messages (two sets – 0-8 and 8-16), study folders (1-office copy,; 1 participants copy).
- Login for iPads: [removed], access REDCap via shortcut and login with your personal login. Email for iPads/Apple ID and Prey Project (iPad tracking program): [removed]
- WiFi at Walgreens: [removed]
- Participant Office folders will be created at the time of recruitment and will include: Appointment/Study Schedule, Communications record, Gift Card Receipts (Appendix L), BMI Record label and Reminder Call Log Form. Office files maintained securely and separately are: Consent Forms (Appendix C), MTRIMM2 Screening Evaluation form (Appendix D).
- At the time of initial recruitment meeting and review of study criteria and consent, participants will be enrolled in REDCap and randomized in the text message program by data collectors (Educational Intervention Group 1 – No Mobile Messaging; or Intervention Group 2 – Text Messaging Group).
 - Participation in text message program will be indicated by the provision of “Cell phone number for receipt of text messages” on the screening evaluation form

- The TEXTIT portal will require first name, mobile phone number, preferred message delivery time, and a unique ID (information available from enrollment and baseline forms)
- For All participant recruitment taking place at The Brancati Center for the Advancement of Community Care or WMC [additional sites were added later]:
 - If participants are interested in enrolling in the MTRIMM2 text messaging program, they will be provided the consent form. Upon obtaining consent, they will be screened by study staff.
 - If eligible, participants will be scheduled to complete Baseline questionnaires in REDCap.
 - Data collectors will organize Participant folder materials based on randomization; e.g. Tips for Texting, written Text messages, Educational/Lifestyle Materials and distribute them in participant folders to Group 1 & 2 participants (Appendix E) (0-8 weeks) (8-16 weeks).

DATA COLLECTION

For MTRIMM2 Program

- **Enrollment, Baseline** Data collection will occur at The Brancati Center for the Advancement of Community Care or WMC.
 - In-person; on-line forms are not expected to take participants more than 60 minutes to complete
 - Study staff will answer participant questions while REDCap forms are being completed and will review forms for completion
 - Study staff will obtain participant height, weight and obtain BMI; record in REDCap and folder labels (Appendix I)
 - Participant will receive Walgreens Gift Card at the completion of Baseline visit (\$10.00)
- **Visit 2 (8 wks)** Data collection will occur at The Brancati Center for the Advancement of Community Care or WMC.
 - In-person on-line forms are not expected to take participants more than 60 minutes to complete
 - Study staff will answer participant questions while REDCap forms are being filled out and will review forms for completion
 - Study staff will obtain participant height, weight and obtain BMI; record in REDCap and folder (Appendix I)
 - Participant will receive Walgreens Gift Card at the completion of Visit 2 (\$20.00)
- **Visit 3 (16 wks)** Data collection will occur at The Brancati Center for the Advancement of Community Care or WMC
 - In-person on-line forms are not expected to take participants more than 60 minutes to complete
 - Study staff will answer participant questions while REDCap forms are being filled out and will review forms for completion
 - Study staff will obtain participant height, weight and obtain BMI; record in REDCap and folder (Appendix I)
 - Participant will receive Walgreens Gift Card at the completion of Visit 3 (\$20.00)
- **Post intervention follow-up (42 wks)** Data collection will occur at The Brancati Center for the Advancement of Community Care or WMC
 - In-person on-line forms are not expected to take participants more than 60 minutes to complete
 - Study staff will answer participant questions while forms are being filled out and will review forms for completion
 - Study staff will obtain participant height, weight and obtain BMI; record in REDCap and folder (Appendix I)
 - Participant will receive Walgreens Gift Card at the completion of Follow-up visit (\$40.00)

- The data manager will receive data collection training from the study coordinator and will be charged with the organization of participant folders containing all of the participant-reported data collected via hard copy

DATA ENTRY AND MANAGEMENT

- An Access data file has been created for monitoring of participant enrollment
 - o Direct link to working file: [removed]
 - o This Access database contains identifiable information and will be password protected
 - o Password: [removed]
 - o A codebook is available to describe the data sets
- Unique participant IDs will be used in all data management tools in order to link electronic participant data in a de-identified format as stated in the IRB research plan.
 - o IDs will be assigned by study staff at enrollment utilizing a unique participant identifier (Appendix I)
 - o These IDs will be written on labels that will be placed on all participant folders at the first study appointment (Appendix I)
 - o Participant unique identifiers will be entered in REDCap for randomization.
- The data manager will be charged with the entry of all participant-reported visits to the internal Access participant tracking spreadsheet.
 - o In the case of any hard copies of data collection; forms will be kept in a locked cabinet in the study coordinator's office, e.g. Consent Forms, Screening Evaluation forms.
- The data manager will be charged with updating the study dataset & codebook following IRB amendments, accordingly MTRIMM_scheduling_codebook_for_access_ (current date)
- Direct link to documents pending most recent IRB amendment approvals: [removed]
- The study coordinator will keep track of groups, which will be updated with the number participating at baseline and each follow-up. (Appendix I, for example)
 - o Direct link to working file: [removed]
- TEXTIT will provide text-message programming data via Excel spreadsheet (message Randomization)
 - o This spreadsheet will be **password protected** as it does contain mobile phone numbers which are sensitive information

DATA ANALYSIS

- When analyzing MTRIMM2 data, the .do file labeled "Importing and Cleaning" should first be run to convert data from the MTRIMM2 Participant Enrollment Access file into a usable .dta file.
 - o Note: Depending on what computer is being used and where that data is stored within the computer, the location of the data source may need to be modified in the actual .do file. To do this, change the text within the .do file that specifies the location of the excel document. Only change the information that is in quotations. For instance:
 - `import excel "location of document", sheet("sheet name") firstrow clear`
 - Follow these same steps to change the location of where the .dta file is saved.
- Most recent versions of this .dta file should be saved with a title that includes that date and version of Stata, in the ".dta files" folder. Any older copies of the data should be catalogued.
- The resulting newly created .dta file should then be run using the .do file labeled "MTRIMM2 Analysis".
- Whenever new analyses are conducted, the analysis should be put in the "MTRIMM2 Analysis" .do file

GIFT CARD RESPONSIBILITIES

- Participants of the study in MTRIMM2 will receive up to a total of \$90.00 in gift cards to Walgreens for their participation in the MTRIMM2 study (Visit 1 - \$10.00, Visit 2 - \$20.00; Visit 3 - \$20.00 and Visit 4 Follow-up \$40.00)

- Gift cards will be provided to participants at the conclusion of each visit following the survey completion
- The Department of Health, Behavior, and Society has a specific policy for how participant payment should be handled. The following roles are required by the department:
 - Card Holder: Maintains card in a locked box
 - Card Verifier: Counts cards after card hold to verify accuracy
 - Card Distributor: Distributes cards to participants
 - Data Verifier: Verifies that cards have been distributed to legitimate participants
- A tracking log will be used to track gift cards purchased and distributed (Appendix J)
 - The log is to be updated daily with any activity associated with card distribution
 - The verifier will reconcile the log and cards on hand to confirm the correct number of cards *on a monthly basis*
 - Log will be printed at the point of reconciliation and signed and dated by both parties to confirm agreement
 - The signed log is kept on file in a designated folder by the study coordinator; this folder kept locked with participant folders
- Given that HBS will limit the amount of cards given to a distributor, the study coordinator must initiate the request for the purchase when necessary
 - Allow for at least two weeks processing
 - In the event that the study coordinator is unable to make the request, the study co-investigator will do so
- For questions regarding the handling of gift certificates, refer to the document titled [“JHSPH Managing Cash Equivalents Training”](#) (A hard copy of the training is available in the gift card tracking folder)

OFFICE MANAGEMENT AND ACTIVITIES

- Log into office computers using JHSPH username & password
- For photo-copying, obtain access to photo-copying machine using the study cost center #[removed]
- Print all materials using [removed]
- For printing labels, Select printer name > Paper source: auto feed Tray 1 > OK > Print. Place labels face up.
- **M-TRIMM2 Shared Drive**
 - Drive path: [removed]
 - Participant files: Password: [removed]
- **MTRIMM Email Accounts:**
 - Check the [removed] email account for MTRIMM communications. Log in to the account at: [removed]
Username: [removed] password: [removed]
 - Use the [email removed] to maintain calendar/appointments for participants.
Username [removed], Password: [removed]
 - iPad(s) Screen Login: [removed]
 - Walgreens clinic exam room keypad: [removed]
 - Walgreens secure hotspot: Verizon: [removed] ; Password [removed]
 - Walgreens secure hotspot: AT&T: [removed]; Password [removed]
- **TEXTIT SMS Platform**
User name: [removed]
Password: [removed]
Email: [removed]

- **CLICKATEL** SMS mobile messaging aggregator (gateway):
Client ID: [removed]
Username: [removed]
Password: [removed]

<https://www.clickatell.com/login/?Redirect=/index>

- **TWILIO Account SID Login**
Username: [removed]
Password: [removed]

Twilio Account SID
[removed]

Twilio Account Token
[removed]

Toll-free number: [removed]

<https://www.twilio.com/>

Appendix A

**MTRIMM2
Meeting Minutes**

Date: ____/____/____

Team members in attendance:

Minutes:

Date of next meeting:

Appendix B (1)

Johns Hopkins Bloomberg School of Public Health

Study Title: Monday Focused Tailored Rapid Interactive Mobile Messaging (MTRIMM2) for Weight Management

Principal Investigator: Lawrence Cheskin, MD

IRB No.: IRB00007115

PI Version Date: 6/9/16

What you need to know about this program

You were randomly picked to get text messages. MTRIMM's text messaging program uses Mondays as a day to give you either words to encourage you, or more information about making healthy lifestyle changes. The program focuses on the eight goals listed below:

- | | |
|--|---------------------------------------|
| 1) Eating only when hungry | 5) Exercising more |
| 2) Increasing physical activity | 6) Eating a balanced diet |
| 3) Lower fat diet | 7) Controlling portion sizes |
| 4) Eating less sugary foods/reduce calories from beverages | 8) Eating better in social situations |

To help you reach these goals, MTRIMM will send text-messages to your cell phone several times a week for 16 weeks. Some messages may ask you to reply with a text. You will have **three hours** to reply. The table below has information about days of the week and the times when you will receive text-messages. It also has examples of the types messages you will receive, and specifies whether you need to reply or not.

Time*	Content example	Same each week?	Should I reply?	What if I replied too late?
Sun 12 pm	“Start fresh on Monday! It is a new week & a new opportunity to reach your goals.”	Yes	No	-
Sun 5 or 7 pm	<u>Question:</u> “Which topics would you like to receive tips about next week? Text "A" for eating/drinking less sugar, "B" for being more active, "C" for eating a balanced diet”	No, choices change	Yes	You will get tips listed under choice “A” for that week
Mon 7 or 9 am	Goal for the Week: “Want an easy way to cut down on calories this week? Just replace soda and juice with water, unsweetened iced tea, or black coffee.”	No, tips change	No	-
Mon 5 or 7 pm	<u>Question:</u> “Have you planned your meals and snacks for the week yet? Please text back "Yes" or "No." Remember planning can help you avoid sugary foods.”	Yes, similar questions	Yes	Your answer will not be recorded automatically
Wed 7 or 9 am	Additional Tip: “Check labels carefully today. Sugar can be disguised as fructose, glucose, corn syrup & juice concentrate. The less of it you drink the better!”	No, tips change	No	-
Wed 5 or 7 pm	“Remember, if you'd like an extra tip or are experiencing a craving, just text back ‘tip’ to this number.”	Yes	Optional	Request tips at any time, as often as you like
Fri 7 or 9 am	“It's Friday! Congratulations on making it to the end of the week! Remember your goals as you plan for the weekend!”	Yes	No	-

Fri 5 or 7 pm	**Question: "How many pounds do you weigh this week? (Please only text back numbers, without abbreviations or words such as "lbs" or "pounds")"	Yes	Optional	Your answer will not be recorded automatically
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* Messages might arrive up to an hour later than the times specified above, although rarely happens


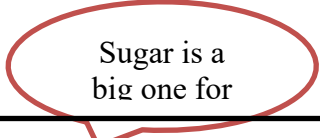

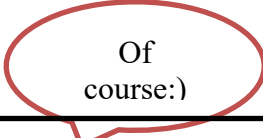
**If you are not able to weigh yourself on Fridays (i.e. if you do not have a scale at home), you do not have to send MTRIMM an answer to the Friday evening questions about your weight. Instead of getting a message congratulating you on losing weight or encouraging you to keep trying, you will get this message: "Remember your progress this weekend and stay strong!"

Cost: Depending on your cell phone plan, you may be charged for text messages based on the plan you have with your carrier. Only U.S. phone numbers will be able to receive messages.

Pause or Unsubscribe: You can text "pause" at any time to stop getting text messages. Once you are ready to start getting messages again, simply text "start" to MTRIMM. It might take a few days for you start receiving text-messages again.

Tips for Texting

- **When to respond to texts?**
 - Some messages may ask you to reply with a text. You will have **three hours** to reply.
 - If you reply too late, you might not receive messages related to the topic you picked, or might receive replies that are not tailored to you.
 - Some messages simply provide information or ask rhetorical question, do not ask you to reply. Please do not respond to those messages.
 - If you reply to those text-messages, you will receive an automatically generated text from MTRIMM. It will tell you that something went wrong and that the MTRIMM team will be notified.
- **How to respond to Texts?**
 - You will be interacting with a computer program that our team has created. It only understands certain types of answers. Text-message that includes a question, will have instructions on how to answer them. Below are examples of correct and incorrect responses.

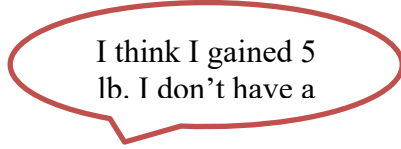
<p>Which topics would you like to receive tips about next week? Text "A" for exercising more, "B" for eating/drinking less sugar, "C" for eating in social</p> <p>Correct Answer: </p> <p>Incorrect Answer: </p>	<p>Have you planned your meals and snacks for the week yet? Please text back "Yes" or "No."</p> <p>Correct Answer: </p> <p>Incorrect Answer: </p>
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<p>[removed]</p> <p>How many pounds do you weigh this week? (Please only text back numbers, without abbreviations or words such as "lbs" or "pounds")</p>	<p>Eliminate sugary snacks from your diet. This week try a piece of fruit instead if you want something sweet!</p>
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Correct Answer



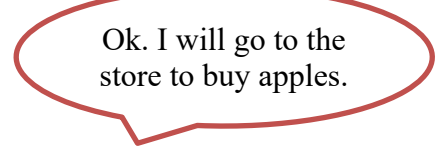
Incorrect Answer



Correct Answer

No reply

Incorrect Answer



Who do I call if I have questions or problems?

- Call the principal Investigator, Dr. Lawrence Cheskin, at [removed] if you have questions, complaints, or believe you have been harmed as a result of being in this study.
- Call or contact the Johns Hopkins Bloomberg School of Public Health Institutional Review Board Office if you have questions about your rights as a study participant.
- Contact the IRB if you feel you have not been treated fairly or if you have other concerns.

The IRB Contact information is:

Address: Johns Hopkins Bloomberg School of Public Health 615 N, Wolfe St., Suite E1100 Baltimore, MD 21205

Telephone: 410-955-3193

Toll Free: 1-888-262-3242

Fax: 410-502-0584

Email: irboffice@jhsph.edu

What does your signature on the Informed Consent Form mean?

Your signature on this form means:

- You have been informed about this study is purposes and procedures
- You have voluntarily agreed to this study
- You agree to share your mobile number and to receive text messages, which can be stopped at any time. You agree to allow the study team to access data regarding your interactions with the text-messaging program.
- You understand that you may be charged for text messages sent and received by this program depending on your cell phone data plan

Appendix B (2)

Johns Hopkins Bloomberg School of Public Health

Study Title: Monday Focused Tailored Rapid Interactive Mobile Messaging (MTRIMM2) for Weight Management

Principal Investigator: Lawrence Cheskin, MD

IRB No.: IRB00007115

PI Version Date: 6/9/16

What you need to know about this program

We are offering a day-of-the-week text messaging program that uses Mondays as a day to give you either words to encourage you, or more information about making healthy lifestyle changes.

If you become a part of this text message study, you will be picked to be in one of two groups randomly; one group will get text messages that will be sent to your cell phone several times a week for 16 weeks; the second group will receive the same information but in paper and will not receive text messaging. For the group that gets sms messages, some messages may ask you to reply with a text. Each message (SMS or on paper) will give you either encouragement or more information about making healthy changes. You may be asked to reply with a text about your physical activity for that day or week, or foods that you craved. You can text “pause” at any time to stop getting text messages. Depending on your cell phone plan, you may be charged for text messages based on the plan you have with your carrier. Only U.S. phone numbers will be able to receive messages.

PROGRAM GOALS: The messages are based on the below goals.

- | | |
|--|--------------------------------|
| 1) Eat only when hungry | 5) exercise more |
| 2) increase physical activity | 6) eat a balanced diet |
| 3) lower fat diet | 7) portion control |
| 4) eat less sugar/reduce calories from beverages | 8) eating in social situations |

If you are randomized in the non-mobile messaging group:

The same mobile messages are provided to you in written format based on the exact same daily schedule as the randomized group that will receive the messages. These are intended for you to read as prescribed to provide you with the same motivational messages and tips throughout your participation in the study. You will receive the written messages from weeks 0-8 weeks and then from weeks 8 through 16 weeks.

Who do I call if I have questions or problems?

-Call the principal Investigator, Dr. Lawrence Cheskin, at [removed] if you have questions, complaints, or believe you have been harmed as a result of being in this study.

-Call or contact the Johns Hopkins Bloomberg School of Public Health Institutional Review Board Office if you have questions about your rights as a study participant.

-Contact the IRB if you feel you have not been treated fairly or if you have other concerns.

The IRB Contact information is:

Address: Johns Hopkins Bloomberg School of Public Health 615 N, Wolfe St., Suite E1100 Baltimore, MD 21205

Telephone: 410-955-3193

Toll Free: 1-888-262-3242

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Email: irboffice@jhsph.edu

What does your signature on the Informed Consent Form mean? Your signature on this form means:

- You have been informed about this study is purposes and procedures
- You have voluntarily agreed to this study

Appendix C

MTRIMM2 CONSENT FORM

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH INFORMED CONSENT DOCUMENT

Study Title: Monday-Focused Tailored Rapid Interactive Mobile Messaging (MTRIMM2) for Weight Management

Principal Investigator: Lawrence J. Cheskin, M.D.

IRB No.: 00007115

PI Version Date: 5/25/16

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- You may choose not to answer any question that we ask.
- We are conducting a research study about whether adding Monday-focused text messages to a standard lifestyle behavioral educational program helps people improve their lifestyle and lose weight better than the standard program alone. Responding to this survey request is voluntary; it is your choice. Completing this survey and submitting it to us means you consent to participate in the study.

Review this form carefully. Please feel free to ask questions about the study before you agree to join. You may also ask questions after you join the study.

Purpose of research project

We are studying whether adding Monday-focused text messaging motivational lifestyle behavioral educational program (MTRIMM2) can help people improve their lifestyle habits and lose weight better than a standard program of behavioral educational program alone. We are making the program available to individuals in the adjacent living and working communities of the Walgreens-Eager Park. This location has been established as the Health Awareness Center, under the direction of the Brancati Center for the Advancement of Community Care. "TRIMM2" text messages are text message reminders and encouragement. You may be selected at random to receive messages on your cell phone about diet and exercise and respond via text messages. The study program will last 42 weeks, with follow-ups at the Walgreens – Eager Park Health Awareness Center. We are asking 200 people to enroll in the study which involves four visits and completing sets of surveys on a computer or tablet at the Walgreens Eager Park Health Awareness Center. The intervention group will receive mobile messages weekly which will continue for sixteen weeks. Message frequency and content will be modified based on individual participant feedback tailored to health risks and goals. At least one message each week will be interactive, prompting participants to respond, and generates an automatic reply based on the participant's response. These reminders are intended to encourage participants to remain engaged in the relevant health behavior changes. Messaging will begin on the Monday of the week following the completion of the baseline survey, and will take approximately 2 minutes to read each week. At the conclusion of week 16, the intervention group will no longer receive text messages. The control group will receive the content from the text messages in written paper format, and will meet with study staff at Baseline and the follow-up visits on weeks 8, 16 and 42 to complete the follow-up visit questionnaires. Both groups will receive lifestyle behavioral education at Baseline and weeks 8.

Why you are being asked to participate

You are being asked to join this research study because you are interested in making lifestyle changes to live healthier and potentially lose weight. You should read the following information and ask as many questions as possible before signing in order to understand what the study involves. To be included you must have and maintain a cell phone that accepts SMS messaging.

Procedures

This is a 42 week Adult intervention study, with follow-up visits at approximately 8, 16 and 42 weeks, at the Walgreens – Eager Park Health Awareness Center. Surveys will be completed online through a REDCap data collection site. REDCap. After the patient has been deemed eligible for the study, consent obtained, the questionnaires can be provided, in-person at follow-up clinic appointments. Participants are asked to complete electronic questionnaires (taking about 30 minutes to complete); completed at eight week, sixteen weeks and forty-two weeks follow-up appointments during the course of the 42 week (10 month) study; these questionnaires are designed to assess compliance and measure improvement. All questionnaires will be available electronically and on paper if requested.

ENROLLMENT/BASELINE (VISIT 1)

If you	Visit #	Visit Length (Min/hrs.)	Weight BMI	Consent Form	Medical/History Form	Weight Efficacy Lifestyle Questionnaire WELQ	International Physical Activity Questionnaire IPAQ	Fruit and Vegetable Screener FVS	Percentage Energy from Fat Questionnaire QFS	The Exercise Benefits/Barrier Scale EBBS	Process Evaluation PE
	Baseline (Visit #1)	1.0	X	X	X	X	X	X	X		
	Visit # 2 (8 weeks)	.45	X			X	X	X	X	X	
	Visit #3 16 weeks	.45	X			X	X	X	X	X	X
	Follow-up (42 weeks)	.45	X			X	X	X	X	X	X

Consent to enroll in the study, you will meet with study staff to complete the Baseline assessments which will ask questions about current health and health-related behaviors, physical activity, diet, Body Mass Index (BMI), height and weight. You will also complete a set of questionnaires as a part of the initial assessment about health goals and health attitudes. The below chart lists the data we will collect from questionnaires at each study visit.

- Following Baseline, you will be randomized to be in one of two groups; one group will receive text messages and will meet with study staff at the follow-up appointments. The second group will receive the same messages in written format and will meet with study staff appointments receiving lifestyle behavioral education consisting of written motivational and encouraging materials.

FOLLOW-UP/WEIGH-IN (VISIT 2 at WEEK 8)

- Each text message will give you either encouragement or more information about making healthy lifestyle changes.
- You may be asked to reply with a text about your diet or activity for that day.
- Data will be collected on the number of text messages, the number of replies made, and how long it takes you to reply.
- You will complete the same set of questionnaires used in the enrollment visit.
- You will meet with study staff for height, weight, lifestyle behavioral education.

FOLLOW-UP/WEIGH-IN (VISIT 3 at WEEK 16)

- You will complete the same set of questionnaires used in the enrollment visit.
- You will meet with study staff for height, weight, BMI, lifestyle behavioral education.
- You will be asked to complete a process evaluation survey about how useful and easy to use the study materials were.

FOLLOW-UP/WEIGH-IN (VISIT 4 at WEEK 42)

- You will meet with study staff for height, weight, BMI, lifestyle behavioral education.
- You will be asked to complete a process evaluation survey about how useful and easy to use the study materials were.

Risks/discomforts

You may be asked questions of a sensitive nature, for example, questions about your weight, mood, and history of medical or mental health problems. It is possible you could feel embarrassed or anxious answering these questions or having physical measurements taken.

You will be given health, diet, exercise, and lifestyle behavioral education. How you use this information is up to you. There is some chance you will have mild stomach symptoms such as loose stools because of changes in your diet. There is risk of muscle discomfort or injury with changes in your exercise routines.

This study is experimental and we do not know if it will work. You should not assume that being in this study will help you lose weight. You may or may not lose weight if you follow the advice we provide.

You will be given advice on your current health and lifestyle habits. You will also receive reading materials to improve your health, diet, exercise, and lifestyle habits. This may assist your weight loss. Also, you will help us learn whether adding motivational cell phone texting to a good nutrition program helps people lose weight.

Payment a study participants you will be provided gift cards to be used at Walgreens at the completion of Visit 1: Enrollment/Baseline (\$10.00); Visit 2; 8 weeks (\$20.00), Visit 3: 16 weeks (\$20.00) and Visit 4: 42 weeks (\$40.00). A total of \$90.00 will be paid for completing the study.

Protecting data confidentiality

We will keep all information you provide to us private to the extent possible by law. Your name will not be on the forms you fill out or on the computer file, only your study number. The paper that links your study number to your name will be kept in a locked cabinet in the Principal Researcher's office. All study materials will be kept in a secure location so no one outside the Study can see them.

Under certain conditions, the people responsible for making sure that the research is done properly, may review your study records. This may include people from Johns Hopkins. All of these people are required to keep your identity private. We will

not give out information that identifies you to people outside of the study without your permission.

Protecting subject privacy during data collection

We will keep the data collection process private. Investigators and/or individuals outside of the study will not be present during data collection and will not have access to information shared and data collected during this process. At the end of the study, all the survey forms will be destroyed.

Alternatives to procedures or treatments

You do not have to participate in this study to enroll as a patient at the Weight Management Center. If you decide not to join this study, you are still eligible for WMC participation.

Cost of participation in the study

Depending on the nature of your cell phone plan, you may be charged for receiving text messages if they are not covered in your monthly fee.

What happens if you leave the study early?

Your participation in this study is voluntary and you have the right to leave the study at any time. If you do not want to join the study, or if you leave the study, you will still receive the same quality of medical care.

Sharing your health information with other

We will not share your health information with other researchers and investigators within and outside of the Johns Hopkins community without your permission. If we do, your health information will always be de-identified. Individuals other than the Principal Investigator and study investigators will not have access to your identity. The Principal Investigator and co-investigators are certified in health-related privacy issues and will not share identifiable health information with others.

Payment of treatment costs for injury or illness from study participation

The study doctor or the JHSPH IRB Office answer our questions and/or help you find medical care if you feel you have suffered an injury. Johns Hopkins and the government do not have any program to provide compensation to you if you suffer injury or other bad effects, which are not the fault of the study staff.

Who do I call if I have questions or problems?

- Call the principal investigator, Dr. Lawrence J. Cheskin, at [removed] if you have questions, complaints, or you believe you have been harmed as a result of being in this study.
- Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:
Address: Johns Hopkins Bloomberg School of Public Health 615 N. Wolfe Street, Suite E1100
Baltimore, MD 21205
Telephone: 410-955-3193
Toll Free: 1-888-262-3242
Fax: 410-502-0584

E-mail: JHSPH.IRBOffice@jhu.edu

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.
- You are agreeing to receive text messages at the number you provide below.

Give one copy to the participant and keep one copy in secure office file

Appendix D

**MTRIMM2
Screening Evaluation**

Demographic Information

Date of Acquisition ____/____/____

Full Name (LAST)_____ (FIRST)_____

Inclusion/Exclusion criteria:

Current Height ____ Weight ____ lbs BMI ____.

(BMI = or >25) ____ Yes ____ No

Do you have a cellular phone that accepts text messages? Yes / No

Are you willing to maintain the cellular phone/plan while participating in the study? Yes / No

Determination of Eligibility (per investigator review):

Eligible? ____ Yes ____ No

If no, why not? _____

Date: ____/____/____

Thank you for taking the time to provide this important information.

Appendix E

**MTRIMM2
Lifestyle Education Materials**

(see Shared drive MTRIMM > MTRIMM2 > Lifestyle Documents

Baseline (0-8 weeks)	<i>Physical Activity and Health The Best Food Choices</i>
Visit 2 (8-16 weeks)	<i>What Can I Eat? Fast Food Tips What Can I Eat? Be more Active</i>

Appendix F

MTRIMM2 Materials

(Italics: for Standard of Care Group 1, provided by coordinator)

Baseline:

1. Consent Form (**note: provide a copy in secure office folder**)
2. Screening Evaluation (**note: place in secure office folder**)
3. Baseline REDCap instruments
4. What I Need to Know overview
5. Folders
6. iPads and stylus
7. Participant form labels (**note: complete weight & BMI in participant folder**)
8. *Educational/Lifestyle materials*
 - a. *Physical Activity and Health*
 - b. *The Best Food Choices*
9. M-TRIMM2 texting program FAQ
10. Texting Tips
11. Written Text messages (Standard of Care Group)(0-8 weeks)
12. Craving Tips (Standard of Care Group)(0-8 weeks)
13. Participant Instructions
14. Gift Card (\$10.00)

Visit 2 (8 wks):

1. Folders
2. iPads and stylus
3. Participant form labels (**note: complete weight & BMI in participant folder and REDCap**)
4. Written Text messages (Standard of Care Group)(8-16 weeks)
5. Craving Tips (Standard of Care Group)(8-16 weeks)
6. *Educational/Lifestyle materials*
 - a. *What Can I Eat? Fast Food Tips*
 - b. *What Can I Eat? Be more Active*
7. Gift Card (\$20.00)

Visit 3 (16 wks):

1. Folders
2. iPads and stylus
3. Participant form labels (**note: complete weight & BMI in participant folder and REDCap**)
4. Gift Card (\$20.00)

Visit 4 Follow-up (42 wks):

1. Folders (**note: complete weight & BMI in participant folder and REDCap**)
2. iPads and stylus
3. Referral sources info (WMC, etc.)
4. Gift Card (\$40.00)

Appendix G

MTRIMM2 Participant Folders

All participant folders should contain the following forms using available self-adhesive fasteners:

Left Side:

1. Flyer
2. Program Overview
3. Participant Study Instructions
4. What You Need to Know (appropriate for randomized group)
5. INTERVENTION GROUP: Tips for Texting

Right Side:

1. Weight/Height and BMI Record Label (affixed to inside back right side of folder)
2. Appointment Schedule
3. STANDARD OF CARE GROUP: Written Text Messages (half at Baseline and the other half at week 16 visit)
4. STANDARD OF CARE GROUP: Craving Tips(half at Baseline and the other half at week 16 visit)
5. BOTH Groups: Lifestyle Materials (Group 1) 0-8 weeks; 8-16 weeks.
 - a. Physical Activity and Health
 - b. The Best Food Choices
 - c. What Can I Eat? Fast Food Tips
 - d. What Can I Eat? Be more Active

MTRIMM2 Participant OFFICE Folders

Left Side:

1. Lifestyle Education form
2. Appointment Schedule

Right Side:

1. HBS Gift Card Receipt Form
2. Reminder Call Log Form
3. Weight/Height and BMI Record Label (affixed to inside back right side of folder)

MTRIMM2 SECURE OFFICE FILES

1. Consent form – signed by participant and study coordinator in ALPHA file
2. Screening Evaluation in ALPHA files

Appendix H

MTRIMM2 Unique Participant ID Designation

[removed]

Appendix I

**MTRIMM2
Labels**

Participant form labels: to be affixed to every file folder, with responses for eligibility and text-message program participation circled. (Label Size: 1/3 Cut – 30 labels per sheet, e.g. [removed])

<p>Participant ID: _____ - _____ Eligible: NO / YES Enrolled: NO / YES</p>

Participant folder labels: To be affixed to the tab of each participant’s unique manila folder and consent form. Sample Unique ID below. (Label Size: 1/3 Cut – 30 labels per sheet; Font: Arial, bold, size 18)

<p>##-####</p>

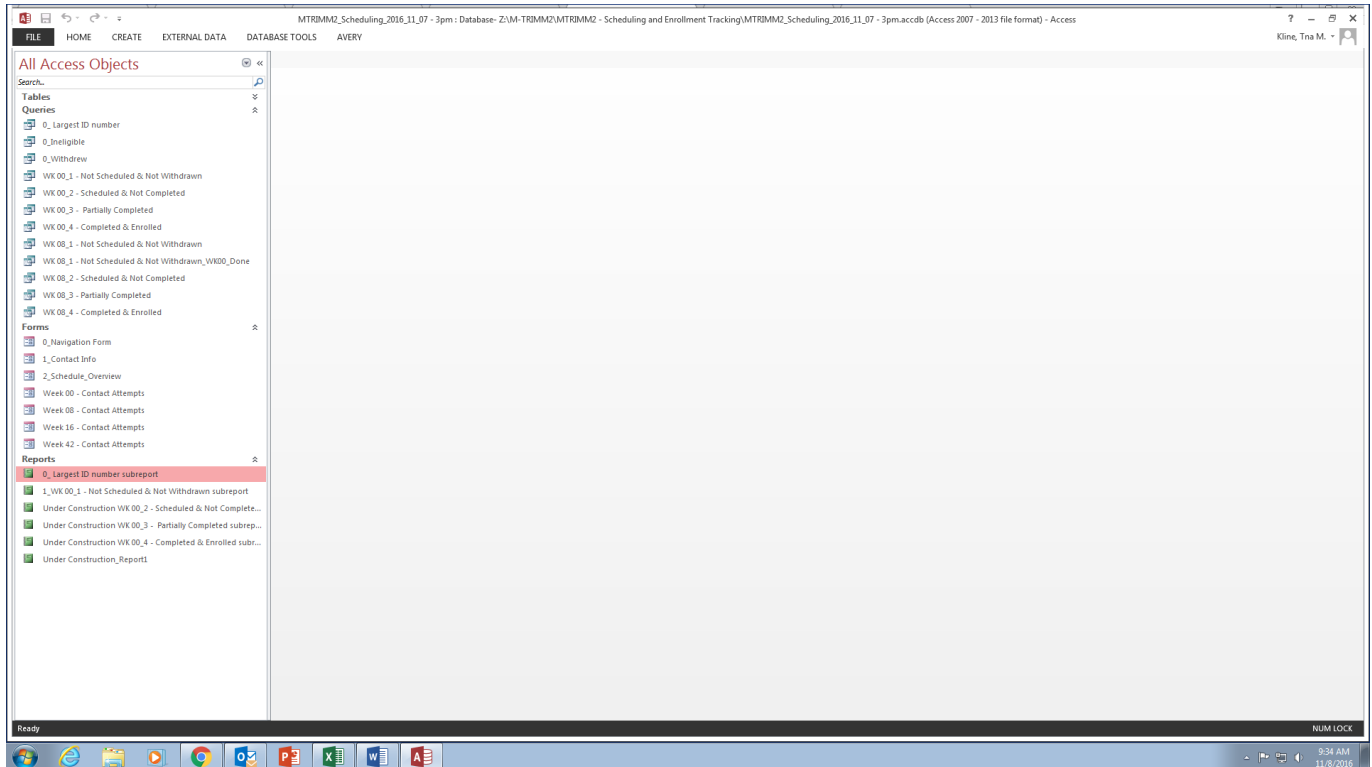
Weight/BMI Diary Labels: To be affixed to participant folders inside back right side of folder. (Label Size: 3-1/3” x 4” – 6 per sheet, e.g. [removed]))

BMI				
Weight				
(MM/DD/YY)				
	Baseline	Visit #2 8 weeks	Visit #3 16 weeks	Visit #4 Follow-up 42 weeks

Appendix J

MTRIMM2 Participant Tracking

The following screenshot displays the MTRIMM2 enrollment and screening ACCESS Database.



Appendix L

Department of Health, Behavior & Society
The Johns Hopkins Bloomberg School of Public Health

HBS GIFT CARD RECEIPT



Received By: _____ Date: _____

Study Visit No.: _____

Type of Gift Card: Walgreens Number of Cards: _____ Denomination: _____

Total Amount of Card(s): _____

Serial Sequence Number of Card(s) issued _____

Initials of Participant: _____

Date Received: _____



HBS Department Verification: _____

Project Role: _____

PI Name: Larry Cheskin, MD

Project/Grant Title: Monday-Focused Tailored Rapid Interactive Mobile Messaging (MTRIMM2) for Weight Management

Budget Information:

Business Area: [removed]

Internal Order or Cost Center Number: [removed]

GL Code: [removed]– Patient Subject/Participant Expense

Appendix M

MTRIMM2 Participant Study Instructions

In this folder, you will find data forms that we will complete each visit to monitor progress while enrolled in the study, as well as other informational materials as a part of the MTRIMM2 study.

There are four sections of the MTRIMM2 study: Baseline, 8-week, 16-week and 42-week. Forms for each section must be completed in clinic on a computer/iPad. If you have questions, please e-mail the MTRIMM2 study team at [removed] or call [removed].

1. Upon receiving this folder and signing the consent forms, you will complete the **five Baseline Forms via REDCap**, the online questionnaire program during your scheduled clinic visit. These forms include: Medical History, Exercise Benefits and Barriers Scale, Fruit and Vegetable Screener, Quick Food Scan, and Weight Efficacy Lifestyle Questionnaire. If you are randomized to receive text messages, you will begin to receive text messages following this appointment. If you are not assigned to the Text Messaging group, you will receive educational/lifestyle brochures at each visit to help encourage and motivate you.
2. About one week before your scheduled 8-week follow-up, you will receive an e-mail from the MTRIMM2 team reminding you of your next scheduled appointment at 8 Weeks and to bring your folder.
3. Bring your folder to your next scheduled appointment (Week 8, Visit 2), at which time you will complete the same forms (these forms include: Exercise Benefits and Barriers Scale, Fruit and Vegetable Screener, Quick Food Scan, and Weight Efficacy Lifestyle Questionnaire), and have your height and weight measured.
4. About one week before your scheduled 16-week follow-up, you will receive an e-mail from the MTRIMM2 team reminding you of your next scheduled appointment at 16 Weeks and to bring your folder.
5. Bring your folder to your next scheduled appointment (Week 16, Visit 3), at which time you will complete the same forms (these forms include: Exercise Benefits and Barriers Scale, Fruit and Vegetable Screener, Quick Food Scan, and Weight Efficacy Lifestyle Questionnaire), and have your height and weight measured. You will also complete a Process Evaluation survey for the past 16 weeks.
6. About one week before your scheduled 16-week follow-up, you will receive an e-mail from the MTRIMM2 team reminding you of your next scheduled appointment at 16 Weeks and to bring your folder.
7. About one week before your scheduled 42-week follow-up, you will receive an e-mail from the MTRIMM2 team reminding you of your next scheduled appointment at 42 Weeks and to bring your folder.
8. Bring your folder to your next scheduled appointment (Week 42, Visit 4), at which time you will complete the same forms (these forms include: Exercise Benefits and Barriers Scale, Fruit and Vegetable Screener, Quick Food Scan, and Weight Efficacy Lifestyle Questionnaire), and have your height and weight measured. You will also complete a Process Evaluation survey for the past 16 weeks.
9. ***Congratulations, you have completed the study! We THANK YOU VERY MUCH for your participation!***

Appendix N

**MTRIMM2
APPOINTMENT SCHEDULE**

PARTICIPANT ID# _____

VISIT WEEK:

- | | | | | |
|--------------------------|----------|-------------------|-------------|-------------|
| <input type="checkbox"/> | VISIT #1 | BASELINE | DATE: _____ | TIME: _____ |
| <input type="checkbox"/> | VISIT #2 | 8 WEEK | DATE: _____ | TIME: _____ |
| <input type="checkbox"/> | VISIT #3 | 16 WEEK | DATE: _____ | TIME: _____ |
| <input type="checkbox"/> | VISIT #4 | 42 WEEK FOLLOW-UP | DATE: _____ | TIME: _____ |

If unable to make appointment, please call MTRIMM2 Study office at:

[removed]

OR EMAIL

[removed]

THANK YOU FOR YOUR PARTICIPATION!

Article information: <http://dx.doi.org/10.21037/mhealth-21-3>