PRS Cover Page for Study Protocol

Title: Parent Feedback Intervention Targeting Student Transitions and Alcohol Related Trajectories (+) Efficacy Study (FITSTART+)

Date: April 26, 2021

ClinicalTrials.gov Identifier: NCT04549454

LOYOLA MARYMOUNT UNIVERSITY

IRB Application Questionnaire for "Extension and Online Adaptation of the FITSTART parent-based intervention to reduce drinking among first-year students."

All materials must be typed.

1. RESEARCH BACKGROUND

Please describe the purpose of your research. Provide relevant background information and briefly state your research question(s). You may provide relevant citations as necessary. (300 Word Max.)

Despite a growing understanding that parents continue to shape adolescents' alcohol use decisions even after students leave the home and matriculate to college, parent influence remains a severely underutilized resource in the fight to curb risky drinking on college campuses—partly because, to date, parent-based interventions (PBIs) have been ineffective at reducing heavy episodic drinking (HED). Recently, we were able to develop a PBI that influenced numerous indicators of student alcohol use, including HED, by combining the informational content that characterizes a typical PBI with a live group-based social norms intervention designed to motivate parents to engage with the informational content more deeply and to really apply it to their interactions with their child. The current project aims to adapt, optimize, and extend this successful intervention in 3 key ways: (1) by employing recent advances in "co-presence" technology that will allow us to move to online delivery of the intervention without sacrificing the benefits of a live group session, (2) by conducting a year-long documentation study to expand the scope of the intervention by identifying specific parenting behaviors that are most strongly associated with reduced student risk across the first year of college, (3) by delivering the intervention across the first semester of college rather than a single session delivered during the summer, and (4) by augmenting the norms and information with engaging professional-quality video content featuring top experts on adolescent parenting.

2. SUBJECT RECRUITMENT

How will subjects be selected? What is the sex and age range of the subjects? Approximately how many subjects will be studied?

How will subjects be contacted? Who will make initial contact with subjects? Specifically, what will subjects be told in initial contact?

If subjects will be screened, describe criteria and procedures.

This study seeks to evaluate both feasibility and efficacy of the FITSTART+ app-based intervention for parents. The goal is to assess efficacy of the intervention version of the FITSTART+ app on student alcohol outcomes, relative to an active control version of the app. Participants in the clinical trial will ultimately be 400 to 600 LMU students who have a parent randomized to use either the intervention or control version of the app. The Registrar will provide student and parent contact information for the incoming freshman class (approx. 1600 students and 3000 parents). Incoming traditional, non-international first-year students (i.e., first-time college students aged 17–20 years) registered to attend LMU during the Fall semester and who have at least one parent/guardian email on file with the admissions office will be emailed an invitation to participate in a three-part web-based survey assessing experiences during their first year of college. Invitations to complete the baseline survey will be sent in July 2021 (T1) via the admissions office who will verify each student's age, year in school, and whether they have a parent/guardian email on file. The baseline survey and each follow-up survey will be open for

approximately 3 weeks. Student participants will receive a $25 electronic gift card for completing each study survey and an additional $10 bonus if they complete all three surveys.

To participate in the study, students must:

1) Be a first-year college student 17–20 years of age.
2) Have a parent/guardian email on file with the admissions office.
3) Be a domestic (i.e., non-international) student.
4) Consent to participate (with parental consent for minors under age 18).

3. PROCEDURES

Summarize fully all procedures to be conducted with human subjects.

This intervention study tests the feasibility of the FITSTART+ program and evaluates the effects of the parent-program on student drinking. That is, the program will be delivered to parents exactly as it might be delivered in the real world, out of the study context (no incentives, knowledge of condition assignment, or awareness of associated student survey study). Simultaneously, alcohol use outcomes will be assessed among the first-year students of participating parents with students incentivized to complete 3 surveys spanning their first year. Recruitment will begin in July 2021 prior to matriculation and will be identical to the IRB approved recruitment procedure in our successful previous R21 FITSTART project (LMU IRB 2014 SP 45). In early summer, the Registrar will provide the research team with new student and parent contact information.

Emails sent by the university's admissions office will only invite students who meet our eligibility criteria to participate in a 3-part longitudinal survey study about their transition into college life. These invitations will mention that they will receive $25 for each 15-minute survey and an additional $10 bonus if they complete all three (for a total of $85). This email will contain a link for interested students to complete the IRB-approved informed consent form. When consenting, students indicate whether they are 18 years of age or older, or under 18. Students 18 or older will provide consent while those under the age of 18 who wish to participate will provide assent and then will be asked for their parent's email address and their parents will be sent a consent form (Consent Appendix). As part of the consent form, students will also agree to the potential linking of their data with data provided by their parent(s) who may also be participating in a separate study. The form will specify that their survey responses will NOT be shared with their parents under any circumstances and their participation in the study will be confidential. If students agree to the potential parent-data linkage, they will immediately be redirected (triggered automatically by Qualtrics) to begin the baseline survey. Incoming first-year student recruitment will continue until 700 students have completed the baseline survey.

All parents of students who complete the baseline survey will be invited via email to take part in the FITSTART+ program. To sign up, parents will need to click a link in the email to visit the FITSTART+ landing page which will include a general description of the application (no information about alcohol), a description of the parenting experts featured in the application, and a parent verification form. The verification form, which will be a Qualtrics survey embedded in the landing page, will serve two important purposes: it will (1) match parents to their students in the dataset; and (2) randomize parents to the treatment or control version of the app. The randomizer will be set up in Qualtrics to balance assignment to an app condition by students' birth sex. At the end of the verification form, parents will receive a web URL linking to the sign-up page for the application to which they were randomized. Parents who click the link will be prompted to create their user account. In order to not artificially bias parents' app use, parents will be unaware that there is more than one version of the app, they will not be incentivized to use the app, and they will not be told that their child is participating in a survey study.

4. RISKS / BENEFITS

What are the potential benefits to subjects and/or to others?

What are the reasonably foreseeable risks to the subjects? (Risks may include discomfort, embarrassment, nervousness, invasion of privacy, etc.) If there are potential risks to subjects, how will they be minimized in advance? How will problems be handled if they occur?

A. Potential Risks

Psychological risks posed by the research are primarily related to the sensitivity of some of the measures. Student participants will complete measures assessing alcohol-related beliefs and behaviors that may be private. These questions may make subjects uncomfortable or be perceived as an intrusion on their privacy. They also will be asked to report on potentially illegal behaviors, such as drinking under the legal age. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. To mitigate risks participants will be reminded that they are free to skip any questions that make them feel uncomfortable. Additionally, their responses will not be directly linked to any identifiable information.

B. Potential Benefits

The proposed study will evaluate the efficacy of a parent-based normative feedback intervention that aims to leverage parental influence to reduce the risk for heavy drinking and associated consequences among incoming first-year college students. Parents in the intervention group will learn about the risks of alcohol use among students and discuss strategies to maintain an open dialogue with their child regarding alcohol-related attitudes and expectations. It is anticipated that parents and students in the intervention condition will gain substantial benefit from participating in the study, with regard to parents learning about alcohol risk and communication, and students engaging in less risky alcohol use behaviors and negative alcohol-related consequences. In addition, all student participants in both the intervention and control groups will be monitored for high-risk drinking levels and endorsement of high levels of negative consequences, and will be provided appropriate referrals when necessary. Specifically, participants reporting consumption of potentially lethal doses of alcohol (BAC's above .30) or RAPI consequences scores (incidence) of 16 or above on the initial or any follow-up questionnaire will be contacted and informed of their risk, and provided referrals for clinical services. This is a benefit that would not otherwise occur without study participation.

5. CONFIDENTIALITY

Will subjects be identifiable by name or other means? If subjects will be identifiable, explain the procedures that will be used for collecting, processing, and storing data. Who will have access to data? What will be done with the data when the study is completed? If you are collecting visual images of your subjects please justify this.

Parent/student dyads will be set up in order to link the data. To do this the parents and the students will share the same PIN. If more than one parent decides to participate their PINs will end in either -1 or -2. The sharing of PINs allows for the linkage of data without individuating information attached. This linkage is solely for analytic purposes and will only be used to look at student outcome data.

To maintain confidentiality of data submitted over the internet, participants will submit all information via Qualtrics (Qualtrics has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by the Health Insurance Portability and

Accountability Act). All Qualtrics accounts are hidden behind passwords and all data is protected with real-time data replication. Data transfer will be protected using a Secure Socket Layer with 128-bit encryption. This is the same level of encryption used for most banking transactions and offers the highest degree of protection available for data transfer. The server is physically located in a secure, commercially protected co-location facility with 24-hour locked and monitored keycard access, within a locked room, within a locked server rack, with a locking face-plate protecting the server itself from physical access without authorization. Electronic protection is provided by a commercial-grade firewall, with continuous monitoring of the server for any attempts at electronic invasion. Any associated paper documents will be stored in a locked file cabinet within the lab. Study results will be reported in aggregate, so that individual participants will not be identifiable in any research reports or presentations of the proposed study. As we often receive requests for our data to be used in meta-analyses, data from the study will be kept for 5 years after the completion of the project. After this period of time all data will be destroyed.

6. INFORMED CONSENT

Attach an informed consent form or a written request for waiver of an informed consent form. Include waiver of written consent if appropriate. If your research is being conducted in another language, please include copies of the translated "Informed Consent" or "Waiver of Written Consent" forms.

Please see attached CONSENT APPENDIX for consent forms.

7. STUDENT RESEARCH

When a student acts as principal investigator, a faculty sponsor signature is required on the application form.

N/A

8. RENEWAL APPLICATIONS

When the submission is a Renewal Application, include a summary of the research activities during the previous granting period specifically addressing: number of subjects studied and any adverse reactions encountered, benefits which have been derived, any difficulty in obtaining subjects or in obtaining informed consent, and approximate number of subjects required to complete the study.

N/A

9. PAYMENTS

If subjects are to be paid in cash, services, or benefits, include the specific amount, degree, and basis of remuneration.

Students will receive a $25 gift card for each 15-minute survey and an additional $10 gift card bonus if they complete all three (for a total of $85). Gift cards will be sent to students via email within 48 hours of survey completion via an online gift card service called giftbit (www.giftbit.com).

10. PSYCHOLOGY SUBJECT POOL

When students from the Psychology Subject Pool (PSP) are to be involved as subjects, permission must be obtained from the PSP prior to running subjects.

Forms are available from the Psychology Office in 4700 University Hall. It is not necessary to inform the IRB of approval from the PSP, however the PSP requires IRB approval prior to permission for using the pool being granted.

N/A

11. QUALIFICATIONS AND TRAINING

Describe the qualifications of, or method of training and supervision afforded student experimenters. This includes past experience, type and frequency of student/sponsor interactions during the experiment, and Human Subjects Protections Training.

All experimenters have completed the NIH or CITI Protection of Human Subjects training course. We have attached copies of each researcher's certificate.

12. RANDOMIZATION

Describe criteria for assigning subjects to sub-groups such as "control" and "experimental."

Although the participants among whom outcomes will be assessed are students, parents of these students will be the ones randomized to the treatment or control version of the app. A verification form on the informational FITSTART+ landing page, will serve two important purposes: (1) it will match parents to their students in the dataset; and (2) randomize parents to the treatment or control version of the app. The randomizer will be set up in Qualtrics to balance assignment to an app condition by students' birth sex. At the end of the verification form, parents will receive a web URL linking to the sign-up page for the application to which they were randomized. The treatment condition will receive the FITSTART+ intervention while the control group will receive a similar program which covers all non-alcohol related resources included in the intervention version of FITSTART+ (e.g., general parenting information, university-specific resources).

13. USE OF DECEPTION

If the project involves deception, describe the debriefing procedures that will be used.

Include, verbatim, the following statement in the consent form: "Some of the information with which I will be provided may be ambiguous or inaccurate. The investigator will, however, inform me of any inaccuracies following my participation in this study."

N/A

14. QUESTIONNAIRES AND SURVEYS

Include copies of questionnaires or survey instruments with the application (draft form is acceptable).

If not yet developed, please so indicate and provide the Committee with an outline of the general topics that will be covered. Also, when the questionnaire or interview schedule has been compiled, it must be submitted to the Committee for separate review and approval. These instruments must be submitted for approval prior to their use.

Consider your population. If they are foreign speakers, please include copies in the foreign language.

Please see attached MEASURES APPENDIX

15. PHYSICIAN INTERACTIONS

To ensure that all patients receive coordinated care, the principal investigator is obligated to inform the primary physician (when not the principal investigator) of all studies on his/her patients.

N/A

16. SUBJECT SAFETY

Describe provisions, if appropriate, to monitor the research data collected, to ensure continued safety to subjects.

High-risk drinking levels and the endorsement of high levels of negative consequences by students will be continually monitored during all phases of the study. Specifically, students reporting consumption of potentially lethal doses of alcohol (BAC's above .30) or RAPI consequences scores (incidence) of 16 or above on the initial or any follow-up questionnaire will be contacted and informed of their risk and provided referrals for clinical services. The research team will provide treatment referrals to participants who demonstrate significant increases in alcohol consumption in the follow-up phases compared to baseline assessment. See section 18 for more information about the referral process.

17. REDUNDANCY

To minimize risks to subjects, whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes. Describe provisions.

N/A

18. COUNSELING

In projects dealing with sensitive topics (e.g., depression, abortion, intimate relationships, etc.) appropriate follow-up counseling services must be made available to which subjects might be referred.

The IRB should be notified of these services and how they will be made available to subjects.

Although we do not foresee any Serious Adverse Events (SAE) or Adverse Events (AE) as a result of participating in this study, PI LaBrie will personally offer a brief one-time in-person or phone counseling and assessment session to all student participants reporting alcohol, drug, and mental health related Adverse Events (AEs) and Serious Adverse Events (SAEs) regardless of their relation

to the intervention study in order to assess the situation and offer referral resources. If an AE or SAE occurs, PI LaBrie will first refer the student will be referred to the Community of Care. He will also provide participants with referrals to appropriate personnel at LMU's Student Psychological Services (SPS), the Student Health Center (SHC), and/or outside non-LMU resources. If a SAE is life-threatening, LaBrie will contact public safety if required. Should there be any unanticipated problems that detract from a positive parent or student participant experience in the study, issues will be addressed with participants immediately, and PI LaBrie will work with the University's IRB to swiftly develop and enact a resolution plan. All SAEs, AEs and unanticipated problems will be managed consistent with University IRB guidelines. Additionally, any SAEs or AEs will be reported to the NIH/NIAAA within 24 hours.

If data reveals a SAE or we learn of it through a student, their PIN number associated with their survey data will be located. We will then search the separate data file for the student's contact information. Listed below are the specific resources which will be provided to students if an SAE or AE occurs.

LMU Resources:
Dr. Joseph LaBrie: jlabrie@lmu.edu; (310) 338-5238
Community of Care: (310) 338-3756
SPS: (310) 338-2868
SHS: (310) 338-2881;
https://studentaffairs.lmu.edu/wellness/studenthealthservices/scheduleanappointment/

Non-LMU Resources:
Drug Addiction & Alcohol Abuse Help & Information Resources: https://www.addict-help.com/
NIAAA Alcohol Treatment Navigator: https://alcoholtreatment.niaaa.nih.gov/
Substance Abuse and Mental Health Services Administration: https://www.samhsa.gov/

19. SAFEGUARDING IDENTITY

When a research project involves the study of behaviors that are considered criminal or socially deviant (i.e., alcohol or drug use) special care should be taken to protect the identities of participating subjects.

In certain instances, principal investigators may apply for "Confidentiality Certificates" from the Department of Health and Human Services or for "Grants of Confidentiality" from the Department of Justice.

Please see response to question 5. Numerous safeguards will be put in place to protect participant's identities.

20. ADVERTISEMENTS

If advertisements for subjects are to be used, attach a copy and identify the medium of display.

N/A

21. FOREIGN RESEARCH

When research takes place in a foreign culture, the investigator must consider the ethical principles of that culture in addition to the principles listed above.

N/A

22. EXEMPTION CATEGORIES (45 CFR 46.101(b) 1-6)

If you believe your study falls into any of the Exemption Categories listed below, please explain which category(ies) you believe it falls into and why.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

   All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials, or candidates for public office.

4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through the identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6) Unless specifically required by statute (and except to the extent specified in paragraph (1)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act or other public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

N/A

Please deliver to: Julie Paterson, IRB Coordinator, University Hall, Suite 1718 or jpaterso@lmu.edu.

MEASURES APPENDIX

I was born...

- ○ Female (0)
- ○ Male (1)

I identify as...

- ○ Female (0)
- ○ Male (1)
- ○ Other (2)

I am...

- ○ Heterosexual/Straight (1)
- ○ Gay/Lesbian (2)
- ○ Bisexual (3)
- ○ Queer (4)
- ○ I'm not sure (5)

I consider myself...

- ○ American Indian or Alaska Native (1)
- ○ Asian (2)
- ○ Black or African American (3)
- ○ Native Hawaiian or Other Pacific Islander (4)
- ○ White (5)
- ○ Multiracial (6)

Ethnically, I am...

- ○ Hispanic/Latino (1)
- ○ Not Hispanic/Latino (0)

My age is...

- ○ Under 17 (0)
- ○ 17 (1)
- ○ 18 (2)
- ○ 19 (3)
- ○ 20 (4)
- ○ 21 or over (5)

What is your height?

Feet:

▼ 3 (3) ... 8 (8)

Inches:

▼ 0 (0) ... 11 (11)

What is your weight in pounds?

_____

Are your parents...

- ○ Married (1)
- ○ Divorced (2)
- ○ Separated (3)
- ○ Other (please explain): (4)

_____

Were you living with your parents during your senior year of high school?

- ○ Yes (1)
- ○ No (0)

Who were you living with most of the time during your senior year of high school?

- ○ Mother (1)
- ○ Father (2)
- ○ Other (please explain): (3)

_____

Where are you **currently** living?

- With my parent(s) (1)
- In the LMU dorms (2)
- Off campus with roommates (3)
- Off campus alone (4)
- Other (5)

How often do you see or communicate with your **father** in person or online?

- Never (0)
- Less than monthly basis (1)
- Monthly basis (2)
- Weekly basis (3)
- Daily basis (4)

How often do you see or communicate with your **mother** in person or online?

- Never (0)
- Less than monthly basis (1)
- Monthly basis (2)
- Weekly basis (3)
- Daily basis (4)

The next set of questions will ask about your drinking habits. You may not know the exact answer to all of these questions; in those cases, please make your best guess. Please keep in mind that your responses to the questions in this survey are confidential.

How old were you when you had your first drink of alcohol (more than a sip or a taste)?

▼ I have never tried alcohol (0) ... 21 or older (10)

Who gave you your first drink of alcohol (more than just a sip or taste)?

- Parent (1)
- Family member (not a parent) (2)
- Friend (3)
- Stranger (4)
- I have never tried alcohol (0)

Which best describes your alcohol use?

- I have never tried alcohol (0)
- I am an abstainer (I do not drink at all, but have tried before) (1)
- I am a light drinker (2)
- I am a moderate drinker (3)
- I am a heavy drinker (4)
- I am a problem drinker (5)

This section asks you to report on your drinking over the **past 30 days**.

For all questions, **one drink equals**:

Consider a typical week during the past 30 days. How much alcohol, on average (measured in number of drinks), do you drink on each day of a typical week? If your answer is zero, please enter 0.

	Monday (1)	Tuesday (2)	Wednesday (3)	Thursday (4)	Friday (5)	Saturday (6)	Sunday (7)
Number of drinks							

During the **past 30 days**, on average, how many days per week did you drink?

▼ 0 (1) ... 7 (7)

During the **past 30 days**, on average, how many drinks did you have each time you drank?

▼ 0 (0) ... 25+ (25)

During the **past 30 days**, what is the **maximum** number of drinks you drank during any one drinking occasion?

▼ 0 (0) ... 25+ (25)

Think of the occasion you drank the most in the **past 30 days**. How many **hours** did you spend drinking on that occasion?

_____

During the **past 30 days**, how many times did you have [four/give] or more drinks within a 2 hour period?

▼ 0 occasions (0) ... 7+ occasions (7)

During the **past 30 days**, how many times did you have [eight/ten] or more drinks within a 2 hour period?

▼ 0 occasions (0) ... 7+ occasions (7)

Note: The BYAACQ was used in place of the RAPI to measure alcohol consequences.

Below is a list of things that sometimes happen to people either during or after they have been drinking alcohol. Next to each item below, please indicate whether that item describes something that has happened to you in the **past 30 days**.

	No, never (0)	1 time (1)	2 times (2)	3 times (3)	4-6 times (4)	7+ times (5)
I have had a hangover (headache, sick stomach) the morning after I had been drinking	○	○	○	○	○	○
I've not been able to remember large stretches of time while drinking heavily	○	○	○	○	○	○
The quality of my work or school work has suffered because of my drinking	○	○	○	○	○	○
My drinking has gotten me into sexual situations I later regretted	○	○	○	○	○	○
I have felt very sick to my stomach or thrown up after drinking	○	○	○	○	○	○
I have not gone to work or missed classes at school because of drinking, a hangover, or illness caused by drinking	○	○	○	○	○	○
My drinking has created problems between myself and my boyfriend/girlfriend/spouse, parents, or other near relatives	○	○	○	○	○	○
I have started a serious fight or argument with someone	○	○	○	○	○	○
I have passed out from drinking	○	○	○	○	○	○
I have become very rude, obnoxious, or insulting after drinking	○	○	○	○	○	○

I have been pressured or forced to have sex with someone because I was too drunk to prevent it	○	○	○	○	○	○
I have made inappropriate sexual advances toward someone after drinking	○	○	○	○	○	○
I have had less energy or felt tired because of my drinking	○	○	○	○	○	○
I have neglected my obligations to work, family, or school because of drinking	○	○	○	○	○	○