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## Addressing cancer survivors' cardiovascular health using the Automated Heart Health Assessment (AH-HA) EHR tool: Initial protocol and modifications to address COVID-19 challenges

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### Recommended Citation

Foraker, Randi E; Davidson, Eleanor C; Dressler, Emily V; Wells, Brian J; Lee, Simon Craddock; Klepin, Heidi D; Winkfield, Karen M; Hundley, W Gregory; Payne, Philip R O; Lai, Albert M; Lesser, Glenn J; and Weaver, Kathryn E, "Addressing cancer survivors' cardiovascular health using the Automated Heart Health Assessment (AH-HA) EHR tool: Initial protocol and modifications to address COVID-19 challenges." *Contemporary Clinical Trials Communications*. 22, 100808 (2021).  
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Contents lists available at ScienceDirect

# Contemporary Clinical Trials Communications

journal homepage: <http://www.elsevier.com/locate/conctc>

## Addressing cancer survivors' cardiovascular health using the automated heart health assessment (AH-HA) EHR tool: Initial protocol and modifications to address COVID-19 challenges

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### ARTICLE INFO

#### Keywords:

Electronic health records  
Clinical decision support  
Usability testing  
Cardiovascular diseases  
Cancer survivors  
Breast cancer

### ABSTRACT

**Background:** The purpose of this paper is to describe the Automated Heart-Health Assessment (AH-HA) study protocol, which demonstrates an agile approach to cancer care delivery research. This study aims to assess the effect of a clinical decision support tool for cancer survivors on cardiovascular health (CVH) discussions, referrals, completed visits with primary care providers and cardiologists, and control of modifiable CVH factors and behaviors. The COVID-19 pandemic has caused widespread disruption to clinical trial accrual and operations. Studies conducted with potentially vulnerable populations, including cancer survivors, must shift towards virtual consent, data collection, and study visits to reduce risk for participants and study staff. Studies examining cancer care delivery innovations may also need to accommodate the increased use of virtual visits.

**Methods/design:** This group-randomized, mixed methods study will recruit 600 cancer survivors from 12 National Cancer Institute Community Oncology Research Program (NCORP) practices. Survivors at intervention sites will use the AH-HA tool with their oncology provider; survivors at usual care sites will complete routine survivorship visits. Outcomes will be measured immediately after the study visit, with follow-up at 6 and 12 months. The study was amended during the COVID-19 pandemic to allow for virtual consent, data collection, and intervention options, with the goal of minimizing participant-staff in-person contact and accommodating virtual survivorship visits.

**Conclusions:** Changes to the study protocol and procedures allow important cancer care delivery research to continue safely during the COVID-19 pandemic and give sites and survivors flexibility to conduct study activities in-person or remotely.

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<https://doi.org/10.1016/j.conctc.2021.100808>

Received 9 September 2020; Received in revised form 14 May 2021; Accepted 13 June 2021

Available online 16 June 2021

2451-8654/© 2021 The Authors.

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## 1. Introduction

Although the Institute of Medicine (IOM) provides recommendations to coordinate care and prevention efforts for cancer survivors [1–3], up to 20% of breast and colorectal survivors may not see a primary care provider, [4,5], heightening their risk for lack of preventive services and poor comorbidity management [5–7]. Claims data reveal that only 31–39% of breast cancer survivors received cholesterol screening, significantly fewer than matched women without breast cancer [7]. Ninety percent of oncologists we surveyed reported cardiovascular health (CVH) discussions to be “somewhat” or “very” important; however, 58% “rarely” or “sometimes” discuss CVH with their patients [8]. As a result, oncologists make few referrals for cardiovascular (CV) care to primary care and cardiology for guideline-driven follow-up care [9–12]. Nearly 35% of cancer survivors do not receive assistance from a healthcare provider for lifestyle change [13].

In response to this gap, we developed and deployed a novel, easy-to-use, electronic health record (EHR)-embedded CVH assessment tool which shows a visual, interactive display of modifiable CVH risk factors pulled automatically into the tool from the EHR [14–16]. Designed to serve as a prompt for health-promoting discussions, this tool is presented to providers via the EHR during an encounter with an eligible patient. We chose to deploy this tool during the post-treatment survivorship period (defined as six months or more post-potentially curative treatment, with no evidence of disease) based on preliminary data from oncology providers indicating greater interest in using the tool while providing survivorship care compared to during initial treatment planning or during active treatment [17]. The tool was first implemented in primary care and now incorporates EHR data on cancer treatments with cardiotoxic potential [15]. Our ongoing National Cancer Institute Community Oncology Research Program (NCORP) cancer care delivery research study is an evaluation of this tool, the Automated Heart-Health Assessment (AH-HA), in a new setting of cancer survivorship care. This group-randomized, mixed methods study will recruit 600 cancer survivors and compare outcomes in survivors at intervention sites who use the AH-HA tool with their oncology provider to survivors at usual care sites who complete routine survivorship visits.

During the COVID-19 pandemic, many clinical trials have paused due to the potential risk to participants of conducting in-person visits with study staff, as well as dramatic reductions in healthcare utilization [18]. The AH-HA study is currently recruiting cancer survivors, a vulnerable population with respect to poor COVID-19 outcomes [19]. At the same time, many oncology clinics are postponing in-person survivorship visits or offering virtual visits for non-urgent encounters [20]. Herein, we briefly describe our study design, which originally relied on an in-person approach to recruitment, consent, intervention delivery, and data collection. We present recent modifications to our protocol, which will enable our study team to carry out all aspects of the study virtually.

## 2. Material and methods

### 2.1. Specific aims and study design

**Study aims.** The primary aim of this Wake Forest NCORP Research Base study (WF-1804CD) is to assess the impact of the AH-HA tool on providers' efforts to discuss CVH during oncology visits as compared to usual care. The secondary aims are to assess the impact of the AH-HA tool on providers' efforts to: (1) refer survivors to primary care and cardiology; and (2) manage CV risk (ordering of CVH-relevant labs and treatments); and survivors': (1) completed visits with primary care providers and cardiologists; (2) control of CVH factors (cholesterol, blood pressure, glucose/hemoglobin A1c) and CVH behaviors (body mass index, smoking, diet, and physical activity), as defined by the American Heart Association [21]; (3) perception of CV risk and knowl-

edge of CVH factors; and (4) satisfaction with care. The study will also utilize key informants to examine factors influencing current and future implementation of the AH-HA tool.

**Study design overview.** In this hybrid effectiveness-implementation group-randomized (“cluster-randomized”) clinical trial, 6 intervention practices will integrate the AH-HA tool in their EHR and 6 practices will serve as usual care (control) practices without access to the AH-HA tool. Oncology providers at each intervention site will be trained to use the tool during routine follow-up care with survivors. Eligible survivors ( $n = 600$ ) will provide baseline data before and immediately after their appointment and complete 6-month and 1-year study follow-up assessments. We will compare changes in outcomes from baseline to 1-year in survivors at the intervention and usual care clinics using data from survivor self-reports and the EHR. The study schema is summarized in Fig. 1. The study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03935282) (NCT03935282).

**Randomization and blinding.** The unit of randomization is the oncology practice, or “group”. Group-level randomization accommodates the system-level EHR intervention and minimizes the potential for crossover if enrolled survivors saw multiple providers within a practice. The obvious nature of the clinical decision support tool and the need to work closely with sites to implement the tool in the EHR precludes blinding of survivors, clinicians, and researchers.

**Eligibility criteria.** Eligible practices must be NCORP affiliates or sub-affiliates and: (1) use the Epic EHR; (2) be willing to incorporate the AH-HA tool in their EHR; (3) have at least 2 oncology providers willing to be trained and use AH-HA; and (4) see 100 potentially-eligible survivors for follow-up in the prior 6 months. Survivors must be: (1) 6 months post-potentially-curative cancer treatment for breast, prostate, colorectal, endometrial cancers, or Hodgkin and non-Hodgkin lymphomas; (2) scheduled for a routine cancer-related follow-up care visit with an identified AH-HA provider; (3) able and willing to complete a follow-up assessment in one year; and (4) have no evidence of disease at the time of their last medical visit for all cancers except non-melanoma skin disease.

**Recruitment protocol for survivors.** NCORP site staff will use appointment schedules and registries to identify potentially eligible survivors scheduled for routine follow-up care and will provide study information in-person or via mail, telephone, e-mail, patient portals, or other channels. An informational flyer will be provided to all patients seeing an AH-HA trained provider in settings where the tool is activated, regardless of whether or not they will be recruited for the study. We will track numbers of individuals approached and screened and reasons for nonparticipation. The tool can be used with all eligible patients at the providers' discretion, regardless of their study enrollment.

**Ethics and consent.** This study is approved by the NCI Central Institutional Review Board (IRB) [22] and the Wake Forest Health Sciences IRB. Each participating institution grants authority to the CIRB to serve as the IRB of record for NCORP studies, in accordance with the NIH's single IRB policy [23]. As described below in the section outlining COVID-19-related modifications, the original in-person consent process was amended in June of 2020 to include remote consent options. The first participant was enrolled in the study in October of 2020.

**The AH-HA clinical decision support tool.** Our team developed and deployed a novel, easy-to-use, EHR-embedded CVH assessment tool, based on the American Heart Association's (AHA) Life's Simple 7 [21]. The tool renders a visual, interactive display of CVH risk factors, automatically populated from the EHR [14–16], alongside a tab that indicates the receipt of cancer treatments (yes or no) with cardiotoxic potential. The tool was designed to be relevant to a diverse population of cancer survivors, including those who did and did not receive potentially cardiotoxic treatments, and was developed and refined using input from oncology providers and survivors [17]. The tool does not dic-

## SCHEMA

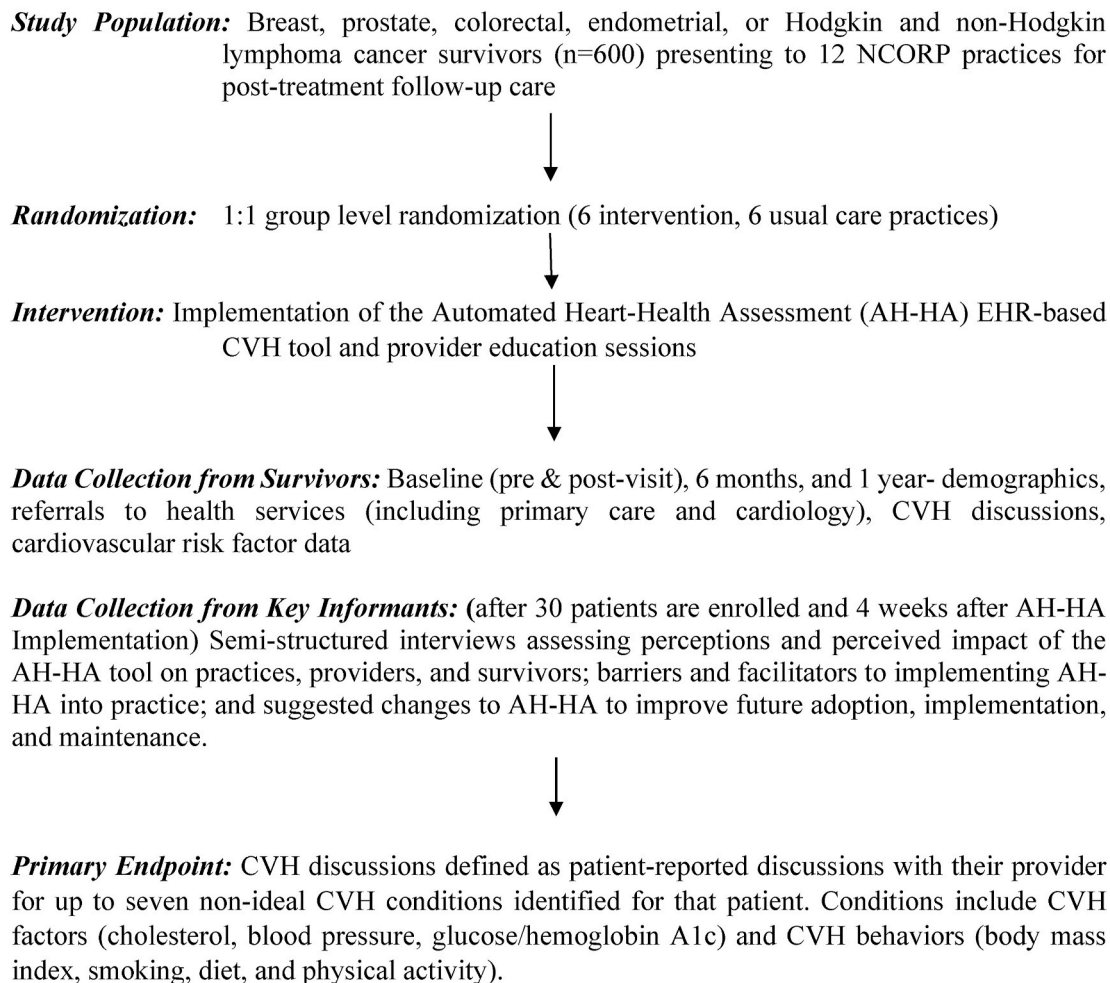


Fig. 1. Study schema.

tate how oncologists should care for their patients, nor is the AH-HA tool intended to replace primary care management of CV risk factors, intensive behavioral interventions to address weight loss or tobacco use, or specialty management of survivors at high risk for cardiotoxicity. Instead, it is expected to facilitate CVH awareness and action by cancer survivors and their oncology providers, enhance referrals, and promote care coordination. Technology implementation principles followed during our previous study are employed for the current study as well [14]. Oncology providers (physicians, nurse practitioners, or physician assistants) will view two 30-min AH-HA tool tutorials online. The educational sessions will review primary prevention of CV disease risk factors according to AHA guidelines for healthcare professionals, cardiotoxicity of cancer treatments, and case-based examples illustrating use of the AH-HA tool in CVH discussions during survivorship care (see Fig. 2 for a visual of the AH-HA tool). The pre-recorded webinar-style provider training sessions provide case-based examples highlighting how cardiotoxic cancer treatment information can be used as contextual information regarding CV disease risk.

**Usual care control group.** Practices randomized to usual care will not have access to the AH-HA tool. Providers will deliver routine survivorship care, which may or may not include discussions of CV risk or related wellness topics.

**Data collection and management (Survivors).** Survivors will complete a pre-visit baseline survey prior to their visit (in-person or online using the REDCap web application). They will complete a routine follow-up

care visit with an enrolling oncology provider and then complete the post-visit baseline survey. Survivors will complete brief follow-up surveys (in-person, by telephone, or online) 6 months and 1 year following the baseline clinic visit. Data are managed using REDCap server software [24,25].

**Data collection and management (Key Informants).** The key informants comprise two groups (n = 42): oncology providers conducting the study visit (n = 30) and administrator/information technology (IT) personnel who were involved in the implementation of the tool (n = 12). Four weeks after AH-HA implementation, qualitative data will be collected from oncology providers in intervention clinics who saw at least two enrolled patients during the study period. In addition, practices will be asked to identify a key clinic administrator who assisted with implementation of the AH-HA tool or who would be important to similar efforts in the future. All participants will be consented for participation and audio recording by staff on-site. Questions will focus on barriers and facilitators to the adoption, implementation, and potential maintenance of the AH-HA tool. Analyses will be descriptive in nature and will help determine strategies for future dissemination and implementation of the AH-HA tool. Interview transcripts will be analyzed using ATLAS.ti software (Atlas.ti Scientific Software Development) and follow the principles and procedures of thematic analysis, a rigorous and widely-used approach that identifies, categorizes, and contextualizes patterns of key themes and explores behavior, interpretation, and consequences of experiences.



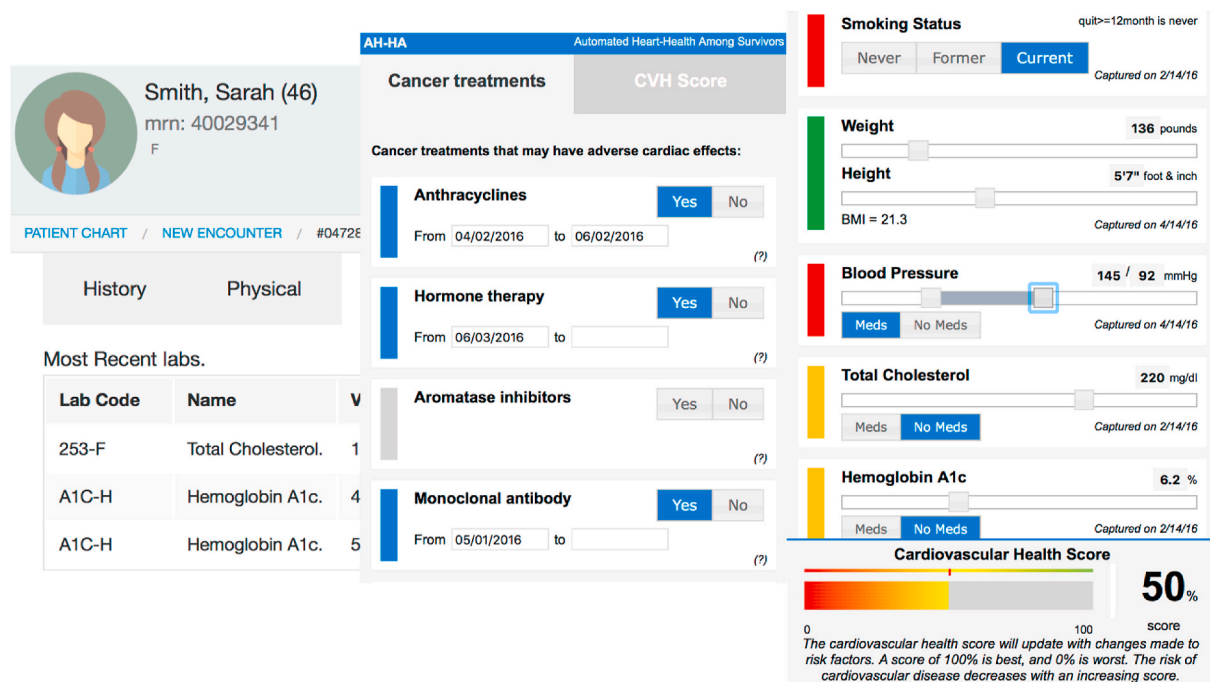


Fig. 2. The ah-ha tool.

**Measures.** A summary of endpoints, measures, measurement strategies, and time points is described in Table 1.

**Effectiveness outcomes.** Immediately after their survivorship care appointment, at baseline, each survivor will be asked if they were counseled on 10 topics: 7 CVH topics [body mass index, physical activity, diet, smoking status, blood pressure, cholesterol, and glucose], and 3 distractor topics (flu vaccination, shingles vaccination, and fall prevention). Questions were adapted from the NCI APECC [26] and FOCUS [9] studies. The primary outcome will be whether non-ideal CVH topics (excluding those missing) were discussed during the visit. We will ask survivors about primary care and cardiology visits in the past year, query the EHR for documentation, and request medical records to ascertain out-of-network visits.

**Implementation outcomes.** Quantitative EHR data from system use logs will be used to determine the frequency and duration of use of the AH-HA tool in intervention clinics for Aim 3 [14]. We will also capture the number of eligible patient visits during which the AH-HA tool was used in intervention clinics and the total number of eligible visits. The primary outcome for these analyses is the ratio of eligible patient visits during which the AH-HA tool was used/total number of eligible visits. Sites will also provide information about the person-hours required for each IT implementation step to determine cost and capacity. This will be completed with the key informant interview 4 weeks after implementation. In the post-visit baseline survey, survivors will complete a questionnaire assessing whether or not they recall seeing or discussing the AH-HA tool with their provider and 5 questions assessing: how much they liked the tool, how helpful it was, how easy it was to understand, how much it improved their understanding, and if they would like to use this tool in the future.

**Statistical considerations.** In this group-randomized trial, we hypothesize that the primary outcome (proportion of CVH discussions with at least one non-ideal CVH factor discussed) will be  $\leq 15\%$  at usual care sites and  $\geq 35\%$  at sites that receive the AH-HA tool. Assuming 6 practices per treatment group, alpha level of 0.05, up to 20% loss to follow-up, and an intraclass correlation coefficient equal to 0.03 (similar to the median value from a publication summarizing values across 13 trials) [27], we will have 80% power to detect the difference hypothesized above with 50 survivors per practice (total sample of 600). A

mixed effects logistic regression model will assess the effect of the intervention on delivery of CVH discussions between intervention and usual care clinics, where treatment group is a fixed effect and practice is a random effect. We plan to conduct two specific subgroup analyses examining the intervention effect stratifying by whether each participant received cardiotoxic treatment as part of their cancer treatment and whether the participant visited a primary care provider in the year preceding the baseline visit. We will also summarize reported discussions for each of the 7 non-ideal topics as well as the proportion of non-ideal topics discussed for each survivor. Linear mixed effect models will also be implemented to assess changes in CVH risk factors (BMI, cholesterol, blood pressure, etc.) between groups with baseline factor levels included as covariate.

**Study protocol features enabling conduct during the COVID-19 pandemic.** Several features of our study (summarized in Table 2) enable virtual deployment of all study activities including recruitment, consent, intervention delivery, and data collection. The study was amended to include a waiver of documentation of consent for all participants (survivors and key informants). A consent script will be used for both in-person and remote (telephone or teleconference) consents and does not require the participant's signature. Instead, staff will document the survivor's consent decision and provide a copy of the consent document to the survivor, if requested.

**Virtual clinic visit considerations.** The baseline assessment and follow-up care visit can be completed in-person or virtually. Site staff will document the format of the designated AH-HA study appointment (in-person or virtually via telephone or video), the type of technology used, and the reason why the visit was virtual. For intervention sites, the virtual visits require videoconferencing with screen sharing capability that shows the participant the AH-HA tool embedded in the EHR. The intervention requires that survivors see the tool and discuss it with the provider in real time. Sites and providers can ask the survivor to provide as many AH-HA specific vitals as possible that they can conduct safely at home (e.g., weight and blood pressure). In the absence of day-of vitals, the AH-HA tool will pull from the most recent data stored in the EHR. We will evaluate for differences in data quality and completeness between patients who have virtual as compared with in-person

**Table 1**  
Measures, measurement strategy, and time point(s).

	Measure	Measurement Strategy	Time Point(s)
Primary Endpoint (Effectiveness)	CVH discussions (at least one non-ideal CVH factor discussed)	Survivor survey; EHR for other CVH factors	Baseline: post-visit
Secondary Endpoints (Effectiveness)	1) Referrals to primary care and cardiology and 2) efforts to manage CV risk (ordering of CVH-relevant labs and treatments)	Medical chart abstraction	1 year
Secondary Endpoints (Effectiveness)	1) Number and date of primary care and cardiology visits in the past year, 2) CVH behaviors (smoking status, body mass index, physical activity, and healthy diet) and CVH factors (total cholesterol, blood pressure, and fasting plasma glucose/A1c), 3) perception of CV risk, knowledge of CVH factors, and patient activation, 4) Satisfaction with care	1 & 2) Medical chart abstraction, including medical records from external providers (survivor survey as secondary verification source/primary for diet and physical activity) 3 & 4) Survivor survey; knowledge difference ascertained in terms of survivors' awareness of the value and categorization of CVH factors (high, somewhat high, normal, don't know)	Baseline; 1 year post-visit; 6 mo, & 1 year
Secondary Endpoints (Implementation)	Proportion and characteristics of survivors for whom AH-HA is utilized in clinic	EHR log data	1 year
Secondary Endpoints (Implementation)	Barriers and facilitators to the adoption, implementation, and maintenance of the tool in intervention practices Tool acceptability	Key informant surveys and interview Survivor Surveys	After 30 patients are enrolled (provider) and 4 weeks after implementation (admin/IT) Baseline: post-visit

visits to ascertain the potential impact of visit type on our study outcomes.

### 3. Discussion

The AH-HA tool is the first of its kind to integrate CVH and cancer treatment information to address the complex CVH needs of survivors. At the time of this publication, there is not a validated algorithm, which combines both general CV and cancer treatment risk into a single risk prediction algorithm for cancer survivors. Thus, AH-HA presents these two factors in separate panels of the AH-HA tool and emphasizes the use of cancer treatment information as contextual information for the general CVH score and factors.

EHR-integrated visualization tools like AH-HA could improve survivorship care, yet tools targeting CVH have not been tested among cancer survivors to increase awareness and trigger appropriate preven-

**Table 2**  
Features of the study design which enable virtual study delivery.

Virtual recruitment, consent, intervention delivery, and data collection	
Survivors	<p><b>Recruitment</b> information provided to potentially eligible survivors prior to their appointment via mail, telephone, e-mail, or patient portals</p> <p><b>Waiver of documentation of consent</b> - consent can be obtained by telephone or videoconference with no mailed documents (AMENDMENT)</p> <p>Use of <b>REDCap</b> as the electronic data collection platform for informed consent documentation and surveys. REDCap is a secure, web-based, research database platform utilized by the Wake Forest NCORP Research Base for many research projects [23]</p> <p>Follow-up survivor data collection (6-month and 1-year) can be collected by phone or completed online using REDCap</p> <p>Routine follow-up care <b>study visit</b> can be completed in-person or remotely (telephone or video) (AMENDMENT)</p> <p>Data for secondary outcomes originating from <b>medical chart abstraction</b> or <b>EHR event logs</b> do not require participant contact</p>
Providers/Key Informants	<p><b>Provider training</b> delivered via webinars and teleconferences</p> <p><b>Waiver of documentation of consent</b> for key informant surveys and interviews (AMENDMENT)</p> <p><b>Key informant interviews</b> conducted by phone and <b>surveys</b> conducted online using REDCap</p>

tative care. Our hybrid effectiveness-implementation group-randomized clinical trial design is expected to yield insights into how such tools can impact patient outcomes as well as barriers and facilitators to integrating such tools into survivorship clinic workflows.

The global COVID-19 pandemic has presented many challenges to ongoing clinical research studies, particularly those that enroll populations who may be at risk, including cancer survivors. We modified our protocol testing the effectiveness and implementation of a CVH clinical decision support tool designed for the outpatient oncology setting to allow all study activities to be conducted virtually and to adhere to the original study timeline. By eliminating the need for in-person contact, we prioritize the safety of research staff and enrolled survivors and enable the study to continue, despite suspension of in-person research activities at some enrolling practices. We saw a need for a more agile and pragmatic approach to our cancer care delivery research to accommodate geographic and practice variability during the current pandemic. The resulting study protocol allows for in-person study activities if they are allowed or resume at individual practices within NCORP. If restrictions on in-person encounters are reinstated during the pandemic or the proportion of oncology visits delivered virtually remains elevated, we will be able to continue our study without interruption. We implemented these changes prior to participant accrual and thus will not have data to compare study activities prior to the amendment being approved.

Our study was originally intended to be delivered in-person in conjunction with an in-person outpatient oncology clinic visit and relied upon NCORP study staff protocols and existing infrastructure for in-person recruitment, consent, intervention delivery, and data collection. However, the adaptations made to our protocol are supported by IRBs and have been implemented by many investigators who are interested in making their studies more accessible to participants who wish to participate virtually rather than in-person (i.e., mHealth studies or online disease registries). While our study is not powered to detect statistically-significant differences between individuals who opt for in-person versus virtual visits in our study, we do plan to assess for the effect of visit type on patient satisfaction, patient-provider interactions, and data quality and completeness.

Under our revised protocol, we will examine the proportion of in-person and virtual study activities and conduct exploratory analyses to examine the potential impact of clinic visit modality (in-person vs vir-

tual) on study outcomes. We believe the results will inform other investigators as they design cancer care delivery research studies to accommodate both in-person and virtual care delivery. We will allow in-person and virtual visits for the duration of the study, track visit modality, and account for this in our data analysis. While we considered remote monitoring of survivors (i.e., physical activity tracking, body weight measurement), we prioritized a pragmatic study design and the testing of the tool within routine oncology practice which does not commonly include use of such tools. We acknowledge the limitations of self-reported data, particularly for virtual visits, but believe such visits will comprise a minority of our total study visits. Ultimately, by accommodating both in-person and virtual visit options, agile cancer care delivery research study processes may best meet the needs of survivors and study staff in diverse communities across the US, during and beyond the COVID-19 pandemic.

Future work is expected to consider opportunities to make the tool available earlier in the cancer care continuum (e.g., during treatment planning) and evaluate the timing of CVH discussions. Repeat use of the tool during cancer care could result in interesting opportunities to examine changes in CV risk alongside and after cancer treatments with and without cardiotoxic potential. We will also explore opportunities to add clinical practice guideline information and validated cardiovascular risk algorithms to the AH-HA tool, as this science matures and they become available for survivors who receive a variety of cancer treatments.

#### 4. Conclusions

Cancer care delivery studies, such as the AH-HA study described above, are vulnerable to disruptions or potential innovations in care delivery that shift healthcare from in-person to remote delivery. The multi-site AH-HA study protocol can serve as an example for researchers seeking to increase virtual study operations to minimize disruptions in study enrollment and follow-up activities during challenging and shifting times in healthcare delivery.

#### Funding

R01CA226078 (PIs: Weaver & Foraker), 2UG1CA189824 (PIs: Lesser & Weaver). NCORP CDR study number WF-1804CD.

#### Declaration of competing interest

The authors declare no potential conflicts of interest.

#### Acknowledgements

Funding source: The project described is supported by the National Institutes of Health and National Cancer Institute (Grant Award Number 1R01CA226078-01 and 2UG1CA189824 Wake Forest NCORP Research Base. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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