Study Title: Emergency Department Healthcare Education Assessment and Response for Teen Relationships (ED-HEART): A Pilot Feasibility Study

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PROTOCOL TITLE:

Emergency Department Healthcare Education Assessment and Response for Teen Relationships (ED-HEART): A Pilot Feasibility Study

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/9/2022	Additional text/email if needed to send survey link after phone call at 6-week check-in	No
2	04/27/2022	Update 6-week check in and 12-week follow up to allow for coordinator to check in at inpatient and outpatient visits during follow up window to complete surveys	Yes
3	05/16/2022	Increase the 12-week survey gift card from $20 to $25	Yes
4	07/20/2022	Add a reminder to contact participant at week 11 for the 12 week survey completion Add option to notify participants of 6-week check in and12-week f/u survey availability via social media.	Yes
5	6/19/2024	Increase sample size to 175	No

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STUDY INFORMATION

1.0 Study Summary*

1.1 Synopsis

Study Title	Emergency Department Healthcare Education Assessment and Response for Teen Relationships (ED-HEART): A Pilot Feasibility Study
Study Design	We will evaluate feasibility of ED-HEART using the Bowen feasibility model and a randomized controlled trial comparing ED-HEART to enhanced usual care among adolescents seen in the ED.
Primary Objective	To determine feasibility of ED-HEART, through assessment of eight constructs: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing.
Secondary Objective(s)	To examine Theory of Planned Behavior constructs that may impact ED-HEART efficacy. To conduct exploratory analysis of factors that may impact efficacy and implementation of ED-HEART.
Study Population	Adolescents (age 14-19 years) seeking ED care
Sample Size	174 adolescents
Study Duration for Individual Participants	12 weeks
Study Specific Abbreviations/ Definitions	adolescent relationship abuse (ARA) emergency contraception (EC) emergency department (ED) Emergency Department Healthcare Education Assessment and Response for Teen Relationships (ED-HEART) motivational interviewing (MI) point of care (POC) reproductive and sexual health (RSH) sexually transmitted infection (STI) theory of planned behavior (TPB)

2.0 Objectives*

2.1 Purpose, specific aims or objectives:

Our primary aim is to determine feasibility of Emergency Department Healthcare Education Assessment and Response for Teen Relationships (ED-HEART). We will conduct a randomized, controlled trial using mixed methodology to assess eight

feasibility constructs: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing.

Secondary aims are to:

- Examine Theory of Planned Behavior constructs that may impact ED-HEART efficacy.
- Conduct exploratory analysis of factors that may impact efficacy and implementation of ED-HEART.

2.2 Hypothesis to be tested/Exploratory study design:

Hypothesis 1.1: ED-HEART will be feasible as measured by data from adolescents and ED stakeholders.

Hypothesis 1.2: Adolescents receiving ED-HEART will report less ARA at three-month follow-up, compared to controls.

☐ Children/Minors (under 7 years of age)
☒ Children/Minors (7-17 years of age)
☐ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☒ Wards of the State
☐ Fetuses
☐ Pregnant Women
☐ Adults with impaired decision-making capacity

☐ CM Employees
☐ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

Adolescents aged 14-17 years:

- Adolescent assent procedures will follow practices accepted by the Society for Adolescent Health and Medicine and current regulatory guidelines and align with those previously used for CM studies involving adolescents
- All adolescents will be encouraged to ask questions, provided necessary time to consider participation, and able to stop participation at any time, should they choose to do so.
- All adolescents will be assured that their decision to participate or not will have no impact on their relationship with and care received at CM.

Wards of the State:

- Assent procedures for Wards of the State will mirror those for non-Wards.
- Procedures will follow practices accepted by the Society for Adolescent Health and Medicine and current regulatory guidelines and align with those previously used for CM studies involving adolescents.
- Adolescents who are Wards of the State will be encouraged to ask questions, provided necessary time to consider participation, and able to stop participation at any time, should they choose to do so.
- All adolescents who are Wards of the State will be assured that their decision to participate or not will have no impact on their relationship with and care received at CM.

7.0 Local Number of Participants

	Group 1: Intervention Arm	Group 2: Control Arm	Total
Enrollment Goal	87	87	174

8.0 Identification and Recruitment of Potential Participants*

Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☐ Chart reviews

☐ By their treating physician who will then provide the study team's contact information to the potential participant/family

☐ By their treating physician who will obtain patient/family permission to share contact information with the study team

☐ By a partnering community-based organization who will then provide the study team's contact information to the potential participant/family

☐ By a partnering community-based organization who will obtain patient/family permission to share contact information with the study team

☐ Self-refer in response to IRB approved advertisements or websites

☒ Through Cerner or other CM sources (e.g., databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

- We will use the Cerner ED tracking board to identify potential participants.

☐ List of candidates provided through the Data Report Request Form

☐ Registry of individuals interested in research opportunities

☐ Past participant list

☐ Participants will roll-over from another research study: Study #_____

☐ Other:

_____

Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☒ Yes

☐ No

- We request a Partial Waiver of HIPAA Authorization for Screening Purposes. See ***Addendum E: Waiver/Alteration of HIPAA Authorization***

Recruitment of Potential Participants:

- We will use our electronic ED tracking board to identify potential adolescent participants. For those who are eligible per age as listed on the tracking board, the study team will check the electronic health record to determine if a research note for this study is present. Those adolescents who have already participated in this study are not eligible. The study team will approach potential participants sequentially during their ED visit based on arrival and availability. We will carefully time our approach of potentially eligible patients to minimize impact on patient care and ED flow. We will ensure balanced enrollment in regard to sex (male/female) using data that is easily accessible on the electronic tracking board.

9.0 Surveys and Psychometric Testing:

Study surveys were developed by the study team and based on extant literature. Surveys will be delivered via REDCap and completed on a

smart phone, desktop, or tablet computer. Surveys and their domains are listed below.

- Adolescents:
    - Baseline Survey (intervention, control arms): unique code questions,[39] demographics, ARA victimization and perpetration,[35,40,41] recognition of abusive behaviors,[35,41] self-efficacy,[42] consequences of ARA, ARA resource knowledge/use,[35] readiness to engage in healthy relationship behaviors
    - Exit Survey (intervention arm only): fidelity, acceptability, self-efficacy,[35] use of POC resources, ARA disclosure
    - Follow-up Survey (intervention, control arms): unique code questions,[39] ARA victimization and perpetration,[35,40,41] recognition of abusive behaviors,[35,41] self-efficacy,[35] consequences of ARA, ARA resource knowledge/use

10.0 Additional Research Activities

Data collection from the medical record: A study team member will use a REDCap instrument to collect insurance type from the medical record for each participant. Additionally, upon completion of enrollment, we will collect aggregate medical record data (i.e., the number of participants for whom each order is used) using the Cerner study order set (this is an order set designated for use for any POC resource for which a medical record order is required).

Screening Log: The study team will maintain an adolescent screening log that includes patient age, sex, and reason for study exclusion. Age and sex will be obtained from the Cerner ED tracking board. No PHI will be included in the Screening Log. The Screening Log will enable the study team to determine the number of adolescents who are excluded and for what reason(s), the number who are potentially eligible for participation but the enrollment opportunity is missed, etc.

Refusal Log: The study team will maintain a refusal log to better understand potential differences between adolescents that participate and those that do not. Adolescents who decline to participate will be asked if they will provide information anonymously. If they agree to do this, they will complete an anonymous survey that assesses age, sex, gender, race, ethnicity, primary language, and reason for not participating. This survey will be administered via REDCap/tablet computer. If the adolescent declines to complete the refusal survey, the study team member will complete items on age and sex (available on the

ED tracking board used for screening purposes) and reason for study declination, if provided.

11.0 Follow-up

- Participants will complete a 6-week check-in to confirm and update contact information. This will be done via email, text, that has the weblink to a REDCap survey that asks if current contact information is current and offers opportunity to update contact information if needed. We will send up to 2 emails and/or 2 text reminders for the 6-week check in. If by week 7 the participant has not completed the follow-up survey, a study team member will call them using the phone number(s) provided to remind them about the survey (maximum number of phone calls = 3). If needed at the time of the call, the follow-up survey weblink will be sent via email and/or text.
- Option to notify participants of 6-week check in and 12-week follow up survey availability via social media using a Children's Mercy Hospital channel (e.g. Facebook, Twitter, Instagram, etc.).
- Participants will receive a reminder contact about the upcoming survey, sent one week ahead of the 12-week survey (at week 11) via the participant's preferred method of contact and/or social media handle using a Children's Mercy Hospital channel.
- Participants will complete the Follow-up Survey at 12 weeks (completion window 10-14 weeks).
- Participants will receive an email and/or text inviting them to complete the follow-up survey using a weblink provided. We will send up to 2 emails and/or 2 text reminders, as needed. If by week 13 the participant has not completed the follow-up survey, a study team member will call them using the phone number(s) provided to remind them about the survey (maximum number of phone calls = 3). If needed at the time of the call, the follow-up survey weblink will be sent via email and/or text.
- To aid in completion of the Follow-Up Surveys, the study team will check the medical record to see if participants have scheduled appointments at Children's Mercy during the 6 week and 12 week follow-up window. If they have an appointment, or are admitted to Children's Mercy, the study team will approach them at this time to offer opportunity to complete the Follow-up Survey via tablet computer at this appointment.

12.0 Genetic Analysis Information

N/A

13.0 Sharing of Results with Participants

We will not share results of research procedures with participants. Results derived from clinical care procedures (i.e., lab testing) will be shared with participant by the ED team as per usual standard of care.

14.0 Risks to Participants*

Breach of confidentiality: As with any study, there is potential for breach of confidentiality. Strict measures will be taken to ensure participant privacy and confidentiality. All data will be managed in accordance with hospital institutional review board and HIPPA requirements to ensure confidentiality and protection of research participants. Participants will provide assent/consent and complete data collection privately to maintain confidentiality. Study personnel will not use study data and records for any purpose other than conducting the study. Only researchers involved in this study will have access to the collected data. All data will be de-identified then stored in the secure REDCap database, and all participants will be assigned a unique identification number. The contact information needed to facilitate the 6-week check-in and 3-month Follow-up will not be linked to survey data. All personally identifiable information will be kept strictly confidential and stored in REDCap and only accessible by Dr. Randell and the necessary, designated study staff. At the completion of data collection and gift card provision, personally identifiable information will be destroyed.

Mandatory reporting: During the consent process, we will inform participants that we are unable to maintain confidentiality if they verbally disclose abuse that requires a mandated report by state law or relationship behaviors that raise significant concern for safety of a minor (i.e., < 18 years of age) adolescent participant.

Emotional distress: Participants may experience distress triggered by the study topic. However, our prior experience with similar studies and available published evidence suggests this risk is minimal.[43-45] We include information in the consent process that reminds participants that they are not required to answer questions that make them feel uncomfortable and may choose to terminate study participation at any time. CMH social workers and a community-based intimate partner violence advocate are available 24 hours daily for patients and families; participants will be informed of this availability during the informed consent process, as well as upon interview completion. Additionally, each participant will receive a list of teen community resources (e.g., local intimate partner violence

agency, teen resource center, mental health resources, and agency advocating for sexual minority youth; national suicide hotline, ARA, and sexual exploitation resources), such that they may contact needed resources at any time without disclosure of need to the study team.

Study risks are not greater than minimal for all participants.

15.0 Potential Benefits*

Participants may benefit directly from the teen resource list that will be provided to each participant. Participants in the intervention arm may benefit from receipt of the ED-HEART intervention. Information provided in the teen resource list and ED-HEART intervention may enable participants to better delineate healthy vs. unhealthy relationship behaviors, to provide support for peers experiencing ARA, and to access CM and community resources for common issues, including ARA.

Benefits to society/science may include 1) improved care of adolescents treated receiving care in ED settings in the future, through ED-HEART implementation, and 2) better understanding of effective interventions to promote healthy adolescent relationships and mitigate harms of ARA.

16.0 Investigator Assessment of Risk/Benefits Ratio*

16.1

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	

☒	Not Greater than Minimal Risk
☐	Greater than Minimal Risk

17.0 Payment, Reimbursement and Tangible Property provided to participants*

Is payment, reimbursement, or tangible property part of the study?

☒ Yes ☐ No *(If No, delete the following subsections)*

Payment to Participants:

☐ Greenphire/ClinCard
☐ Gift Card: (Merchant:_____)
☒ Other: __CC pay_____

Payment Schedule: Adolescent participants may receive a total of $50 over 3 months for study participation, as indicated in the table below.

Initial visit	6-week check-in	3 months
$20	$5 (to be added to final payment)	$25

Reimbursement: N/A

Tangible Property: N/A

18.0 Compensation for Research-Related Injury

Being in this study involves no more than minimal risk, therefore we do not require compensation for research-related injury.

19.0 Economic Burden to Participants

Participants may incur costs related to text messaging and data charges for surveys completed on their cellular phone. Participants may incur costs related to follow up after the ED visit at which they enroll in the study (e.g., positive STI testing).

20.0 Parental Permission and Adult Consent Process*

20.1 All participants will provide informed consent/assent before participating in study procedures, as described below.

Written Informed Permission/Consent

☐ **Written informed permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: N/A

☒ **Written informed consent of adult participants**

Study group(s) to which this method applies: Adolescent participants age 18-19 years of age will provide written consent.

☐ **Written informed consent of participants turning 18**

Study group(s) to which this method applies: N/A

Waiver of Documentation of Permission/Consent

Permission/Consent form provided but signature will **NOT** be obtained (e.g., verbal consent)
Must complete *Addendum A: Waiver of Documentation of Permission/Consent*

☒ **Waiver of written documentation of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: We request waiver of written parent/LAR permission for adolescent participants 14-17 years of age. Verbal permission will be obtained for the minor adolescent to independently provide assent.

See ***Addendum A: Waiver of Documentation of Permission/Consent***

☐ **Waiver of written documentation of consent of adult participants**

Study group(s) to which this method applies:

☐ **Waiver of written documentation of consent of participants turning 18**

Study group(s) to which this method applies: N/A

Waiver or Alteration of Permission/Consent

☒ **Waiver/Alteration of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: We request a waiver of parent/LAR permission for adolescent participants 14-17 years of age presenting to the ED without a parent/LAR.

See ***Addendum B: Waiver of Permission/Assent/Consent***

☐ **Waiver/Alteration of consent of adult participants**

Study group(s) to which this method applies:

☒ **Waiver of documentation of consent of participants turning 18**

Study group(s) to which this method applies:

Additional Methods

☒ **Obtaining permission/assent/consent of non-English speaking parents or participants**

Study group(s) to which this method applies: We will obtain parent/LAR permission from Spanish-speaking parents presenting with adolescent participants 14-17 years of age. See ***Addendum C: Non-English Speaking Participants***

☐ **Surrogate decision maker consent form adults not capable of consenting for themselves**

Study group(s) to which this method applies: N/A

20.2 Permission/Consent/Consent at 18 Discussion: N/A

20.3 Documentation of Permission/Consent/Consent at 18*:* The 6-week check in and 3-month follow-up surveys will include a question asking the patient if they have turned 18 since they enrolled in the study. For those that answer "yes," we will use branching logic to ensure that they consent to participate at this point.

20.4 Identification of participants turning 18*:* N/A

21.0 Assent of Pediatric Participants

21.1 Select the option(s) that apply to the study:

☐ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

☐ *The capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*

☐ *The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

☐ **Obtaining assent of pediatric participants is NOT PRACTICLE given the context of this study** (e.g., minimal risk, no direct contact with participants). **Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent***

☒ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.**

21.2 Assessment of Ability to Assent: Study team members will verify with the clinical care team that the patient has the capacity to assent.

21.3 Assent Discussion: Informed assent will occur during the ED visit in a private setting (i.e., parent/LAR will not be present during the assent process). The study team will:
1) Provide ample opportunity for potential participants to ask questions and to consider participation, including coming back later during the visit to allow the adolescent time for consideration.
2) Use teach-back to confirm comprehension of study procedures.
3) Communicate that current and future care at CM will not be impacted by the decision to participate in the study or not.

21.4 Documentation of Assent or Inability to Assent: We will use eConsent to document participant assent

22.0 HIPAA and Confidentiality

22.1 HIPAA Authorization

☒ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form) from adolescent participants 18-19 years of age.

☒ Partial Waiver of HIPAA Authorization:
We request a partial waiver of HIPAA Authorization for:

- Use of the ED tracking board to facilitate recruitment and pre-screening and data collection from the electronic health record.

See ***Addendum E: Waiver/Alteration of HIPAA Authorization***

☐ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g., signature will not be obtained)
See ***Addendum E: Waiver/Alteration of HIPAA Authorization***

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained):

See ***Addendum E: Waiver/Alteration of HIPAA Authorization***

☐ If Other, explain:

22.2 Data confidentiality:

- PHI will be stored in a secure CM REDCap file, accessible only to members of the study team.
- We will destroy PHI at the earliest opportunity. We will maintain PHI through completion of enrollment and data analysis. PHI will then be deleted.
- PHI will only be accessed by members of the study team as necessary for study procedures. Good Clinical Practice guidelines will be followed in order to ensure that study data is not disclosed to unauthorized persons.
- Study team training will include the importance of data confidentiality and mechanisms to protect confidentiality.

22.3 As this is an NIH-funded study, a Certificate of Confidentiality has been issued for this study.

23.0 Provisions to Protect the Privacy Interests of Participants*

23.1 The study team will take great care to protect participant privacy.

Recruitment and enrollment will occur privately.

Participants will be assigned a study number. Surveys will be completed confidentially and will not contain identifying information. We will use a unique, participant-created code to link study surveys over time, such that participant identity is not linked to the study survey data.[39] Contact information used to facilitate follow-up survey completion will be stored in a separate REDCap tool and thus not linked to study data. Identifying information necessary for gift card provision will be obtained upon survey completion via a separate REDCap tool and thus this information will not be linked to an individual participant's survey data.

All data will be managed in accordance with the CM Institutional Review Board and HIPAA requirements to ensure confidentiality and protection of research participants. Study team members will not use study data and records for any purpose other than for conducting the study. PHI will be kept in a password protected database that is separate from the study survey database. PHI will be deleted at the earliest opportunity. There are no patient identifiers recorded in the permanent research record. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the OHRP, the Sponsor, or the Sponsor's designee.

23.2 To ensure participants feel at ease with study procedures, we will thoroughly explain study procedures, ensure ample opportunity for questions at any point during the study, provide assurance that participation is voluntary and can be terminated at any point, and provide assurance that the decision to participate or not will not impact the participant's relationship with Children's Mercy

23.3 Study team members will only have access to data required to complete their designated study duties. Study team member training will include necessity of and mechanisms to protect privacy and confidentiality.

24.0 Withdrawal of Participants*

All participants may withdraw from the study at any time by notifying the research team. If a participant withdraws from the study, any data collected up to that point will be kept and deidentified for analysis purposes.

DATA MANAGEMENT

25.0 Data Collection*

Sources of data include adolescent participants (surveys, audio recordings of ED-HEART delivery), the medical records of adolescent participants (chart review by study team), the Cerner ED tracking board, and Health Educator field notes. See Section 9 (Surveys and Psychometric Testing) for a detailed description of survey data.**Sensitive Data:** Study data includes report of ARA and receipt of POC RSH resources accessed during the ED visit.

Identifiable Data: PHI sufficient to enable delivery of the study follow-up survey and to enable monitoring of intervention fidelity (i.e., audio recording of ED-HEART delivery) will be recorded. This information will not be retained as a part of permanent study data.

1. Name/Initials	☐ Accessed only	☒ Recorded

2. All elements of date (except year) directly related to an individual (e.g., date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded
3. Medical record number	☐ Accessed only	☒ Recorded
4. Account number	☐ Accessed only	☒ Recorded
5. Health plan identification number	☐ Accessed only	☐ Recorded
6. Social Security Number	☐ Accessed only	☐ Recorded
7. Device identifiers and serial number	☐ Accessed only	☐ Recorded
8. Certificate/License number	☐ Accessed only	☐ Recorded
9. Telephone number	☐ Accessed only	☒ Recorded
10. Fax number	☐ Accessed only	☐ Recorded
11. Email addresses	☐ Accessed only	☒ Recorded
12. Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
14. Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
15. Biometric identifiers, including finger and voice print	☐ Accessed only	☒ Recorded
16. Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded
17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g., student or employee ID number)	☐ Accessed only	☐ Recorded
18. Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
19. Other:	☐ Accessed only	☐ Recorded

26.0 Adverse Events and Unanticipated Problems*

Monitoring: The PI and study team will meet weekly during enrollment and the 3-month follow-up period to identify and discuss adverse events and unanticipated problems. Study team members will promptly notify the PI if an adverse event or unanticipated problem is identified.

Reporting: We will follow Policy 5.11 Reportable Events of the CM Research Program Policies and Procedures in regards to reporting adverse events and other unanticipated problems to the CM IRB.

27.0 Data Analysis

We will generate a descriptive summary of feasibility using the Bowen model's eight constructs (Table 2).

Table 2: Assessment of Bowen Feasibility Constructs

Construct	Definition	Assessment measures
Acceptability	To what extent is ED-HEART suitable?	Adolescent surveys, Health Educator field notes
Demand	To what extent is ED-HEART likely to be used?	Proportion of screened adolescents eligible; proportion of eligible adolescents enrolled; Health Educator field notes
Implementation	To what extent can ED-HEART be delivered as planned?	Fidelity assessment per adolescent survey, Health Educator field notes, audio recordings of intervention delivery
Practicality	What factors make delivery challenging or facilitate delivery?	Health Educator field notes
Adaptation	To what extent does ED-HEART perform in a new system?	Comparison with published outcomes in original setting[33]
Integration	To what extent can ED-HEART be integrated within existing system?	Health Educator field notes
Expansion	To what extent can the existing system be expanded to provide ED-HEART?	Health Educator field notes
Limited efficacy	Are ED-HEART outcomes promising?	Primary outcome: any ARA at 3-month follow up[33], per adolescent survey

Acceptability ratings will be collapsed to dichotomous variables. ED-HEART will be deemed acceptable if the test of the proportion of very/fairly satisfactory ratings for adolescents, the health educator, and ED staff being <85% is not statistically significant. We will compare ED length of stay between the two arms, and calculate the mean/median number of interruptions per participant, with a list of reasons for interruption. For limited efficacy assessment, our primary outcome is any ARV as individual types of abuse rarely occur in isolation and HEART is designed to address ARV broadly. We will compare odds of reporting ARA at follow-up for the two arms by fitting a logistic regression model with any ARV at follow-up (yes or no) as the dependent variable, baseline ARA

(yes or no) as a covariate, and study arm as focal predictor. This approach should have higher statistical power than the Fisher's Exact Test used in the power analysis, making our sample size somewhat conservative. We will analyze secondary outcomes (ARA perpetration, ARA victimization, recognition of abusive behaviors, knowledge of ARA resources, self-efficacy to use harm reduction strategies, use of harm reduction strategies and resources) similarly. Factors potentially affecting intervention efficacy (e.g., sex, gender, race/ethnicity, recognition of behaviors as abusive, intention to engage in healthy relationship behaviors, adolescent change talk, MI fidelity [MI-consistent/-inconsistent behaviors], intervention intensity [number of intervention topics discussed]) will be considered as additional model predictors. We will summarize demographics and report baseline prevalence of any ARA and individual types of ARA. We will check for differences in demographics and baseline variables between the two arms, as well as for demographic differences between participants and refusals.

2.3 A sample size of 69 per arm provides 80.4% power to detect a between-arm difference, assuming control and intervention arm TVD rates of 0.55 and 0.30, respectively, at 3 months at follow-up (two-sided Fisher's Exact Test at alpha=0.05). We set a final sample as n=174 participants (n=87 each arm) to account for an estimated 20% loss to follow up, based on our previous work.

28.0 Data and Specimen Management*

Data Management: Data will include that obtained from the study surveys and medical record, as described above.

Data will be collected via REDCap or paper survey or EHR review. Data from the surveys and EHR will be stored in REDCap. Paper surveys, if used in the event of a REDCap or other IT issue, will be stored in a locked office of the investigators.

Deidentified data will be exported from REDCap to statistical programs for analysis (e.g., SAS, SPSS, Excel). All data will be securely stored on password-protected CM servers.

Strict measures will be taken to ensure participant privacy and confidentiality. Participants will be assigned a unique study identification number. Additionally, survey data will be collected using a unique, participant-created code such that a link between participant survey number and participant identity do not need to be linked.[39] The study REDCap project will be set up such that the study team will not be able to link survey data to individual participant identity. All personally identifiable information needed to facilitate data collection and intervention fidelity review will be kept strictly confidential, stored on

REDCap, and accessible only to designated study team members. Only study team members needing access to data to fulfill their study responsibilities will have access to the data. Non-study team members will not have access to the data.

Data will be stored per CM records retention policy.

Specimen Management: N/A

Biosafety Information

Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

29.0 Storage/Banking of Data and Specimens for Future Research

N/A

30.0 Provisions to Monitor the Data to Ensure the Safety of Participants

N/A as this study does not involve more than Minimal Risk to participants.

STUDY MANAGEMENT

31.0 Setting & Locations

Study processes will occur at Children's Mercy, with participant recruitment and procedures occurring in the EDs. The treating ED team, an ED social worker, and

an intimate partner violence advocate are available to participants 24 hours daily in the ED setting.

32.0 Multi-Site Research

All study procedures will occur at CM. However, some co-investigators are from non-CM institutions: Elizabeth Miller, MD, PhD (University of Pittsburgh), Ann Davis, PhD (University of Kansas Medical Center), Megha Ramaswamy, PhD (University of Kansas Medical Center). These study members are categorized as not participating in human participants research as they will at no time interact with study participants or have access to identifiable data.

33.0 International Research

N/A

Addendum A: Waiver of Documentation of Permission/Consent

Regulatory Criteria: *To qualify for a waiver of documentation of parental permission or adult consent, the study must fit into at least one of the three scenarios below. Indicate which scenario(s) applies.*

☐ **The only record linking the participant and the research would be the permission/consent form and the principal risk is potential harm resulting from a breach of confidentiality.** Each parent/LAR or adult participant will be asked whether they want documentation linking the participant with the research, and the parent/LAR's or adult participant's wishes will govern.

OR

☒ **The research presents no more than minimal risk of harm to participants and involves no procedures for which written parental permission or adult consent is normally required outside of the research context.**

OR

☐ **The parent(s)/LAR or adult participants are members of a distinct cultural group or community in which signing forms is not the norm**, the research presents no more than minimal risk of harm to participants and an appropriate alternative mechanism for documenting that informed parental/LAR permission or adult consent was obtained will be provided. Describe the alternative mechanism provided:

Addendum B: Waiver/Alteration of Permission/Assent/Consent

What's the difference between a "waiver" and an "alteration" of parental permission, child assent, or adult consent?

- A "waiver" of parental permission, child assent, or adult consent is when **all 9 required elements of permission/consent are waived.** If the IRB approves a waiver, then the study team does not need to obtain the parental permission or adult consent in order to include a participant in the study.

- An "alteration" of parental permission, child assent, or adult consent is when **one or more of the 9 required elements are waived** because they are not relevant to the research activity. If the IRB approves an alteration, then the study team must still obtain parental permission or adult consent in order to include a participant in the study, but certain elements may not be required in the form/discussion.

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	Study participation entails no more than minimal risk for participants.
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	Exclusion of adolescent presenting to the ED unaccompanied by a parent would result in sampling bias. Adolescents commonly present to the ED unaccompanied by a parent. Further, a common reason for adolescents to seek medical are without a parent is to address reproductive and sexual health concerns; these adolescents are at increased risk for ARA and should not be excluded from this study.
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	PHI is needed to enable data collection at the 12-week follow up. PHI collected is limited to that needed for 12-week follow up.
The waiver/alteration will not adversely affect the rights and welfare of the participants	Waiver of parental permission for adolescents presenting to the ED unaccompanied by a parent will not adversely affect the rights and welfare of participants as this study is minimal risk and all participants will provide assent.

Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

Proposed Alteration (if applicable):

Select which required elements of permission are to be omitted.

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the participant;

☐ A description of any benefits to the participant or to others that may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

☐ A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Provide the rationale for omitting the item(s) selected: N/A

Addendum C: Non-English Speaking Participants

There are special considerations that must be made when obtaining permission/assent/consent from participants who prefer to communicate in a language other than English. To ensure that adequate processes are in place to obtain effective permission/assent/consent from these participants address each of the items below.

Indicate which language(s) other than English are understood by prospective participants or representatives.

☒ Spanish
☐ Arabic
☐ Burmese
☐ Somali
☐ Vietnamese
☐ Other:_____

Describe the plan for enrolling non-English speaking participants (e.g., fully translated consent forms, use of Qualified Bilingual Study Staff or interpreters):

For enrollment of minor participants with Spanish-speaking parents who are present at the time of the ED visit, we will use:

- Qualified bilingual study staff or an interpreter.
- A Spanish version of the Study Information Sheet for Parents.

If providing fully translated consent forms, explain if the ORI Translation Program for internally and/or federally funded studies will be used, or if translation services will be obtained through the study sponsor or some other service.

As this is a federally funded study, we will use the ORI Translation Program for documents requiring translation (i.e., Study Information Sheet for Parents).

Addendum D: Surrogate Decision Maker Consent

N/A Not applicable

Addendum D: Surrogate Decision Maker Consent

Not applicable

Addendum E: Waiver/Alteration of HIPAA Authorization

What's the difference between a "waiver" and an "alteration" of HIPAA Authorization?

- A "waiver" of HIPAA Authorization is when **the requirement to obtain authorization is completely waived.** If the IRB approves a waiver, then the study team does not need to obtain HIPAA Authorization in order to include a participant in the study.

- An "alteration" of HIPAA Authorization is when **one or more of the required elements of authorization are waived.** If the IRB approves an alteration, then the study team must still obtain HIPAA Authorization in order to include a participant in the study, but certain elements may not be required in the form/discussion.

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. Assurance that PHI will not be reused or disclosed to any other person or entity:	Partial Waiver of HIPAA Authorization and Alteration of HIPPA Authorization: a. Only researchers involved in this study will have access to PHI and will use it only for study purposes as described in this protocol. Recorded data will be stored in the secure REDCap database and all participants will be assigned a unique study identification number. b. All recorded PHI will be deleted upon study completion, such that only de-identified data is permanently stored as part of this study. c. PHI will not be reused or disclosed to anyone not involved in this research. Good Clinical Practice guidelines will be

	followed in order to ensure that information will not be disclosed to unauthorized persons.
The research cannot practicably be conducted without the waiver/alteration, i.e., explain why a signature for HIPAA Authorization cannot be obtained.	Partial Waiver of HIPAA Authorization for pre-screening/recruitment: Data will be accessed prior to recruitment of participants by reviewing the clinic electronic tracking boards. PHI will not be recorded prior to obtaining informed permission/assent/consent.
The research cannot practicably be conducted without access to and use of the PHI, i.e., explain why access to PHI is needed for this study.	Partial Waiver of HIPPA Authorization: Without access to PHI via the Cerner electronic tracking boards for screening/recruitment, we will be unable to practicably identify which patients are potentially eligible for study participation.

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