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Addressing Social Determinants of Health during Clinical Care Visits to Promote Equitable Behavior Change and PREVENT Cardiovascular Disease

Protocol Version 8
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Background and Introduction:

Obesity among youth in the United States, particularly those of low-socioeconomic status (SES), is a major public health concern that puts youth at risk for poor cardiovascular health (CVH).[1-3] Inequities may be due, at least in part, to differential delivery of and compliance to behavior change prescriptions.[4] Environmental barriers (*e.g.,* poor access to safe places play and healthy food outlets) more prevalent in low-SES neighborhoods may prevent patients from being active and eating healthy which can improve CVH.[5-7] Health equity depends on the successful implementation and sustainment of tailored, evidence-based interventions to address risk behaviors in settings (*e.g.,* clinics) that reach a large number of adolescents.

Social determinants (*e.g.,* social and built environments) have an important impact on health outcomes.[8-10] Yet these factors are often ignored at the point-of-care. Providers lack time and patient- and community-specific data necessary to provide tailored, evidence-based care within their routine practice.[11] Interactive Behavior Change Technology enables a data-driven, patient-centered approach to prevention that has potential to be scaled across clinics, populations and disease types.[12] Increasing awareness of community resources (*e.g.,* parks, community centers, farmer's markets) has resulted in weight loss in children.[13] Yet, an EHR-compatible tool has not been used to provide adolescents with patient-centered, community resources at the clinic visit. This research will fill this critical gap with our novel Patient-centered Real-timE interVENTion (PREVENT) tool.

Significance:

Only 4% of adolescents meet the American Heart Association's Life Simple 7 CVH metrics (*e.g.,* obesity, physical activity and healthy food intake) that are important for preventing cardiovascular disease, and this percentage was even lower among those of low-SES. [3,7,14-16] Increasing physical activity and healthy food intake using effective interventions that are scalable, sustainable, and elicit equitable change across populations are necessary to address the approximately 19% of adolescents with obesity.[7]

Primary care physicians reach a large number of adolescents and have the potential to reduce poor CVH during well-child visits.[17] Yet, providers lack the training and time to identify and address health behavior issues.[18,19] Evidence-based behavior change has not been adopted into practice, despite technological advances (*e.g.,* Interactive Behavior Change Technology) that can facilitate this with little burden.[20]

To achieve health equity, behavior change interventions should address the environment surrounding at-risk youth.[21] The ability to be physically active and improve healthy food intake is dependent on the built environment[22-24] and/or knowledge of existing resources and infrastructure (*e.g.,* transportation) to access resources, particularly for low-SES populations.[25-28] Linking youth and their families to resources (*e.g.,* parks, community centers, healthy food outlets) is a practice that aligns with the American Academy of Pediatrics recommendations for community pediatricians[29] and the Chronic Care Model.[30] Several primary care-based interventions have linked patients to community resources and show promising weight loss in adults and children.[13,31,32] Yet, taking such

interventions, coupled with evidence-based behavior change strategies and integrating them into a clinical practice workflow has not been tested in adolescents.

1.0 Study Aims:

The proposed research will test the feasibility of administering PREVENT, a pragmatic, equitable approach to prevention, in the Late Effects Clinic at St. Louis Children's Hospital and the St. Louis Children's Specialty Care Center (CSCC) to prepare for subsequent implementation and dissemination. The central hypothesis is that PREVENT will improve patients' attitudes toward behavior change recommendations, to better adhere to recommendations and improve CVH.

Aim 1. Determine barriers to current and future implementation of the PREVENT tool (e.g., usability, acceptability, motivation, workflow compatibility) to inform adoption and maintenance.

Aim 2. Assess the impact of the PREVENT tool on patients' attitudes toward behavior change recommendations and on the control of CVH risk factors (*e.g.,* body mass index [BMI], physical activity and healthy food intake).

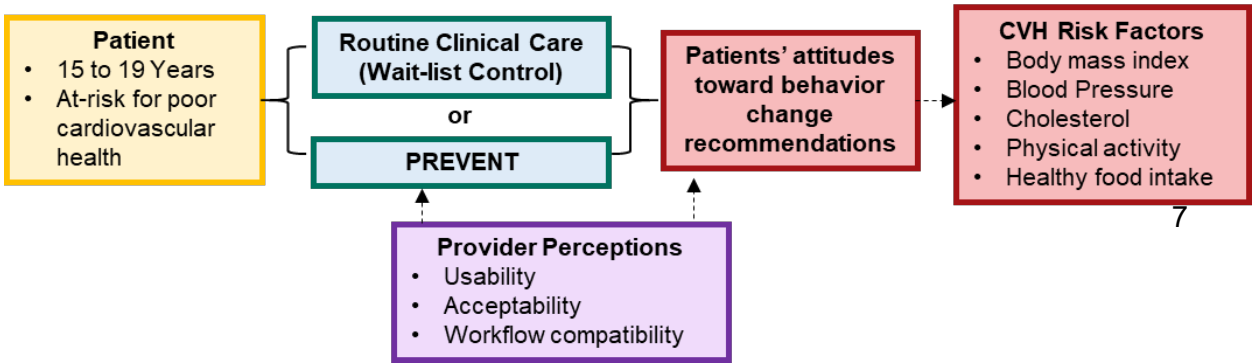
2.0 Summary of Study Plan

Table 1: Timeline of Activities (by quarter)

Year	1				2			
Quarter	1	2	3	4	1	2	3	4
Recruit Advisory Board								
Develop Manual of Procedures								
IRB Approval								
Train Study Staff								
Advisory Board Bi-Annually								
Recruit								
PREVENT Feasibility Study								
Data Analysis								
Manuscript Development								
Refine PREVENT Tool								
R01 Submission								

Fifty adolescents aged 12 to 19 years at risk for poor CVH (BMI ≥ 85th percentile) will be recruited over a 9-month period (**Table 1**) from the Late Effects Clinic and randomized to intervention or wait-list control (**Figure 1**). Provider's and patient's perceptions of barriers to implementation and maintenance of PREVENT (*e.g.,* usability, acceptability, motivation for use, workflow compatibility) will be examined using: 1) surveys administered to all providers at clinic; 2) semi-structured interviews with 5-10 diverse providers (*e.g.,* physicians, nurses, clinic staff, clinical research associates); and 3) two focus groups, one with patients (n=10) and one with parents (n=10) (**Aim 1**). These evaluations will be guided by RE-AIM[33] and administered following the intervention period. Implementation (*e.g.,* intervention delivery, fidelity, time

Figure 1: Feasibility Trial Overview



of use) will be examined using direct observation and audio recordings of 15 provider-patient interactions while using PREVENT. Patient attitudes toward behavior change recommendations and risk factors (BMI z-score, cholesterol, blood pressure, physical activity and food intake) will be measured using surveys, physical activity tracking devices (accelerometers) and EHR-data extraction at baseline and 3-months (**Aim 2**). An advisory board will be established and meet bi-annually to provide adolescent (n=5), parent (n=5) and provider (n=5) perspectives on study implementation and inform revisions to PREVENT.

Key dates (Table 1).

- Provider training: October 2020-January 2021
- Patient recruitment: February 2021- April 2021
- PREVENT feasibility study: January 2021-September 2021

3.0 Study Population

We will evaluate the PREVENT tool at the Late Effects Clinic at St. Louis Children's Hospital and the CSCC with:

1. Fifty adolescents aged 12 to 19 years at risk for poor CVH (BMI $\geq 85^{th}$ percentile) and their parents.
2. All providers and clinic staff (physicians, nurses, clinic staff, clinic research associates) who were involved with the implementation of PREVENT at the Late Effects Clinic.

3.1 Patient eligibility criteria.

1. Adolescents 12 to 19 years
2. Prior diagnosis of pediatric cancer (diagnosed <21 years of age).
3. Not receiving active therapy for their cancer
4. Receiving care from the Pediatric Hematology/Oncology staff and physicians at St. Louis Children's Hospital or the St. Louis Children's Specialty Care Center
5. At risk for poor CVH (BMI $\geq 85^{th}$ percentile)

3.2 Provider eligibility criteria. All providers and clinic staff (physicians, nurses, clinic staff, clinic research associates) in the Pediatric Hematology/Oncology program at St. Louis Children's Hospital and the CSCC.

3.3 Parent eligibility criteria. A parent or legal guardian of a study participant. The parent or legal guardian must have been present at the clinic visit in which the PREVENT tool was administered to the study participant.

4.0 Study Procedures

4.1 Recruitment

4.1.1 Patient recruitment. A designee at the clinic will query the clinic's EHR using inclusion/ exclusion criteria to develop a list of eligible patients with contact

information (parent contact information will be used for patients ≤18 years). Study staff will mail a letter informing them of the study and then recruit via telephone. The letter will be addressed to the parent/guardian if the patient is ≤18 years of age; otherwise, the letter will be addressed to the patient. The recruiter will describe the study and administer a phone-based screener. If interested and eligible, patients will be consented and enrolled.

A subset of patients (n=10) and their parent (n=10) will be recruited to participate in a focus group discussions following the intervention period. Recruitment will leverage contact information collected during the feasibility trial to recruit over the phone or email.

4.1.2 Provider recruitment. The study team will present the study and review the consent document at the clinic's monthly research meeting and allow time for providers to ask questions. If an eligible provider is not in attendance, the provider will be contacted via email to schedule an individual meeting conducted over zoom to explain the study and review the consent document.

4.2 Enrollment and Consent

4.2.1 Patient enrollment. If patient is interested, the consent form will be reviewed over the phone. Adequate time will be allotted to allow the patient to ask any questions. Additionally, the patient may use the contact information provided on the consent document to follow-up with additional questions prior to completing the consent. If the patient is 18 years or younger, we will ensure that the parent is on the phone while we review the consent document. If the parent is not available, we will call back to discuss the consent form. Following this conversation, an electronic consent (developed in REDCap with guidance from the ICTS mHealth Research Core) will be emailed. The study team will send a test email in a secure manner (i.e., [secure] in subject line) prior to sending consent to verify the participant's identify. The email will instruct the participant to send all information as a response to this thread and not to remove the "[secure]" from the subject line. All future email correspondence will follow this protocol. If the patient is 18 years or younger, the parent and patient will be required to complete the consent document. If the patient is at least 19 years of age, the parent is not required to provide consent. If the patient does not have access to complete an electronic form, a consent will be mailed with a return envelope to receive written consent. Postage costs will be covered by the study. Once consent is obtained, the patient will received an emailed or hard copy of the signed document. Following consent, the patient will complete baseline measures (questionnaires administered electronically or by mail; accelerometers administered by mail). Following baseline measurement, patients will be randomized to intervention or wait-list control and attend their clinic visit. The study staff will call the participant one-week before their clinic visit to remind them of their appointment time, give them details about the appointment and address any barriers they may be facing to complete baseline measurements. Follow-up

measures will be administered immediately following the clinic visit (within 48 hours) and 3-months after the clinic visit electronically and by mail. Patients will only return to the clinic for a routine visit at 3-months if it meets their standard of care based on their baseline clinical values for CVH risk. Wait-list control will be sent tailored prescriptions via the PREVENT tool following the completion of follow-up measurements. Participants will receive up to $75 dollars in gift cards for participation. Participants will receive $25 after baseline, $25 after 3-month follow-up and $25 for wearing an accelerometry device to measure their physical activity.

Patients (n=10) and their parents (n=10) who participate in focus groups will provide an additional written consent in-person prior to the start of the discussion. Consent will be administered in a single room with patients and parents. Once consent is administered, patients and parents will be divided into two private rooms to conduct separate focus groups simultaneously.

4.2.3 Provider enrollment

Following the presentation of the study at the clinic's monthly research meeting, all eligible providers will be sent electronic consent documents and provided with Dr. Kepper's contact information (phone and email) to ask additional questions. If consent is not received, the study team will follow-up with providers via email or phone.

4.3 Schedule of Events

4.3.1 Patient Schedule of Events

We anticipate that study participation will be between 4 and 5 months from the point of recruitment to completion **(Figure 2)**.

Figure 2: Timeline of events for an enrolled patient.

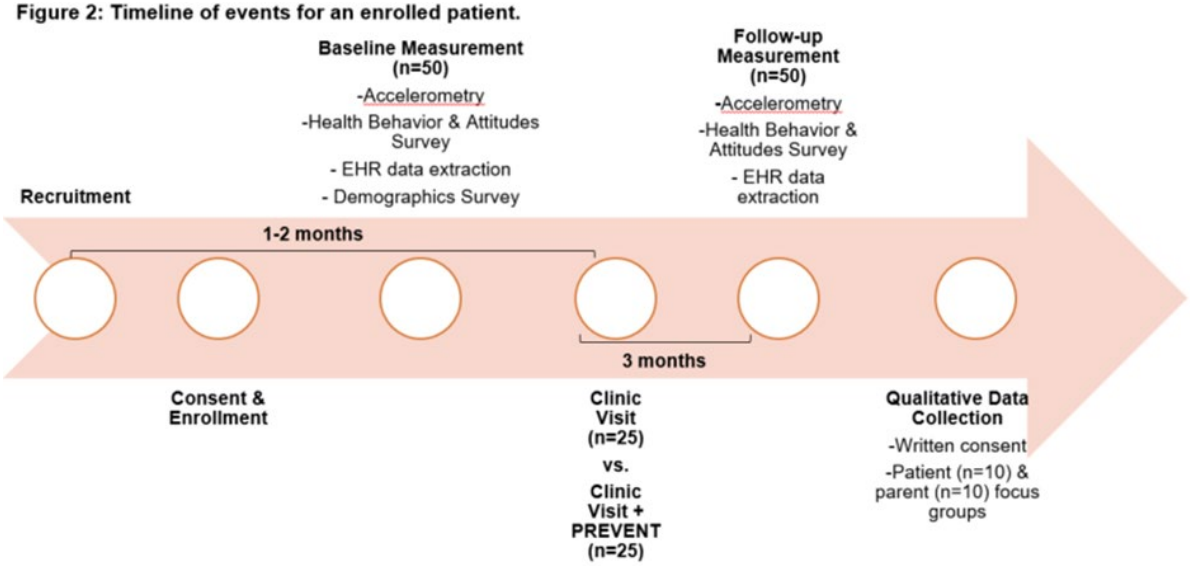
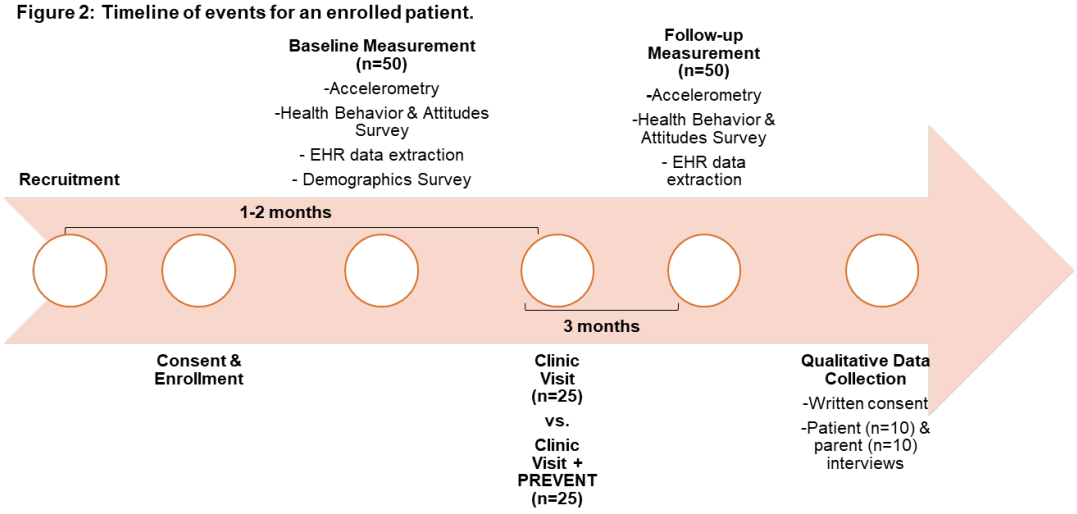


Figure 2: Timeline of events for an enrolled patient.



Consent, enrollment & baseline measurement will occur electronically or via mail prior to the clinic visit. The patient will complete a written signed consent,

complete a survey assessing their health behaviors and attitudes and wear an accelerometry device for 7 days prior to the clinic visit. Parents/legal guardians of study participants will be asked to complete a baseline demographics survey delivered electronically before the clinic visit or completed in the waiting room at the clinic visit. In addition, study staff will extract EHR data (patient demographics and CVH risk factors) and upload the most recent information into the PREVENT tool prior to the patient's clinic visit. The patient will be randomized to intervention or wait-list control.

PREVENT tool interaction (intervention). The patient will attend a routine clinic visit remotely or in-person at the Late Effects Clinic at either St. Louis Children's Hospital or the St. Louis Children's Specialty Care Center. During this visit, the provider will use PREVENT on a tablet or computer (in-person or via a teleconference call) to discuss risk, and deliver a tailored behavior change plan inclusive of patient-centered community resources. The PREVENT tool will be pre-loaded by study staff with all necessary patient information (demographics and CVH risk factors) and show the date in which these data were collected. The provider may update any patient information at the time of the visit. PREVENT uses a robust informatics approach developed by Dr. Foraker (secondary-mentor)[34-36] to visually display Life's Simple 7 Cardiovascular Risk Factors (*e.g.,* weight, blood pressure, inactivity) and calculate the patient's overall risk for developing cardiovascular disease. Physical activity and food intake recommendations that are tailored to the patient's current weight status and health behaviors using evidence-based recommendations (Trim Kids,[37] the Stoplight Diet[38]) proven to be effective in youth are delivered to the patient. An interactive map of community resources near the patient's home will allow the patient to select resources that will support the recommended behavior change. Community resources (e.g., parks, fitness and recreation centers, farmer's markets, food pantries) were pulled from YELP using an API key. Resources were validated against lists manually generated via online searching of physical activity and food departments and organizations (e.g., the department of parks, recreation and forestry) and google. A final action plan (behavior change prescription, community resources and education) will be provided to the patient at the visit and/or electronically via email or text-message. Patient follow-up will be supported by automatic email or text-message check-ins at 4, 8 and 12 weeks. Within the 4-, 8- and 12- week email/text message check-ins the patient will be asked to answer questions about meeting their physical activity and nutrition goals. Based on the response, the patient will receive an automated email and/or text message with an updated prescription.

Wait-list control. Patients will attend a routine care visit in-person or remotely. A PREVENT action plan (behavior change prescription, community resources and education) will provided to the patient via email after the completion of follow-up measurement.

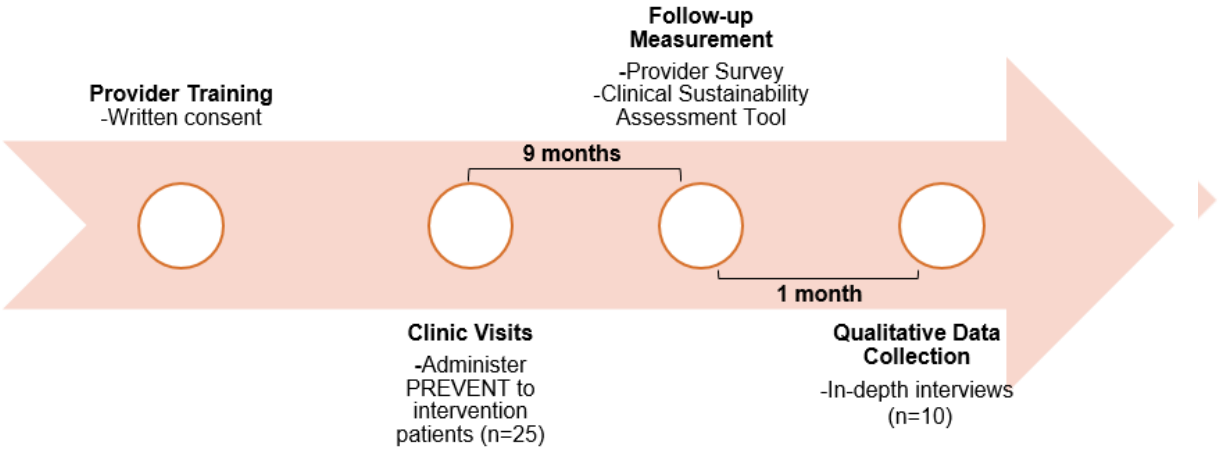
Follow-up measurement. Immediately following the clinic visit (within 48 hours) all patients will be sent electronically a brief 10-question (yes/no) survey regarding their clinical interaction. Participants randomized to intervention will also receive questions about their satisfaction with the

PREVENT tool. Three months after the patient's clinic visit, they will be sent the Health Behavior & Attitudes Survey electronically and an accelerometer via mail. Only patients who presented with abnormal values for CVH risk factors will return to the Late Effects Clinic to complete a routine clinic visit in accordance with the standard of care for these high-risk patients. Study staff will extract the most-recent EHR data for CVH risk factors for all patients.

Qualitative data collection. Semi-structured interviews will be completed within one month of the completion of follow-up measurement for all participants that received the PREVENT tool.

4.3.2 Provider Schedule of Events

Figure 3: Timeline of events for providers.



We anticipate that providers study participation will be approximately 11 months in duration. All providers at The Late Effects Clinic will be invited to view an online training on how to use the PREVENT tool prior to the start of patient recruitment. The online training will be recorded and disseminated to ensure that all providers are able to view the training. At this time, providers will be supplied login credentials to access the PREVENT tool. Following the training, all providers will be asked to complete the Clinical Sustainability Assessment Tool electronically. Once the intervention period begins, study staff will notify the provider if their patient was randomized to intervention to ensure that PREVENT is used during the care visit. Tablets will be available at the clinic if providers choose to use them to administer the PREVENT tool. However, the PREVENT tool can be administered via any computer or tablet using their login credentials. A subset of patient-provider interactions (n=15) may be observed and recorded while PREVENT is being used. Providers who used PREVENT will be asked to complete an electronic follow-up survey. Within one month of completing the intervention, providers will participate in in-depth interviews. Interviews will be held in-person, over the phone or using zoom technology.

4.4 Data Collection Methods

Theoretical underpinnings. This feasibility study will apply principles of Designing for Dissemination, Implementation and Sustainability (D4DIS) to understand factors critical to external validity and refine the existing PREVENT tool to fit well with provider's and patient's needs, assets and timeframes.[39] We seek to speed translation of the PREVENT tool into practice by simultaneously collecting mixed method data regarding determinants of current and future implementation of the PREVENT tool, guided by the new Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) framework.[40,41] The updated RE-AIM framework will be used to identify barriers to implementation and dissemination as outlined in **Table 3**.

Table 3: RE-AIM Outcome Measures

RE-AIM Construct	Measure	Data Source	Stakeholder
Reach	Representativeness compared to eligible clinic population	EHR data; Demographics survey	Patients
Efficacy	Changes in health behaviors and attitudes; Change in CVH risk factors	Health Behavior & Attitudes Survey; accelerometry; EHR data	Patients
Adoption	Usability; acceptability; consistency with priorities/values	Patient and parent interviews; Provider survey	Patient, parent, provider
Implementation	Intervention delivery; fidelity to the protocol; time of PREVENT use; compatibility with workflow	Direct observation, audio recordings of implementation	Patient
Maintenance	Barriers and enabling factors for continued implementation of PREVENT	Qualitative interviews; Provider survey; Clinical Sustainability Assessment Tool	Provider

4.4.1 EHR data extraction. Patient demographics (e.g., sex, date of birth, race/ethnicity) and the most recent risk factors for CVH (height, weight, fasting blood glucose, total cholesterol, blood pressure, smoking status) will be extracted at baseline (prior to clinic visit) and at follow-up (3-months). Available EHR data will be uploaded into PREVENT prior to the clinic visit but may be updated within the PREVENT tool at the time of the clinic visit if updated values are attained. CVH risk factor data within the tool at the time of the clinic will be used as baseline values and used to determine changes from baseline to follow-up. Only patients with abnormal baseline values will return for a follow-up clinic visit at 3-months. Therefore, we acknowledge that not all patients will have updated

information for CVH risk factors (BMI, fasting blood glucose, total cholesterol and blood pressure) from baseline). This feasibility study is intended to determine what data are commonly available for a future study. We expect that height and weight will be the most commonly available data point at baseline and 3-months. Therefore, body mass index (BMI) is our primary health outcome and will be calculated based on CDC growth charts using height and weight.

4.4.2 Demographics Survey will be used to collect parent and family demographics (e.g. annual household income, education-levels, family's medical history) from parents of study participants (n=50) at baseline. The survey will be sent electronically using REDCap to give the parent the option of completing the survey prior to the clinic visit. Alternatively, the parent may complete the questionnaire while in the waiting room at the clinic.

4.4.3. Health Behavior & Attitudes Survey will be used to collect physical activity and nutrition behaviors and attitudes from adolescent patients (n=50) at baseline and follow-up. This information will be used to populate the PREVENT tool's risk profile and determine changes in physical activity and nutrition behaviors and attitudes from baseline to post-intervention. The physical activity questions are adapted from the International Physical Activity Questionnaire (IPAQ) that has been validated for use in adolescents.[42,43] Nutrition questions are generated based on the Stoplight Diet[38] for adolescents and the Rapid Eating Assessment for Participants - Shortened Version.[44] Attitudes toward behavior change questions were adapted from two validated surveys: 1) [45-47]the Treatment Self-Regulation Scale [48,49] and 2) the Rapid Eating Assessment for Participants - Shortened Version.[44]

4.4.4 Accelerometers will be administered to patients at baseline and 6-month follow-up to objectively measure levels of physical activity (light, moderate, vigorous) and sedentary behaviors. At baseline, accelerometers will be mailed to participants after consent is obtained and returned by mail using a provided pre-paid envelop or at the clinic visit. The following materials will be sent via mail with the accelerometer device: a pre-paid return envelope, a welcome letter, and directions for use. Participants randomized to the intervention group will also receive a document detailing "what to expect" at their clinic visit. At follow-up, accelerometers will be mailed including a pre-paid return envelope. Participants will be asked to wear the device for 7 days including 2 weekend days on a belt (provided) around their waist. Participants will be instructed to remove the device only when bathing or swimming; they will continue to wear the device while sleeping.

4.4.5 Patient and parent qualitative interviews will examine facilitators and barriers to *maintenance*. Semi-structured interviews will be conducted individually with patients (n=10) and parents (n=10). Questions will assess satisfaction with their provider interaction, the PREVENT tool's design, physical activity and nutrition prescriptions, community resources (*e.g.,* are there other resources that would be helpful, did these resources help you or your child achieve the goals)

and, more generally, other ways the clinic may help them achieve behavior change.

4.4.6 Provider survey will be conducted following the intervention to evaluate *adoption* and understand potential for *maintenance.* All providers will complete a web-based survey adapted from five previous instruments. The acceptability, appropriateness, and feasibility of the PREVENT tool will be assessed using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM).[44] Questions regarding the provider's satisfaction with five aspects of health information technology: content, accuracy, format, ease of use and timeliness are adapted from Dr. Foraker's (Co-I) previous research.[34] Question to assess providers intent to change their behavior and continue using PREVENT (maintenance) were adapted from Legare's CPD Reaction Questionnaire.[50-52] We also include several team-developed items to align with previous measurement in the tool development phase.

4.4.7 Direct observation, audio recordings of 15 patient-provider interactions will generate the following *implementation* outcomes: the delivery of the PREVENT tool (*e.g.,* who is delivering the tool, how the provider delivers the information), whether it was delivered as intended (fidelity) and compatibility with clinic workflow. Additionally, observation will provide information on how the patient interacts with the tool. An observation form will be used by study staff to systematically observe PREVENT use. Audio recording will occur only while PREVENT is being used and will be assessed by two study staff to identify themes in patient-provider interaction and clinical decision-making.

4.4.8 Patient follow-up surveys will be sent electronically at 4-, 8- and 12-weeks to assess whether patient's are obtaining their physical activity and food intake goals and provide tailored feedback (e.g., updated goals and motivation).

4.4.9 Provider qualitative interviews will be conducted following the 4-month period to understand potential for *maintenance*. Thirty-minute interviews will be performed with a diverse group of 5-10 providers (*e.g.,* physicians, physician assistants, nurses, clinic staff) at the clinic, by phone or by zoom technology. Interviews will be used to gain in-depth insight on what providers liked about the PREVENT tool, whether PREVENT is consistent with their and their clinic's priorities/values, and barriers and enabling factors for sustaining PREVENT in their clinic.

4.4.10 Clinical Sustainability Assessment Tool (CSAT) will be administered to all providers at the Late Effects Clinic following the intervention. CSAT will be administered to determine clinic-level readiness and capacity for sustainability of the PREVENT tool.[53] Clinic-level factors include organization, financial, regulatory and political barriers.

5.0 Statistical Considerations

5.1. Hypotheses.

Aim 1. We hypothesize that the majority of providers, patients and parents will express positive views about the PREVENT tool and its sustained use in clinical settings.

Aim 2. We hypothesize that patients who receive PREVENT will have greater improvements in attitudes toward behavior change recommendations, adherence to recommended behavior change and CVH compared to those who did not receive PREVENT during their clinic visit.

5.2. Data Analysis Plan

Statistical analysis will be performed using SAS v9.4 (quantitative data) and NVivo12 software (qualitative data).

For our Aim 1 hypothesis, analyses will be largely descriptive (using means, medians and frequencies) for adoption, implementation and maintenance outcomes using survey and observation data. Aim 1 will also be tested using qualitative data. In-depth interview and observation data will be professionally transcribed, anonymized, and imported into NVivo10 software for thematic analysis. The following steps will be performed for in-depth interviews and observation data. Guides will be developed and piloted. Coders (n=2) will read over all transcripts and develop a draft of the coding tool. We will practice coding at least three transcripts together to make sure all concepts are adequately captured in the tool. Once the tool is finalized, coders will be assigned transcripts for coding, ensuring each one will be coded by at least two people for reliability and decreased positionality bias. We will summarize codes into general themes and highlight main findings with quotes.

Our Aim 2 hypothesis will be tested using EHR data, accelerometry and patient survey data. Accelerometry data will be processed and analyzed using Actigraph software and SAS v9.4 using protocols validated in adolescents. The participants' demographics and anthropometrics will be summarized using mean and standard deviation by treatment groups. The differences of factors of interest (physical activity, dietary intake, and CVH risk factors) between the 2 study groups at baseline will be compared using linear regressions. Change from baseline between study groups will be tested using linear regressions. Statistical significance will be defined as $p<0.05$.

Ultimately, Aim 1 and Aim 2 quantitative and qualitative data will be integrated to determine overall feasibility, revise the PREVENT tool and identify barriers to current and future implementation that will inform an implementation strategy for the larger trial.

6.0 Data Management

Data will be stored on a secure information technology-maintained computing infrastructure behind the Washington University in St. Louis firewall, which has been certified to store protected health information. Paper forms will be stored in the principal investigators locked

office in a locked file cabinet. Accelerometry data will be downloaded and stored on the secure Washington University Server using patient ids. Data will be erased from the device immediately following download. All audio recording of patient visits and interviews will be transferred onto the secure server and de-identified. Audio-recordings will be deleted from the physical devices. Data from the PREVENT tool will also be stored on a secure information technology-maintained platform (Google Firebase) that complies with HIPPA standards. We will take consistent measures to protect the confidentiality of these data. When the data are collected and ready for analysis, the dataset will be downloaded by Dr. Kepper and used only for the purposes identified in these analysis. Only approved members of the research team will have access to these data.

Table 4. Summary of Data Storage

Data	Location
Informed consent/assent documents	REDCap; paper forms
Healthy Behavior Survey	REDCap
Acclerometry data	Washington University Server
EHR data	Washington University Server
Direct observation form	REDCap
Provider qualitative interviews	Washington University Server
Provider survey	REDCap
Adolescent and parent interviews	Washington University Server
Data entered into PREVENT	Google Firebase

7.0 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed (three years after closure of the study), consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

8.0 Data Safety and Management

8.1 Data Safety and Monitoring Board The principal investigator (Dr. Kepper) will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

8.2 Reporting of Unanticipated Problems, Adverse Events or Deviations Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

9.0 References

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