CARE Trial Protocol

****Reporting guidelines taken from SPIRIT 2013 statement****

Administrative Information

1. Title

Clinical Trial of a Supporter-Targeted Intervention to Improve Outcomes in Recent Sexual Assault Survivors (CARE)

2. Trial registration

2a. Trial identifier and registry name

If not yet registered, name of intended registry

ClinicalTrials.gov ID: NCT05345405

3. Protocol version

Date:

April 14, 2025

Version:

4

4. Funding

(Sources and types of financial, material, and other support)

Department of Justice, Office on Violence Against Women Grant #2020-SI-AX-0007

5. Roles and responsibilities

5a. Names, affiliations, and roles

Name	Study Role	Affiliation
Emily Dworkin	Principal Investigator	UW
Michele Bedard-Gilligan	Co-Investigator	UW
JP Santos	Research Coordinator	UW
Margee Quinn	Research Coordinator	UW
Jenna Mohr	Research Assistant	UW
Carolina Ibarra	Research Assistant	UW
Angela Simler	Research Assistant	UW
Jenna Mohr	Research Assistant	UW
Maddie Lacoste	499 Research Assistant	UW
Sarah Ton	499 Research Assistant	UW
Olivia Baldwin	499 Research Assistant	UW
Abril Beretta	Volunteer Research Assistant	UW
Skye Fitzpatrick	Advisory Board Member- Researcher	York University

Rebecca Campbell	Advisory Board Member- Researcher	Michigan State
Josef Ruzek	Advisory Board Member- Researcher	*Retired*
Matthew Cordova	Advisory Board Member- Researcher	Palo Alto University
Tara Wolfe	Advisory Board Member- Practitioner	FORMERLY- WA Office of Crime Victim Advocacy
Richard Torrance	Advisory Board Member- Practitioner	WA Office of Crime Victim Advocacy
Terri Stewart	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Annette Simpson	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Laura Merchant	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
George Gonzalez	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Whitney Hellyer	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Candice L Orfao	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Maria Lee	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Roshelle Cleland	Advisory Board Member- Practitioner	Lutheran Community Services Northwest
Millini Goodman	Advisory Board Member- Practitioner	Lutheran Community Services Northwest
Vanya Nanda	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Minu Ranna-Stewart	Advisory Board Member- Practitioner	Harborview Abuse and Trauma Center
Natalia Garcia	Inclusivity Consultant	UW/Seattle VA
Isha Metzger	Inclusivity Consultant	University of Georgia
Natalie Watson-Singleton	Inclusivity Consultant	Spelman University
Soo Jeong Youn	Inclusivity Consultant	Massachusetts General Hospital / Harvard Medical School

5b. Name and contact information for the trial sponsor

N/A

5c. Role of study sponsor and funders

OVW has no role or ultimate authority in the study design, collection, analysis or interpretation of the data, writing the report, or the decision to submit the report for publication.

5d. Composition, roles, and responsibilities

Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

N/A

Introduction

6. Background and rationale

6a. Description of research question and justification for undertaking the trial

Including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Sexual assault is a common form of trauma: approximately 36% of women, 17% of men, and 34–47% of transgender and gender diverse individuals are sexually assaulted in their lifetime. Three quarters of survivors have elevated symptoms of posttraumatic stress disorder (PTSD) one month after sexual assault. Natural recovery of PTSD symptoms is common, but 41% of survivors still have PTSD 12 months later. There is evidence that early interventions— those delivered within 3 months of trauma—are effective. Early interventions have reduced PTSD severity among sexual assault survivors. Existing early interventions focus only on sexual assault survivors and do not target the social contexts in which survivors' recovery occurs. However, these social contexts are important to recovery. Nearly all survivors seek help from supporters (e.g., friends, family, romantic partners), often soon after assault. Unfortunately, most survivors receive negative reactions when they seek help, and these reactions increase risk for psychopathology. Importantly, supporters do not necessarily respond in negative ways with malicious intent, but instead due to a lack of knowledge about effective responses, a lack of knowledge about survivors' preferences, or difficulty managing their emotional reactions. To our knowledge, one prior preventative intervention has aimed to improve responses to disclosures. Supporting Survivors and Selves trained groups of undergraduate students in support skills in anticipation of receiving a future disclosure of interpersonal violence. In a randomized clinical trial, this intervention led to improvements in intended responses but did not change actual responses among those who prospectively received a disclosure. There is currently no empirically-supported intervention to improve supporters' ability to respond effectively to survivors in the immediate aftermath of sexual assault and thereby improve survivors' downstream outcomes. We created CARE (Communication and Recovery Enhancement) to address the lack of early interventions to improve supporters' responses. CARE is intended for survivors of past-10-week sexual assault and a support person of their choice. It involves two telehealth sessions with a clinician and a supporter, with the survivor present (dyadic version) or without the survivor present (supporter-only version).

6b. Explanation for choice of comparators

This pilot randomized clinical trial uses a unmasked, prospective, parallel group, superiority design.
Participants are allocated 1:1:1 (unstratified) to dyadic CARE, supporter-only CARE, or waitlist control. Assessments are completed via self-report at baseline, post session 1, and 1, 2, and 3 months postbaseline.

7. Objectives

(Specific objectives or hypotheses)

The goal of this protocol is to describe our methods for a pilot randomized clinical trial of dyadic and supporter-only CARE. Our goals are to understand feasibility, acceptability, and preliminarily characterize efficacy. We hypothesize:
H1: Dyadic and supporter-only CARE will be rated as acceptable by survivors and supporters at 1-month follow-up.
H2: Dyadic and supporter-only CARE will lead to increases in survivor and supporter knowledge from baseline to 1-month follow-up.
H3: Dyadic and supporter-only CARE will improve disclosure experiences (i.e., increasing survivor disclosure frequency, reducing supporter negative reactions, increasing supporter responsiveness) at 1-month follow-up compared to waitlist.
H4: Dyadic CARE and supporter-only CARE will improve functional outcomes among survivors (i.e., PTSD, stress, relationship quality) and supporters (i.e., stress, relationship quality) at 3-month follow-up compared to waitlist.

8. Description of trial design

Type of trial

(eg, parallel group, crossover, factorial, single group)

Parallel group, three arm

Allocation ratio

1:1:1

Framework

(eg, superiority, equivalence, noninferiority, exploratory)

Superiority

Methods: Participants, Interventions, and Outcomes

9. Study setting

Description of study settings

Remote

Reference to where list of study sites can be obtained

N/A

10. Eligibility Criteria

Inclusion criteria

Inclusion Criteria (Survivors):

- Age 14+ years
- Can speak/read English or Spanish
- Have access to a Zoom-capable device
- Screened for eligibility within 10 weeks of sexual assault, defined as any unwanted, distressing sexual contact (e.g., unwanted touching, coerced sexual activity, rape)
- Able to attend first study session within 2 weeks of screening
- Elevated PTSD symptoms at screening as operationalized by a Primary Care PTSD Screen score of 2/5 or above
- Able to identify an eligible supporter
- Have a way to receive survey links and complete surveys privately (i.e., without potential device or account access by the supporter)

Inclusion Criteria (Supporters):

- Age 14+ years
- Can speak/read English or Spanish
- Have access to a Zoom-capable device
- Able to attend first study session within 2 weeks of survivor's screening
- Are in contact with the survivor at least once a week
- In the opinion of the survivor, are able to make an independent decision about whether or not to participate in the study
- Have a way to receive survey links and complete surveys privately (i.e., without potential device or account access by the survivor)

Exclusion criteria

Exclusion Criteria (Survivors):

- Active psychosis
- Active suicidal intent

Exclusion Criteria (Supporters):

- Perpetrated the sexual assault
- Engaged in severe past-year violence or abuse (as defined by the survivor) against the survivor
- The survivor has not told the supporter about the sexual assault at the time of screening and was not already planning to tell the supporter
- In the opinion of the survivor, relational conflict exists between the survivor and supporter that potentially could be exacerbated by program participation

Eligibility criteria for study centers (if applicable)

N/A

Eligibility criteria for individuals who will perform the interventions

The intervention will be delivered by either the principal investigator (a licensed clinical psychologist) or a staff member trained by the principal investigator

11. Interventions

11a. Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Intervention

Both telehealth sessions will be 90 min and will be delivered using a slide deck and a script. Sessions will be audio recorded for supervision and fidelity tracking. Clients will be sent an electronic and/or paper workbook following session 1. The clinician will complete a clinical note regarding content coverage and clinical observations. In session 2, the note will document attendance, homework completion, and skills practice. We will also assess homework completion and skills practice via survivor and supporter self-report at 1-month follow-up.

Dyadic CARE

Dyadic CARE involves two telehealth sessions with a clinician, the survivor, and a supporter of the survivor's choice. Session content uses cognitive-behavioral strategies (e.g., encouraging non-avoidance) to encourage communication and improve supporters' responses in trauma-related conversations. Between sessions, both the survivor and the supporter are instructed to review session content and have guided discussions with the assistance of a workbook.

Supporter-Only CARE

Supporter-only CARE involves two telehealth sessions with a clinician and a supporter of the survivor's choice, without the survivor present. Session content uses cognitive-behavioral strategies (e.g., encouraging non-avoidance) to

encourage communication and improve supporters' responses in trauma-related conversations. Between sessions, both the survivor and the supporter are instructed to review session content and have guided discussions with the assistance of a workbook.

Comparison

Waitlist Control
After completing baseline, participants will be invited to schedule a CARE session in 3 months (i.e., after the completion of all study assessments). The version of CARE received at that point will be selected by the survivor. Participants will complete self-report assessments at post-session-1, Month 1, Month 2, and Month 3.

11b. Criteria for discontinuing or modifying allocated interventions for a given trial participant

Participants who withdraw consent for participation will no longer be contacted by study staff or sent automated reminders to complete study tasks.

Participants will be withdrawn from the research if at any point if it becomes known that a participant does not meet eligibility criteria for the study, if a participant's condition deteriorates, or if it becomes known that they require a higher level or different type of care that is incompatible with study participation. If this occurs, participants will be asked to withdraw from the study and appropriate referrals will be made.

Once enrolled, both survivors and supporters may choose to opt out of all study questionnaires and still receive the intervention, although they will not be paid for questionnaires. Survivors and supports are permitted to individually withdraw without affecting the eligibility of the other participant (i.e., if a survivor withdraws or cannot be reached, the supporter may still receive the intervention and be paid for questionnaires), but the survivor participant may request to withdraw both themselves and their supporter from the study at any time.

11c. Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence

All assessments will occur via online self-report surveys. These will be auto-generated from our secure online system, and participants will receive reminders from the clinician within one week of not completing surveys, to remind participants to submit their answers. Survivors and supporters will be paid $10, $10, $20, $30, and $40 for baseline, post-session-1, 1-month, 2-month, and 3-month assessments, respectively (total possible per person: $110). Participants may choose to be paid via preloaded debit card or emailed gift card.

Staff will do weekly checks and audits of all study interactions & documentation to ensure protocol adherence.

11d. Relevant concomitant care and interventions that are permitted or prohibited during the trial

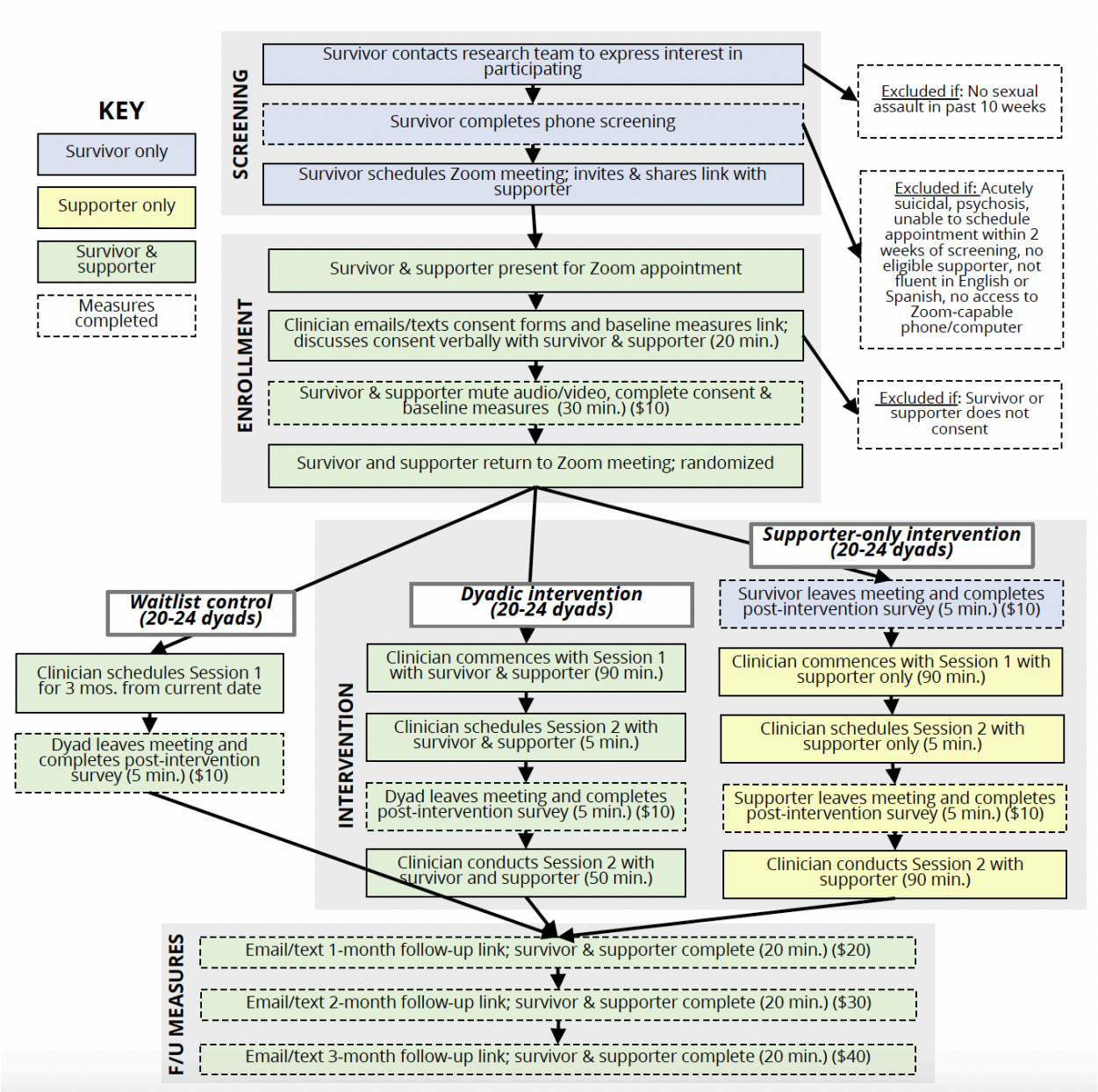
Participants will not be restricted from accessing any care or interventions during the course of the trial. It is likely that individuals recruited from the Harborview Abuse and Trauma Center and other key recruitment sites will receive treatment for sexual-assault-related distress while enrolled in the study.

12. Outcomes

See ClinicalTrials.gov

13. Participant timeline

(A schematic diagram is highly recommended)



14. Sample size

Estimated number of participants needed to achieve study objectives

60-72 dyads (120-144 participants)

How sample size was determined

Including clinical and statistical assumptions supporting any sample size calculations

As this is a pilot trial, the sample size was selected primarily for feasibility rather than significance testing.

15. Recruitment

Recruitment sites and procedures; site-specific and general strategies for achieving adequate participant enrollment to reach target sample size

Our primary partnership is with a sexual assault nurse examiner (SANE) program embedded in a large, urban level 1 trauma center that conducts SANE exams in the emergency department and schedules all patients for follow-up visits with a SANE and social worker 1-2 weeks later. SANEs and social workers pass out study flyers to patients and their supporters in the emergency department and at follow-up visits. Research staff are available on site at follow-up visits so that interested survivors could be screened as part of their visit. We also reached non-treatment-seeking survivors via mass emails to the enrolled student body at the University of Washington.

Methods: Assignment of Interventions (for Controlled Trials)

16. Allocation

16a. Sequence generation

Participants will be randomly assigned to intervention or control via a computer-generated randomization schedule. Randomization will not be stratified.

16b. Allocation concealment mechanism

The participant management system will not reveal the randomization condition until the patient has completed all baseline measures.

16c. Implementation

The web developers responsible for hosting the surveys and participant management site (Rivulent Web Design) will generate the allocation sequence. The study clinician assigned to the dyad will enroll participants and assign them to interventions.

17. Blinding (masking)

17a. Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Due to the nature of the intervention, neither participants nor study staff can be blinded to allocation. Baseline and follow-up assessments will occur via self-report; thus, no blinding of clinical assessors is needed.

17b. If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

N/A

Methods: Data Collection, Management, and Analysis

18. Data collection methods

18a. Plans for assessment and collection of outcome, baseline, and other trial data

Including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

All assessments will occur via online self-report surveys. Survey invitations and reminders will be sent via email or text message. Participants will complete follow-up questionnaires after session 1 and at 1, 2, and 3 months post-baseline to assess changes in knowledge, disclosure, and symptoms. We selected these time points because recovery occurs most rapidly within the first 3 months post-assault (Dworkin et al., 2021).
Survivors and supporters will be paid $10, $10, $20, $30, and $40 for baseline, post-session-1, 1-month, 2-month, and 3-month assessments, respectively (total possible per person: $110). Participants may choose to be paid via preloaded debit card or emailed gift card and will be provided with referrals.

18b. Plans to promote participant retention and complete follow-up

List of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

The following steps will be taken to promote retention:

- We will collect extensive contact data from participants and attempt to reach them for all follow-up assessments unless directed otherwise.
- Participants will receive text, email, and/or phone call reminders to complete the study surveys.
- Survivors and supporters will be paid $10, $10, $20, $30, and $40 for baseline, post-session-1, 1-month, 2-month, and 3-month assessments, respectively (total possible per person: $110). Participants may choose to be paid via preloaded debit card or emailed gift card.
- The study clinician will emphasize the importance of completing study surveys.
- The study clinician will instruct participants to complete the post-intervention survey once they terminate the initial CARE appointment.

19. Data management

Plans for data entry, coding, security, and storage

Including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.

Entry and coding

Data will be completely digital; no data entry will be needed. In some cases, scale scores will be automatically calculated by custom programming. When this does

not occur, study staff will create SPSS syntax and a data dictionary referencing scoring procedures.

Security and storage

All data will be identified only by a Personalized Identification Number (PIN). Data will be collected using a secure server supporting 128-bit encryption. This level of encryption provides the highest level of protection against hackers, computer break-ins, etc. The CSHRB owns a secure server (hosted by Digital Fortress, Inc.) to which participants log in using a unique PIN created for study purposes. IP address is not stored, and data are identified only by the PIN, not the participant's name. Data transfer will be protected using a Secure Socket Layer with 128-bit encryption (internet security provided by VeriSign). This is the same level of encryption used for online banking transactions. The server is physically located in a secure, commercially protected co-location facility with 24 hour locked and monitored key-card access, within a locked room, within a locked server rack, with a locking face-plate protecting the server itself from physical access without authorization. Electronic protection is provided by a commercial-grade firewall, with continuous monitoring of the server for any attempts at electronic invasion. The password to the account will only be known to the Principal Investigator, Mentors, and other relevant research staff. All data stored in the online repository will be encrypted using the official Advanced Encryption Standard (AES) algorithm and with a 128-bit key length. A master list of names and code numbers will be stored on a password-protected computer under the supervision of the Principal Investigator, and will be available only to research staff on this project.

Research assistants will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including graduate and undergraduate research assistants and study staff) will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. Data will be retained on computers with restricted and password protected access, without links to the master code list. All data based on this research will be reported in aggregate form. No individual respondents will be identified. The link between identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

20. Statistical methods

20a. Statistical methods for analyzing primary and secondary outcomes

Reference to where other details of the statistical analysis plan can be found, if not in the protocol

Analyses will be conducted with the intent-to-treat sample. As this study is not powered to detect statistical significance, we will examine the direction and magnitude of effects to preliminarily understand efficacy and test significance in an exploratory manner only. Within-group ds will be calculated as the mean-level difference in scores from baseline to follow-up for each condition divided by the standard deviation of change scores. Between-group ds will represent relative change between conditions and will be calculated as the difference between within-group ds.

Acceptability (H1)
We will use descriptive statistics to summarize acceptability ratings among dyads randomized to dyadic or supporter-only CARE. We will use independent-samples t-tests and between-group ds to compare acceptability by condition.

Efficacy (H2–4)
We will calculate within- and between-group *d*s to represent mean changes on focal outcomes. We will use the reliable change index to quantify whether change is unlikely to be attributable to measurement error, and we will report odds ratios for differences in percent with reliable improvement by condition. We will also report the percent of participants meeting diagnostic criteria based on the PCL at baseline and 3-month follow-up.

Paired sample t-tests will evaluate mean changes from baseline to follow-up. We will test time-by-condition interactions in random-effects models using maximum likelihood estimation to account for missing data. We will test covariates including relationship type, study clinician, participant age, and prior assault history. We will conduct sensitivity analyses with English and Spanish-language participants separately.

20b. Methods for any additional analyses
(eg, subgroup and adjusted analyses)

We will test moderation and visually examine results across groups as a function of:

- Baseline PTSD severity and PCL score ≥ cutoff of 33
- Relationship type (friend, parent, partner, other)
- Caregiver burden (Impact on Friends - Ineffectiveness Subscale)

We will conduct sensitivity analyses in the following samples:

- English speakers only

20c. Analysis population and missing data
Definition of analysis population related to nonadherence (eg, as randomized analysis), and any statistical methods to handle missing data (eg, multiple imputation)

We will use an intent to treat analysis, in which participants will be retained in the group to which they were originally randomized. Outcome data from all participants will be included in analyses. We will also explore the use of randomization-based efficacy estimators (White, 2005).

Methods: Monitoring

21. Data monitoring

21a. Data monitoring committee

Composition of data monitoring committee (DMC)

N/A

Summary of its role and reporting structure

N/A

Statement of whether it is independent from the sponsor and competing interests

Reference to where further details about its charter can be found, if not in the protocol

N/A

Alternatively, an explanation of why a DMC is not needed

Given that this is a pilot trial of an intervention with minimal risks, we will not retain a data monitoring committee.

21b. Description of any interim analyses and stopping guidelines

Including who will have access to these interim results and make the final decision to terminate the trial

No interim analyses will be conducted.

We will employ the following stopping rule for the clinical trial: if there is clear evidence of harm. Although we do not expect any physical harms or serious psychological harms beyond minimal distress, we have several procedures for monitoring harm from the intervention, including asking participants to contact us if they experience any adverse events, offering additional resources to those with very high levels of mental health symptoms and problem drinking that we identify through data monitoring, and providing resources after baseline and at every follow-up time point. We do not expect there to be overwhelming evidence of the harm of the intervention, but we will monitor this and stop the trial if this is indicated. We also do not expect that there will be no likelihood of demonstrated treatment benefit (futility) for the intervention as compared to control.

22. Harms

Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

All participants will be fully informed of how to contact the investigators and/or the UW IRB to report complaints or adverse events via explicit instructions in the consent form. The PI and co-I Bedard-Gilligan are well-versed in the requirements and procedures for monitoring and reporting adverse events and complaints to the IRB for review. Dr. Bedard-Gilligan has managed this process as PI of several previous clinical trials and will work closely with Dr.

Dworkin to provide guidance and consultation in this process. All adverse events will be reviewed by Dr. Dworkin and other members of the treatment team to determine the seriousness of the adverse events. The PI and co-Is have a wealth of experience in managing adverse psychological events both in the context of clinical trials research and clinical practice and are competent to handle any adverse psychological events which may arise. We will follow institutional policies for reporting serious adverse events (SAEs) and adverse events (AEs) to the IRB and OVW. On a daily basis, Dr. Dworkin will be responsible for data and safety monitoring and will provide continuous, close data monitoring. Dr. Dworkin will follow UW's SAE reporting policy in promptly reporting SAEs to the UW Institutional Review Board (IRB) and to OVW. Dr. Dworkin will report all SAEs to the IRBs within 24 hours. A report of all non-serious adverse events will be provided to the IRB yearly. The PI and co-Is will meet twice a year regarding safety and monitoring procedures. This meeting will be used to review any problems in implementing procedures. Dr. Dworkin will also monitor safety data as part of the yearly review. Safety evaluations will include AEs and longitudinal symptom measures. Safety evaluations will also consider factors external to the study, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

23. Auditing

Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

No auditing will be conducted.

Ethics and Dissemination

24. Research ethics approval

Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

We have obtained ethical approval from the University of Washington IRB.

25. Protocol amendments

Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)

Any modifications to the protocol which could impact the conduct of the study, potential benefits to the participants or participant safety, including changes to study objectives, study design, target population, sample sizes, study procedures, or significant administrative aspects, will require a formal amendment to the protocol. This amendment will be approved by the study PI and the IRB prior to implementation.

Administrative changes (i.e., minor corrections and/or clarifications that have no effect on the way the study is conducted) will be documented by the PI, and approved by the IRB if necessary.

26. Consent or assent

26a. Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)

During the phone screening, the research staff person will explain the screening process and the broader study and obtain verbal informed consent for screening from the survivor. The study clinician will obtain verbal informed consent at the initial study appointment from both dyad members. Both dyad members will then complete a separate electronic consent form on their own before the baseline assessment that again presents information about the broader study and involves consent to be randomized and participate in the intervention.

26b. Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

N/A

27. Confidentiality

How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

We have taken precautions to ensure that privacy is protected.

- Participants will be told that they can decline to answer any questions they do not want to answer.

- Data will be collected using a secure server. IP address will not be stored, and data will be identified only by the PIN, not the participant's name. Data transfer will be encrypted with the same level of encryption used for online banking transactions. The password to the account will only be known to the Principal Investigator, Co-Investigators, and research coordinator.
- Electronic data will be stored in secure servers and accessed only via a password-protected interface. Direct identifiers will be stored separately from research data, and linked only with an ID number. The linkage code will be kept in a computer file with restricted access and will not be available to the public or individuals not directly involved in the research. We will maintain the link for 1 year after the end of the study to ensure that all data are accounted for and no further subject contact is required. Only members of the research team will have access to the data, with the research team signing confidentiality agreements. Computer data will be stored on a main server that is firewall and password protected, with appropriate back up procedures in place. No names will be associated with study data or with published reports, which will only contain data in aggregated form. Access to subject data will be limited to study staff, on an as-needed basis, for research purposes only. We need to retain contact information (e.g., phone numbers, emails) in order to contact participants for follow-up assessments. We will retain this contact information in a password protected computer system. These data will not be shared with individuals who are not directly involved in the study.
- The research team will not have access to survivor files for recruitment purposes and will not be involved in identifying or initiating contact with participants. Instead, clinical staff who already have access to survivor files as part of their regular clinical duties will be responsible for identifying potential participants and informing them about the study, while staying independent from enrollment, consent, intervention delivery, and data collection procedures.
- All participants will be informed of exceptions to confidentiality (i.e., current, imminent suicidality/homicidality; current child abuse, elder abuse) both verbally and in the written consent form at their initial baseline evaluation. Participants will be informed that in cases of reported current threat to safety to either self or others, or abuse of a vulnerable population, mandatory reporting laws apply, and confidentiality may be broken in order to ensure safety. There will be no subject identifying features on entered data.
- We will be covered by a Privacy Certificate from the National Institute of Justice. This certificate offers the highest protection available by law for research data.
- Research assistants will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project (including graduate and undergraduate research assistants and study staff) will complete the required NIH training in protection of human research participants.
- Participants will be instructed to complete telehealth sessions in a private

location, and privacy will be verbally verified with participants by study staff before the session begins. Participants will be instructed to not say names during study sessions. Zoom appointments will take place on a HIPAA-compliant platform and the waiting room feature will be used to prevent unauthorized access.

28. Declaration of interests

Financial and other competing interests for principal investigators for the overall trial and each study site

None

29. Access to data

Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

30. Ancillary and post-trial care

Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

N/A

31. Dissemination policy

31a. Plans for investigators and sponsor to communicate trial results

To participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

Results will be presented in peer-reviewed journal articles (with appropriate deposit in publicly-accessible databases as required as a condition of DOJ funding), conference presentations, and community presentations.

31b. Authorship eligibility guidelines and any intended use of professional writers

The research team will adhere to the American Psychological Association's (2001) publication credit guidelines for authors (p. 350-351; Principle 6.23, a-c).

Authorship order is based on scientific contributions to the research and the manuscript. Proposed authorship order is subject to renegotiation if an author fails to fulfill his/her agreed upon role in a timely manner. If the manuscript has not progressed within 6 months of the date of this agreement, the data return to the authorship pool and another author may be designated to take the lead on the paper.

31c. Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

No plans to grant public access.

Appendices

32. Informed consent procedures

Model consent form and other related documentation given to participants and authorised surrogates

33. Biological specimens

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

N/A

Please review this form before your appointment. You will have a chance to discuss this form with a study staff member and then sign it during your appointment. **You don't need to sign it in advance.**

UNIVERSITY OF WASHINGTON

Survivor Consent Form (Stage 2)

KEY STUDY INFORMATION

We are asking whether you want to consent to participate in a research study. The research study aims to understand whether a program is helpful to survivors and their supporters.

Participation involves:

1. **Two ~90 minute telehealth CARE program appointments** that focus on how you and your supporter can communicate in ways that may help you recover. You will be randomly selected to get the program in one of three ways:
   a. **Option 1:** You and your supporter attend the program appointments together starting today. The first 90-minute appointment would start after your finish your questionnaires, so your entire appointment time today would be ~2.5 hours. You will both get a workbook to work on together after your appointment.
   b. **Option 2:** Your supporter attends the program appointments alone starting today and will be asked to meet with you to teach you about what they learned using a workbook that we will give both of you.
   c. **Option 3:** You choose which version of the program you want, and you get it in 3 months.
2. **Five online questionnaires**: We will invite both you and your supporter to fill out online questionnaires today and every month for the next 3 months. You will each earn **$110 total if you complete all of these questionnaires**. You will be paid:
   a. $10 for a 20-minute questionnaire at the beginning of the appointment today
   b. $10 for a 5-minute questionnaire at the end of the appointment today
   c. $20 for a 20-minute questionnaire in 1 month
   d. $30 for a 20-minute questionnaire in 2 months
   e. $40 for a 20-minute questionnaire in 3 months

The possible **benefits** of consenting to participate are learning more about yourself or understanding yourself better, improving communication between you and your supporter, or helping other people who have been sexually assaulted by contributing to research on this topic.

The possible **risks** are that you might find the questionnaires to be sensitive or upsetting. You might not get your preferred version of the program or get it right away. You might feel distressed if you or your supporter do not want to participate or use the CARE skills. It is possible that participating in this program could call attention to problems you are having in your relationship.

This study is **confidential**. The information you share with us will be kept confidential and will not be stored with your name or contact information. We will not share your responses with your supporter, and we will not share your supporter's responses with you. Only the research team will have access to this information. There is an important exception: if you tell us about a serious threat to your safety or someone else's safety, we will need to tell someone else.

Participation is completely **voluntary** (meaning it's up to you). This study is not a part of any other clinical services you may be receiving and will not affect any other services you get. You can choose not to participate or end your participation at any time without any consequences.

If you don't want to participate but still want support, we will help connect you with services.

Please review this form before your appointment. You will have a chance to discuss this form with a study staff member and then sign it during your appointment. **You don't need to sign it in advance.**

DETAILED STUDY INFORMATION

Researchers:

Dr. Emily Dworkin, Principal Investigator
Dept. of Psychiatry and Behavioral Sciences, University of Washington
206-221-6932, edworkin@uw.edu

Dr. Michele Bedard-Gilligan, Co-Investigator
Dept. of Psychiatry and Behavioral Sciences, University of Washington
206-616-4215, mab29@uw.edu

Researchers' Statement

We are asking you to be in a research study that is funded by the Department of Justice's Office on Violence Against Women. The purpose of this statement is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

You may choose to review this form and make a decision about participating separately from your supporter, or together. You may also talk privately about your decision to participate with your supporter, without the researcher present, should you wish to do so. However, to participate, both you and the person you came to this appointment with must agree to participate.

PURPOSE OF THE STUDY

We are doing a study of a program that aims to help survivors and their supporters communicate in ways that may help survivors recover after an unwanted sexual experience. The study's goal is to understand whether this program is helpful. We aim to enroll a total of 60-72 survivors and 60-72 of their supporters in this study.

STUDY PROCEDURES

Participation in this voluntary study takes 3 months and involves two parts:

(1) Filling out 5 questionnaires

How the questionnaires work:

We will ask you and your supporter to both fill out a 20-minute questionnaire at the beginning of the appointment today, then fill out the same questionnaire again in 1, 2, and 3 months. We will ask you to fill out a 5-minute questionnaire at the end of the appointment today. If your appointment today is interrupted, you will be sent this survey when you complete your appointment (which must occur within the next 14 days). We will send you a link for each questionnaire. You will have 14 days to complete each questionnaire.

Payment for questionnaires:

You will each earn **$110 total if you complete all of these questionnaires**. You will be paid:

a. $10 for the 20-minute questionnaire at the beginning of the appointment today
b. $10 for the 5-minute questionnaire at the end of the appointment today
c. $20 for the 20-minute questionnaire in 1 month

d. $30 for the 20-minute questionnaire in 2 months
e. $40 for the 20-minute questionnaire in 3 months

You can choose to get an emailed gift card from a variety of retailers (including Amazon, CVS, Target, and Safeway), or get a pre-loaded Visa cash card (which you may pick up at Harborview or have mailed to you).

The kinds of questions you will be asked:

The questionnaires will ask sensitive questions about your feelings and mood, your opinions about your relationships, your ability to function in your life, and characteristics of the unwanted sexual experience.

We will also ask you questions about your relationship with the person who came to this appointment with you today. Their surveys will include questions about you. To help make sure both of you know who we mean when we ask you questions about each other, we will mention their first name in your surveys, and your first name in their surveys.

You do not have to answer any questions you do not wish to answer. You can stop filling out questionnaires at any time. You can choose to not fill out a questionnaire at all. Here are some examples of the most sensitive questions:

In the past month, how much have you been bothered by:

- *Avoiding memories, thoughts, or feelings related to the unwanted sexual experience?*
- *Having strong negative feelings such as fear, horror, anger, guilt, or shame?*

Have any of the following unwanted sexual experiences happened?

- *Someone had oral sex with me or made me have oral sex with them without my consent by using force, for example holding me down with their body weight, pinning my arms, or having a weapon.*
- *A man put his penis into my vagina, or someone inserted fingers or objects without my consent by taking advantage of me when I was too drunk or out of it to stop what was happening.*

If you had to decide today whether or not you want to participate in the legal process for the unwanted sexual experience, what would you choose?

Getting your contact information:

We will ask you to give us your preferred contact information (your phone number, email, or social media information) so that we can contact you to send you the follow-up questionnaires. Your name and contact information will never be stored with the answers you give in the questionnaires. The information that you share is up to you, but we cannot send you questionnaires if we do not have contact information.

(2) Getting the CARE program

What the program involves:

This program is not therapy. There are different options for getting the program, but all of them involve getting information about how to communicate with each other in ways that support your healing. The option that you get is decided randomly (like flipping a coin).

- **Option 1:** You and your supporter attend a ~90 minute long CARE program appointment together today and a second appointment in about 2 weeks. The first 90-minute appointment would start after your finish your questionnaires, so your entire appointment time today would be ~2.5 hours. After the appointment today, you will both be sent a workbook that goes over what you learned and gives you some exercises to practice your new skills. You will be asked to meet with each other privately to practice your skills after your appointment today. In the event that you are unable to complete the first CARE program appointment today, please be aware that this appointment must be completed within 14 days. Your second CARE program appointment must be completed within 30 days.
- **Option 2:** Your supporter attends a ~90 minute long CARE program appointment alone today and a second appointment in about 2 weeks. After the appointment today, you would both still be sent a workbook that goes over what the supporter learned and gives you some exercises to practice your new skills. You would be asked to meet with each other privately after your appointment so that your supporter can teach you the skills that they learned in the program. With this option, you would still get the benefits of the program without having to be in the appointments. We are testing out this option because we know that attending an appointment can be hard when someone is going through a crisis, and having some people get the program in this way would tell us whether the program works just as well without the survivor there.
- **Option 3:** You choose which version of the program you want (with your supporter or your supporter alone), and you get that version in 3 months.

We are unable to make changes to your version of the program after it is assigned. If you get the program where you attend sessions together, both you and your supporter will need to be present for sessions to receive the program. If you get the version of the program where your supporter attends sessions alone, you will only be able to receive the program if they attend the sessions.

Audiorecording the program appointments:

We will audiorecord the appointments so that we can make sure that the clinician is covering all the topics they need to cover. If you give us any feedback about the program during the appointments, we will use the recordings to type out and save the feedback without your name attached. We will not use this recording for any other purpose and will destroy it as soon as we have checked it.

Payment for the program appointment:

Neither you nor your supporter will be paid for participating in the program: you will only be paid for questionnaires. You can still get paid for filling out the questionnaires even if you do not participate in the program.

Participation in this research is voluntary. That means it's your decision.

- **To enroll in the study, both you and your supporter must both consent to participate.** However, you should each make your own decision about whether you want to participate. You may also tell us that you no longer want both you and your supporter to participate, in which case we will withdraw both of you from the study. However, you cannot replace your supporter with a different person.

- **It's up to you whether you complete the questionnaires.** You may skip over any questions you do not want to answer or decide to stop participating at any time. You can still receive the program even if you don't fill out the questionnaires. If one person drops out after enrolling, the other person can still fill out questionnaires.
- **It's up to you whether you complete the program appointments**. You can end your participation in the program at any time- even during an appointment. Even if you or your supporter choose to opt out of program appointments, you can still do questionnaires and be paid.
- **This study and the program we are studying are not part of your clinical services.** Deciding not to participate will not affect any services you get at any other site serving survivors of unwanted sexual experiences (e.g., Harborview). Your decision to participate, and everything you tell us today, will not be recorded anywhere in your clinical files.

RISKS, STRESS, OR DISCOMFORT

There might be risks associated with being in this study.

- The main risk of this study is that we will be asking you sensitive and private questions. These questions may make you feel uncomfortable or may feel intrusive.
- You might feel uncomfortable about your supporter being asked questions about their relationship with you and their experiences supporting you.
- If your supporter does not attend program sessions, you will not be able to continue with the program alone or replace them with another supporter.
- It is possible that participating in this program could call attention to problems you are having in your relationship.
- It is possible that you might not get your preferred version of the program, which could be disappointing or distressing.
- It is possible that you might be chosen to get the program in 3 months. If you would prefer to get the program right away, waiting to get the program might be disappointing or distressing. It is possible that problems could emerge within the 3 months that might affect whether this program is right for you; if this happens, we might need to refer you to other services instead of continuing with the program.
- Although this program is based on research about what is helpful, some people may not find it helpful.
- You might feel distressed if you want to participate and/or use the CARE skills and your supporter does not, or if your supporter wants to participate and/or use the CARE skills and you do not.
- It is possible that participating in this program could call attention to problems in your relationship. It is possible that this could be distressing or affect your relationship.
- If someone else has access to the account or device where you receive links to surveys for this study, and unintentionally or intentionally accesses that account or device while you are actively taking a survey (before you finish the last question and submit your responses), they could see your survey responses. To prevent this, it is important that you

receive links at a private account, complete all surveys on a private device with security features enabled, and submit your survey as soon as possible.

If you feel upset, or if you have any questions or need assistance, you can tell the clinician, or you can contact any of the study personnel listed above.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate in this study but still want resources to help you cope, we can provide you with a list of information and referrals located within the community, and help connect you with services if you wish.

BENEFITS OF THE STUDY

You might not experience any direct benefits from participating in this study. **Here are some possible benefits:**

- You might learn more about yourself, your experience with unwanted sexual contact, and your relationships as you fill out the questionnaire, which could be helpful.
- Your supporter might learn new ways to support you by being a part of this program, and you and your supporter might learn more helpful ways to communicate with each other and work together to support your recovery.
- Participating in this study could help people who have been sexually assaulted. To learn how to help survivors of unwanted sexual experiences, we need to do studies to see what's helpful. This is one of those studies. If we learn that this program is helpful, we will be able to make it available to other people who have been sexually assaulted.
- Participating in this study is a way to support research on the topic of sexual assault.

CONFIDENTIALITY OF RESEARCH INFORMATION

Any identifiable information collected about you will be used only for research and statistical purposes. **We will use the information gathered in this study in two main ways:**

- We will create research reports and presentations about this study that summarize its findings without singling out any one participant. Your name and identifying information will not be included in any research reports or presentations of this research.
- A file containing answers to questionnaires from everyone who participates will be given to the National Archive of Criminal Justice Data so it can be shared with other researchers doing similar work at other locations. Everyone's answers will be labeled with an ID number. The file will be checked to make sure that there is nothing in it that could tell anyone who you are. There will be no names, contact information, or any other personally-identifying information in the file.

Everything you tell us will be confidential. We will not share your responses with your supporter, and we will not share your supporter's responses with you. We have taken **steps to protect your confidentiality**.

- The questionnaires will be completed using a secure server, which provides the highest available level of protection for your confidentiality.
- All of your questionnaire responses will be labeled with an ID number, rather than your name, the name of the person participating in this study with you, or any other

information that would tell people who you are. Only the research team will know your ID number. That way, no one will be able to figure out your identity or the identity of the person participating in this study with you, even if they looked at the answers to your questionnaires.

- We will put your ID number, name, and contact information in a special secured computer file. This file will be separate from all other information you give us as part of the study. The research team are the only ones who will have access to this file, and we will not share it with others. We will only use this file to contact you to complete the study, pay you for your participation, and find your ID number. We will retain your name and contact information until the end of the record retention period required by state and/or federal law.
- We have obtained a Privacy Certificate from the National Institute of Justice. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you can share information about yourself or your part in this research if you wish. The Certificate expires when the funding for this study ends. Currently this is 10/31/24. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected even after the expiration date.

We also ask you to take some steps to protect your own and each others' confidentiality.

- To make sure that no one can see your survey responses while you are in the middle of taking a survey, we ask you to make sure that no one else has access to the phone, laptop, or email accounts where you receive your survey links. You can do this by only asking us to send your survey links to an account or device that no one other than you has access to, and that you submit your surveys as soon as possible.
- It is important to remember that the first name of the person you are participating in this study with will show up in the questions we ask you, and your first name will show up in their questions. Because of this, we ask you to help protect each others' confidentiality by not sharing the link to the questionnaire with anyone else, and filling out the questionnaire on a private, secure device.
- We encourage you to ensure that you are attending this session from a private location, and make sure that others cannot hear or see what's happening.
- We encourage you to check in with each other if there is anything that you would prefer the other person not share in this appointment. If you would like to do this, we will put you into a Zoom breakout room before we begin.

However, there are **some important exceptions to confidentiality**:

- The confidentiality of the data cannot be guaranteed if you report future criminal intent.
- If we learn that you intend to harm yourself or others, or that anyone is at imminent risk of harm, we must report that to the authorities.
- If you tell us about child/elder abuse, we are not allowed to report that unless you give us permission. We will give you the option of giving us permission but it will be up to you.

- Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

INFORMATION FOR ADOLESCENTS

You do not need permission from a parent or guardian to be in this study. This is because, in Washington State, teens age 13-17 are allowed to seek help for mental health concerns without parental consent.

If you tell us about past abuse, we will not tell anyone without your permission. Instead, we will give you the option of talking with us about the pros and cons of contacting the authorities, and different options for doing so. We will only tell the authorities if you fill out a form saying it's okay.

FUTURE USE OF DATA

Data identified only by your ID number (not your name, contact information, or any other information that may identify you) may be shared with other researchers doing similar work on other campuses, be combined with data from other campuses in some research reports, and/or may be used to develop procedures used in future studies. These data will be retained indefinitely, identified only by the ID number.

OTHER INFORMATION

You may refuse to participate or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If at any point we determine that you are not eligible for this study, if your condition deteriorates, or if it becomes known that you require a higher level or different type of care, we will withdraw you from the study and not invite you to complete any remaining surveys or sessions. We will provide you referrals for services if this happens.

You should not incur any expenses from your participation in this research. You are free to participate in other programs such as support groups, treatment, therapy, etc. while involved in the study.

If you become concerned about problems you're experiencing related to the unwanted sexual experience, or if you experience discomfort as a result of your participation, you can contact one of the researchers listed above to discuss your concerns. We will be happy to provide referrals for services. You can contact study personnel by phone or email during regular business hours.

RESEARCH-RELATED INJURY

If you think you have been harmed from this research, contact one of the study investigators right away. They will treat you or refer you for treatment. You may also reach out to them if you have questions about the study or your rights as a participant. Their contact information is at the beginning of this form.

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions and discuss this decision with my supporter, if I wish to do so.

If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have

questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.

[ ] I accept. I want to participate in this study.

[ ] I do not accept.

Please review this form before your appointment. You will have a chance to discuss this form with a study staff member and then sign it during your appointment. **You don't need to sign it in advance.**

UNIVERSITY OF WASHINGTON

Supporter Consent Form (Stage 2)

KEY STUDY INFORMATION

We are asking whether you want to consent to participate in a research study. The research study aims to understand whether a program is helpful to survivors and their supporters. Participation involves:

1. **Two ~90 minute CARE telehealth program appointments** that focus on how you and the survivor can communicate in ways that may help them recover. You will be randomly selected to get the program in one of three ways:
    a. **Option 1:** You and the survivor attend the program appointments together starting today. The first 90-minute appointment would start after your finish your questionnaires, so your entire appointment time today would be ~2.5 hours. You will both get a workbook to work on together after your first appointment.
    b. **Option 2:** You attend the program appointments alone starting today. The first 90-minute appointment would start after your finish your questionnaires, so your entire appointment time today would be ~2.5 hours. You will be asked to meet with the survivor privately after your first appointment and teach them about what you learned using a workbook that we will give both of you.
    c. **Option 3:** The survivor chooses which version of the program they want, and you get it in 3 months.
2. **Five online questionnaires**: We will invite both you and the survivor to fill out online questionnaires today and every month for the next 3 months. You will each earn **$110 total if you complete all of these questionnaires**. You will be paid:
    a. $10 for a 20-minute questionnaire at the beginning of the appointment today
    b. $10 for a 5-minute questionnaire at the end of the appointment today
    c. $20 for a 20-minute questionnaire in 1 month
    d. $30 for a 20-minute questionnaire in 2 months
    e. $40 for a 20-minute questionnaire in 3 months

The possible **benefits** of consenting to participate are learning more about yourself or understanding yourself better, helping the survivor in your life, or helping people who have been sexually assaulted by contributing to research on this topic.

The possible **risks** are that you might find the questionnaires to be sensitive or upsetting. You might not get your preferred version of the program or get it right away. and being in the program might make some people feel upset. You might feel distressed if you or the survivor do not want to participate or use the CARE skills. It is possible that participating in this program could call attention to problems you are having in your relationship.

This study is **confidential**. The information you share with us will be kept confidential and will not be stored with your name or contact information. We will not share your responses with the survivor, and we will not share the survivor's responses with you. Only the research team will have access to the information you share with us. There is an important exception: if you tell us about a serious threat to your safety or someone else's safety, we will need to tell someone else.

Participation is completely **voluntary** (meaning it's up to you). This study is not a part of any other clinical services you may be receiving and will not affect any other services you get. You can choose not to participate or end your participation at any time without any consequences.

If you don't want to participate but still want support, we will help connect you with services.

Please review this form before your appointment. You will have a chance to discuss this form with a study staff member and then sign it during your appointment. **You don't need to sign it in advance.**

DETAILED STUDY INFORMATION

Researchers:

Dr. Emily Dworkin, Principal Investigator
Dept. of Psychiatry and Behavioral Sciences, University of Washington
206-221-6932, edworkin@uw.edu

Dr. Michele Bedard-Gilligan, Co-Investigator
Dept. of Psychiatry and Behavioral Sciences, University of Washington
206-616-4215, mab29@uw.edu

Researchers' Statement

We are asking you to be in a research study that is funded by the Department of Justice's Office on Violence Against Women. The purpose of this statement is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

You may choose to review this form and make a decision about participating separately from the survivor, or together. You may also talk privately about your decision to participate with the survivor, without the researcher present, should you wish to do so. However, to participate, both you and the survivor must agree to participate.

PURPOSE OF THE STUDY

We are doing a study of a program that aims to help survivors and their supporters communicate in ways that may help survivors recover after an unwanted sexual experience. The study's goal is to understand whether this program is helpful. We aim to enroll a total of 60-72 survivors and 60-72 of their supporters in this study.

STUDY PROCEDURES

Participation in this voluntary study takes 3 months and involves two parts:

(1) Filling out 5 questionnaires

How the questionnaires work:

We will ask you and the survivor to both fill out a 20-minute questionnaire at the beginning of the appointment today, then fill out the same questionnaire again in 1, 2, and 3 months. We will ask you to fill out a 5-minute questionnaire at the end of the appointment today. If your appointment today is interrupted, you will be sent this survey when you complete your appointment (which must occur within the next 14 days). We will send you a link for each questionnaire. You will have 14 days to complete each questionnaire.

Payment for questionnaires:

You will each earn **$110 total if you complete all of these questionnaires**. You will be paid:

a. $10 for the 20-minute questionnaire at the beginning of the appointment today
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You can choose to get an emailed gift card from a variety of retailers (including Amazon, CVS, Target, and Safeway), or get a pre-loaded Visa cash card (which you may pick up at Harborview or have mailed to you).

The kinds of questions you will be asked:

The questionnaires will ask sensitive questions about what it has been like for you to support the survivor, what you know about how to support survivors, and your personal demographic characteristics.

We will also ask you questions about your relationship with the survivor. Their surveys will include questions about you. To help make sure both of you know who we mean when we ask you questions about each other, we will mention their first name in your surveys, and your first name in their surveys.

You do not have to answer any questions you do not wish to answer. You can stop filling out questionnaires at any time. You can choose to not fill out a questionnaire at all. Here are some examples of the most sensitive questions:

Indicate how much you agree or disagree with the following statements about what it's been like to try and help the survivor.

- *I feel preoccupied with the details of the assault.*
- *I feel disturbed dealing with his/her assault.*

How often did you respond in each of the following ways?

- *Told them that they were irresponsible or not cautious enough.*
- *Got so upset that you needed reassurance from them.*

Getting your contact information:

We will ask you to give us your preferred contact information (your phone number, email, or social media information) so that we can contact you to send you the follow-up questionnaires. Your name and contact information will never be stored with the answers you give in the questionnaires. The information that you share is up to you, but we cannot send you questionnaires if we do not have contact information.

(2) Getting the CARE program

What the program involves:

This program is not therapy. There are different options for getting the program, but all of them involve getting information about how to communicate with each other in ways that support the survivor's healing. The option that you get is decided randomly (like flipping a coin).

- **Option 1:** You and the survivor attend a ~90 minute long CARE program appointment together today and a second appointment in 2 weeks. The 90-minute appointment would start after your finish your questionnaires, so your entire appointment time today would be ~2.5 hours. After the appointment today, you will both be sent a workbook that goes over what you learned and gives you some exercises to practice your new skills. You will be asked to meet with each other privately to practice your skills after your appointment today. In the event that you are unable to complete the first CARE program appointment today, please be aware that this appointment must be completed within 14 days. Your second CARE program appointment must be completed within 30 days.
- **Option 2:** You attend a ~90 minute long CARE program appointment alone today and a second appointment in 2 weeks. After the appointment today, you would both still be sent a workbook that goes over what the supporter learned and gives you some exercises to practice your new skills. You would be asked to meet with each other privately after your appointment to teach the survivor the skills that you learned in the program. This way, the survivor still get the benefits of the program without having to be in the appointment. We are testing out this option because we know that attending an appointment can be hard when someone is going through a crisis, and having some people get the program in this way would tell us whether the program works just as well without the survivor there. In the event that you are unable to complete the first CARE program appointment

today, please be aware that this appointment must be completed within 14 days. Your second CARE program appointment must be completed within 30 days.

- **Option 3:** The survivor chooses which version of the program they want, and you get that version in 3 months.

We are unable to make changes to your version of the program after it is assigned. If you get the program where you attend sessions together, both you and the survivor will need to be present for sessions to receive the program. If you get the version of the program where you attend sessions alone, the survivor will only be able to receive the program if you attend the sessions.

Audiorecording the program appointments:

We will audiorecord the appointments so that we can make sure that the clinician is covering all the topics they need to cover. If you give us any feedback about the program during the appointments, we will use the recordings to type out and save the feedback without your name attached. We will not use this recording for any other purpose and will destroy it as soon as we have checked it.

Payment for the program appointment:

Neither you nor the survivor will be paid for participating in the program: you will only be paid for questionnaires. You can still get paid for filling out the questionnaires even if you do not participate in the program.

Participation in this research is voluntary. That means it's your decision.

- **To enroll in the study, both you and the survivor must both consent to participate.** However, you should each make your own decision about whether you want to participate. The survivor also has the right to tell us that they no longer want both themselves and you to participate, in which case we will withdraw both of you from the study. However, the survivor cannot replace you with a different supporter.
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There might be risks associated with being in this study.

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- You might feel uncomfortable about the survivor being asked questions about their relationship with you and their experiences being supported by you.
- If you do not attend program sessions, the survivor will not be able to continue with the program alone or replace you with another supporter.

- It is possible that you might not get your preferred version of the program, which could be disappointing or distressing.
- It is possible that you might be chosen to get the program in 3 months. If you would prefer to get the program right away, waiting to get the program might be disappointing or distressing.
- Being in the program may remind you of problems you're having and could make you feel upset.
- Although this program is based on research about what is helpful, some people may not find it helpful.
- You might feel distressed if you want to participate and/or use the CARE skills and the survivor does not, or if the survivor wants to participate and/or use the CARE skills and you do not.
- It is possible that participating in this program could call attention to problems you are having in your relationship. It is possible that this could be distressing or affect your relationship.
- If someone else has access to the account or device where you receive links to surveys for this study, and unintentionally or intentionally accesses that account or device while you are actively taking a survey (before you finish the last question and submit your responses), they could see your survey responses. To prevent this, it is important that you receive links at a private account, complete all surveys on a private device with security features enabled, and submit your survey as soon as possible.

If you feel upset, or if you have any questions or need assistance, you can tell the clinician, or you can contact any of the study personnel listed above.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate in this study but still want resources to help you cope, we can provide you with a list of information and referrals located within the community, and help connect you with services if you wish.

BENEFITS OF THE STUDY

You might not experience any direct benefits from participating in this study. **Here are some possible benefits:**

- You might learn more about yourself, your experience providing support, and your relationships as you go through this study, which could be helpful.
- You might learn new ways to support the survivor by being a part of this program, and you and the survivor might learn more helpful ways to communicate with each other and work together to support their recovery.
- Participating in this study could help people who have been sexually assaulted. To learn how to help survivors of unwanted sexual experiences, we need to do studies to see what's helpful. This is one of those studies. If we learn that this program is helpful, we will be able to make it available to other people who have been sexually assaulted.
- Participating in this study is a way to support research on the topic of unwanted sexual experiences.

CONFIDENTIALITY OF RESEARCH INFORMATION

Any identifiable information collected about you will be used only for research and statistical purposes. **We will use the information gathered in this study in two main ways:**

- We will create research reports and presentations about this study that summarize its findings without singling out any one participant. Your name and identifying information will not be included in any research reports or presentations of this research.
- A file containing answers to questionnaires from everyone who participates will be given to the National Archive of Criminal Justice Data so it can be shared with other researchers doing similar work at other

locations. Everyone's answers will be labeled with an ID number. The file will be checked to make sure that there is nothing in it that could tell anyone who you are. There will be no names, contact information, or any other personally-identifying information in the file.

Everything you tell us will be confidential. We will not share your responses with the survivor, and we will not share the survivor's responses with you. We have taken **steps to protect your confidentiality**.

- The questionnaires will be completed using a secure server, which provides the highest available level of protection for your confidentiality.
- All of your questionnaire responses will be labeled with an ID number, rather than your name, the name of the person participating in this study with you, or any other information that would tell people who you are. Only the research team will know your ID number. That way, no one will be able to figure out your identity or the identity of the person participating in this study with you, even if they looked at the answers to your questionnaires.
- We will put your ID number, name, and contact information in a special secured computer file. This file will be separate from all other information you give us as part of the study. The research team are the only ones who will have access to this file, and we will not share it with others. We will only use this file to contact you to complete the study, pay you for your participation, and find your ID number. We will retain your name and contact information until the end of the record retention period required by state and/or federal law.
- We have obtained a Privacy Certificate from the National Institute of Justice. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you can share information about yourself or your part in this research if you wish. The Certificate expires when the funding for this study ends. Currently this is 10/31/24. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected even after the expiration date.

We also ask you to take some steps to protect your own and each others' confidentiality.

- To make sure that no one can see your survey responses while you are in the middle of taking a survey, we ask you to make sure that no one else has access to the phone, laptop, or email accounts where you receive your survey links. You can do this by only asking us to send your survey links to an account or device that no one other than you has access to, and that you submit your surveys as soon as possible.
- It is important to remember that the first name of the person you are participating in this study with will show up in the questions we ask you, and your first name will show up in their questions. Because of this, we ask you to help protect each others' confidentiality by not sharing the link to the questionnaire with anyone else, and filling out the questionnaire on a private, secure device.
- We encourage you to ensure that you are attending this session from a private location, and make sure that others cannot hear or see what's happening.
- We encourage you to check in with each other if there is anything that you would prefer the other person not share in this appointment. If you would like to do this, we will put you into a Zoom breakout room before we begin.

However, there are **some important exceptions to confidentiality**:

- The confidentiality of the data cannot be guaranteed if you report future criminal intent.
- If we learn that you intend to harm yourself or others, or that anyone is at imminent risk of harm, we must report that to the authorities.

- If you tell us about child/elder abuse, we are not allowed to report that unless you give us permission. We will give you the option of giving us permission but it will be up to you.
- Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

INFORMATION FOR ADOLESCENTS

You do not need permission from a parent or guardian to be in this study. This is because, in Washington State, teens age 13-17 are allowed to seek help for mental health concerns without parental consent.

If you tell us about past abuse, we will not tell anyone without your permission. Instead, we will give you the option of talking with us about the pros and cons of contacting the authorities, and different options for doing so. We will only tell the authorities if you fill out a form saying it's okay.

FUTURE USE OF DATA

Data identified only by your ID number (not your name, contact information, or any other information that may identify you) may be shared with other researchers doing similar work on other campuses, be combined with data from other campuses in some research reports, and/or may be used to develop procedures used in future studies. These data will be retained indefinitely, identified only by the ID number.

OTHER INFORMATION

You may refuse to participate or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If at any point we determine that you are not eligible for this study, if your condition deteriorates, or if it becomes known that you require a higher level or different type of care, we will withdraw you from the study and not invite you to complete any remaining surveys or sessions. We will provide you referrals for services if this happens.

You should not incur any expenses from your participation in this research. You are free to participate in other programs such as support groups, treatment, therapy, etc. while involved in the study.

If you become concerned about problems you're experiencing related to supporting the survivor, or if you experience discomfort as a result of your participation, you can contact one of the researchers listed above to discuss your concerns. We will be happy to provide referrals for services. You can contact study personnel by phone or email during regular business hours.

RESEARCH-RELATED INJURY

If you think you have been harmed from this research, contact one of the study investigators right away. They will treat you or refer you for treatment. You may also reach out to them if you have questions about the study or your rights as a participant. Their contact information is at the beginning of this form.

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions and discuss this decision with the survivor, if I wish to do so.

If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.

[ ] I accept. I want to participate in this study.

[ ] I do not accept.