Incorporating Cardiovascular Risk Assessment into Adolescent & Young Adult Visits to Improve Cardiovascular Health

(Short title: Incorporating CV Risk Assessment in AYA Visits)

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PROTOCOL TITLE: Incorporating Cardiovascular Risk Assessment into Adolescent & Young Adult Visits to Improve Cardiovascular Health

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FUNDING SOURCE: This study is funded by the NIH National, Heart, Lung and Blood Institute.

REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	10/01/2020	Removed clinical trial portion of study
2	10/12/2020	Removed external collaborator not engaged in research
3	05/07/2021	Removed several survey questions and added study flyer
4	06/24/2021	Removed more survey questions; modified interview guide
5	8/13/2021	Added pre-screening phone calls to protocol
6	9/18/2021	Clarified which health care providers are eligible, updated health care provider recruitment email. Requested waiver of parental permission under certain circumstances. Updated consent procedures.
7	4/4/2022	Updated protocol to reflect recruitment changes in Aim 2
8	5/10/2022	Updated protocol to include Aim 3
9	10/28/2022	Increased enrollment size to 60 participants

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1. Study Summary

Study Title	Incorporating Cardiovascular Risk Assessment into Adolescent & Young Adult Visits to Improve Cardiovascular Health
Study Design	Survey/Questionnaire and Behavioral Intervention
Primary Objective	Adapt a cardiovascular disease risk assessment tool for use in adolescent and young adult clinical practices in Atlanta
Secondary Objective(s)	1. Use qualitative methods to elicit information about what adaptations are needed to make a cardiovascular disease risk assessment tool and a companion behavioral intervention appropriate with adolescents/young adults 2. Adapt a cardiovascular disease risk assessment tool and companion behavioral intervention into a single integrated application for use in primary/reproductive care settings serving adolescent/young adult women 3. Pilot the new cardiovascular disease risk assessment tool in primary/reproductive care settings serving adolescent/young adult women
Research Intervention(s)/Interactions	Mobile app (#HerHeart) development; survey/questionnaire; audio-recorded interviews
Study Population	Adolescent and young adult women presenting for care at the CHOA Hughes Spalding Adolescent Medicine clinic and the Grady Health System Teen Program
Sample Size	60 adolescent/young adult women 10 health care providers
Study Duration for individual participants	Phase 1: one hour Phase 2: six months Phase 3: three months
Study Specific Abbreviations/ Definitions	AYA – adolescent and young adult CHOA – Children's Healthcare of Atlanta CVH – cardiovascular health CVD – cardiovascular disease HBM – Health Belief Model HCP – health care providers HHS – Healthy Heart Score

	VAS – Visual Analog Scale
Funding Source (if any)	This study is being considered for funding by the NIH National, Heart, Lung and Blood Institute.

2. Objectives

The purpose of this study is adapt a Healthy Heart Score tool for use in adolescent and young adult (AYA) clinical practices in Atlanta. Our central hypothesis is that a developmentally appropriate lifestyle-based risk prediction tool, delivered during wellness, mental health, and reproductive health visits and reinforced through personalized goal setting, will be acceptable to young women and their providers and feasible to integrate into practice. The aims of the present study are as follows:

Aim 1. Using qualitative methods, elicit information about what adaptations are needed to make the Healthy Heart Score risk assessment tool and a companion behavioral intervention appropriate for use with AYAs and HCPs. We will survey and interview 20 AYA women and 10 HCP in primary care wellness, mental health, and reproductive health practice settings.

Aim 2. Adapt the Healthy Heart Score risk assessment tool and a companion behavioral intervention into a single integrated application for use in primary/reproductive care settings serving AYA women. We will recruit 10 additional AYA to iteratively test the new application using user-centered design principles.

Aim 3. Evaluate the usability and initial feasibility of #HerHeart. We will recruit 60 additional AYA participants and the same 10 HCPs from Aim 1 to evaluate the usability and feasibility of the web tool.

3. Background

Cardiovascular disease (CVD) remains the number one killer of women in the US despite decades of progress in risk factor detection and treatment.[1] Awareness of CVD risk and risk factor control remain critical barriers to reversing this trend. In our study of young adults participating in the National Health and Nutrition Examination Survey 2011-2014, a substantial proportion of participants with hypercholesterolemia (43.1%), hypertension (37.3%) and diabetes (30%) at the time of their study exam reported no awareness of these diagnoses, and >75% of young adults with borderline levels of these risk factors were unaware of their risk.[2] This is highly concerning given the high proportion of young adults who will transition from borderline or intermediate cardiovascular health (CVH) to poor CVH as they reach middle age.[1] Furthermore, even intermediate CVH in adolescence and young adulthood is associated with subclinical markers of CVD later in life.[3-6]

Low CVD awareness among AYAs is compounded by the notion that they are "young invincibles" with little concern for their long-term health.[7] Multiple explanations are posited for this perceived invincibility, including ongoing development of the prefrontal cortex into the mid-20s [8] and age-related differences in the ability to project risk.[9] As adolescents age, the

length of time they can project into the future increases, as does their motivation to act in the present when benefits may not be realized until the future.[9] In our previous work, we found adolescents and young adults are cognitively capable of understanding short, medium, and long-term risk for CVD and report motivation to act now to prevent future CVD.[10] Unfortunately, in a separate study, we found 90% of young women remain unaware of the fact that CVD is the number one cause of death for women in the US.[11] Interventions designed to improve CVD awareness and mitigate CVD risk with adolescents and young adults have been limited to unique populations, such as college students,[12] or have focused on only a few CVD risk factors at a time, such as smoking, nutrition, physical activity, or obesity.[13] Few interventions have targeted young women specifically, adolescents more generally, or addressed adolescent and young adult motivations to improve their health.

This project will advance the state of the science regarding CVD risk communication with adolescent and young adult women within primary and reproductive health care systems. Adolescents and young adults are infrequently screened for CVD risk factors during health care encounters,[14] and many young people do not have a routine source of primary care.[15] Grounded in the conceptual framework of the Health Belief Model (HBM),[16] this feasibility study will incorporate CVD risk assessment into wellness, mental health, and reproductive health visits for adolescent and young adult women in two clinical practices that serve a primarily African American population with low socioeconomic status and high cardiovascular risk. We will address two key concepts of the Health Belief Model: a) targeting adolescent and young adult women's perceived susceptibility to CVD, and b) providing a cue to action to set personalized goals for improving their CVH as they transition to adulthood. We hypothesize that a lifestyle-based risk prediction tool (the Healthy Heart Score) coupled with a companion behavioral intervention can be adapted for use as an integrated application for young women.

4. Study Endpoints

Phase 1: Using qualitative methods, elicit information about necessary adaptations to the Healthy Heart Score risk assessment tool and a companion behavioral intervention. The primary endpoint of this portion of the study is the collection of survey and interview data from 20 AYA and 10 HCP.

Phase 2. Adapt the Healthy Heart Score (HHS) risk assessment tool and behavioral intervention frameworks into a single integrated application. The primary endpoint of this portion of the study is the creation of the single integrated application, #HerHeart.

Phase 3. Evaluate the usability and initial feasibility of #HerHeart. The primary endpoint of this portion of the study is the assessment of the usability of the tool and the feasibility of recruitment for a larger clinical trial.

5. Study Intervention / Design

This is a three-part study. In Aim 1/Phase 1, we will use qualitative data to understand necessary adaptations to two existing tools developed for adults. In Aim2/Phase 2, we will use user-centered design to make those adaptations in conjunction with participants. Aim 3/Phase 3 will test the usability of the developed tool and the feasibility of a larger clinical trial.

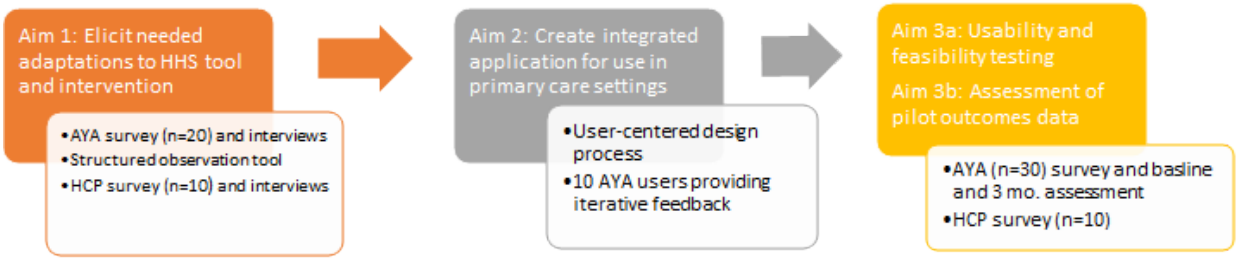

Figure 2. Timeline for the proposed study: Aim 1: months 0-6, Aim 2: months 7-12; Aim 3: months 12-24

Procedures Involved

Table 1. Summary of data collected in Aim 1.

Aim 1 Measures – AYA	Aim 1 Measures - HCP
i. Brief Initial Survey • Age • Race/ethnicity • Mother's highest level of education • Zip code • VAS • AHA Women's Health Survey	**v. Provider Survey** • Age • Gender • Race/ethnicity • Degree • Practice Site • Years in Practice
ii. Structured Observation Tool (time stamps)	**v. Provider Semi-Structured Interview: HHS/DPP** • Current Provision of CVD prevention care • Comfort with CVD risk assessment • Barriers/facilitators to providing CVD care • Perceived relevance of HHS/DPP • Practicality of using CVD application in practice
iii. Semi-Structured Interview re: HHS • Health Belief Model domains • Length of time to complete tool • Optimal location to complete tool • Understanding of questions • Suggested adaptations	
iv. Semi-Structured Interview re: DPP modules • Optimal delivery modality • Preferred frequency/timing of messages • Understanding of content • Necessary adaptations	

Phase 1: AYA participants (n=20) will complete a brief initial survey on a tablet to collect data listed in Table 1. Participants will also complete the Visual Analog Scale (VAS) to allow them to estimate their perceived 10-year risk of CVD, lifetime risk of CVD, and perceived severity of CVD. Additionally, participants will complete the Healthy Heart Score (HHS) beta version and answer questions following a semi-structured interview guide to elicit thoughts and comments about the app (AYA Data Collection.pdf). Participants will be queried about the optimal length of time to spend completing the tool, the optimal location (i.e., at the doctor's office, online, in school), level of understanding of the questions and the risk prediction visualization interface, and suggested adaptations to the dietary and physical activity subdomains. Next, participants will provide be asked to suggest possible interventions to address healthy behaviors (i.e., health coach, text reminders, etc.). We will inquire about the optimal modality for delivering the suggested intervention (i.e., various social media platforms, app-based, text-based) and preferred frequency and timing of follow-up messages. Finally, we will elicit participant reactions to potential names so we can brand the single integrated application. Additionally, 10 providers will undergo an abbreviated version of the aforementioned procedures and complete an interview using a provider-specific semi-structured interview guide (HCP Data Collection.pdf) to inquire about topics listed in Table 1.

Data analysis from the AYA and HCP surveys will be primarily descriptive. Data will be summarized overall, and by location and cohort. Interviews will be recorded, transcribed, and inputted into Dedoose Version 7.0.23, a web application for managing, analyzing, and presenting qualitative and mixed method research data (SocioCultural

Research Consultants, LLC, Los Angeles CA). At least two members of the research team will code all transcripts. Through several iterations and consensus discussions, we will ensure adequate thematic coding agreement (K= 70%). Identified themes will be used to adapt the HHS tool.

Phase 2: We will employ an iterative user-centered design process to beta-test the integrated application with up to 10 additional AYA women. The additional AYA women will be recruited from the Emory Pipeline Collaborative (EPiC). Working with the Georgia CTSA Innovation Catalyst, we will engage in cycles of rapid prototyping, starting with a simple prototype that represents the integrated application on a storyboard and adapt the content based on user feedback. We will then work with the Georgia CTSA App Hatchery to program the web-based integrated application compatible with mobile devices equipped with Android or iOS operation systems. Finally, we will engage AYA participants in live prototyping, presenting them with a functional prototype to react to as they complete the assessment tool in real-time.

Throughout the design process, we will conduct observational field tests by gathering information about how AYA participants use the application in real-time. We will elicit their feedback on the usability and desirability of the integrated application throughout the process, and adjust the application based on their feedback. We will also examine automatically generated data from the application itself to identify patterns of activity and common problems. The end-product of Aim 2 will be the final integrated application consisting of a lifestyle-based CVD risk assessment and companion behavioral intervention. For the remainder of the protocol, we will refer to the integrated application as #HerHEART; however, the application will formally be named with input from participants in Aim 1.

Aim 3 Measures – AYA			**Aim 3 Measures - HCP**
Primary Outcomes (3-month Time Frame) • Changes in overall #HerHeart risk score • Changes in overall composite of diet • Changes in fruit and vegetable intake • Changes in red and processed meats intake • Changes in sugar and sweetened beverages • Changes in nut consumption • Changes in alcohol consumption • Changes in nicotine use • Changes in cereal fiber • Changes in physical activity	**Secondary Outcomes (3-month Time Frame)** • Changes in BMI • Changes in SBP • Changes in DBP	**Exploratory Outcomes** • WAMMI for #HerHeart • WAMMI for Healthy Heart Score • Likelihood of recommending #HerHeart to friends (0-10) • Likelihood of behavior change (0-10) • VAS • Eating Disorder Diagnostic Scale (EDDS) • # of participants approached • # who agreed to participate • Completion/dropout rate	**Exploratory Outcomes** • WAMMI for #HerHeart • Usefulness of #HerHeart to practice (0-10) • Likelihood of incorporating #HerHeart into practice (0-10)

Phase 3: We will recruit 60 additional AYA women and the same 10 HCPs from Aim 1 to evaluate the #HerHeart tool's usability and feasibility. AYA participants will complete a brief initial survey consisting of demographic information and the Visual Analog Scale (VAS) and the #HerHeart tool in clinic. AYA participants will the rate the usability of the #HerHeart tool using the Website Analysis and Measurement Inventory (WAMMI), the likelihood they would recommend the app to their friends, and the likelihood of behavior change. AYA participants will then be offered the opportunity to continue into the 3-month intervention phase. We will document the reasons for declining as part of tracking feasibility. At the beginning of the intervention phase, participants will complete the Eating Disorder Diagnostic Scale (EDDS). Participants will then be texted 1 month and 2-months post-enrollment reminding them of any goals/areas of improvement indicated by their end assessment in the #HerHeart Tool. Three months post-enrollment, participants will attend the final study visit in the phlebotomy room on the second floor of CHOA Hughes Spalding. In this visit, AYA participants height, weight and blood pressure will be measured. Participants will also be asked to complete the #HerHeart tool again and the same online study scales collected at baseline (EDDS and VAS). They will also be asked to complete the Harvard Healthy Heart Score and evaluate the usability using the WAMMI. HCP participants will complete a survey consisting primarily of demographic information and the #HerHeart tool. HCP participants will then rate the usability of the tool using the WAMMI, the usefulness of the #HerHeart to their practice and the likelihood they would incorporate it into usual clinical care.

Data analysis will consist of descriptive statistics for the WAMMI and Likert scale surveys. Usability will be defined as >80% of AYA and HCP rating the application as above average on the WAMMI. Acceptability to HCP will be defined as a mean of 8 out of 10 Likert Scale items. Paired t-tests will be used to compare the baseline and 3-month data for the continuous scales (EDDS, VAS).

Primary outcomes will include changes in overall #HerHeart risk score, composite dietary score, fruit and vegetable intake, red/processed meats intake, soda and sweetened beverages intake, nut consumption, cereal fiber consumption, alcohol consumption, nicotine use, and physical activity over a 3-month period. Secondary outcomes will include changes in BMI and systolic and diastolic blood pressure over a 3-month period. Exploratory outcomes will include usability of the HerHeart tool and Healthy Heart Score as assessed by the WAMMI, adolescents' likelihood of recommending the tool to friend, adolescents' self-reported likelihood of behavior change, adolescents' understanding of heart disease risk as measured by VAS, change in EDDS score, number of participants approached and participated, completion/dropout rate, HCP rated usefulness of HerHeart tool to the practice, and HCP rated likelihood of incorporating HerHeart tool into practice.

All phases: The probability and magnitude of risks will be minimized by conducting study procedures in private settings, collecting data in REDCap, a secure web-based application designed exclusively to support data capture for research studies, and collaborating with the Georgia CTSA to ensure data security of the mobile app.

6. Data and Specimen Banking

Data from surveys/questionnaires, audio recordings, and interviews will be stored until the completion of data analysis and manuscript publication. Only approved study personnel listed on the protocol will have access to the data.

7. Sharing of Results with Participants

Personal Healthy Heart Score risk assessments will be shared with participants at each stage of the study. Participants will be encouraged to share their results with their primary care physicians, but results will not be directly shared with others.

8. Study Timelines

Individuals in Aim 1/Phase 1 will participate for ~one hour, one time. Individuals in Aim 2/Phase 2 will participate for up to two hours for each design session which will occur over 6 months. Aim 3/phase 3 will occur over 3 months. The total duration of the overall study is 15 months, which includes subject participation and data analysis.

9. Subject Population

Subjects will be recruited from the CHOA Hughes Spalding Adolescent Medicine Clinic and the Grady Teen Health Program. The following inclusion/exclusion criteria will be used for subject recruitment:

Inclusion Criteria (AYAs):

- Patient at CHOA Hughes Spalding Adolescent Medicine Practice or the Grady Health System Teen Program
- Age 13-21 years

- Self-identifying as non-Hispanic Black or White race (inclusive of Hispanic ethnicity)
- Self-identifying as female
- Visit type is annual wellness/health check, behavioral/mental health, or reproductive/gynecological health
- Consistent access to a mobile device with internet capability

Exclusion Criteria (AYAs):

- Cognitive impairment limiting ability to complete study procedure
- Spoken and written language other than English

- Diagnosis of hypertension, diabetes, or hyperlipidemia requiring medications, or atherosclerotic cardiovascular disease
- Past or current diagnosis of a DSM-V eating disorder
- Diagnosis of schizophrenia, bipolar disorder, or psychiatric hospitalization in the past 12 months
- Pregnant at the time of the study.

Inclusion Criteria (HCPs):

- Clinical team member (physician or nurse practitioner, nurse, social worker, psychologist, health educator, medical assistant, dietitian) at the CHOA Hughes Spalding Adolescent Medicine Practice or the Grady Health System Teen Program
- Practicing at one of the study sites at least twice per month on average over the past year

Exclusion Criteria (HCPs)

- Member of the research study team

10. Vulnerable Populations

The proposed study involves the vulnerable population of children under the legal age of consent to procedures involved in the research. Though the research involves no more than minimal risk, we will take safeguards to protect the rights and welfare of these individuals. Written parental permission will be obtained for all individuals under the age of 18 years if the parent or legal guardian is present at the time of recruitment. Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. Only parents or legal guardians listed in the child's medical record will be able to provide permission. We will request a Waiver of Parental Permission as permitted under permitted under 45 CFR 46.408(c) for those patients under 18 years of age who present alone for a visit for reproductive health visits. Adolescents have the legal right to seek care for certain sexual health services, including contraception and sexually transmitted infection testing and treatment, in the state of Georgia. To contact the parent or guardian for consent to participate in research would violate the adolescents' legal right to privacy by disclosing their presence at the clinical practice, even though the study does not discuss sexual health.

Additionally, we will obtain written assent from all children to ensure they understand the study and agree to participate. In the event a child's parent or guardian is not present, we will obtain written consent from the child using a consent form that provides adequate study information for the subject to make an informed decision. For patients 18 years or older, we will discuss how the study will use and disclose individually identifiable health information and obtain written consent. Because participants may receive clinical care from the PI or Co-I, who are providers at the CHOA Adolescent Medicine practice and the Grady Teen Health Program, the consent and

assent process will be carried out by the research coordinator. This will aid in minimizing coercion or undue influence by the PI.

11. Local Number of Participants

We will recruit 90 AYA subjects and 10 HCP subjects. Participants will be recruited from the CHOA Adolescent Medicine Practice and the Grady Health System Teen Program.

12. Recruitment Methods

For aims 1 and 3, the research coordinator will preliminarily screen AYA patients from the CHOA Adolescent Medicine Practice and the Grady Teen Health Program using the Epic Electronic Medical Record system. Patients who meet preliminary eligibility criteria (race, gender, age) will be added to the screening log (Screening Log.xlsx) and contacted via phone by the research assistant to see if they are interested in participating in the study when they come in for their clinical visit. For aim 2, participants will be recruited from the Emory Pipeline Collaborative (EPiC).

- Participants will be recruited both in-person and virtually, due to current COVID-19 public health recommendations.
- Patients reached via phone will be provided a brief overview of the study and the research coordinator will administer the screening eligibility questionnaire (Screening Survey.docx).
- Those who are eligible and interested in participating will be asked if they prefer to attend a study visit either an hour before or an hour after their clinical visit. Participants will also have the option to book a separate study visit at a time not related to their clinical visit, to occur via Zoom.
- Patients reached via phone who are not interested in participating will be noted as such on the screening log.
- Patients who are not reached via phone using the screening criteria but eligible for the study may still be approached at the time of their clinical visit.
- For patients attending the clinic in person, the research coordinator will approach eligible AYAs in the waiting room of the clinics and lead them to a private sitting area in order to provide a brief overview of the study and administer the screening eligibility questionnaire (Screening Survey.docx).
- For patients attending the clinic via telemedicne, the physician conducting the visit will ask the patient if they are interested in learning about the study. If so, the research coordinator will schedule a date and time with the patient to provide a brief overview of the study and administer the screening eligibility questionnaire via a password-protected Zoom videoconference.

If ineligible, participants will be informed that they are not eligible to participate in the study. If eligible, AYA participants will then carry out the consent and study procedures for each study phase as described in Section 21 and 6, respectively. Interested participants will the carry out

the study procedures as described in Section 6. Consent and study procedures will only occur in the context of a study visit, and not via initial phone screening and recruitment.

To assist with recruitment efforts, a recruitment flyer containing information about the study (eligibility requirements, study procedures, time commitment, etc.) will be distributed in the CHOA Adolescent Medicine practice. The flyers will be distributed to eligible patients who may not have time to begin the study procedures due to normal clinic flow (i.e., patient gets called back to exam room before we can consent them and begin the study).

Compensation for participants will be as follows:

- Aim 1: AYA and HCP subjects will receive a $25 gift card.
- Aim 2: AYA subjects will receive a $50 gift card.
- Aim 3: AYA will receive up to $60 and HCPs will receive $25

13. Withdrawal of Participants

Participants will be told that they can drop out of the study at any time during the study. Participants who become pregnant or become cognitively impaired throughout study duration will be withdrawn from the study without their consent. Furthermore, participants who become otherwise unable to participate in the research procedures due to health-related concerns will be withdrawn from the research without their consent at the discretion of the PI. Data collection will cease for participants who withdraw from the research and these individuals will not be included in the final data analysis.

14. Risks to Participants

This proposed study involves no more than minimal risk. Completion of the Healthy Heart risk assessment tool in its current form includes the risk that AYA participants disclose heavy alcohol or tobacco use. Participants may find learning about their cardiovascular risk distressing. After learning about their cardiovascular risk, participants may make changes to their exercise or dietary habits outside of what is recommended in the behavioral intervention or would be recommended by their HCP. Participation in the interviews also carries the risk of AYA's self-disclosure of health information. All efforts will be made to remind participants not to provide identifying information during the interviews. Breach of confidentiality is a risk for both AYA and HCP participants. To ensure participant confidentiality, study identification numbers will be assigned to each participant and used throughout the duration of the study when referring to subjects. The codes that link the name of the participant and the study identification number will be kept confidential by the PI in a secured cabinet. Only the authorized study team with appropriate training will have access to the data.

15. Potential Benefits to Participants

The direct benefit to AYA participants in the survey and interviews in each aim is gaining information about their health. The direct benefits to HCP in Aim 1 includes learning about new tools or methods that can potentially be used to increase CVD awareness in patients. Overall this study has the potential to inform prevention practices applicable to millions of young women living in the United States and to possibly lower the burden of cardiovascular disease among women.

Though not considered a benefit, subjects will be compensated for participation in this study. In Aim 1, AYA and HCP subjects will receive a $25 gift card for completing surveys and interviews. In Aim 2, AYA participants will receive a $50 gift card for participating in the design sessions. In Aim 3, AYA participants will receive $25 for completing the usability assessment and up to $35 for completing the intervention phase; HCPs will receive $25 for completing the usability assessment.

16. Data Analysis, Management and Confidentiality

The main aim of the proposed study is to adapt the Healthy Heart Score tool based on participant feedback. As such, all data will be descriptive only.

Data from surveys/questionnaires, audio recordings, and interviews will be stored until the completion of data analysis and manuscript publication. Only approved study personnel listed on the protocol will have access to the data. To secure the study data, all study team members will obtain appropriate biomedical or sociobehavioral CITI training. Only participants' study identification codes will be inputted into computer-based databases. The codes that link the name of the participant and the study ID will be kept confidential in a secured cabinet. The self-report measures will be administered via REDCap, which will be programmed to check data at the time of entry to ensure that entered values are within the specified range and that items are not inappropriately skipped. Questionnaire and audio recorded data will be imported directly into a password-protected data file stored on the Emory University server. The server is protected by the Emory network, and a secured log-in is required from all users.

17. Provisions to Monitor the Data to Ensure the Safety of Participants

We will establish a Data and Safety Monitoring Plan that consists of the PI and the biostatistician on the project. All data will be collected using computerized self-report questionnaires or recorded interviews. Only participants' study identification codes will be inputted into computer-based databases. The codes that link the name of the participant and the study ID will be kept confidential in a secured cabinet. The self-report measures will be administered via REDCap, which will be programmed to check data at the time of entry to ensure that entered values are within the specified range and that items are not inappropriately skipped. The data will be imported directly into a password-protected data file stored on the Emory University server. The server is protected by the Emory network, and a secured log-in is required from all users.

In order to ensure the integrity and validity of the data, [redacted] will conduct ongoing review of reports that describe study operations and present data by site to ensure that problems are identified and corrected in a timely manner. The following reports will be generated for routine review:

- Screening, recruitment, enrollment, and retention reports by each recruitment site
- Protocol compliance reports to identify protocol deviations by each recruitment site
- Data quality reports – describe missing, erroneous, and inconsistent data to ensure protocol is followed and deviations are tracked by each recruitment site
- Identification/reporting of serious adverse events
- Quarterly visits to clinical sites to review study procedures

If data quality and integrity issues are uncovered, the following correction processes will occur:

- If the quality of the data compromised, an audit of all related data will be conducted by [redacted].
- If systematic errors are uncovered, [redacted] will review these errors and update the protocol (with IRB approval) to address the cause of the systematic errors.
- If detection processes are not adequately discovering issues related to data quality, new processes will be developed to adequately detect data quality issues.
- If systematic protocol violations are occurring, staff will be retrained by [redacted]

Diligent safety monitoring will be conducted throughout this study in compliance with the following required elements of the Emory IRB's continuing review process:

1. Tracking of subject accrual (enrollment, drop-outs, demographics)
2. Timely and appropriate reporting of informed consent process deficiencies, protocol deviations, privacy breaches, conflicts of interest, and/or changes in personnel
3. Ongoing monitoring and appropriate reporting of adverse event activity including:
    a. frequency of unanticipated, internal, related or possibly related, and serious or more prevalent than expected adverse events

    b. frequency of deaths occurring during the study or within 30 days of study termination, even if expected or unrelated
4. Interim assessment of risk/benefit relationship in reference to adverse event occurrences, preliminary observations, and emerging information

5. Timely and appropriate IRB submission of safety-related documents such as audit reports, sponsor progress reports, and other materials or communications that might impact the safe conduct of this study
6. Active cooperation with the IRB and other applicable entities in the event of a random or for-cause internal or external audit

The PI and biostatistician will meet quarterly to review data quality and safety events, including any protocol deviations, and to adjudicate adverse events as required by the IRB. Additionally, participant safety monitoring will occur at each follow-up study visit. The PI will provide a summary of the DSM report to NHLBI on an annual basis. The DSM report will include the participants' socio-demographic characteristics, expected versus actual recruitment rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, and any actions or changes with respect to the protocol. The DSM report to NHLBI will also include, when available, the results of any data analyses.

18. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

Participants will interact with the research coordinator during recruitment, the informed consent process and data collection. Recruitment will occur via the phone or in-person in a private area of the waiting room. Informed consent and data collection tasks will be carried out in a private research room (in-person visits) or on a password-protected Zoom videoconference. There will be no other individuals interacting with or observing the participants. The PI and/or Co-I, who may be familiar with participants from their time receiving treatment in the clinic, will also interact with participants to answer study-related questions as needed. All questions will be answered in a private setting in order to reduce the risk of observation by anyone not participating in the research.

Only the PI, Co-I, and research coordinator will be able to access the participants' medical for the sole purpose of determining eligibility. Only the authorized study team on this proposal will have access to study-related data. All study staff will complete biomedical or socio-behavioral training through the Collaborative IRB Training Initiative Program (CITI). Data will be stored on the Emory servers in password-protected files.

To ensure participant confidentiality, study identification numbers will be assigned to each participant and used throughout the duration of the study when referring to subjects. The codes that link the name of the participant and the study identification number will be kept confidential by the PI in a secured cabinet. Only the authorized study team with appropriate training will have access to the data. All identifiers,

including audio files, will be destroyed after completion of data analysis and manuscript publication.

19. Economic Burden to Participants

Individuals will not incur any medical costs by participating in the proposed study. Costs related to transportation for study visits (i.e. vehicle fuel) are expected; however, participants will be compensated as follows:

- Aim 1: AYA and HCP subjects will receive a $25 gift card.
- Aim 2: AYA subjects will receive a $50 gift card.
- Aim 3: AYA will receive up to $60 and HCPs will receive $25. AYA participants will receive reimbursement/compensation for travel costs.

20. Consent Process

Written informed consent will be obtained for all individuals 18 years and older. For patients under the legal age of consent (17 years and younger), written assent and parental permission will be obtained if the parent or guardian is present in clinic. If the parent or guardian is not present in clinic, and contacting them to consent to the research would violate the adolescent's right to privacy regarding certain sexual health services, we will invoke the Waiver of Parental Permission given this study poses no more than minimal risk. For those visiting the clinic in person, patients and their parent/legal guardian (if present) will be approached either via the pre-visiting screening and recruitment process or in the waiting room of each recruitment site to see if they are interested. In either case, the research coordinator will carry out the consent/assent process in a private room (research room) of the clinic. For those visiting the clinic via telemedicine, the physician will ask patients and their parent/legal guardian (if present) if they are interested in receiving more information about the research study at a later time. If so, the research coordinator will schedule a time to contact the potential participants and carry out consent/assent procedures using a password-protected Zoom videoconference. The consent process will take approximately 15 minutes. If the eligible participant or the parent/legal guardian has any questions about the study, they will be answered at this time. In order to minimize the possibility of coercion or undue influence, the consent process will be carried out by the research coordinator, who has no influence on or connection to the medical care received by the patients. The research coordinator will not obtain a written signature for consent until the entire study has been explained and all questions have been answered.

Non-English-Speaking Participants

The data collection instruments used in the study will be written in English. Therefore, it will be inappropriate to include subjects who are not proficient in English. This is not to say that the research topic does not apply to adolescents who are not proficient in English; however, addressing these populations within the proposed study would not be possible.

Participants who are not yet adults (infants, children, teenagers)
Prospective participants who have not attained the legal age for consent (e.g. individuals under the age of 18 years), as determined by the age in their medical record, will be required to give written assent. Written parental permission will also be obtained for these individuals if the parent or guardian is present. Parental permission will be obtained from one parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. Only parents or legal guardians listed in the child's medical record will be able to provide permission. If the parent or guardian is not present, we will not contact them for the sole purpose of informed consent as doing so may violate the adolescents' right to private healthcare for certain sexual health services. We will instead present the participant with a consent form that provides enough information for the subject to make an informed decision. Given this study includes no more than minimal risk, we have applied for a Waiver of Parental Permission as permitted under permitted under 45 CFR 46.408(c) for those patients under 18 years of age who present alone for a visit for reproductive health visits.

21. Setting

Participants will be recruited from the CHOA Hughes Spalding Adolescent Medicine Practice and the Grady Health Teen Clinic Program. For patients visiting the clinics in person, recruitment procedures will take place either before the visit using the screening and recruitment phone call or in the waiting rooms of each clinic, while consent/assent and study procedures will take place in a private office. For patients visiting the clinics virtually (telemedicine) recruitment, consent, and study procedures will take place via Zoom videoconferencing (password-protected). Participants who agree to participate in the intervention in Aim 3 will attend a study visit at the Emory Children's Center Research Unit.

A CHOA community advisory board will be made available to us. The advisory board consists of local business, community and nonprofit leaders who are not only dedicated to community service, but also focused on the needs and well-being of children in their communities. Board members work as advocates and liaisons between the community and Children's.

22. Resources Available

The CHOA Hughes Spalding Adolescent Medicine Practice serves approximately 2000 adolescents ages 13-21 years of age annually for primary care wellness visits, as well as consultative behavioral/mental health and reproductive health visits. The Grady Teen Clinic, a Title X funded family planning program, provides a dedicated teen-friendly space to both male and female adolescents ages 12 through 20 years and serves approximately 1500 adolescents annually. For the proposed study, we will need to

recruit 60 AYA participants ages 13-21 years over the course of one year. We will devote three days out of the week to recruitment in order to reach our recruitment goal.

Both medical and psychological resources are available to participants who experience anticipated consequences of human research. [redacted], the project PI, is a provider at the CHOA Adolescent Medicine practice and can provide research-related care to patients at the recruitment site, as needed. Additionally, [redacted], the project Co-I, is a provider at the Grady Health Teen Program and can provide research-related care to patients at the recruitment site, as needed. The Adolescent Medicine practice also has two additional medical doctors, a nurse practitioner, and a licensed psychologist who will be made aware of the research study and will be able to provide care as needed to patients experiencing any stress identified via the research protocol. The Grady Health Teen Program has an additional medical doctor, a nurse practitioner, and a health educator/case manager who will be made aware of the research study and will be able to provide care as needed to patients experiencing any stress identified via the research protocol.

All persons assisting with the research will be adequately informed about the protocol, research procedures, and their duties and functions. Furthermore, all persons assisting with the research will receive appropriate CITI training

23. References

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