An intervention to reduce adolescent pregnancy: Girls Invest

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Girls Invest Study Procedures

A Two-armed Randomized-Controlled Trial will be be implemented across demographically similar communities and ensure adequate numbers recruited. Girls will be recruited from community and school-based partnerships. Groups of an average of 10-13 girls from each of 18 sites will be randomized to: 1) *Girls Invest* or 2) a wait-list control condition (n= 9 groups per arm; total of about 208 girls). Control condition participants will receive *Girls Invest* after 6 months follow-up.

Inclusion Criteria. Participants will include girls ages 15-22 years of age who are participating in local school-based and community programs primarily serving Latina adolescent girls in the San Diego area. Community partners include community-based health centers that have teen-focused programs. School based partnerships include high schools and community colleges. Randomization will be stratified by site type (i.e. we will randomly assign an equal number of high schools to be in the treatment group and control group; we will do the same for community colleges and community-based partnerships).

Recruitment and Screening. The project coordinator will be responsible for training and oversight of data collection staff. Data collection staff will consist of young females who will be trained on research ethics, all data collection activities, and sensitivity when working with this population.

Partnerships were developed between Girls Invest and community based programs as well as schools predominantly serving the Latinx community such as: City Heights, San Ysidro, Southeast San Diego, El Cajon, Vista, Chula Vista, and National City.

We will work with community based programs as well as local schools, and community colleges to conduct recruitment. These partnerships will involve our team going into particular programs or classes to recruit a group of adolescent girls. Given that some group-based programs and/or classes are still virtually held, we will hold orientation sessions either in-person or via zoom. These sessions will include a description of Girls Invest as well as the research study. Among girls who are interested, we will support them to download the app, complete consent forms via the app, and to take the baseline survey. Girls will also complete the savings account application. If parental consent is needed prior to the orientation, we may make arrangements for girls to download the app ahead of the orientation or provide the program with hard copies of the consent form for girls to have parents sign ahead of the orientation day (if in-person)

At schools, our recruitment may also include in-class presentations. Presentations will involve a presentation on financial literacy related topics, including how money and intimate relationships intersect, followed by a brief presentation of our Girls Invest program and study for those who may be interested. We will stay after class if anyone has questions or wants to enroll. The PI will not recruit in any of her own classes at SDSU. We will assure students that participation does not affect their grade in the class.

Informed consent and data collection. Informed consent for index participants will occur in-person during a group orientation or via a phone or online chat. The consent forms can be signed with hard copies or via the app. All index participants will be assigned a unique identifier to link baseline and follow-up assessments.

Parental consent will be obtained for those participants between the ages of 15-17 years. After signing the consent form, each eligible participant (<18 years of age) will be provided with two copies of the parental consent form, along with a stamped and addressed envelope, which can be used to mail back the signed parental consent form (one copy of the parental consent will be kept by the parent/guardian). Participants can also choose to do the signed parental consent via

the app. After signing their consent forms, all participants will be given access to the app (via a username and password); however, initially they will only have access to the resource sheet (providing local resources) along with consent forms, including forms for parental consent. Parents/guardians will be able to sign the consent via the app. All consent forms will be filed and stored separately from other app and survey data. Parental consent forms will be available in both English and Spanish.

Baseline and follow-up questionnaires will take approximately 45 minutes and will be self-administered via an online survey. During an initial orientation, as time permits, participants will take the online baseline survey during that time. The online surveys can be taken by participants on their own as well. If participants take the baseline survey on their own, participants will be encouraged to complete the questionnaire in a safe and private location. In cases where participants do not complete the app-based questionnaire on-time or need assistance, staff will provide assistance and offer to meet participants to complete the survey in-person. The survey requires an ID, which will be provided to participants. Upon completion, questionnaire data will not be accessible via the online platform nor the mobile device.

Randomization and Retention. Each group (n=18) will be randomized to study condition. Randomization will be stratified by site type (i.e. we will randomly assign an equal number of high schools to be in the treatment group and control group; we will do the same for community colleges and community-based partnerships). Participants randomized to the *Girls Invest* intervention will be notified with a brief orientation on how to use the app with contact information for study staff in case they have questions. App-based data on completion of modules and completion time will also be collected. Control group participants will be notified that they will be on the wait-list and complete the intervention after 6 months. Regardless of study condition, all participants will be linked to the online application for their savings accounts (ID can be uploaded online as well) upon completion of the baseline survey. For participants in the control group, accounts will become active after the 6 months follow up survey is complete. To maximize retention, incentive payments will be escalated: $25 at baseline and $30 at 6 months follow-up via Amazon e-cards. Participants will also be contacted via the app (or a phone call by study staff) every two months to update contact information. Those who do not complete follow-up questionnaires via the app will be contacted up to 4 times followed by contacting participant's alternate contacts, using methodology we have used effectively in previous studies. If these efforts are not successful, participants will be classified as non-respondents. Using similar tracking methods, our previous work with a similar sample achieved a 92% retention rate at 6 months follow-up.

Assessing the feasibility, fidelity, acceptability, and scalability of *Girls Invest* (Aim 1). Data logs will serve to monitor study progress in recruitment (e.g. proportion eligible, interested, refused, and ability to recruit at least 1 friend), participant retention (e.g., differential dropouts by condition), adherence (e.g., savings account enrollment), and adverse events. Information on recruitment and retention (as well as intra-cluster correlation of endpoints within social networks) will help inform sample size determination for a subsequent full-scale trial. Contamination will be assessed via items on the follow-up survey (e.g. control participants' knowledge of *Girls Invest* or any participants in the *Girls Invest* intervention). App-generated data will assess engagement with and completion of *Girls Invest* (e.g. # modules completed, time spent on each) and used to identify completers (80% of the *Girls Invest* modules) versus non-completers.

Evaluation of acceptability and receptivity will include in-depth interviews (up to n=30; similar proportions index participants and peers, 5 with non-completers) to evaluate participants' experiences with *Girls Invest* (e.g. content, app dynamics, savings account features), and identify mechanisms underlying any intervention effects (e.g. did the intervention affect

economic vulnerability? how did these effects influence girls' sexual and contraceptive decision-making? Were certain components most impactful?) These will take place via a phone or online call or in private space at La Maestra. Based on our previous work, we expect 20 interviews to be sufficient for saturation of themes; however, we will conduct additional interviews (up to an additional 10) if needed. Participants will be paid $30 for in-depth interviews. For those participants who are <18 years of age, we will obtain parental consent using the main study consent form, rather than using a separate form for in-depth interviews. Details of the in-depth interviews will be provided in these main study parental consent forms. While details are included in the main study consent form for participants, we will also review all of the in-depth interview procedures and details in a separate consent form provided immediately prior to the in-depth interview.

Statistical Power and Analyses on Economic, Social, and Health Behavior Risks. (Aim 2) Sample size calculation is based on intermediate outcomes (Figure 1) with at least 25% prevalence at baseline. To achieve 80% power, we will require 208 participants (approximately 13 in each of 16 groups) to be able to determine a moderate effect size of 0.52 (26% difference between the two arms on intermediate factors in Figure 1), using an intra-class correlation coefficient (ICC) of 0.03 given the group structure, type I error of 0.025, and 20% attrition (conservatively estimating 80% retention over 6 months). Note the sample size has taken multiple comparisons (using Bonferroni adjustment) into account. In addition, we may likely have a lower ICC, which would afford greater statistical power.

To assess clustering within groups (n=18), random effects models will calculate ICCs. We will conduct intent-to-treat analyses using crude and adjusted mixed effects logistic and linear regression models with a focus on intermediate variables (Figure 1) to assess group-by-time effects, with adjustments for clustering and intervention engagement and completion. To assess random imbalances (at baseline) and differences in attrition by condition, we will perform chi-square analyses and t-tests. We will adjust for relevant covariates to address imbalances between conditions. Differences in attrition between study conditions will be noted as potential threats to validity. We will also explore variations in observed intervention effects by savings behaviors, module completion, as well as relevant factors identified via in-depth interview findings.

Figure 1. Girls Invest Components and Expected Outcomes

Girls Invest Components

Savings Account: Creation of savings account with subsidies deposited based on completion of app trainings

Gender and Financial skills training via app: Focused on skills and knowledge needed within the financial lives of adolescent girls

Intermediate Outcomes

Economic-Related Outcomes
- Decreased perceived economic vulnerability
- Improved financial literacy
- Improved self-efficacy to navigate financial systems
- Increased savings intentions
- Improved expectations related to a) future career and educational goals, and b) economic autonomy
- Decreased perceived need for financial reliance on male partners

Social Risk Factors for Adolescent Pregnancy
- Increased attitudes supportive of contraceptive use
- Increased intentions and prioritization for using contraception and delaying pregnancy
- Increased self-efficacy to make sexual/reproductive decisions in relationships
- Increased knowledge of healthy versus unhealthy relationships

Outcomes

Economic-Related Outcomes
- Improved financial situation and economic self-sufficiency (e.g. greater income generation, savings)
- Decreased financial reliance on male partners

Social Risk Factors for Adolescent pregnancy
- Decreased intimate partner violence
- Decreased male partner control over reproductive/sexual decisions

Sexual Health Behaviors
- Increased use of effective contraception
- Increased condom use
- Decreased frequency of sexual activity

Impact

Decreased Risk for Adolescent Pregnancy