

Information Collection Request
New

Supporting Statement B for

The Girl Power Project Efficacy Trial

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Name: Sascha Ellington

Address: 4770 Buford Highway, Mailstop F74, Atlanta, GA
30341

Telephone: (770) 488-6037

Fax: (770) 488-6391

Email: SEllington@cdc.gov

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B.1 Respondent Universe and Sampling Methods

The target sample will be a convenience sample of girls ages 14 to 18 years living in the United States. To meet eligibility criteria to participate participants must: (a) be between ages 14-18 years old, (b) be a girl, (c) have daily access to a smartphone with a text message plan and internet, (d) understand written and spoken English, (e) live in the United States, and (e) not be currently pregnant. Although our intervention was designed for girls 15 to 17 years old, for the purpose of this study we will recruit girls from a larger age range. Literature suggests that when interventions are targeting pregnancy reduction, expanding services to younger teens is highly encouraged. Given that 14 year old girls are about to enter, and that 18 year old girls have just exited, our target recruitment age range, it will be beneficial for long term data to gauge the perceptions of these individuals.

To identify eligible subjects we expect to screen 3,000 interested individuals who access the screener through the recruitment website. Approximately 1,200 participants will be recruited for the study. Recruited subjects will be randomly assigned to either the intervention or control group. The study is open to girls of any racial or ethnic background. However, we will more heavily recruit black and Latina girls by focusing recruitment efforts in cities with high black and Latina adolescent populations. In addition, we will target our banner ads to these aforementioned populations. We will also continuously track the age and race/ethnicity of enrolled participants and refocus our recruitment strategies to achieve a balanced sample. The recruitment targets by race and ethnicity are shown below.

Table 1: Targeted Enrollment

Targeted Enrollment: 1, 200			
Ethnicity	Females	Males	Total
Hispanic or Latino	360	0	360 (30%)
Not Hispanic or Latino	840	0	840 (70%)
Total	1,200	0	1,200
Combined Race/Ethnicity	Females	Males	Total
American Indian/Alaska Native	60	0	60 (5%)
Asian	60	0	60 (5%)
Native Hawaiian/Pacific Islander	0	0	0 (0%)
Black or African American	360	0	600 (50%)
White	360	0	120 (10%)
Hispanic any race	360	0	360 (30%)
Racial Categories Total	1,200	0	1,200

Sample Size and Statistical Power:

In order to find meaningful differences between both groups we need a final sample size of 768 girls. This estimate assumes that among our target population at baseline, 50% of vaginal intercourse events have involved an effective birth control method. We expect to see this number increase to 60%, a 10% absolute difference, or an effect size of 20%, a power of 0.8 and an alpha of 0.05 for a two-arm study. We used Shieh-O'Brien approximation calculated in SAS statistical software to calculate a final sample size of N=768 girls in the two groups combined. We expect a gradual 40% attrition rate from the moment of enrollment to the 6-Month Survey (20% between enrollment and 3-Month Survey, and an additional 20% from the 3-Month Survey and 6-Month Survey). Therefore we need to recruit at least 1,200 girls in order to have a final sample of 768. The calculation was done as follows: $1,200 - 20\% = 960$ (at 3-Month Survey) - $20\% = 768$ at 6-Month. We expect to recruit older adolescents at a higher rate than younger ones. Availability of smartphones may preclude young girls from participating. Therefore, we will recruit over a three month period or until we successfully enroll 768 girls needed for the study.

B.2 Procedures for the Collection of Information

Enrollment Process

All recruitment methods will direct girls to the Recruitment Website where they will watch a brief video explaining the purpose of the study and the terms of participation. Once girls decide to join they will be directed to a page to assess eligibility criteria. If they are eligible, the website will direct them to the enrollment page. If they are not eligible, they will receive a messaging stating that they are not eligible and will not be able to continue with enrollment.

Eligible girls will first read and sign a consent form followed by consent comprehension questions (See **Attachment 10**: Informed Consent). For the purpose of this study, we will allow participants under the age of 18 to self-assent. A waiver of parental consent is consistent with federal regulations, is necessary to make this study possible, and is a common practice for research involving services youth already have access to without parental consent. A full description of our rationale to waive parental consent can be found in **Attachment 11**: Parental Consent Waiver. After consenting to the study, participants will complete a study enrollment form which will collect demographic and contact information (See **Attachment 3**: Enrollment Questions). The enrollment will take place online through the Enrollment Database. Once enrolled, participants will complete the baseline survey also administered through the Enrollment Database. Following an intent-to-treat protocol, upon completion of the baseline survey, participants will be computer-randomized into an intervention and control group. Participants will view a page with instructions on how to access their corresponding app; intervention group will gain access to Crush and the control group will gain access to nutrition app currently available in the app marketplace.

This is a single-time research study in which participants will be required to complete

questionnaires and navigate a health education mobile app over a 6-month period. Both groups will fill out the same survey at baseline, 3-month and at 6-month. The intervention group will have additional questions regarding the use of the website. At the end of the 6 months, participants in the control group will gain access to the health app and we will track utilization data unobtrusively through web analytics which does not constitute a response burden on the participant. (See **Attachments 4-9: Surveys**). Web analytics will only be collected from participants navigating Crush only when they are logged in as users. Data will not be collected from any other web activity participants engage in. After the study concludes, participants will no longer be able to access the intervention via the login page, therefore no navigation data will be collected

Recruitment of Non-Probability Sample:

See **Attachment 13: Recruitment Materials** for storyboards of each recruitment method.

Online Banner ads: Subjects will be recruited using banner ads on social media sites (e.g. Facebook, YouTube, SnapChat, Instagram). Banner ads will display a combination of The Girl Power Project logo, pictures of girls, or the recruitment video. The text included on or with the banner ad will encourage girls to join the study by: providing information about the study, inviting girls to contribute to testing an app for girls like them. Social media ads (eg Facebook) have restrictions on the number of characters surrounding each banner, and the size of the text on each banner graphic. Therefore, banner ad messages are kept very brief in compliance with these restrictions.

Subjects who click on these banner ads will be directed to the Recruitment Website. This recruitment website is where girls are able to read about the purpose of the study, terms of participation, funders and to get in touch with the researcher if necessary. The website will prominently display a brief (1-2 minute) video of a girl their age describing the purpose of the study and the terms of participation. This video will also be used in banner ads.

Word of mouth: Healthy Teen Network will also recruit by word of mouth by disseminating information about the study through their network of youth serving organizations. The target audience of this communication is adults who work directly with youth in order to have them support our recruitment efforts in their agencies. We will email banner ads agencies can place on their websites visited by youth, Twitter tweets they can use in their account, banners for their Facebook page, flyers/business cards to distribute directly to youth or to post in their offices.

Passive Snowball Recruitment: We expect passive snowball recruitment to occur where participants share information about the study with their friends and other girls. The recruitment website will have a sharing tool to allow potential participants to share the Recruitment Webpage. Facebook banner ads can also be “liked” allowing for the banner to appear on their friends’ wall feed.

Tiered Recruitment Strategy: We will initiate face-to-face recruitment through our network agencies immediately. However, we will use a gradual approach to social media. We will first initiate a Facebook campaign with a relatively small number of potential viewers (20,000 to 60,000 daily viewers). We will slowly increase the reach of the campaign to up to 180,000 viewers. Depending on the demographics of the participants we are enrolling,

we may adjust the target audience of the campaign to ensure we get a balance sample of younger and older adolescents, and black and Latina adolescents.

All recruitment strategies will guide potential participants to TheGirlPowerProject.org website. This website has been developed solely for this study. On this website, subjects will learn about the study purpose and terms of participation. The subjects can enroll in the study on this website. Upon completion of the eligibility, enrollment and consent processes, participants will be randomly assigned to either the intervention or control groups in a blinded manner. All participants will receive on their phones a text message with the link to the online survey. Upon completion of the survey, participants will receive instructions on how to access the assigned application (either Crush or the placebo mobile application).

Data Collection Procedures:

This study will not employ any methods for sample stratification. All eligible and interested participants will be able to join the study and will be randomized into the control or intervention groups. Recruitment will occur on a rolling basis. Participants will begin the study immediately after enrolling, so each will have a different date in which they will receive the 3 months and 6 months survey. The electronic enrollment database will keep track of enrollment dates and will send surveys automatically at the stated intervals. Participants will receive a link to the survey which can be completed on their smartphone. Participants will be reminded via text message for 2 weeks to complete the survey. After 2 weeks the survey will close and they won't be able to complete the survey. This will allow us to control for data entered beyond the 3 month interval. However, participants will continue to be active participants and will receive the survey at 6 months. All surveys administered to both groups will be the same with minor exceptions.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The project is an online study that does not require any face-to-face interaction with the participants. There are potential sources of nonresponse error in this intervention study. We have established several ways to reduce missing data and incomplete surveys, and reduce attrition in this study.

Throughout the entire study both the treatment and control groups will receive daily text messages related to sexual health and Crush content (intervention group), or related to general health and nutrition (control group). We will also send seasonal greetings, survey links, and other study related communication via text message, through a third party provider. The purpose of the daily texts is to: 1) keep participants engaged and actively visiting Crush, 2) identify phone numbers that are no longer working so we can communicate with the participants through other means, and 3) reduce the attrition over the 6 month period.

Participants will receive a \$10 store gift cards and a gift wristband (valued \$1.00) upon registration. Participants will receive a \$10 gift card at 3 month follow-up and a \$15 gift card at 6 month follow-up. Once participants complete the baseline survey, we will

manually verify the enrollment information to confirm that there are no duplications of participants (individuals trying to register twice). Duplications will be identified by comparing eligibility criteria against enrollment information, verification of email address and telephone number, and time of completion of baseline survey. For example, if the survey was completed under 5 minutes, it is clear that the person was not reading the questions and just clicking through. Participants who are identified as duplicates will not be able to continue in the study and will be notified by text message. Participants who are confirmed in the study will be issued a store gift card. The online gift card will be sent via text message within 2-3 business days.

B.4 Test of Procedures or Methods to be Undertaken

We have conducted cognitive interviews with 5 girls from the target population to test the survey questions and response options. Girls were recruited from the youth advisory group that has worked collaboratively in this project during its development phase. We will also conduct a small pilot test with no more than 9 participants to test the process of enrollment and consent. We will also test the texting system and survey completion. The purpose of the pilot test is to establish a more accurate time burden response for each data collection process, and identify potential for attrition during the initial stages of enrollment.

Non response is a common problem in survey research, particularly when surveys are self-administered. Given the length and sensitivity of the survey questions and the age of the participants, non-response is expected. Online surveys, as we are using, are helpful in reducing the number of missing values, and inconsistent data. For example, the survey will flag a question to the respondent if a question is left blank, or if a value is incongruous with the question (e.g. entering the value of 100 for age). Respondents will receive text messages reminding them to complete a survey, or to continue responding to an incomplete survey. We will examine the amount of missing values in all variables and scale items. Multiple imputation techniques will be used to correct for the missing data.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Data collection will be conducted by Healthy Teen Network staff members led by Dr. Genevieve Martinez-Garcia. Statistical analyses will be conducted by Mr. Paul Mowery. He has substantial expertise in quantitative methods. Dr. Martinez-Garcia and other research staff will be responsible for monitoring data collection, management of participants' incentives, and will also conduct ancillary analysis of data collected. Dr. Martinez-Garcia has experience conducting research with adolescents on sexual and reproductive health issues. Dr. Ralph DiClemente will provide support in the research design, participant recruitment, and interpretation of evaluation results. Dr. DiClemente is a well-known expert in the field and has substantial experience conducting RCTs of digital interventions with adolescents.

Data Collection:

Genevieve Martínez-García, PhD PI

Senior Researcher, Healthy Teen Network
Tel. (410) 685-0410
genevieve@HealthyTeenNetwork.Org,

Research Consultant:

Ralph DiClemente, PhD
Rollins School of Public Health
Emory University
1518 Clifton Road, NE
Atlanta, GA 30322

Statistical Consultant:

Mr. Paul Mowery, MA
Biostatistician
Biostatistics, Inc
Tel. (404) 358-4124
moweryp@biostatisticshealth.com

CDC Staff:

Athena P. Kourtis, MD, PhD, MPH
Division of Reproductive Health
Centers for Disease Control and Prevention
4770 Buford Highway, NE, MS F74
Atlanta, GA 30341-3717
Tel. (770) 488-5216, FAX (770) 488-6391
apk3@cdc.gov

Sascha Ellington, MSPH
Division of Reproductive Health
Centers for Disease Control and Prevention
4770 Buford Highway, NE, MS F74
Atlanta, GA 30341-3717
Tel. (770) 488-6037, FAX (770) 488-6391
sellington@cdc.gov