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Feasibility Study of the My Health Coach App for Adults with Fetal Alcohol Spectrum Disorders (FASD)

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PREFACE

This study represents the third phase of a larger research project developed for a UH2 application through the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), which has been funded by the National Institutes on Alcohol Abuse and Alcoholism since 2003. The project aims to develop a mobile health (mHealth) application (app) for adults with fetal alcohol spectrum disorders (FASD). In the first phase (IRB Study #00004616), we utilized focus groups to engage adults with FASD in the development of the mHealth intervention, currently called "My Health Coach." In our second phase (IRB Study 0007156), we used an online survey to obtain feedback on the developed concept from a broader sample of adults with FASD. In this third phase, we are conducting a feasibility trial of the developed mHealth intervention.

1. PURPOSE OF STUDY

This project is a partnership with identified leaders in the adult FASD community, known as the Adult Leadership Collaborative (ALC). Their motto is: "Nothing About Us Without Us." The purpose of this study is to conduct a feasibility study of the My Health Coach app we have developed from stakeholder feedback in prior phases. We will test both the acceptability and feasibility of the app for adults with FASD as well as trial procedures. These data will inform our future larger-scale randomized controlled trial.

We will recruit adults with FASD online through well-established methods by our research group and our ALC partners. Eligible adults will try out the app on their own smartphones. Online assessments will be completed at the start of the study and six weeks later. Interviews will also be completed to further understand user experiences.

This project has the potential to make significant contributions to the field as there are currently no evidence-based supports for adults with FASD.

2. BACKGROUND AND RATIONALE

Prenatal alcohol exposure affects the developing brain and other organ systems and can result in a set of conditions termed fetal alcohol spectrum disorders (FASD; [1]). FASD are prevalent conditions, affecting about 2 to 5% of the North American population [2]. Although FASD have been primarily studied in children, it is well established that FASD are life-long conditions that impact multiple domains functioning. Adults with FASD often require a higher level of supports to participate in home, community, occupational, and social settings [3].

Despite the high prevalence, most people with FASD do not receive appropriate diagnosis or services. Research has documented that 80% or more of people with FASD go undiagnosed [4]. Getting an early diagnosis and appropriate services are two important protective factors against mental health symptoms and other later life problems such as school disruptions, trouble with the law, and substance use [3].

Unfortunately, research on effective services for people with FASD is limited, and almost non-existent for adolescents and adults. In addition, there are major barriers to accessing available services and supports in the community. Barriers to care occur because a knowledgeable and skilled workforce is lacking [5-6], and there are individual- and family-level barriers such as limited financial resources, transportation, and stigma [7].

This project will initiate formative research to guide the development of mHealth tools for adults with FASD. Most adults have a smartphone and mHealth apps have the advantage of being easily scalable and can reduce barriers to access. In addition, mHealth apps are well-suited for providing information, self-monitoring, goal-setting, and real-time synchronous communication, all of which can be effective behavior change techniques [8].

Consistent with the Developmental Origin of Health and Disease (DOHaD) hypothesis, emerging research is documenting high rates of co-occurring chronic health conditions associated with prenatal alcohol exposure in humans and animal models [9,10]. In fact, the ALC has been instrumental in directing attention to this important issue and leading a large survey-based study on this topic [11]. Adults with FASD require concrete and accurate information to understand their condition and practical ideas to meet their needs and build on their strengths. Our mHealth app, currently called My Health Coach, will offer adults with FASD evidence-based education about their condition and tools to promote their own self-management and health advocacy goals. My Health Coach is grounded in self-determination theory [12] and integrates well-established behavior change strategies [13]. It uses a just-in-time adaptive intervention design [15] and a simple and engaging chatbot interface. This will provide adults just the right type and amount of support, when they are most receptive.

Partnering with the ALC to develop and conduct the research is an important strength of this study. Gathering key stakeholder input is crucial when developing new treatments and supports for a given condition. But partnering with identified leaders in the community to help shape the research questions and guide data collection and interpretation enriches the quality of the data and ensures the right questions are being asked.

3. ADMINISTRATIVE ORGANIZATION

This study is led by Drs. Christie Petrenko and Cristiano Tapparello. Dr. Petrenko is faculty at Mt. Hope Family Center and has appointments in the departments of Psychology and Pediatrics. Dr. Tapparello is faculty in the department of Electrical and Computer Engineering. They will oversee all research staff, implementation of human subjects' protections, and data collection, management, analysis, and reporting.

All data collection will be through our research team at the University of Rochester. Participants will be recruited online and complete informed consent, screening, and survey through our REDCap database, hosted at the University of Rochester. Interview data will be collected via HIPAA-complaint Zoom. Additional data will be collected through the My Health Coach app developed and managed by our team and hosted on a URMC Amazon Web Services (AWS) account.

4. STUDY DESIGN

This feasibility study will use a single group design with assessment timepoints prior to the receipt of the app and 6-weeks later. Primary outcomes assessed will include quality of life, self-determination theory constructs (i.e., autonomy, competence, relatedness), self-management, and barriers to care. Acceptability of the app and trial procedures will also be assessed at the 6-week timepoint.

5. SUBJECT POPULATION

The study population will include adults (18+) with FASD. We will aim to enroll 48 adults with FASD to achieve a final sample of 40 participants with complete data. Additional participants will be enrolled if attrition is greater than anticipated.

In prior studies conducted by the ALC, 45% of participants were from Canada, 40% from USA, 9% European countries, 5% Australia / New Zealand, and 2% African countries. As such, we anticipate the vast majority of participants in our study will also be from the US and Canada. However, some will likely come the EU and UK and fall under GDPR requirements. A "Notification for Collection and Use of Personal Data" is included in the REDCap Screening Module immediately after the Study Consent Form to inform all participants from the EU or UK about compliance with GDPR requirements.

It is also possible that some adults with FASD will have legal guardians due to decisional impairment (in either specific or global domains). For these adults to participate, their legal guardian would also need to review the study consent form and provide written permission. Legal guardianship in Canada is rare but is used sometimes for adults with FASD in the US. A question in the screening module asks about legal guardianship. For those adults who indicate they have a legal guardian, our research team will contact that person to go over the permission form and obtain the needed signature through REDCap.

6. INCLUSION AND EXCLUSION CRITERIA

- Adult 18 years or older
- Have a history of prenatal alcohol exposure or FASD diagnosis (based on self-report)
- Have fluency in English
- Own an Android or iOS (iphone) smartphone
- For adults with a legal guardian: their parent or guardian needs to provide written permission for them to participate

Participants who are not able to speak English will be excluded from the study at this time as the My Health Coach app and surveys are only currently available in English.

7. RECRUITMENT METHODS

We will use well-established recruitment methods previously used by our University of Rochester research group and ALC partners. Recruitment materials include study flyers and social media tiles (see uploaded). These materials will be distributed as follows:

- Dr. Petrenko will share study recruitment materials with providers and community advocates who regularly interact with adults with FASD
- We will post study information on our team's Twitter account (@FMFConnect) and newsletter (www.fmfconnect.com)

- CIFASD investigators can inform research participants or patients in their local sites or clinics for which they have routine access
- FASD United (Formerly National Organization on Fetal Alcohol Syndrome) is a member of CIFASD and has a mission to educate the public about FASD and disseminate research and policy information. They can disseminate the study flyer through their Weekly Round-Up newsletter, significant social media presence, and to their state and local affiliates who can share in their communities
- ALC partners will share recruitment materials through their social media and other networks
- Organizers/moderators of popular social media groups can be sent recruitment materials and can choose to share with their members

We would also like to invite participants to consider participating in the current study who completed informed consent and screening for our prior focus group study (IRB Study #00004616) or online survey (IRB Study 0007156). These adults would be sent an email (see email language template) including the study recruitment flyer. Interested participants from prior studies would need to follow the same consenting and data collection procedures outlined below as other new participants. Recruitment materials would direct them to the REDCap Screening Module.

8. CONSENT PROCESS

This study includes 2 documents: 1) Adult Information Sheet, and 2) Legal Guardian Permission.

Interested adults with FASD will be directed to the link to the study REDCap Screening Module from recruitment materials. Participants will first be given the option whether they would like to learn about the study by 1) reading the Study Information Sheet or 2) view a video summarizing this information. After reviewing either option, they will be asked several questions assessing their understanding of the information. All participants will be given the option to download a copy of the Information Sheet for their records. This will also allow them sufficient time to review the form and discuss it with other people in their life if they choose. There will also be a section where they can indicate if they have any questions, and our study coordinator will call them. The study coordinator's contact information will also be presented if participants want to contact the coordinator with questions while reading the document/watching the video. The study coordinator will document contact in the study contact log in REDCap. Additional items will screen for eligibility and obtain contact information. There will also be a question about whether they have a parent/legal guardian, so we can contact that person if needed to obtain permission. Given the broad range of functioning within this population, the Information Sheet language was adapted in some places to be at a lower reading level. Headings were also added, similar to the Adolescent Assent template.

We request a waiver for documentation for the Study Information Sheet. The primary identifying information collected as part of this study are participant contact information in the REDCap Screening Module. This contact information would allow us to contact participants in several anticipated scenarios, such as: if they indicate they have questions about the study, they provide inconsistent information we need to clarify (e.g., country they live in vs. response

for “live in UK or EU”), or to send them surveys or schedule interviews. This contact information would also allow us to remove or change participant data as requested by a participant under GDPR requirements if needed. Identifying information will be stored separately from other de-identified data sources. In addition, this study is minimal risk and involves procedures (e.g., survey responses, app usage) for which written consent is not normally required outside the research context. There is also not an easy way to verify participant identify for written eConsent without creating an additional step for participants involving communication with research staff through another method (e.g., email, phone).

After reviewing the information sheet, participants will be directed in REDCap to answer screening questions to assess eligibility for the study (see Screening Form). If eligibility criteria clearly aren’t met (e.g., out of age range, no smartphone, etc), participants will be informed immediately that they aren’t eligible and the module will end. Screening data will be maintained for ineligible participants to aid in clinical trial reporting requirements (e.g., documenting numbers screening, eligible vs. ineligible, and reasons).

For adults who appear to meet criteria or in cases where they answer “unsure” for any of the questions, further contact information will be gathered. Contact information will also include necessary variables to generate their “globally unique identifier” (GUID), which is used in other CIFASD studies and required for the NIAAA-Data Archive (https://nda.nih.gov/s/guid/nda-guid.html).

Legal Guardians: For legal guardians, written permission will be obtained using REDCap’s eConsent signature field. A study team member will contact the legal guardian based on information provided by the participant in their survey. During this contact the study team will provide the legal guardian a passcode to enter when completing the eConsent to serve as verification of their identity. The legal guardian will then select “Next Page” and a read only copy of the consent will be generated that they can review, download, and/or print. At the bottom of the page, they will need to select “I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document.” Once this is selected, they will be able to submit the signed consent form.

Upon completion of the permission survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project’s File Repository in REDCap (to allow for versioning). The e-Consent Framework in REDCap also records their IP address and displays this information in the file repository in order to help regulate potential duplicate forms from a single IP address. A PDF file of the completed consent form will be available for download by the user. The PDF can also be emailed to legal guardians or printed/sent to them in the mail on request if they are unable to open or save a copy electronically on their device.

Participant completion of the study permission document also triggers an automatic notification to the study coordinator, who will log-in to REDCap and review the consent. She will then add her name and date to the eConsent document. However, the date study staff sign the eConsent may differ from that of the participant; for example, if the participant completes the forms on a weekend. The coordinator will also document the date of this review in the

study database and download a copy of the consent form to maintain in study records. Next the coordinator will review screening responses and demographic variables to assess eligibility and will document this in the study database.

This study is funded by the National Institute of Health (NIH). A Certificate of Confidentiality is automatically included as part of the notice of award. Language regarding the Certificate of Confidentiality is included in the consent documents.

Due to an increase in fraudulent participants across studies, we have developed a lab-wide guide to minimize, detect, and systematically manage fraudulent participants (see uploaded). For this study (as of June 2023), if "red flags" (e.g., common email formula, unusual emails; see lab-wide guide for other examples) are identified by research staff, they will follow lab scripts to withdraw the participant.

9. STUDY PROCEDURES

The project research assistant will track participants in REDCap once enrolled and will facilitate timely completion of research assessments. All participants will be encouraged to complete assessments, regardless of their level of engagement with the My Health Coach app. Actual user data from the app (whether minimal or extensive) will be important in addressing study aims.

After informed consent, participants will be asked to complete a set of baseline surveys (see details on the assessment battery below). To be most sensitive, given the unique neurobehavioral profiles of participants, administration will be flexible based on participant needs and can include surveys completed independently online, over the phone or Zoom with research staff, or through the mail. Afterwards, they will be provided information on how to install the app on their phones. Study staff will be available to troubleshoot problems with installation or app use. After 6 weeks, all participants will be re-contacted to complete follow-up surveys. User implementation data will be gathered through the app. To further assess acceptability, satisfaction, and barriers and facilitators of app use, the study research assistant will complete qualitative interviews with participants over HIPAA-complaint Zoom or telephone. Interviews will be recorded and later transcribed verbatim.

Study Assessment Battery

Measure	Baseline	6-Week Follow-up
Quality of Life: Personal Well-being Index – Intellectual Disability Version	X	X
Self-Determination: The Basic Psychological Need Satisfaction and Frustration Scale	X	X
Self-Management	X	X
Barriers to Healthcare Checklist	X	
FASD Education	X	
Basic Demographics	X	
Acceptability: Theoretical Framework of Acceptability measure		X

Qualitative Interview on User Experience		X

Qualitative Interview. The semi-structured questioning route will cover the following topics: 1) overall impressions of My Health Coach; 2) experience using the app (both facilitators and barriers of use); and 3) perceived impact on their health and well-being. Interviews are expected to last about 30 minutes.

My Health Coach app. The My Health Coach app is designed to offer adults with FASD evidence-based education about their condition and tools to promote their own self-management and health advocacy goals. It uses a chatbot interface to engage with users and help navigate through the app features. The user will be able to customize their chatbot as well as their own avatar to ensure they feel comfortable while using the app. Key features include a daily check-in, which records mood, physical health symptoms, sleep quality, and positive activities completed each day. Daily answers can be referred back to as needed. The app also includes a tracker the user can cusstomize to track things such as medication or daily tasks. Next, the app will also include a library where users can access evidence-based factsheets on their condition and strategies to aid with condition management. Lastly, the app will send a daily message notification. These will include strategies, FASD facts, and positive affirmations.

10. AUDIO/VIDEO RECORDINGS

Qualitative interviews will be recorded using HIPAA-complaint Zoom with a digital recorder audio back-up. Research staff will be at Mt. Hope Family Center when completing interviews, using UR computers. Recordings will uploaded from the local machine as soon as possible to a URMC Box folder for this project managed by the IT team at Mt. Hope Family Center. Only research staff involved on this project will have access to recordings. Recordings will then be transcribed verbatim by research staff. After all transcripts have been rechecked, audio and video recordings will be deleted.

11. RISKS TO SUBJECTS

Participants may experience psychological risks associated with participation in this study, such as discomfort or boredom in answering questions or providing feedback about the app. There is also a risk of loss of confidentiality. All data collected for the proposed research study will be kept confidential to the extent allowed by law. Although it is unlikely given the nature of this study, if participants disclose that someone is being maltreated or is a danger to self or others, research staff will need to break confidentiality to make a report to the appropriate authority to ensure safety, as mandated by law. We believe that all identified risks are reasonable given the proposed procedures for protecting against risk.

Protections Against Risks

To minimize risk associated with psychological discomfort, participants will be given the option to skip questions they feel uncomfortable answering. Multiple procedures will be implemented to protect participant confidentiality. In terms of data storage and management, any hard copy data will be secured in locked file cabinets within locked offices, available only to program staff. Electronic data will be stored on URMC managed Box folder for this project, and only project staff with appropriate permissions will be able to access the data. Forms with

identifying information will be separated from the data collected and only subject numbers will be retained in data analysis files.

Multiple levels of protection will be put in place to reduce the risk of loss of confidentiality for data collected through the app. A local datastore will protect the mobile application against network failures and connectivity issues. This local datastore will be transparently synchronized with the Cloud database so that all the querying and security features will be always available regardless of network connectivity. Collected data will be stored using a random code that will not allow direct identification of a particular subject, while any data that identify the user will be stored separately. All the connections between the mHealth app and the Cloud, as well as access and storage to the Cloud database, will use state of the art authentication and encryption algorithms (e.g., HTTS, SSL and TLS). The Cloud architecture and services will be built and are managed by Dr. Tapparello, under a University-managed Cloud account, and in compliance with University policy. Security and Benchmark compliance reports generated by Lacework will be received and reviewed daily by Dr. Tapparello. Access to the data stored on the Cloud will be restricted, access to the data with be logged and backups will be created to allow the users to restore them if/when necessary. Appropriate policies will be set up so that users will be able to add and modify their own data but will be prevented from viewing and modifying other users' data. My Health Coach will also not alter the security settings of the user's phone, access stored information in the phone, or access device functionalities without explicit user consent. A passcode (or touch ID/Face ID) will be required to access the content of the app, and all the personal data stored by the app will be encrypted automatically whenever the device is locked.

All information obtained for research will be kept strictly confidential (as allowed by law) by research staff. Participants will be told about all exceptions (e.g., child/dependent adult abuse, harm to self or others) to confidentiality during the consent process. Project staff will be closely supervised by Dr. Petrenko and instructed on confidentiality, including what information is confidential, the limits of confidentiality, and to whom to report concerns.

The My Health Coach app is viewed as a "value-added" intervention. Participants can continue to receive care as usual in their community. The alternative to participating in this study is not to participate.

12. POTENTIAL BENEFITS TO SUBJECTS

Participants may not experience any direct benefits from participating in this study. However, participants in prior FASD research studies at MHFC have commented on how they value and derive personal satisfaction in participating in research to increase knowledge about this under-recognized condition and effective strategies to benefit other people with FASD. It is also possible, although not guaranteed, that participants might derive benefit from using the My Health Coach app. Possible benefits may include improved self-management, advocacy, and quality of life.

13. COSTS FOR PARTICIPATION

There are no costs to participate.

14. PAYMENT FOR PARTICIPATION

Participants will receive a $25 gift card for completing: baseline surveys, 6-week follow-up surveys, and the qualitative interview, for a possible total of $75 if all activities are completed.

15. SUBJECT WITHDRAWALS

Subjects will be advised during the consent process that they have the right to withdraw from the study at any time without prejudice. They can choose to use the app as much as they want (or not at all). We are interested in obtaining survey data as well as feedback about the user experience from as many participants as possible, including those who chose not to use the app or found it hard to navigate. This information is useful in identifying ways to improve the app and facilitate user engagement. Subjects can choose not to complete any or all of the study assessments. They can also completely withdraw from the study with no future contact if they choose. In this case, any data they have previously provided may be used in analyses.

16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

All data will be used solely for research purposes and will be securely locked in designated file cabinets, URMC managed Box folder dedicated to project, Project REDCap database, and an encrypted, HIPAA-complaint Cloud database (AWS; for data collected via the app; see above). Identifying information will be stored separately from other data, which will be stored by research ID number (GUID). Multiple procedures will be implemented to protect participant data collected through the app, which are further detailed in the section "Protections Against Risks" and Data Security Assessment form. Only senior key personnel and project research staff will have access to the data.

The following table summarizes the project data flow. MHFC IT will set up and manage permissions for URMC Project Box folder. Only project staff will have access to REDCap and Box folders. Dr. Petrenko will coordinate with the CIFASD5 Coordinating Center to facilitate required data uploads to NIAAA-Data Archive as required by the grant for eligible de-identified data (pre-post surveys; all other data exempt).

Data Element	How Data Collected	Where Data is Stored	How Data is Managed
Information Sheet, Screening Survey, Contact Information	REDCap	REDCap, Back-ups URMC Box	MHFC IT; Project Staff
Legal Guardian Permission Form (eConsent)	REDCap	REDCap, Research staff signed copy of permission form on URMC Box	MHFC IT; Project Staff
Baseline (T1) Surveys	REDCap	REDCap, Back-ups URMC Box, CIFASD/NIAAA-DA	MHFC IT; Project Staff; CIFASD5 Coordinating Center
6-week	REDCap	REDCap, Back-ups	MHFC IT; Project Staff;

Follow-up (T2) Surveys		URMC Box, CIFASD/NIAAA-DA	CIFASD5 Coordinating Center
Follow-up Interview	Zoom, back-up audio recording	URMC Box	MHFC IT; Project Staff; Audio/video data is transcribed verbatim; audio/videos deleted once transcript verified
My Health Coach App usage data and User's inserted data	User device synchronized with AWS	URMC-managed account on AWS	Access is restricted to authorized individuals and every access to the data will be logged, data is encrypted in transit and at rest. AWS account is set up in compliance with UR/URMC policies and monitored by Lacework.

15. DATA / SAMPLE STORAGE FOR FUTURE USE

All data (de-identified and identifying) will be securely stored locally for an indefinite period. De-identified and identifying information will be stored separately as detailed above. Novel research questions may arise in the future that this important dataset could answer. Future studies may also be interested in long-term follow-up of individuals who participated in this research. Retaining identifying information would facilitate contacting individuals (subsequent to new IRB approval) to see if they would be interested in participating in follow-up research. MHFC has well-established data security procedures in place for long-term storage and maintenance of data. Only approved project staff will have access to data.

De-identified pre-post data from this study will also be submitted to the National Institute on Alcohol Abuse and Alcoholism Database ($NIAAA_{DA}$) at the National Institutes of Health (NIH), as required. As a CIFASD Project, the CIFASD5 Data Coordinating Resource will facilitate required timely data harmonization and uploading to the $NIAAA_{DA}$. Recommended language has been included in the Information Sheet and Permission forms, including a link to more information about the data archive and sharing policies: https://nda.nih.gov/niaaa.

16. DATA AND SAFETY MONITORING PLAN

Because the research involves the provision of a mobile health intervention for adults with FASD, the risk for a serious adverse event due to provision of the intervention is low. Adverse events that could occur in adults with FASD could include aggression or violence towards others, maltreatment, self-harm or suicidality, or the need for inpatient hospitalization. However, these occurrences are unlikely to be a direct consequence of participation in the proposed research or interventions.

Dr. Petrenko will assume ultimate responsibility for the safety and well-being of research participants and the integrity of data collected. Dr. Petrenko has conducted several RCTs with children and adults with FASD and their families. She is a licensed psychologist in the state

of New York and is involved in other clinical and research activities at MHFC where maltreatment and suicidality are commonly reported.

The well-being of participants will be monitored throughout the course of the proposed research. If there are concerns regarding a participant during interactions with research staff, staff will immediately contact Dr. Petrenko for consultation and a plan will be developed to address the concerns raised. Additionally, because MHFC provides other treatment programs, there are other back-up clinical supervisors available for consultation for immediate needs. A phone tree will be established, similar to other projects at MHFC, and will be provided to research staff. Dr. Petrenko will meet with research staff at least weekly to provide supervision and will assess participant well-being. Dr. Petrenko will consult with other co-Investigators and clinical staff at MHFC, as appropriate, to address participant well-being concerns.

An independent safety monitoring board has also been established for the larger project, consisting of researchers and clinicians with relevant expertise with at-risk populations, clinical trial monitoring, and human subjects protections and technology. ISM members and their areas of expertise are listed in the following table:

Name	**Title & Affiliation**	**Relevant Areas of Expertise & Experience**
Sheree Toth, Ph.D.	Director & Professor, Mt. Hope Family Center, University of Rochester	Clinical psychologist; developmental psychopathology; relational interventions; maternal depression; maltreatment; prevention of teen depression; has conducted multiple large-scale intervention trials with high-risk populations.
Lynn Cole, M.S. PNP	Clinical Director, Kirch Developmental Services Center, Neurodevelopmental and Behavioral Pediatrics, University of Rochester Medical Center	Pediatric nurse practitioner; physical and mental health of children with developmental disabilities; intellectual disability, FASD, autism, and cerebral palsy.
Anthony Pisani, Ph.D.	Associate Professor in Psychiatry and Pediatrics, Center for the Study and Prevention of Suicide, University of Rochester Medical Center	Clinical psychologist; suicide prevention; public health messaging; safe and ethical use of technology in prevention science

The ISM committee will review and suggest modifications to research protocols and consent documents to assure scientific integrity and adherence to human subjects' protection policies. They will meet with the PI and co-Investigators twice a year to monitor safety issues and provide feedback on scientific and ethical issues relating to project implementation. The IRB will be notified immediately of any adverse events via telephone and submission of a

"University of Rochester Serious Adverse Event Report". Such events would also be reported to NIAAA. The proximity of committee members will also facilitate their ability to monitor data management activities. The committee may ask to review data for quality control purposes.

Ethically, we are committed to ensuring the welfare of people with FASD. Any significant mental health or safety issues detected during the conduct of this investigation will be discussed with participants and options for the receipt of services presented.

17. DATA ANALYSIS PLAN

Pre-Post Intervention Outcomes. Descriptive statistics, reliability indices, and pre-post effect sizes (Cohen's d) will be calculated for baseline and follow-up quantitative measures and user implementation data. Data will provide useful estimates to inform larger randomized control trials of the app. Data will also guide further app refinements.

Qualitative Interviews. Data will be analyzed thematically to understand users' experiences with the My Health Coach app and research trial. The purpose is to inform further app development. Thematic analysis focuses on identifying patterns or themes within the data. Consistent with the approach advocated by Miles, Huberman, and Saldana [15], research team members will first familiarize themselves with the data, iteratively reviewing each transcript, and independently assigning initial codes ("first-level coding"). The team will then come together and discuss, operationalize, and refine each code. We will also generate "second-level codes" which consider categories or deeper meanings among first-level codes. During this process we will examine interrelationships and networks among codes and build a preliminary thematic framework. Transcripts will then be recoded and codes refined through further discussion and consensus, as needed. Participant and group "fit" with the framework will also be assessed, with confirmatory and disconfirmatory evidence for the model examined. Participant matrices may also be utilized to examine variance in themes across participants and key demographic factors, pre-post intervention change, or usage patterns.

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