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CCSS Analysis Concept Proposal

Study Title: Evaluation of Cardiovascular Health Outcomes among Survivors 2 (ECHOS2) Pilot: Translating ECHOS into an mHealth platform

Funding: St. Jude/Washington University Implementation Science Collaborative

Working Groups:

Cancer Control – Primary

Chronic Disease – Secondary

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BACKGROUND AND SIGNIFICANCE

Compared to the general population, childhood cancer survivors are at a 15-fold excess risk for heart failure (HF)[1] and 7-fold excess risk for death due to cardiac causes,[2] attributable to prior exposure to chest-directed radiation and/or anthracycline chemotherapy.[3-10] Approximately two thirds of the nearly 500,000 childhood cancer survivors in the U.S. received one or both exposures as part of curative cancer treatment, rendering many vulnerable to the long-term cardiotoxic effects of these agents.[10-13] Specifically, the incidence of congestive heart failure is <5% for individuals exposed to cumulative doxorubicin-equivalent doses of anthracyclines <250 mg/m^2, approximately 10% for those who received between 250 mg/m^2 and 600 mg/m^2, and >30% in those exposed to >600 mg/m^2.[10] Consequently, risk-stratified practice guidelines have been developed to facilitate screening for and early detection of asymptomatic cardiomyopathy in exposed survivors,[14-17] ultimately seeking to reduce progression to symptomatic and potentially fatal HF. Despite these efforts, adherence to recommended screening is poor, with fewer than 30% of those Childhood Cancer Survivor Study (CCSS) participants treated with ≥300 mg/m^2 completing screening.[18] Magnifying this problem, most survivors are no longer followed at a cancer center [18,19] and are unaware of their risks and recommendations for cardiac surveillance.[20]

The **E**valuation of **C**ardiovascular **H**ealth **O**utcomes among **S**urvivors (**ECHOS-1**, R01NR011322, NCT01003574, M-PI: Hudson, Cox) trial informed survivors about personalized cardiac risk and follow-up recommendations and provided motivational support for cardiomyopathy screening (echocardiograms). Eligible survivors at risk for cardiomyopathy were randomly assigned to receive either: 1) a mailed personalized survivorship care plan with cardiomyopathy surveillance recommendations (standard care), or 2) standard care plus telephone counseling by an advanced practice nurse (APN) that incorporated motivational interviewing tailored to survivors' baseline measures of knowledge, motivation, health beliefs, affect, and self-efficacy. After one year, the APN arm was >2 times more likely than the standard care arm to complete screening (52.2% vs. 22.3%, respectively; RR

2.3, 95% CI: 1.7-3.1).[21] While highly effective, APN phone counseling is resource intensive, preventing dissemination of this effective strategy to the greater than 500,000 survivors in the U.S. An eHealth version of the intervention, which is not dependent upon personalized APN counseling, may overcome this critical resource barrier.

To address this need, we translated ECHOS into an eHealth intervention, using the Computerized Intervention Authoring System (CIAS) as the software platform. Working collaboratively with a childhood cancer survivor advisory group and individual health care provider advisors, we engaged in an iterative, user-centered process of intervention adaptation, testing, and refinement. This involved modifying the original ECHOS intervention for eHealth administration, developing supplemental materials and videos to address barriers identified in ECHOS and in discussions with survivor and provider advisors, and conducting cognitive interviews to gauge usability and acceptability of the intervention.

To test the feasibility and effectiveness of the intervention, we propose a single-arm pilot study followed by a 2-arm randomized controlled trial that utilizes the CIAS platform to deliver the new ECHOS intervention to childhood cancer survivors, and thereby increase the rate of cardiac screening completion. To maximize acceptability of the intervention for patients, we will seek regular guidance at critical time points from survivor and provider advisors regarding the intervention's content, format, and delivery strategy.

SPECIFIC AIMS/RESEARCH HYPOTHESES

Primary aim (Pilot):

Aim 1: Conduct a single-arm pilot study of survivors to evaluate the tool's acceptability and usability, and the extent to which it produces beneficial changes in key health cognitions and emotions (i.e., perceived risk, worry, severity, barriers, benefits, and self-efficacy).

Primary aim (subsequent RCT):

Aim 1: To determine the efficacy of an eHealth intervention compared to standard of care for improving screening echocardiogram adherence in childhood cancer survivors.

Aim 2: Explore whether perceived risk, severity, barriers, benefits, and self-efficacy mediate the effect of the intervention on 12-month echocardiogram completion.

This study aims to establish a highly scalable intervention to increase adherence to cardiac surveillance among childhood cancer survivors who have received cardiotoxic therapy. Incorporating intensive advisor (patients/caregivers and providers) involvement throughout the duration of the study period will likely increase the feasibility, efficacy, and acceptability of the intervention, thereby increasing the likelihood of success for future dissemination and implementation efforts to childhood cancer survivors who are broadly geographically distributed throughout the U.S.[22]

METHODS

A. Study Population (pilot and subsequent RCT)

1. Childhood Cancer Survivors Study (CCSS) participants meeting the following criteria:
    i. ≥18 years of age
    ii. Prior cardiotoxic therapy
        1. Cumulative doxorubicin equivalent anthracycline dose ≥100 mg/m^2 and/or
        2. ≥15 Gy chest radiation involving cardiac structures
        3. No history of cardiomyopathy (using CCSS graded CTCAE condition)

4. No echocardiogram in the past 5 years
5. At least 2 years post cancer treatment
6. Have access to a smart phone, tablet, or desktop or laptop computer

2. Pilot (n=50)
3. RCT (n=TBD)

B. Intervention:

1. CIAS– Through the St. Jude Children's Research Hospital/Washington University School of Public Health Collaborative, we have developed and gathered preliminary data on acceptability and usability of a CIAS-based eHealth intervention through the use of 12 cognitive interviews with cancer survivors selected from the Barnes Jewish Health System and CCSS advisory board. We conducted the cognitive interviews in an iterative cycle of development, testing, and adaptation. The intervention is ready and available for pilot testing.

   Within CIAS we have developed avatar-led motivational interviews seeking to assess barriers to and readiness to obtain screening echocardiograms. The CIAS platform is designed to respond to user input, specifically addressing areas of concern through already developed avatar-led responses, educational videos, and patient testimonials.

   i. Contents of the CIAS intervention are as follows. Participants will engage in two data collection **sessions**, approximately one week apart. Within each session there are several **sections** which organize the flow and content, including welcome sections, a section targeting the intervention components, a section detailing the steps and practical challenges for getting screened, and conclusion sections. **Modules** within the sections address each intervention target. Module 1 is required, but all other modules are optional. Section 1: Welcome and Assessment
      1. Assessment Survey
      2. Module 1: Knowledge/Education

   ii. Section 2: Optional Modules (Intervention Targets)
      1. Module 2: My Thoughts about My Risk (Perceived Severity and Susceptibility)
      2. Module 3: My Reasons (Importance/benefits)
      3. Module 4: My Worries or Concerns
      4. Module 5: My Support System (Social Influence)

   iii. Section 3: How to Get Screened
      1. Module 6. Steps for Screening
      2. Module 7. My Challenges

   iv. Section 4: Session 1 End
      1. Goal Setting

   v. Section 5: Session 2 Welcome

1. Repeat Modules 2-7 as desired

vi. Section 6: Intervention End

2. Procedure

i. Research staff will engage in the informed consent process with potential participants via Zoom or over the phone

ii. Individuals who consent will be asked to open a link to the survey on their phone, laptop, desktop, or tablet. Study staff will be available to help address technical problems.

iii. Participants will:

1. Complete the Baseline Survey on the Qualtrics survey platform

2. Automatically re-direct to the CIAS platform and engage with the intervention content (session 1 – maximum 1 hour)

iv. One-week post-baseline, they will be sent an invitation to complete a second session on CIAS (maximum 30 min). Participants will:

1. Access the session 2 content in CIAS (section 5)

2. Review any desired optional modules (sections 2 and 3)

3. Complete the intervention (section 6)

4. Automatically re-direct to the Post-test Survey on the Qualtrics survey platform.

v. 1-month post-baseline, they will complete the Follow-up Survey via Qualtrics, or on paper if desired.

vi. After each data collection point participants will receive a gift card or check depending on their preference. (Baseline Survey and Session 1: $40, Session 2 and Post-Test Survey: $20, Follow-up Survey: $20).

C. Primary outcomes/Dependent variables

Overview: Health belief model structures the *content* of the intervention; Self-determination theory structures the *strategy*

1. **Pilot Aim 1:** Acceptability and usability, and the extent to which it produces beneficial changes in key health cognitions and emotions

i. Baseline Survey (see Appendix for exact item wording)

1. Health belief model constructs targeted by the intervention –

a. Knowledge about echocardiograms and the effects of their treatment on health (5 Investigator created items)

b. Perceived risk of having heart problems (2 – Waters et al., 2021)

c. Perceived severity of having heart problems (1 – ECHOS-1)

d. Perceived barriers to getting echocardiogram (6 – ECHOS-1 self-efficacy scale and from advisor/stakeholder meetings)

e. Perceived benefits of getting echocardiogram (3 – from advisor/stakeholder meetings)

f. Overall self-efficacy of getting echocardiogram (3 – Waters et al., 2021)

g. Worry about having heart problems (1 – Waters et al., 2021)

h. Intentions of getting echocardiogram (3 – Waters et al., 2021)

2. Self-determination theory constructs targeted by the intervention – 24 items

    a. Competence

        i. Confidence in getting echocardiogram (1 – confidence ruler; concept overlaps with Health Belief Model (HBM) construct of self-efficacy and barriers)

    b. Autonomy

        i. Perceived importance of getting echocardiogram (1 – importance ruler and 8 – ECHOS-1)

        ii. Perceived choice of getting echocardiogram (7 – ECHOS-1 items)

        iii. Decision-making readiness (1 – readiness ruler)

    c. Relatedness

        i. Social norms/influence of getting echocardiogram (6 – ECHOS-1 items)

3. SDT constructs ***not*** targeted by the intervention but potentially covariates – 21 items

    a. Autonomy

        i. Self-regulation (15 – ECHOS-1 Treatment Self-Regulation Questionnaire (TSRQ) items)

    b. Relatedness

        i. Provider relationship (6 – ECHOS-1 Health Care Climate Questionnaire items)

4. Participant characteristics ***not*** targeted by the intervention but potentially covariates – 14 items

    a. Socio-demographics (age, sex, education, race, ethnicity, marital status, financial strain, numeracy)

    b. Health care access (health insurance status, usual source of care)

5. Mental health items ***not*** targeted by the intervention but potentially covariates – 15 items

    a. Depressed mood (4 – PROMIS Item Bank v1.0 – Emotional Distress-Depression – Short Form 4a)

    b. Perceived Stress (4 – ECHOS-1 items)

    c. Anxiety (4 – PROMIS Item Bank v1.0-Emotional Distress-Anxiety – Short Form 4a)

d. Medical Anxiety

ii. Post-test Survey

1. Health belief model constructs (knowledge about the effects of their treatment on health and echocardiograms, perceived risk of having heart problems, perceived severity of having heart problems, perceived barriers to getting echocardiogram, perceived benefits of getting echocardiogram, self-efficacy of getting echocardiogram, worry about having heart problems, intentions of getting echocardiogram)
2. Self-determination theory constructs (confidence, importance, readiness, perceived choice, social norms/influence)
3. Implementation outcomes (feasibility, usability, satisfaction)

iii. 1-month follow-up survey

1. Movement toward screening (i.e., made a plan to set an appointment with healthcare provider to discuss screening; made an appointment to discuss screening; had appointment to discuss screening; scheduled screening; obtained screening)
2. Implementation outcomes (feasibility, usability, satisfaction)

1. **RCT Aim 1:** Receipt of an echocardiogram within 1-year of study enrollment.

D. Analytic approach

1. Preliminary analyses

i. Calculate descriptive statistics (i.e., frequencies, means, SDs, min/max, and median) for each individual variable at each timepoint (i.e., baseline, post-test follow-up, and 1-month follow-up)

ii. Run exploratory factor analysis (EFA) or confirmatory factor analysis (CFA) and check Cronbach α for each *a priori* scale at each timepoint

iii. Create *a priori* scales of main constructs at each timepoint, where appropriate

iv. Calculate descriptive statistics (i.e., frequencies, means, SDs, min/max, and median) for each construct scale at each timepoint (i.e., baseline, post-test follow-up, and 1-month follow-up)

v. Explore bivariate relationships between each construct scale and each key covariate (i.e., gender, education, race, ethnicity, numeracy, health insurance status, usual source of care, financial status) for each timepoint

vi. Explore bivariate relationships between movement toward screening and each key covariate (i.e., gender, education, race, ethnicity, numeracy, health insurance, usual source of care, financial status)

vii. Explore bivariate relationships between each construct scale and each exploratory covariate (i.e., depressive symptomatology, perceived stress)

viii. Explore bivariate relationships between the movement toward screening and each exploratory covariate (i.e., depressive symptomatology, perceived stress)

2. Main analyses

i. Evaluate change in health belief model and self-determination theory construct scales from baseline to post-test survey (unadjusted, adjusted for key covariates, adjusted for exploratory covariates)

ii. Calculate descriptive statistics for implementation outcomes (at post-test and 1-month follow-up)

iii. Examine change in implementation outcomes from post-test to 1-month follow-up

E. Statement of relevance

Adult survivors of childhood cancer are at risk for late-onset cardiomyopathy due to prior anthracycline and cardiac radiation exposure, yet despite the establishment of screening guidelines to facilitate early identification and intervention, most survivors and their primary care providers are unaware of these recommendations and are not completing screening echocardiograms. This proposal is designed to improve survivor adherence to cardiomyopathy screening using eHealth-delivered texts/push messages/video vignettes tailored towards individual baseline behaviors and perceived barriers to screening. We expect the intervention to increase cardiomyopathy screening adherence, potentially reducing cardiovascular morbidity and mortality in this at-risk population.

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APPENDIX

Baseline Survey

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
Knowledge	KnowledgeScore KnowledgeDrugs KnowledgeRadiation KnowledgeECG KnowledgeBlood KnowledgeTrtBefSymp	Intro text: Please read the following questions and mark your response. 3-point response scale (1 = yes; 2 = no; 3 = don't know) 1. Anthracyclines are drugs that are used to treat cancer. Can drugs called anthracyclines cause heart damage? [Y] 2. Can getting radiation to the chest cause heart damage? [Y] 3. Is an echocardiogram a test that doctors use to see if your heart is damaged? [Y] 4. Does having an echocardiogram involve getting blood drawn? [N] 5. Can heart damage be treated more easily if it is caught before symptoms appear? [Y]	Intervention target	Sum correct responses; consider DK incorrect	*ad hoc* based on information provided to participants	5
New after CI round 1						
Static Text		The remaining questions throughout this survey will refer to an echocardiogram. This is also called an echo. This test uses ultrasound to take pictures of the heart.				
Perceived risk	PerceivedRiskScore		Intervention target	Examine EFA and Cronbach's alpha; for intervention, consider DK "not at all likely." For analysis, examine frequency of DK and then determine whether to analyze separately or as missing.	Waters et al., MDM, 2020; Table 1	3
Perceived absolute likelihood	AbsLikelihood	In your opinion, how likely is it that you will have heart problems in the next 20 years because of your cancer treatment? (1 = Not at all likely; 2 = a little likely; 3 = somewhat likely; 4 = very likely; 5 = extremely likely; don't know)				

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
Absolute feelings of risk	AbsFeelings	How easily do you feel you could have heart problems in the next 20 years because of your cancer treatment? (1 = Not at all easily; 2 = a little easily; 3 = somewhat easily; 4 = very easily; 5 = extremely easily; don't know)				
Worry	Worry	How worried are you about having heart problems because of your cancer treatment? (1 = not worried at all; 2 = a little worried; 3 = somewhat worried; 4 = very worried; 5 = extremely worried)				
Perceived severity	Severity	In your opinion, how serious would it be for you to have heart problems because of your cancer treatment? (1 = not serious at all; 2 = a little serious; 3 = somewhat serious; 4 = very serious; 5 = extremely serious)	Intervention target	See if loads with perceived risk construct above	ECHOS-1	1
Perceived benefits	BenefitScore	Intro Text: The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	Examine EFA and Cronbach's alpha	*ad hoc* based on survivor advisory board comments	6
	BenefitEasyTreat	1. Having an echo could help find heart problems when they are treatable				
	BenefitLiveLonger	2. Having an echo could help me live a longer life				
	BenefitMoreActive	3. Having an echo could help me live a more active lifestyle				
	BenefitTakeControl	4. Having an echo is a way for me to take control of my health				
	BenefitMoreTime	5. Having an echo could help me spend more high-quality time with loved ones				
	BenefitNoSurgery	6. Having an echo could lower my chances of needing heart surgery in the future				
Barriers	BarrierScoreR	Intro Text: The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. These questions are about your activities in the next 3 MONTHS. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	Reverse score responses for data analysis; Removed 3-5 because they're addressed elsewhere in intervention; for analysis dichotomize (1=if participant says "1-3" on *any* of the	*ad hoc* based on survivor advisory board comments	6

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
				remaining items, 0=participant does not)		
	BarrierTransportR	1. I can arrange transportation to get an echo in the next 3 months.				
	BarrierArrangeThingsR	2. I can arrange other things in my life to have an echo in the next 3 months.				
	BarrierPayR	3. I can find a way to pay for an echo in the next 3 months.				
	BarrierMakeApptR	4. I can make an appointment for an echo in the next 3 months.				
	BarrierKnowHowR	5. I know how to go about getting an echo in the next 3 months.				
	BarrierFindPlaceR	6. I can find a place to have an echo in the next 3 months.				
Overall self-efficacy	SelfEfficacyScore	The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. These questions are about your activities in the next 3 MONTHS. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	Examine EFA and Cronbach's alpha	Waters et al., MDM, 2020, Table 1; *ad hoc* coping self-efficacy	3
	SelfEfficacySure	1. I know for sure I can get an echo in the next 3 months if I really want to				
	SelfEfficacyConfident	2. I am confident that I can get an echo in the next 3 months.				
	SelfEfficacyObstacles	3. I can find a way to get an echo in the next 3 months even if there are obstacles in my path				
Medical anxiety	MedAnxScore	Please choose the answer that best matches how you feel about each sentence below. 5-point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; 5 = all the time)	Intervention target	Examine EFA and Cronbach's alpha	N/A	3
	MedAnxUncertain	1. How often do you feel uncertain about your future health?				
	MedAnxComeBack	2. How often do you worry that your cancer will come back?				
	MedAnxProblem	3. How often do you worry that a problem with your health will be discovered if you go to a doctor for a routine check-up?				

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
Perceived importance	ImportScore	The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	I changed the response scale; using "true" doesn't always work with participants who are very literal. - Examine EFA and Cronbach's alpha - see if we can reduce # of items	N/A	8
	ImportForMe	1. It is important to me to get an echo				
	ImportValueToMe	2. I believe getting an echo could be of some value to me.				
	ImportUseful	3. I think that an echo is useful to detect potential problems.				
	ImportProtect	4. I think getting an echo is important because it can protect my health.				
	ImportHasValue	5. I would be willing to get an echo because it has some value to me.				
	ImportLiveLonger	6. I think getting an echo could help me to live longer.				
	ImportBeneficial	7. I believe getting an echo could be beneficial to me.				
	ImportActivity	8. I think getting an echo is an important activity.				
Perceived choice	ChoiceScore	The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	I changed the response scale; using "true" doesn't always work with participants who are very literal. - Examine EFA and Cronbach's alpha - see if we can reduce # of items	N/A	7
	ChoiceGetTest	1. I believe I have some choice about getting an echo.				
	ChoiceNotMyChoiceR	2. I feel like it is **not** my own choice to have an echo. *(need to reverse-score before analysis)*				
	ChoiceNoChoiceR	3. I don't really have a choice about getting an echo. *(need to reverse-score before analysis)*				
	ChoiceHaveToGet	4. I feel like I have to get an echo. (*need to reverse-score before analysis)*				
	ChoiceHaveNoChoiceR	5. I will get an echo because I have no choice. *(need to reverse-score before analysis)*				

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
	ChoiceWantTo	6. I will get an echo because I want to.				
	ChoiceHaveToR	7. I will get an echo because I have to. *(need to reverse-score before analysis)*				
Social norms and influence	NormScore	The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	Multiply each Think*Want pair and then sum all 3 products together We added "recommended tests, like echos" instead of "echos" here and throughout this construct due to participant confusion on their family/friends not knowing what an echo is (see CI group 2 notes)	N/A	6
	NormFamilyThink	1. Members of my immediate family think I should get recommended tests, like echos.				
	NormFamilyWant	2. I want to do what members of my immediate family think I should do about recommended tests, like echos.				
	NormFriendsThink	3. My close friends think I should have recommended tests, like echos.				
	NormFriendsWant	4. I want to do what my close friends think I should do about recommended tests, like echos.				
	NormRelativesThink	5. My relatives think I should have recommended tests, like echos.				
	NormRelativesWant	6. I want to do what my relatives think I should do about getting recommended tests, like echos.				
Confidence ruler	ConfidenceRuler	How sure are you that **<u>you</u>** could get an echo? (Likert scale multiple choice, 0 to 10, 0 – not at all sure, 5-moderately sure, 10 – extremely sure)	Intervention target	There's some data suggesting that visual analogue scales like this perform worse than Likert-type scales - examine how well this correlates with overall self-efficacy above.	April	1

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
				Examine how well this correlates with overall self-efficacy above.		
Importance ruler	ImportanceRuler	How important is it to **<u>you</u>** to get an echo? (Likert scale multiple choice, 0 to 10, 0 – not at all important, 5- moderately important, 10 – extremely important)	Intervention target	We also updated this to reflect a Likert scale with radio buttons due to feedback from the CAB	April Carcone Adapted from https://motivationalinterviewing.org/readiness-ruler-worksheet	1
Decision making readiness	ReadinessRuler	How ready are **<u>you</u>** to get an echo? (Likert scale multiple choice, 0 to 10, 0 – not at all ready, 5- moderately ready, 10 – extremely ready)	Intervention target			1
Intentions	IntentionScore	The next questions are about echocardiograms, also called echos. Please choose the answer that best matches how you feel about each sentence below. These questions are about your activities in the next 3 MONTHS. 5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly)	Intervention target	Examine EFA and Cronbach's alpha	Waters et al., MDM, 2020, Table 1	3
	IntentionIntend	1. I intend to have an echo in the next 3 months				
	IntentionWant	2. I want to have an echo in the next 3 months				
	IntentionLikely	3. I am likely to have an echo in the next 3 months				
Provider relationship	ClimateScore	5-point Likert scale (1 = disagree strongly; 2 = disagree some; 3 = neither agree nor disagree; 4 = agree some; 5 = agree strongly). *Healthcare providers have different styles of interacting with patients. We would like to know more about how you have felt about your interactions with your current healthcare provider.* ***<u>Please think about your current healthcare provider that you see most often, like a primary care provider</u>****. Your responses are confidential. Please feel free to be open and honest.*	Potential covariate/moderator	Short version - Examine EFA and Cronbach's alpha	https://selfdeterminationtheory.org/pas-health-care-climate/	6
	ClimateChoices	1. I feel that my current provider offers me choices and options.				
	ClimateUnderstood	2. I feel understood by my current provider.				

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
	ClimateConfidence	3. My current provider conveys confidence in my ability to make changes.				
	ClimateEncourage	4. My current provider encourages me to ask questions.				
	ClimateListen	5. My current provider listens to how I would like to do things.				
	ClimateSeeThings	6. My current provider tries to understand how I see things before suggesting a new way to do things.				
Static Text Psychological symptoms		The next set of questions asks about your feelings in the past 7 days. We ask these questions to help us understand if this program works well for people who may be feeling a variety of ways.	Potential covariate/moderator			4
Depressive symptoms	DepressionScore	In the past ***7 days*** … 5=point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; 5 = all the time)			PROMIS Item Bank v1.0 – Emotional Distress-Depression – Short Form 4a	
	DepressionWorthless	1. I felt worthless				
	DepressionHopeless	2. I felt hopeless				
	DepressionDepressed	3. I felt depressed				
	DepressionHelpless	4. I felt helpless				
Anxiety symptoms	AnxietyScore	In the past ***7 days*** … 5=point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; 5 = all the time)			PROMIS Item Bank v1.0-Emotional Distress-Anxiety – Short Form 4a	4
	AnxietyFearful	1. I felt fearful				
	AnxietyFocus	2. I found it hard to focus on anything other than my anxiety				
	AnxietyWorries	3. My worries overwhelmed me				
	AnxietyUneasy	4. I felt uneasy				
Perceived stress	StressScore	The questions in this scale ask you about your feelings and thoughts during the last ***month***. In each case, please indicate how often you felt or thought a certain way. 5=point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; 5 = all the time)			ECHOS-1	4

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
	StressNoControl	1. In the last month, how often have you felt that you were unable to control important things in your life?				
	StressConfidentR	2. In the last month, how often have you felt confident about your ability to handle your personal problems?				
	StressGoYourWayR	3. In the last month, how often have you felt that things were going your way?				
	StressDifficulties	4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?				
Self-regulation	SelfRegScore	Intro Text: The next questions are about echocardiograms, also called echos. How much do you agree with each of the sentences below? 5-point Likert scale (1 = do not agree at all; 2 = agree a little; 3 = agree some; 4 = agree a lot; 5 = agree completely)	Potential covariate/moderator	I changed the response scale; using "true" doesn't always work with participants who are very literal. Reduced number of response options from 7 to 5. This seems really repetitive with items above. - Refer to scoring guide to identify subscales, then for each subscale examine EFA and Cronbach's alpha	N/A	**15**
	SelfRegResponsibility	1. I would have a recommended test, like an echo, because I want to take responsibility for my own health.				
	SelfRegFeelGuilty	2. I would have a recommended test, like an echo, because I would feel guilty or ashamed of myself if I did not have the test.				
	SelfRegBestThing	3. I would have a recommended test, like an echo, because I personally believe it is the best thing for my health.				
	SelfRegUpsetWithMe	4. I would have a recommended test, like an echo, because others would be upset with me if I did not have the test.				
	SelfRegDoNotThink	5. I really don't think about getting a recommended test, like an echo.				
	SelfRegCarefulThought	6. I would have a recommended test, like an echo, because I have carefully thought about it and believe it is very important.				

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
	SelfRegFeelBad	7. I would have a recommended test, like an echo, because I would feel bad about myself if I did not get the test.				
	SelfRegImportantChoice	8. I would have a recommended test, like an echo, because it is an important choice I really want to make for my health.				
	SelfRegFeelPressure	9. I would have a recommended test, like an echo, because I feel pressure from others to have the test.				
	SelfRegEasy	10. I would have a recommended test, like an echo, because it is easier to do what I am told than to think about it.				
	SelfRegConsistent	11. I would have a recommended test, like an echo, because it is consistent with my health goals.				
	SelfRegApprove	12. I would have a recommended test, like an echo, because I want others to approve of me.				
	SelfRegImportant	13. I would have a recommended test, like an echo, because it is very important for being as healthy as possible.				
	SelfRegOthersSee	14. I would have a recommended test, like an echo, because I want others to see I can do it.				
	SelfRegDoNotKnow	15. I don't really know why I would have a recommended test, like an echo.				
Static Text Socio-demographics		This next set of questions asks you to let us know a little bit more about yourself. We ask these questions so that we can make sure this program is helpful to people with all different backgrounds.	Potential covariate/moderator			12
Age	Age	What is your age (in years)? (_____)		Years, numeric value only		
Gender		How do you identify? (1 = Man; 2 = woman; 3 = nonbinary; 4 = I prefer to self-describe: _____)				
Race	AIAN, Asian, Black, NHPI, White	Do you consider yourself (1 = American Indian or Alaska Native; 2 = Asian; 3 = Black or African American; 4=Middle Eastern or North African; 5 = Native Hawaiian or Pacific Islander; 6 = White; 7=I prefer to self-describe [open text entry]) [check all that apply type]				
Ethnicity	Hispanic	Do you consider yourself Hispanic, Latino, Latina, or Latinx? (1 = yes; 2 = no)				
Educational attainment	Education	What is the highest level of education you completed? (1 = Less than high school diploma; 2 = High school diploma or equivalent; 3 = Trade or vocational-technical school; 4 = Associate degree; 5 = Bachelor degree; 6 = Postgraduate degree			https://hints.cancer.gov/view-questions-topics/question-	

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
					details.aspx?PK_Cycle=13&qid=593	
Marital status	Marital	What is your marital status? (1 = Single, never been married; 2 = Married, living as married, or living with a romantic partner; 3 = Divorced; 4 = Separated; 5 = Widowed)			https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=13&qid=593	
Financial status	FinancialScore			Standardize items before combining to account for the different response scales		
	FinancialUnexpectedBill	1. If you were faced with an unexpected $400 medical bill that was not covered by insurance, how would you best describe your situation? (1 = not able to pay; 2 = able to pay with difficulty; 3 = able to pay comfortably).			Shepperd, MDM, 2018 and https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm	
	FinancialEndsMeet	2. Which of these statements best describes your current situation. (1 = I really can't make ends meet; 2 = I manage to get by; 3 = I have enough to manage plus some extra; 4 = Money is not a problem - I can buy whatever I want)			Shepperd, MDM, 2018 and https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm	

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
					Lipkus IM, Klein WM, Rimer BK. Communicating breast cancer risks to women using different formats.	
Numeracy	NumeracyScore	Intro text: The next few questions ask you to answer some questions about numbers. We ask these questions so we can make sure this program is helpful to people who think about numbers in different ways.		Sum number of correct and dichotomize 0/1/2 (limited numeracy) vs. 3/4 (adequate numeracy)	Cancer Epidemiol Biomarkers Prev. 2001;10(8):895–8.	
	NumBiggestRisk	1. Which of the following numbers represents the biggest risk of getting a disease: (1 = 1 in 100; 2 = 1 in 1000; 3 = 1 in 10; 4 = don't know				
	NumFairCoin	2. Imagine that we flip a fair coin 1,000 times. What is your best guess about how many times the coin would come up heads in 1,000 flips? *Please enter a number between 0 and 1,000.*				
	NumHowMany	3. Imagine that the chance of getting a disease is 1%. If there were 1,000 people, about how many would be expected to get the disease? Please enter a number between 0 and 1,000.				
	NumWhatPercent	4. Imagine that the chance of getting an infection is 1 in 1,000. What percent (%) of people would be expected to get the infection? *Please enter a number between 0 and 100. Do not include a % sign.*				
Health status			Potential covariate/moderator			2
Health insurance status	Insurance InsuranceNo InsuranceEmp InsuranceComp InsuranceMedicare InsuranceMedicaid InsuranceMilitary InsuranceIHS InsuranceOther InsuranceOtherText	Are you <u>currently</u> covered by any of the following types of health insurance or health coverage plans? [check all that apply] (1 = No; 2 = Yes - Insurance through a current or former employer or union (including plans through another person's employer); 3 = Yes - Insurance purchased directly from an insurance company, including Marketplace plans; 4 = Yes - Medicare, for people 65 and older, or people with certain disabilities; 5 = Yes - Medicaid, Medical Assistance, or any kind of government-assistance plan for those with low incomes or a disability; 6 = Yes - TRICARE, VA , or other military			https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2021/EnglishQuest.pdf	

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Other source (if applicable)	# Items
		health care; 7 = Yes - Indian Health Service; 8 = Yes - Other (please describe on next screen)___)				
Usual source of care	UsualSource	Is there a place that you USUALLY go to if you are sick and need health care? (1 = No, there is no place; 2= Yes - A doctor's office or health center; 3 = Yes - Urgent care center or clinic in a drug store or grocery store; 4 = Yes - Hospital emergency room; 5 = A VA Medical Center or VA outpatient clinic; 6 = Some other place)			https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2021/EnglishQuest.pdf	

Post-Test Survey

Include all measures from pre-test survey EXCEPT the purported moderators: Self-regulation; Provider relationship; Psychological symptoms; Socio-demographics; Health status.

Also include the implementation outcomes variables listed below for the follow-up survey.

1-Month Follow-Up Survey

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Row # from "Survey item source and scoring" sheet	Other source (if applicable)	# Items
Client Evaluation of Treatment	EvaluationScore	Please help us improve our Heart Health program by answering some questions. We are interested in your honest opinions, whether they are positive or negative. Please answer all questions. We also welcome your comments and suggestions. Thank you very much; we really appreciate your help. 5-point Likert scale (1=Not at all; 2=A little; 3=Somewhat; 4=Very; 5=Extremely)	Usability, Feasibility, Satisfaction,	Examine EFA and Cronbach's alpha	N/A	Adapted from Idalski, Carcone, et al. (2020) adaptation from Larsen DL, 1979.	13
	EvalOverallSatisfied	1. Overall, how satisfied are you with the Heart Health program?					
	EvalMeetExpectations	2. How much did the Heart Health program meet your expectations?					
	EvalUseful	3. How useful was the Heart Health program for you?					
	EvalMeetNeeds	4. How well did the Heart Health program meet your needs for learning about getting screened for heart damage?					
	EvalGetThinking	5. How much did participating in the Heart Health program get you thinking about getting screened for heart damage?					
	EvalEasy	6. How easy was it for you to use the Heart Health program?					
	EvalSatisfiedHelp	7. How satisfied are you with the amount of help you received for getting screened for heart damage?					
	EvalComfortable	8. How comfortable did you feel using the Heart Health program?					
	EvalUseAgain	9. If you needed assistance again, how likely would you be to use the Heart Health program again?					
	EvalRecommend	10. If a friend were in need of similar help, how likely would you be to recommend the Heart Health program to them?					
	EvalQuality	11. How would you rate the quality of the Heart Health program? (1=Poor, 2=Fair, 3=Good, 4=Very good, 5=Excellent)					
	EvalMissTopics_R	12. How many important topics did the Heart Health program miss? None (0); 1; 2; 3; 4; 5 or more (5)					

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Row # from "Survey item source and scoring" sheet	Other source (if applicable)	# Items
	EvalLikeBestLeast	13. Please tell us in your own words what you thought of the Heart Health program. What did you like best? Least? What would you change? [Open-ended text response]					
1-Month Follow up ONLY							
Move toward behavior – distal behaviors	MTBDistal	Have you looked into and/or shared any of the information we discussed in the Heart Health program? This could be things like sharing the information with family or loved ones, thinking about overcoming challenges you might run into when trying to get a heart function test, or planning what you might say when talking to a healthcare provider about the test. [yes=1/no=2]					
Move toward behavior – Proximal behaviors		Have you done any of the following since you completed the Heart Health program? [Several yes=1/no=2 items]		If participant says "yes" to any of these in the list, then code them as having made movement towards getting screened.			
	MTBIdentifyProvider	1. Identify a provider to ask for the heart function test					
	MTBSetDiscussAppt	2. Set an appointment with your healthcare provider to discuss getting a heart function test					
	MTBTalkToProvider	3. Spoken with your healthcare provider about getting a heart function test					
	MTBSetTestAppt	4. Set an appointment to get a heart function test					
	MTBGotTest	5. Got a heart function test					
	MTBOther	6. Something else not listed, please describe: [open ended text response]					
	MTB[Name from above]ShareYes	Would you like to share anything about what it was like to <ENGAGE IN PROXIMAL BEHAVIOR>? If so, please write a sentence or two in the box below.		Display for each of the proximal behaviors listed above the			

Construct	Variable name	Items and response scale	Type of construct	Analytic notes	Row # from "Survey item source and scoring" sheet	Other source (if applicable)	# Items
	MTB[Name from above]ShareNo	Would you like to share anything about why you didn't <ENGAGE IN PROXIMAL BEHAVIOR>? If so, please write a sentence or two in the box below.		participant responds 'yes' to Display for each of the proximal behaviors listed above the participant responds 'no' to			