

Location-based Smartphone Technology to Guide College Students Healthy Choices (Healthy Detours)  
Protocol  
NCT02996864  
8/16/2016

## Overview

The *Healthy Detours* app will be tested in a 12-week randomized controlled trial (RCT) with 300 college students at Louisiana State University (LSU) during the Fall 2016 and Spring 2017 semesters. RCT enrollment will be split between these two semesters, with approximately 150 students enrolling during each 12-week period. Students will be randomized to either the *Healthy Detours* app or to an active control condition app.

USDA's *SuperTracker* was originally proposed to serve as the control app for the research project. However, only the *SuperTracker* web page is currently functioning, thereby eliminating it as an appropriate control condition for the *Healthy Detours* app.

The research team agreed on the following criteria for the control app:

- Must be publically available at no cost to the user
- Must be compatible with both Android and iPhone platforms
- Must come from a reputable source
- Must not be an app specifically designed for weight loss; weight monitoring apps may be included

Based on these criteria, *Calorie Counter* by FatSecret was selected as the RCT control condition app.

## Recruitment

RCT participants will be recruited from the student population at LSU. Recruitment methods will include but are not limited to: flyers posted on campus and at businesses in the immediate area; social media posts; email and newsletter announcements by various departments and student organizations; online announcements through myLSU and SONA; recruitment tables set up at various campus events before and during the semester; recruitment presentations during classes and events; and by classified ads posted on Craigslist and the LSU newspaper, *The Reveille*.

Potential participants will be directed to an online baseline screening questionnaire to determine eligibility. They will also schedule their enrollment visit through this site.

## Preliminary Enrollment

A standardized enrollment procedure will be utilized for the RCT (**Appendix A**). From the recruitment materials, students will be directed to the **baseline screener questionnaire (Appendix B)** that is to be created by KB production staff. Students attempting to enroll in the study through PBRC will be directed to the enrollment website by sending a website link to the students' email.

Eligibility to participate in the RCT will be determined through the information provided by the student in the enrollment website. Students that are considered "screen fails" will be thanked and encouraged to participate in other research activities.

Students that meet eligibility criteria will be directed to the **online consent form (Appendix C)**. Here, students will be asked to read the consent information and indicate that they understand and agree to the terms of the study. Students unwilling to provide consent will be thanked for their interest and encouraged to participate in future research projects.

**Note:** This is considered an informal consent; a formal consent will be provided at the baseline enrollment meeting. The purpose of this informal consenting is to ensure that students are aware of the parameters of their participation prior to the baseline enrollment meeting to prevent attrition.

Students meeting eligibility requirements and providing online consent will be prompted to schedule a time for the baseline enrollment session (**Appendix D**). They will be provided a list of times that PBRC will be holding mass enrollments, and will indicate which of those sessions they are available to attend. Participants will also be prompted to schedule their 12-week follow-up visit at this time.

If a student is unavailable to attend one of these mass enrollment/follow-up sessions, they will be contacted by PBRC to arrange a one-on-one enrollment meeting.

**Note:** These one-on-one enrollment sessions are tentative and dependent on how quickly participants are being recruited. If recruitment fills quickly, only those with mass enrollment availability will participate in the study.

Participants will be assigned C-Numbers once they have registered for an enrollment meeting. The C-Numbers for RCT participants are assigned numerically beginning with C00-03-0201 and going up to C00-03-1000.

Upon completing the online enrollment process, participants will automatically receive an email confirmation for their enrollment and exit interview dates. Participants will receive an email reminder three days and one day prior to these meetings (**Appendix E**).

As a backup to the scheduler programming, KB and PBRC will also receive these email confirmations and reminders through their project-specific email accounts: [healthydetours@kleinbundel.com](mailto:healthydetours@kleinbundel.com) and [healthydetours@pbrc.com](mailto:healthydetours@pbrc.com).

## **Baseline Enrollment Meeting**

Based on their provided availability, participants will attend a baseline enrollment meeting on LSU campus. The following protocol will be employed at the baseline enrollment meetings:

1. Study Orientation: PBRC staff will provide an overview of the study and allow an opportunity for participants to ask questions
2. Written Consent, Identity Confirmation & W-9: Participants will be asked to provide written consent indicating they understand the terms of the study. Participants will confirm their identity during this step by showing PBRC staff their LSU ID, and they will be asked to complete a W-9 form.

3. Online Surveys: Participants will complete four **online surveys (Appendix G)** using a study tablet
4. Randomization: Participants will be randomized to a study condition
5. App Download: Participants will download their respective app
6. App Registration & Tutorial: Participants will be given a tutorial on how to use their study app and will be assisted in inputting personal information (class schedule, activity level, etc.) into the app
7. Exit Interview Scheduling: Participants will schedule a 12-week follow-up meeting with researchers

### **Step 1: Study Orientation**

PBRC staff will provide an overview of the study with a PowerPoint presentation. They will explain the purpose of the study, participant inclusion, study procedures, and participant compensation. Participants will be informed that they are expected to frequently use the app, and that their back end data will be tracked. Staff will notify participants that they will receive the 6-week interim survey link via email, and that they may receive app updates throughout the 12-week period. Participants will be instructed to download any app updates they may receive.

### **Step 2: Written Consent & Identity Confirmation**

Following the study orientation, participants will be asked to review and sign the consent forms (**Appendix F**). PBRC staff should bring extra copies in case participants want to keep a copy of the form. When collecting the signed consent forms, PBRC staff should confirm the participants' identities and LSU enrollment status by checking their student IDs. Only students whose identities and LSU statuses have been confirmed will be enrolled in the study.

Participants will be required to complete a W-9 form in order for LSU to process their compensation. Participants must provide their Social Security Numbers (SSNs) on this form.

### **Step 3: Online Surveys**

PBRC staff will hand out tablets for participants to complete the baseline surveys. Participants will first complete the KB-programmed baseline survey using the following link:

<https://www.questionpro.com/a/TakeSurvey?id=4781126>

After participants have finished the KB-programmed baseline survey, they will be instructed to take the ASA24 using the following link: <https://asa24.nci.nih.gov/>

PBRC staff will be required to enter the ASA24 username and password that is associated with the participant's Subject ID and C-Number. The list of ASA24 usernames and passwords is included in **Appendix H**. See below for information on C-Numbers.

## Tablets

The links for the online baseline survey, the ASA24, and the YouTube tutorial have been bookmarked on all six tablets provided to PBRC by KB. A majority of these tablets are password protected, and PBRC staff should be given the passwords to all of the tablets they will be using.

For the Apple products (iPads), PBRC staff may be required to know the KB email account associated with the tablets. The login information provided below is universal for all KB Apple products.

- Email address: [☰](#)
- Passcode: =

## Participant C-Numbers

PBRC staff can access participant C-Numbers through the Admin Healthy Detours Study site.

1. Visit [www.healthydetoursstudy.com](http://www.healthydetoursstudy.com) and click on the Admin link:
2. Click on an individual within the schedule to view his/her C-Number

## Step 4: Randomization

Participants should be instructed to notify PBRC staff once they have finished the ASA24. At this point, participants will be randomized to their study condition. The randomization link for each participant will be within the individual's Healthy Detours Schedule Page. PBRC staff will click on this link to determine the participant's study condition.

## Step 5: App Download

Based on the randomization assignment, participants will download either the Healthy Detours app or Calorie Counter by FatSecret. There are four scenarios associated with this step, dependent on randomization assignment and participant phone type.

### Control Group – Android User

1. From the Google Play store, search FatSecret, locate the Calorie Counter by FatSecret app, and install the app onto the participant's phone.

### Control Group – iPhone User

1. Locate the App Store on the participant's phone by searching for it in the drag down bar
2. Open the App Store and select "Search" in the bottom right corner
3. Search for FatSecret, locate the app, and download it onto the participant's phone

### **Intervention Group – Android User**

1. Go to the phone's settings.
2. Go to Security (you may have to select "More" to get to Security)

3. Find Unknown Sources and make sure it is checked
4. Open the internet browser in the phone and type in:  
<http://mdata.kleinbuendel.com/HeathyDetours/app/hdcurrent.apk>

5. The app will start to download. You will see a blinking arrow on the top left of the screen. When the arrow stops blinking, pull downward on the screen from the arrow. You will see the file name `hdcurrent.apk`. Select this file to open.
  
6. This pop-up page will appear, notifying users of the privacy agreement. Users must agree to this and Install.



7. Once installed, you may open the app.

### **Intervention Group – iPhone User**

1. Since KB programmers will know the randomization prior to the enrollment meeting, intervention group iPhone users will receive an email invite once they arrive to the meeting to beta test the Healthy Detours app. This will be sent to the email address linked to the participants' iTunes account. Participants should be instructed to not look at their phones while they are providing consent and completing the online surveys. When ready to install the app, open the TestFlight email and select "Start Testing"

2. You will be taken to this page and provided with a redemption code. This code should be written down for possible future use. If TestFlight has not already been installed, click on the blue link to download the program to the phone.
  
3. You will be taken to the Apple Store. Select "Get" and then "Install." Once the app has been installed, select "Open."

Accept TestFlight's Terms of Service and Apple's Privacy Policy and indicate that TestFlight can send the user notifications

4. Healthy Detours should automatically appear in the user's queue. Select "Install," and then "Open." Once the app is open, allow Healthy Detours to access the participant's location. After selecting "Allow", you will be brought to the Registration Page.

## Step 6: App Registration & Tutorial

### Intervention App

The Register page will appear when intervention participants open the Healthy Detours app for the first time. PBRC staff should assist these participants in entering the following information.

1. User Name: Participants should enter their first and last name
2. Email: Participants should enter the email address that has consistently been provided to PBRC staff. Notably, iPhone users should enter the email address that is associated with their iTunes account.
3. Phone: Participants should enter their cell phone number
4. C-Number: PBRC staff should enter the participant's C-Number (**see page 6**).

Need to add Class Schedule screenshots when they are made available

After intervention participants have registered to Healthy Detours, PBRC staff should give them a tablet to watch the video tutorial: <https://youtu.be/oi9mCUCTmMM>

The link to the YouTube video has been bookmarked on all KB tablets. This video is also available within the Learn to Detour feature of the app.

### Control App

Participants randomized to the control group will be prompted to register for FatSecret when they open the app for the first time. PBRC staff may assist the participants in this registration process.

1. Participants will open the app and select Start Now. They will first be asked to set a goal. Participants may choose whichever goal they want.
2. Participants will input their gender, activity level, weight, height, and date of birth.
3. Participants will sign up with an email address and a password for their account. Participants should be instructed to use the same email address on file with PBRC for this step.
4. Participants will be brought to the home screen of the app.
5. PBRC staff should give control participants the paper-based control tutorial (**Appendix I**) for their reference.

## Step 7: Exit Interview Scheduling

### Six-Week Assessment

An invitation to complete the 6-week interim assessment will be sent to RCT participants via email. Participants who do not complete the surveys within 3 days of invitation will receive an email reminder.

### Posttest Assessment

Participants will receive a reminder email approximately 1 week prior to their previously-scheduled posttest assessment. In addition to the four previously completed surveys, participants will complete the System Usability Scale and the Usage Rating Profile-Intervention (URPI) scale (**Appendix J**) at this meeting. The *Healthy Detours* app will be removed from the participants' phones at this time.

### Participant Compensation

Participants who complete the Posttest Assessment will be informed that their check for \$200 will be requested from LSU Accounts Payable by study staff, and that LSU will mail their checks in approximately 4-6 weeks