

Evaluating an Educational Intervention for Improving Provider Recognition and Response to IPV Experienced by Veterans and their Families – A Mixed Method Pilot Randomized Trial

1.0 Background /Introduction

Canadian military and veteran populations experience elevated rates of the risk factors associated with committing or being the victim of intimate partner violence (IPV). Relative to the general population, Canadian military and veteran populations are more likely to report a history of child maltreatment exposure (1), as well as substance and mental health-related challenges related to deployment, re-deployment, and combat exposure (2); each of these experiences has been found to be associated with the likelihood of IPV perpetration or victimization (3-7). Population-level estimates of IPV prevalence among Canadian veterans—which include retired/discharged members of the Canadian Armed Forces (CAF; Royal Canadian Navy, Canadian Army, and Royal Canadian Air Force) and retired members of Royal Canadian Mounted Police—are not available. However, a recent systematic review and meta-analysis of predominately American studies showed that one in eight active duty personnel and veterans self-report perpetrating IPV in their intimate relationship and one in five report recent IPV victimization (8). Similarly, approximately 30% of individuals who are members of the CAF or whose partner is a member of the CAF self-report IPV victimization (9, 10). By extension, this indicates that at the population level, close to one-third of CAF veterans or their partners, will experience some form of IPV victimization in their lifetime and this proportion is likely an underestimate.

Healthcare and social service providers (HSSP) who work with veteran populations have an important role in the prevention of IPV recurrence and associated impairment (11, 12). However, increasing evidence (13-24) indicates that generally, HSSPs receive insufficient training related to recognizing and responding to IPV in their clinical encounters; providers report discomfort initiating conversations about IPV, a lack of time to adequately recognize and respond to disclosures, and challenges with determining appropriate referrals and reporting requirements. These challenges can be exacerbated in the context of veteran populations given unique healthcare and social service structures and stigma related to disclosing IPV. It is also important to note that the optimal approach for preparing HSSPs with the knowledge and skills to effectively recognize and respond to IPV, remains unclear. Educational interventions that have been evaluated vary in their instructional approaches and fail to consider active controls (i.e., comparator programs that also focus on IPV, but use different instructional methods). They also tend to focus on physical and sexual IPV, as well as screening; this is despite evidence and statements from the World Health Organization, the National Institute of Health and Care Excellence and the Canadian Task Force on Preventive Health Care that indicate there is no evidence that universal screening for IPV reduces IPV recurrence or improves the health outcomes of individuals exposed to IPV. Finally, few educational interventions acknowledge the complex overlap between IPV, children's exposure to IPV, and other forms of family violence, including child physical, sexual, and emotional abuse and neglect (25). Collectively, this information indicates an urgent need for educational interventions and associated evaluations that address all forms of IPV and related forms of family violence, across healthcare and social service disciplines working with veteran members, and which provide evidence for the optimal educational approach for improving provider knowledge and skills to effectively recognize and respond to IPV.

1.1 Overview and Rationale for Selection of Violence, Evidence, Guidance, Action Project (VEGA) Education Intervention

The Violence, Evidence, Guidance, Action (VEGA) Education Resources¹ are a novel education intervention that has the potential to improve the preparation of healthcare and social service providers (HHSPs) to be able to effectively recognize and respond to IPV and related forms of family violence, including child maltreatment (CM), in their clinical encounters. VEGA resources were developed based on systematic reviews and consultation with individuals belonging to 22 national healthcare and social service organizations, including the Royal College of Physicians and Surgeons of Canada (see www.vegaproject.mcmaster.ca). VEGA resources follow a competency-based framework and a participatory, encounter-based curriculum that includes four learning modules: (a) the epidemiology of IPV and CM; (b) strategies for safely recognizing and responding to (i) IPV and (ii) CM; and (c) principles for ensuring safe clinical encounters for IPV and CM discussions. VEGA can be completed as a self-directed learning opportunity or in a workshop that is led by two trained facilitators; both approaches take approximately 3.5 hours to complete. *Importantly, neither of the VEGA educational approaches have been evaluated as an adjunct to standard HSSP education for improving HSSP knowledge and skills related to IPV.*

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2.0 Study Design

2.1 Study objectives

The overall goal of this study is to determine the acceptability and feasibility of administering the VEGA intervention to Canadian veteran service providers, adjunct to standard HHSP education. We also aim to generate initial estimates of the effectiveness of the VEGA resources for improving knowledge and skills for recognizing and responding to IPV and CM in this population. Our initial secondary objective was to contribute to the knowledge base regarding the optimal educational approach for education in IPV and CM among veteran-serving HSSPs. These objectives were to be achieved by conducting a two-arm pilot randomized controlled trial of 80 veteran-serving HHSPs that compares the two educational approaches: self-directed VEGA (experimental arm) and facilitator-led VEGA (active control arm).

As of March 2023, after consulting with our collaborators at the Atlas Institute, we are moving to a one-arm pilot trial of the self-directed VEGA resources. Due to low enrollment, we want to focus on our primary aim which is to deliver the VEGA resources to this population of HHSPs. Facilitator-led VEGA requires a minimum number of participants in order to move forward with a single workshop which is proving harder to achieve given the longstanding infrastructure challenges related to the COVID-19 pandemic for front-line service providers and their schedules. With support from our collaborators at Atlas, we are now restricting our intervention delivery to the self-directed VEGA resources given the freedom with which participants can complete the intervention independently with varying schedules.

We are now focusing on achieving sample size aims for one of the two arms of the study and no longer going to evaluate the facilitator-led VEGA. Our primary aim will be achieved by

conducting a one-arm pilot trial of 40 veteran-serving HHSPs where participants will complete self-directed VEGA.

2.1.1 Two arm pilot randomized controlled trial (February 2022 to May 2023).

Primary outcomes of feasibility will be obtained by the RC tracking the recruitment and administration of the VEGA resources. The perceived acceptability and impact of the approaches will be determined by qualitative interviews conducted in a sub-sample of participants. The evaluation of secondary outcomes will be powered to detect moderate self-reported improvements in IPV and CM knowledge and skills, as well as preparedness and self-efficacy related to recognizing and responding to IPV and CM. These secondary outcomes will be obtained via self-report surveys administered at baseline (Time 1), post-education (Time 2), and at 3-month follow-up time points (Time 3).

2.1.2 Mixed Method Research Design.

We will use the embedded-experiment (QUAN(qual)) mixed method research design (26, 27). A strand of quantitative data collection will provide important acceptability and feasibility metrics related to enrollment, retention, attrition, data completeness, as well as exploratory estimates of education effect for the VEGA resources. The qualitative strand of data collection will generate important contextual information regarding the tenability of an RCT, the perceived value and impact of the VEGA resources and examine the *why* of acceptability and feasibility, as well as educational impact (or not) from the perspective of veteran-service providers.

2.1.3 Primary and Secondary Aims

Primary Aims: To determine the feasibility and acceptability of an RCT comparing two VEGA educational approaches, the self-directed vs facilitator-led VEGA, in HHSPs who serve veterans and their families. To determine the feasibility of the RCT we will use four outcomes: (i) the number of HHSPs who meet eligibility criteria and (ii) who agree to be randomized to either self-directed or facilitator-led VEGA education approaches, both overall and per week of recruitment, (iii) the proportion of HHSPs who complete each arm, with completion consisting of the review of all module content and the animated simulations in the case of self-directed VEGA and full attendance of the virtual workshop in the case of facilitator-led VEGA and (iv) the feasibility of collecting trial outcome data at Time 1, Time 2, and Time 3. The acceptability of the facilitator-led and self-directed educational approaches as well as their value and impact will be determined via the coding of qualitative interview data from a sub-sample of participants.

Our aims are that (i) we will recruit, on average, 5 providers per week and achieve our sample aims of 80 participants within 16 weeks, (ii) the proportion of providers who contact the research team about participation and who consent to randomization will be 70% or greater, (iii) the proportion of providers who are randomized and complete their assigned intervention will be 70% or greater for each arm and (iv) the proportion of missing data for each time-point will be less than 20%.

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As of March 2023, we will revise primary outcomes (ii) and (iii) to (ii) the number of HHSPs who consent to participate in the study and complete self-directed VEGA, both overall and per week of recruitment, (iii) the proportion of HHSPs who complete self-directed VEGA, with completion consisting of the review of all module content and the animated simulations in the case of self-directed VEGA. Our aims are (ii) the proportion of providers who contact the research team about participation and who consent to participate will be 70% or greater and (iii) the proportion of providers who complete self-directed VEGA will be 70% or greater.

Qualitative description will be used to expand and extend what we learn about acceptability and feasibility of implementing the VEGA training approaches and associated research activities and detail the pros and cons of each educational approach; we anticipate that participants will not identify any fatal flaws related to the conduct of an RCT.

Secondary Aims: Six secondary outcomes are included to evaluate the VEGA training. These include self-reported HHSP (a) knowledge and skills as well as (b) preparedness and (c) self-efficacy related to recognizing and responding to IPV and CM in veterans and their families.

We hypothesize that we will see significant increases in preparedness, knowledge and skills, and self-efficacy for both CM and IPV in both the experimental and AC arms from Time 1 to Time 2 and Time 1 to Time 3. We also predict that these improvements will be slightly attenuated in the experimental arm.

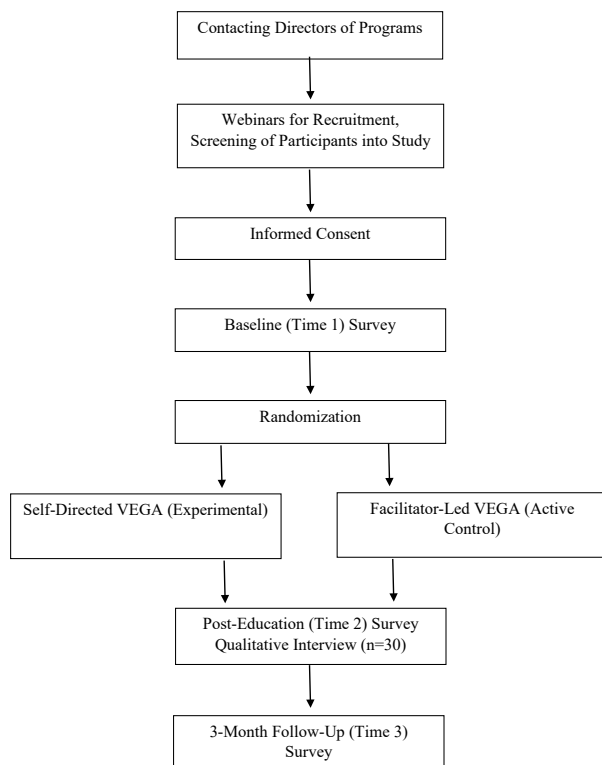
As of March 2023, we will not be assessing differences in changes in our secondary outcomes between the experimental and AC arms. We hypothesize we will see significant increases in preparedness, knowledge and skills, and self-efficacy for both CM and IPV in the experimental (i.e. self-directed) VEGA arm from Time 1 to Time 2 and Time 1 to Time 3. Qualitative data pertaining to perceived value and impact will corroborate the quantitative findings.

2.2 Sampling and Recruitment

To determine the feasibility of evaluating the effectiveness of both of VEGA's educational approaches, as well as to generate preliminary estimates of effect for sampling and effect size calculations, a two-arm pilot randomized controlled trial (RCT) will be used (28). Eligible participants will be randomly assigned to receive either self-directed (i.e., experimental) or facilitator-led (i.e., active control (AC)) VEGA. The RCT will follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines and will be registered with clinicaltrials.gov, following ethics approval. The trial design is summarized in Figure 1 below.

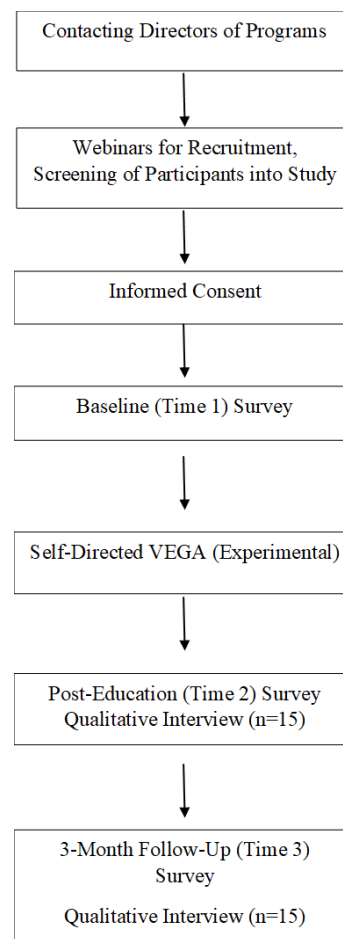
Figure 1. Pilot Randomized Controlled Trial – Participant Flow

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As of March 2023, we will be using a one-arm pilot trial. Eligible participants will be asked to complete self-directed VEGA only.

Figure 2. Pilot Trial – Participant Flow as of March 2023



2.2.1 Eligibility and Screening

Study participants will be recruited from a population of veteran-serving HSSPs working within programs, agencies, and organizations recommended by the Atlas Institute for Veterans and Families, examples include the Veteran Affairs Canada (VAC) Assistance Service, the Veteran Family Program, or the Operational Stress Injury Clinics. These contacts will be within Atlas' and the research team's professional networks. Direct recruitment of providers will also take place via social media accounts of research team members and partnering agencies [see CoE_VEGA_Social Media Drafts_V2_10APR2023]. Veteran-Serving HSSPs are eligible for inclusion if:

- i. They are healthcare or social service professionals.
- ii. They are working with military and/or RCMP veterans or military and/or RCMP veteran's family members in a direct service capacity at least one day per week OR they have at least two years or more of experience working with military and/or RCMP veterans or their family members in a direct service capacity OR they have worked with 15 or more patients that were either military and/or RCMP veterans or their family members in a direct service capacity.
- iii. They are willing and capable of providing informed, written consent and completing all project activities in English.

Exclusion Criteria: HSSPs who have previously registered to access VEGA materials; HSSPs who are currently enrolled in or expected to enroll in any other educational intervention focused on family violence (intimate partner violence, child maltreatment, childhood exposure to IPV) within the study time period.

Directors of programs and agencies/organizations recommended by Atlas as well as providers belonging to the professional networks of the teams' will be contacted by the Research Coordinator (RC) and PI via email and provided with a one-page overview of the study and the opportunity to meet with the research team to address study-related questions [see "Step 1: Initial Contact of Program Directors and Professional Contacts" in CoE_VEGA_EmailScripts_V8_12MAY2023"]. If a meeting takes place, during the meeting, the team will discuss the study with the program directors/professional contacts and program directors will be asked to sign an Expression of Interest (EOI) form [see "CoE_VEGA_EOI_V3_24MAY2022"]. The EOI form asks program directors to support (a) HSSP completion of VEGA training components, and (b) HHSPs to complete research activities outside regular work hours to receive study honoraria. The Expression of Interest form also asks program directors to confirm that the program is not currently participating in other research projects concerning family violence. During the meeting, the team will obtain verbal consent from the directors of enrolled programs to allow staff to attend study-related webinars, led by the project team, prior to the launch of recruitment efforts. Webinar content will review staff eligibility criteria, as well as recruitment and research-related procedures. Following the completion of the webinars, directors of the enrolled programs will distribute recruitment materials via email to all providers; materials will encourage interested participants to contact the research team [see "Step 2: Webinar Content and Recruitment Materials" in

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“CoE_VEGA_EmailScripts_V8_12MAY2023”]. These materials include a one-page flyer that summarizes the study purpose, what the VEGA intervention is generally about, and honorarium available to participants for completing the research components [see “CoE_VEGA_OnePageFlyerB_V4_29MAR2023”]. These recruitment materials will also be available in French.

As of March 2023, after feedback from our sponsor, we are removing the request to have a meeting with directors at programs/agencies and professional contacts in our initial email script. We have replaced this with a simple request to contacts to distribute the one-page flyer attached to the email, to their network. If contacts express an interest in allowing us to present webinars to providers, we will inform them via email that the webinars are not overseen by HiREB and give them the opportunity to obtain REB approval of the slides and their content [see pg. 2 of CoE_VEGA_EmailScripts_V8_12MAY2023”].

We will also recruit using a snowball subject sampling method. Participants will be invited to share the study with their contacts to allow for an accumulation of participants over time. At the conclusion of completing the consent process, the 'source' participant will be asked if they know any other residents meeting our eligibility criteria and whom they think may be interested in participating in this study. If the participant indicates that they do know someone that may be interested and who may meet the study eligibility criteria, the source participant/participants will forward the study information letter and one-page flyer to the individual(s) so that the individual(s) can contact the research team, if they are interested in participating. It will be up to the participant as to whether or not they indicate to the individual(s) in that email as to whether or not the participant actually participated in the study.

2.2.2 Informed Consent

Once a provider has initiated contact with the research team, the research assistant (RA) will, depending on the participant's preference, either arrange a telephone call to discuss the study and ask eligibility and demographic screening questions or send them a link to the screening & demographics questionnaire hosted on REDCap [see “Step 3: Initial Contact from Participant & Arranging Screening and Demographics Questionnaire” in “CoE_VEGA_EmailScripts_V8_12MAY2023”]. During the call, the RA will first give a short description of the training and research components of the study with the opportunity of providers to ask questions. If participants choose to self-complete the questionnaire online, there will also be a short description of the study before participants complete the questionnaire on REDCap. The screening and demographics questionnaire will contain a series of questions to determine the eligibility of providers for the study, defined by the inclusion and exclusion criteria above. It will also ask a series of sociodemographic questions [for eligibility and demographic questions, see “Appendix A: Screening Eligibility and Demographic Questionnaire REDCap Form” in “CoE_VEGA_ScreeningCallScript_V7_03APR2023”]. If completing measures over the phone, the provider's answers will be entered by the RA into REDCap. We will obtain written consent from providers to keep their responses to the screening and demographics questionnaire should they end up being ineligible or do not end up participating in the study. This is for the purpose of comparing those who end up participating to those who do not end up participating to understand

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if our criteria are potentially excluding a particular group of people or if those who do not end up participating belong to a particular group.

After completing the eligibility and demographic questions, providers will be informed of their eligibility for the study. This communication will occur via phone [see pg. 2-3 of CoE_VEGA_ScreeningCallScript_V7_03APR2023] or email [see pg. 4-5 of CoE_VEGA_EmailScripts_V8_12MAY2023] based on the participant's preference.

Providers will be emailed a link to an electronic version on REDCap and a pdf version of the Letter of Information/Consent (hereafter referred to as “consent form”) [see “Step 4: Electronic Consent Form” in “CoE_VEGA_EmailScripts_V8_12MAY2023”]. Together, the RA and practitioner will review the Letter of Information/Consent [see “CoE_VEGA_ConsentForm_V8_03MAR2023”] per International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines and institutional policy. Providers will be encouraged to take as much time as they need to review the consent form and will be provided the opportunity to speak with the RA on the phone if they have any questions at any time. The consent form will outline the purpose of the study, the commitment that will be required of participants, the potential risks and benefits associated with study participation, and all the measures the research team will take to protect their confidentiality. It will be the responsibility of the person obtaining consent to ensure that participants understand the extent of their role in the research. The RA obtaining consent will foster an open exchange of information, encouraging potential participants to ask questions prior to research involvement, to review the pdf copy of the consent form at any time, and to continue to ask questions that may arise at any point during the study if they participate. Details of the consent form will be presented in simple language as approved by the Research Ethics Board (REB) of the institutions involved. If the participant indicates they are ready to complete the consent form, they will be asked to select the option “I agree to participate in the study,” to enter their full name and the date, and electronically sign in the consent form on REDCap. After completing this and submitting on REDCap, the RA will download a PDF copy of the consent form with the participant's responses from REDCap. They will add the following using Adobe PDF software: “Consent form administered by,” and print their name, electronically sign, and date. If the participant prefers to provide written consent using the PDF copy of the consent form, we will make this option available to them and they can print their name, sign and date, and submit this to the RA or LPI by email or to the LPI by mail. The RA will print their name, sign and date, on this form where it says “consent form administered by.”

Once the participant provides written consent, the RA will send the baseline (Time 1) questionnaire. The Time 1 questionnaire will be sent via an email that will contain a link to the assessment measures hosted in REDCap. Providers will be asked to complete measures within one week of receipt of the email.

2.2.3 Randomization

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Randomization will occur after consent has been obtained and the web-based baseline (Time 1) survey is complete. As indicated in the previous section, randomization will occur five business days before the facilitator-led VEGA session the participant is available to attend is scheduled. Participants will be randomly assigned to one of the two conditions using stratified block randomization, with a block size of 4 (blocking factor of 2), using an internet-based randomization service; <https://www.randomize.net/>. Randomization will be stratified based on sex at birth with two levels to this variable: female and male.

Participants will be informed of their treatment arm status by the RC. The RC will not reveal participant allocations to the RA who will be directly involved in the quantitative data collection. Participants will also be encouraged not to inform the RA of their allocation.

As of March 2023, participants will not be randomized to complete either facilitator-led or self-directed VEGA, all participants will be asked to complete self-directed VEGA.

2.2.4 Education Intervention

Self-Directed VEGA – Experimental Arm uses an approach where participants complete the Violence, Evidence, Guidance, Action Project (VEGA) content online as a self-directed educational activity, at their own pace in a series of modules. Individuals will register to access the VEGA Education Resources site at <https://vegaproject.mcmaster.ca/>. Registration will be free. They will be asked to provide their name and email to be sent the online resources. They will also be asked to agree to terms of use to access this site. Participants will be sent an information sheet that outlines the steps to register and access the VEGA materials online [“CoE_VEGA_SelfDirectedRegistration_V6_03MAR2023.”]. Participants have the option of completing the self-directed VEGA arm in either English or French as the VEGA Educational Resources site offers the content in French and English. The consent form will inform participants this is an option for the self-directed VEGA arm only. The information sheet for registering for self-directed VEGA will also show participants how to access the French version of the VEGA online modules [CoE_VEGA_SelfDirectedRegistration_V6_03MAR2023.”].

Participants will be asked to direct all content-related questions to the RC who will forward them to the VEGA team to see if they can be answered. Participants will be provided the contact information for the VEGA IT Team who will address any technology-related questions they may have while completing the self-directed VEGA program [see “RISE with Veteran Service Providers – Training Program Assignment” in CoE_VEGA_EmailScripts_V8_12MAY2023]. If they haven’t completed them already, participants will receive reminders via email every two days from the RC reminding them to complete the self-directed VEGA online modules [see “RISE with Veteran Service Providers – Online Modules Reminder” in CoE_VEGA_EmailScripts_V8_12MAY2023”].

Participants will be asked to complete the self-directed VEGA at their convenience, within one week of when they are informed they have been asked to complete the self-directed VEGA program. It will take approximately 3 hours for participants to complete all modules.

Facilitator-Led VEGA – Active Control Arm uses a group-based approach where participants complete the Violence, Evidence, Guidance, Action Project (VEGA) content as a virtual or face-to-face workshop (i.e., *facilitator-led VEGA*). In this study, all workshops will be virtual to prevent social gathering during COVID-19. The AC intervention will be facilitated via Zoom technology, by two trained facilitators with between 15 to 20 participants in each workshop (keeping the recommended 10:1 participant-to-facilitator ratio) and will last approximately 3 hours. The workshop approach is delivered by trained facilitators and is standardized via the use of a flexibly structured facilitator's guide.

As of March 2023, no participants will be asked to complete facilitator-led VEGA, as we are removing this arm from the study.

VEGA training takes approximately 3 hours to complete and pedagogical elements for both approaches have been informed by education scholarship. Below is a table outlining the common pedagogical elements in the self-directed and facilitator-led VEGA education interventions (Table 1).

Table 1: Pedagogical Elements of Self-Directed VEGA (i.e., experimental arm) and Facilitated VEGA (active control arm) Educational Approaches

Pedagogical Elements	Self-Directed VEGA (<i>Experimental Arm</i>)	Facilitator-Led VEGA (<i>Active Control Arm</i>)
Didactic Material[45]	Asynchronous reading	Synchronous lecturing
Deliberate practice[46, 47]	Case-Based Animated Simulations	Case-Based Role play
Enabling learning tools [48]	Virtual Patients, Clinical Handbook, Clinical Scripts	Virtual Patients, Clinical Handbook, Clinical Scripts
Test-enhanced learning [43]	Individual multiple-choice questions with response feedback	Group-based polling (i.e., multiple-choice) and feedback.

3.0 Data Collection

3.1.1 Feasibility Statistics

The RC will keep track of the number of providers who: (a) agreed to be screened; (b) are eligible for participation; and (c) enroll. We will also record the number of: (d) emails/phone calls needed to arrange all research assessments; (e) participants who drop out; participants who (f) could not be reached for follow-up; (g) complete the intervention; and (h) partially complete vs. fully complete research assessments for our Primary Objectives. As an indicator of feasibility, we will also record the total time to complete all quantitative assessments.

3.1.2 Quantitative Assessments

A trained research assistant (RA) will gather all data from all participants during three study assessment time points. Quantitative assessments will be hosted on REDCap and will be available online using a web-based link and emailed to participants at three time points: the week before they begin the VEGA training (Time 1), post-education (Time 2), and 3-months after the Time 1 survey is completed (Time 3). Participants will be asked to complete the surveys within one week, from the date they are initially sent, on their own time. Time 1 surveys will be sent

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after completing the consent form, Time 2 will be sent the day after the online modules are due to be completed (experimental arm), and Time 3 will be sent 3 months after this date, to be completed within two weeks. Each survey will take approximately 30 minutes to complete. A detailed list and description of study measures can be found below. The format of all of surveys, listing all of the questions in each questionnaire can be found in [“CoE_VEGA_QuantitativeSurvey_V3_12MAY2022”]. Due to changes in requirements for continuing education credits, we created an alternative version of the survey [“CoE_VEGA_QuantitativeSurveyB_V3_24MAR2023”] that excludes the measures “Child Maltreatment Knowledge and Skills Questions developed by the VEGA team” and “Satisfaction with VEGA training” because the VEGA team will administer questions required for continuing education credits. As of March 2023, all participants in the study will be administered this version [CoE_VEGA_QuantitativeSurveyB_V3_24MAR2023], we will not be administering the original version [CoE_VEGA_QuantitativeSurvey_V3_12MAY2022]. As a courtesy, participants will also have the option of completing the surveys in either English or French. Before each survey, they will be asked if they would like to complete the current survey in English or French.

3.1.3 Qualitative Interviews

Informed consent procedures for the quantitative strand (see above) will include permission for the research team to approach participants for qualitative data collection. Given that the qualitative data will complement the quantitative strand of data collection, we will use purposive criterion sampling strategies to select a sub-sample of the providers ($n = 30$) to participate in a one-on-one semi-structured interview with the research team via Zoom conducted in English. We will endeavour to stratify recruitment of qualitative participants by sex at birth (~15 male; ~15 female).

Half of the individual semi-structured interviews ($n = 15$) will take place post-intervention completion and half will take place ($n = 15$) will take place 3 months after the intervention has been completed. Interviews will be up to 60-minutes in length. Interviews will be scheduled between an experienced qualitative, education research scholar and the participant at the participant's convenience. Given that members of the research team (Co-PIs and RA) will be involved in the coordination and delivery of VEGA resources and quantitative data collection components, it is essential to have a contract interviewer to conduct the qualitative interviews to support the unbiased collection of data. Interviews will occur by Zoom, using the audio function only (or by phone, if the participant prefers). Interviews will be audio recorded, and will be transcribed verbatim. A semi-structured interview guide of 5-to-7 key questions and probes will guide the interview [see “CoE_VEGA_Qualitative Interview_V6_12MAY2023”]. Field notes completed by the interviewer will document observations, patterns or dialectical positions which may be relevant to analysis.

3.2 Measures

3.2.1 Secondary Outcome Measures

Child Maltreatment Vignette Scale (Pelletier et al., 2014; Pelletier & Knox, 2017). The Child Maltreatment Vignette scale (29, 30) is a psychometrically validated measure of knowledge and skill accuracy related to recognizing and responding to child maltreatment. Respondents will be prompted to review 14 distinct analog vignettes that depict a range of signs

and symptoms of possible CM exposure. Upon completing their review of each vignette, providers will be asked to indicate their responses to two questions, “For any child/youth in this scenario, do you have reason to suspect child maltreatment?” and “Would you report this case to Child Welfare Services?” These changes to the question wording and small changes to the wording of the scenarios were made to align the measure with the Canadian context. Responses will be scored as either correct (‘1’) or incorrect (‘0’) as predetermined, *a priori*, by a panel of CM experts; **a mean “knowledge and skill accuracy” score will be produced for analysis**, with higher scores indicative of greater knowledge and skill accuracy related to CM. They will also be asked their relative confidence in their response on a scale from 50-100%. This will be administered as part of the surveys at **all three timepoints**. In a future RCT, this would be one of the primary outcomes of interest since this is a robust measure of practitioner knowledge and skills related to CM. Time to administer is approximately 15 minutes.

Child Maltreatment Knowledge and Skills Questions (Developed by VEGA Team).

Participants will be asked a series of questions about their knowledge and skills related to recognizing and responding to child maltreatment. These were developed by the VEGA training research team to capture specific aspects of CM knowledge directly addressed in the VEGA intervention and which are outside the scope of the child maltreatment vignette scale. The questions ask about the following topics (and more not mentioned here): parental/family risk factors for family violence, what future outcomes are associated with child maltreatment, other possible signs of child abuse, and principles for good documentation and providing ongoing care to children experiencing maltreatment. A full list of the questions can be found in Section 2.4 of the quantitative survey (see Section 2.4 of CoE_VEGA_QuantitativeSurvey_V3_04MAY2022). Including this measure in our study will allow us to make cross sample comparisons.

The Physician Readiness to Manage Intimate Partner Violence Survey (Short et al., 2006; Connor et al., 2011).

The Physician Readiness to Manage Intimate Partner Violence Survey (PREMIS) is a 67-item self-report tool that was developed to assess physician management of intimate partner violence across 10 subscales (31, 32). Survey questions are grouped into four major sections (1) background (four scales concerning previous IPV training, perceived IPV knowledge and preparation), (2) actual knowledge, (3) IPV attitudes and beliefs, and (4) practice issues (a 13-item scale of self-reported behaviors concerning individual and office IPV practices and policies).

- a. **PREMIS Section III: IPV Knowledge.** The IPV knowledge section, consisting of multiple answer, multiple choice, and true-false questions will be used to measure IPV knowledge and skills. An IPV “knowledge score” will be computed following previous scoring guidelines (Short et al., 2006). In a future RCT, this would be a primary outcome of interest to measure practitioner knowledge and skills related to IPV. **This will be administered as part of the surveys at all three timepoints.** Time to administer is approximately 10 minutes.

- b. PREMIS: Adapted Preparedness Subscale.** The preparedness subscale of PREMIS asks respondents to indicate the extent to which they feel prepared to address various aspects of IPV recognition and response when working with their clients across 10 items; these aspects include the conduct of safety assessments, asking appropriate questions about IPV, responding to IPV disclosures, among others. Response options are on a 7-item Likert type scale ranging from “Not prepared” (1) to “Quite Well Prepared” (7) and items are averaged to generate a mean score for practitioner preparedness, with higher scores indicative of generally greater preparedness to recognize and respond to IPV.

For the purposes of this study, an adapted version of the preparedness subscale was used to assess preparedness to recognize and respond to IPV. The last item, “Fulfill state reporting requirements for (a) IPV, (b) child abuse, and (c) elder abuse” was dropped because other questionnaires in this survey address providers’ self-reported ability to fulfill these requirements, for a total of 9 items. Total scores for preparedness to respond to IPV will be calculated by summing the responses selected for all 9 items and will range from 9 to 63.

An adapted version of the preparedness subscale was administered to assess provider’s preparedness to recognize and respond to CM. All items were changed to be related to CM instead of IPV (e.g., “ask appropriate questions about IPV” was changed to “ask appropriate questions about CM”). Several items were dropped from the subscale as they are not relevant in the case of CM: “Help an IPV victim assess whether their life is in danger,” “Conduct a safety assessment related to IPV”, “Help an IPV victim create a safety plan,” for a total of 6 items. Total scores for preparedness to respond to IPV will be calculated by summing the responses selected for all 6 items and will range from 6 to 42.

These two versions of the preparedness subscale will be administered at Time 1, Time 2, Time 3. Time to administer is approximately 2 minutes, a total of 4 minutes to administer both the IPV and CM versions.

- c. PREMIS: Opinions.** The Opinions section of the PREMIS asks respondents to indicate their level of agreement/disagreement with various statements about care of those with IPV across 32 items. Response options are on a 7-item Likert type scale ranging from (1) Strongly Disagree to (7) Strongly Agree. We will use an adapted version of this scale which dropped items related to their compliance with legal requirements for IPV. This adapted version will be used to measure provider attitudes and beliefs about IPV and care of those with IPV in five subscales: (1) preparation, (2) workplace issues, (3) self-efficacy, (4) alcohol/drugs, and (5) victim understanding. We will follow previous methods to calculate these subscales by averaging the responses to items that make up the subscale (Short et al., 2006). **The opinions section of the PREMIS will be administered at Time 1 and Time 3, with the exception of the self-efficacy questions which will be administered in a**

separate section at Time 2 as well. It will take approximately 10 minutes to complete.

- d. PREMIS: Self-Efficacy Subscale.** The self-efficacy subscale of the PREMIS comprises three questions from the Opinions section of the PREMIS: “I ask all new patients about abuse in their relationships,” “I feel comfortable discussing IPV with my patients,” and “I am able to gather the necessary information to identify IPV as the underlying cause of patient illnesses (e.g. depression, migraines).” **The self-efficacy score is calculated by averaging the responses of these three items.** This will be a primary outcome of interest in a future RCT as a measure of provider’s self-efficacy to recognize and respond to IPV. **The three items comprising this subscale will be administered at Time 1, Time 2, and Time 3,** and will take approximately 1 minute to administer.

Mandatory Reporting Self-Efficacy Scale (Ayling, 2019). The Mandatory Reporting Self-Efficacy Scale (MRSES) is a 7-item self-report measure that asks respondents to indicate the extent to which they perceive their ability to implement a series of behaviours related to mandatory reporting of CM (33). Informed by Bandura’s self-efficacy theory and recommendations for self-efficacy scales (34), response options are anchored on a scale from 0 to 100 with statements at 0, 50, and 100 indicating: “cannot do at all (0)”; moderately can do (50)”; and “highly certain can do (100).” A total score is generated by summing items across the scale for each participant, with higher scores indicative of greater self-efficacy related to recognizing and reporting suspected CM. We anticipate that this measure will be a key mediator of interest in a future definitive RCT given that across provincial and territorial jurisdictions in Canada (including Ontario), a suspicion of CM meets the threshold for a report to child protection authorities (35,36). This will be administered as part of the surveys at all three timepoints. Time to administer is approximately 5 minutes.

Brief Individual Readiness for Change Scale (Goldman, 2009). The Brief Individual Readiness for Change (BIRCS) scale is a 5-item readiness for change tool (39). The scale’s purpose is to screen for practitioners’ readiness for change, in other words their receptivity to learning and applying new evidence-based research practices. For the purpose of this study, the items were adapted to assess provider’s readiness to recognize and respond to all forms of (a) IPV and (b) CM in their practice. Response options range from ‘0’ Strongly Disagree to ‘4’ Strongly Agree. Two items were added, “I believe recognizing and responding to [IPV/CM] in my practice improves outcomes for my clients,” and “I am motivated to learn about [IPV/CM]” to capture other aspects of providers’ readiness to learn about IPV and CM and their beliefs about how this will impact their practice. Total and average scores will be calculated by summing or averaging the item responses for both the original scale items and with the added two items. These two versions of the scale will take approximately 1 minute each to complete and will be administered at Time 1 and Time 2.

3.2.2 Other Measures

Demographics

Sociodemographic characteristics will be collected for all participants who are screened for the study, whether they are ineligible or eligible. These will include their age, province of practice, highest level of education attainment, their major discipline, their sex at birth and their self-identified gender. We will also collect some characteristics about the current organization or practice they work for, specifically what populations among military and/or RCMP veterans and their families they serve and if consent is required by the veteran for the participant to provide services to a family member. A full list of all demographic questions can be found in “Appendix A: Screening and Demographics Call REDCap Form” of “CoE_VEGA_ScreeningCallScript_V7_03APR2023.”

Previous Training in Intimate Partner Violence and Child Maltreatment

At Time 1 only, participants will be asked questions to gauge their previous education or training in IPV and CM. Participants will be given a definition of IPV and CM and asked in what subject areas of IPV and CM they have received education and training in, and which of these environments (up to three) have been the most helpful.

Thoughts and Beliefs about Recognizing and Responding to IPV and CM in Professional Roles

Participants will be asked to rate their agreement with four statements about how much they believe (1) recognizing IPV (2) recognizing CM (3) responding to IPV and (4) responding to CM is a part of their professional role. We are recruiting a wide variety of HHSPs that we anticipate may vary in their self-perceptions of how relevant recognizing and responding to IPV and CM is in their professional roles. This will be administered at Time 1 and Time 2 and will take approximately 1 minute to complete.

Satisfaction with VEGA Training

At Time 2, participants will complete a series of multiple choice and short-answer questions asking what they thought about the VEGA training. These questions will apply to all participants whether they completed self-directed or facilitator-led VEGA. Questions will include whether they believe the intended learning outcomes were achieved, what they thought of the instructional materials and educational scenarios, and how they would rate the usefulness of VEGA.

4.0 Statistical Analyses

4.1 Quantitative Analyses

4.1.1 Sociodemographic Characteristics: Descriptive statistics (means, standard deviations, relevant quantiles, and proportions) will be used to report the sample of HHSP's sociodemographic characteristics.

4.1.2 Primary Outcomes: Descriptive statistics (totals, means, standard deviations) will be used to compare primary outcomes to a priori thresholds for acceptability and feasibility outlined in section 2.1.2 Primary Aims.

4.1.3 Secondary Outcomes: Our secondary outcomes will be analyzed via generating bivariate correlations and regression coefficients for variables we hypothesize to be mediators, moderators, and outcomes for a definitive trial.

4.1.4 Missing Data: We will use a force-choiced framework in REDCap in to reduce the possibility of missing data..

4.2 Sample Size

We will recruit a voluntary sample of 80 HHSPs that will be randomized to either the experimental or AC arm. We have selected this sample size given previous work which indicates that 40 HSSPs per arm would provide 80% power to detect a moderate (0.5 SD – to – 0.6 SD) effect size, which is indicative of a clinically significant outcome (40).

As of March 2023, we are now focusing on achieving sample size aims for one of the two arms of the study and no longer going to evaluate the facilitator-led VEGA. Our primary aim will be achieved by conducting a one-arm pilot trial of 40 veteran-serving HHSPs where participants will complete self-directed VEGA. In following this algorithm, our team will be able to consider the needed recruitment and retention rates to successfully implement a definitive education trial.

4.3 Qualitative Analyses

Transcripts of qualitative interviews, as well as associated field notes, will be managed in Nvivo and analyzed using reflective thematic analysis and constant comparison (41, 42). Reflective thematic analysis via constant comparison and analytic memo-ing will allow for the identification codes, categories, and themes related to implementing and evaluating the VEGA resources among HSSPs working with or who have worked with veterans and their family members (41, 42).

4.4 Integration of Qualitative and Quantitative Data for Interpretation

After conducting separate quantitative and qualitative analyses, quantitative and qualitative data will be integrated for interpretation. Quantitative acceptability and feasibility metrics will be mapped to excerpts of qualitative data on perceived acceptability or educational burden via a mixed method joint display; this display will support a comprehensive interpretation of the extent to which a definitive trial examining VEGA in our sample population is tenable. A separate joint display will cross-tabulate scores on secondary outcome measures with qualitative excerpts of VEGAs perceived value and impact for improving provider knowledge and skills related to IPV and CM alongside a narrative description of findings that integrates our conceptual frameworks for continuing education among HSSPs working with or who have worked with the veteran population (41-43).

5.0 Safety Parameters and Reporting

5.1 Time requested of Participants

Participants will be asked to complete a 15-minute screening call with a RA to determine their eligibility for the study and collect sociodemographic information. Participants randomized into one of the two VEGA education intervention arms will either attend one three-hour session (if in AC arm) or complete approximately three hours of module content online on their own time, within a one-week period. All participants will also be asked to complete three surveys as part of the quantitative research assessments, at baseline (Time 1), post-education (Time 2), and 3 months follow-up (Time 3). The Time 1 survey will take ~30 minutes to complete, the Time 2 survey ~20 minutes to complete and the Time 3 survey ~30 minutes to complete. The time needed to complete one survey will be tracked for the study to better estimate this burden for a future RCT.

Participants who complete all three survey timepoints (baseline, post-intervention, and 3-month follow-up) will receive a \$120.00 gift card to Amazon, Mastercard or Indigo as a token of appreciation for the completion of three quantitative research assessments.

A sub-sample of the participants (n=30) will participate in the qualitative interview which we expect to take approximately 60 minutes. Each qualitative participant will receive a \$60.00 gift card to Indigo, Mastercard or Amazon as a token of appreciation for the completion of the interview.

Table 2: Timepoint Compensation Schedule

Timepoint (data type)	Approximate Length	Compensation for participation (in gift cards):
Screening (survey)	15 minutes	\$0
Baseline (Time 1; survey)	30 minutes	\$40
Post-education (Time 2; survey)	30 minutes	\$40
3-month follow-up (Time 3; survey)	30 minutes	\$40
TOTAL SURVEY COMPENSATION (All participants)	105 minutes	\$120
Interview (Time 2 or Time 3)	60 minutes	\$60
TOTAL COMPENSATION (n=30)	165 minutes	\$180

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Completion of the Child Maltreatment Knowledge and Skills Questions developed by the VEGA team and Satisfaction with VEGA training (which will be referred to as “accreditation questions”) and the self-directed VEGA training has been accredited for 3 MOC credits through the RCPSC and 3 Mainpro+ credits through the CFPC. Certificates of completion can be used for continuing medical education credits through the RCPSC (all physicians except family physicians) or the CFPC (family physicians only) or submitted to practitioner’s college or association for continuing education credit (social workers and any other health professional). All accreditation requirements and administration of certificates will be managed by the VEGA Project.

In addition, providers will receive unrestricted access to *self-directed VEGA* upon completion of the study (i.e., after all qualitative and quantitative data have been collected) to ensure all enrollees have ongoing, indefinite access to the educational information offered by the VEGA educational resources.

5.2 Potential Risks and Plans to Mitigate Risks

5.2.1 Adverse events

The focus of this research is an educational intervention for regulated health and social service providers. Given this information, conducted participation in either arm of the pilot RCT involves minimal risk.

Adverse events are any untoward health-related outcomes that occur during the study, regardless of how related they are to the study intervention. Facilitators and research staff directly interacting with participants will use their training to identify and mitigate all potential participant risks, including ones that may not be directly associated with study participation.

Anticipated adverse events which are relevant to this study include those related to healthcare and social service providers (HSSPs) safety and wellbeing include:

- HSSPs own experience(s) with intimate-partner violence and/or child maltreatment, which may raise or contribute to distress during the educational intervention or during research activities.
- HSSPs experience(s) providing care to veterans or their family members who have experienced intimate-partner violence and/or child maltreatment, which may be distressing.

Anticipated adverse events that are not serious will be discussed as needed by research staff with the Principal Investigators, if the nature of the adverse event is considered to signal unresolved risk to the participant. Emergency medical services will be alerted as required if there is concern about imminent risk to life of an adult or safety of a child. The Principal Investigator, who is a registered and regulated social worker and psychotherapist, will follow regulated reporting requirements as necessary, as well as determine if other steps are needed to mitigate risk to the participant.

5.2.2. Serious Adverse Events

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Serious Adverse Events (SAEs) are defined within this study as any untoward health-related outcome in the study occurring towards a participant that:

- Results in death;
- Is life-threatening (an event in which the participant was at risk of death at the time of the event; it does refer to an event which hypothetically might have caused death if it were more severe);
- Requires inpatient hospitalization or prolongation of an existing hospitalization.
- Results in persistent or significant disability/incapacity

SAEs may be reported by participants or other authorities (e.g., child protection) to research staff or investigators. Serious, yet anticipated study relevant events include hospitalization of a participant due to mental illness; participant suicide; participant hospitalization; life-threatening injury of a participant; participant death. Research staff members will also receive SAE report forms to complete following communication with research participants or collaborators. SAEs will be tracked in an excel database and communicated, as appropriate to the HiREB. In the case of anticipated serious events, providers within our partner organizations or research staff will notify the Principal Investigators as soon as possible, within two business days, or earlier if the provider or research staff member determines that investigator guidance is required to safeguard the safety of the participant or research staff member.

5.3 Risk Mitigation

The following strategies will be taken to mitigate risk to study participants: (1) Research staff will communicate to the Principal Investigator (or designated back-up) of concerns about participant safety or serious mental health problems concerns noted during participant interactions throughout the course of training administration and data collection during regular research team meetings or within same day if concerns are of an urgent nature. (2) In case of mental health or safety emergencies, the Principal Investigator or designated back-up clinician will assess the participant and make appropriate safety or reporting decisions as guided by their clinical expertise (e.g., reporting to GP, child protection, regulatory college, referring for independent assessment). All actions taken to mitigate risk and outcomes of these actions will be documented. (3) If the Principal Investigator determines that a participant must be withdrawn from the study for any reason, the investigator will notify the participant by telephone and inform them of other available options for services in the community. Zoom is an externally hosted cloud-based service approved for confidential research use at McMaster; all zoom-based study activities (i.e., qualitative interviews) will incorporate maximum security features.

Since the content of the questions in the quantitative survey includes describing case scenarios of child maltreatment, we have added 24/7 helplines and helplines specific to healthcare providers to the beginning and end of the quantitative survey as a strategy to mitigate any risk of unanticipated or anticipated feelings of discomfort that may arise.

Risks to research staff will be mitigated with the following steps: We expect there to be little risk to staff as all contact will be virtual or over the phone. Injuries or threats to staff will be documented and discussed at weekly research meetings. Details of occurrence, related outcomes and decisions made (e.g., withdrawal of participant, leave of absence for staff) will be documented in minutes.

6.0 Study Management

6.1 Participant Confidentiality

All attempts will be made to protect the confidentiality of all data. All participants will be assigned their own randomly-generated participant ID. One participant tracking document will contain all identifying information and will link the participant ID to the participant's identifying information. This participant tracking document will be password-protected and stored on a secure McMaster server. Further safeguards will include limiting the collection of participant contact information to that which is necessary. Table 3 below outlines the justification for all identifying information that will be collected.

Quantitative data collected via surveys will be de-identified by storing all quantitative data with only the ID assigned to the participant. Transcripts used for qualitative data collection will be linked to the participant ID as well and any identifying information the participant provides during the interview will be redacted from transcripts.

Identifying information, including all identifying information stored in the participant tracking document, will be deleted one month after all data collection for the RCT is complete. Each audio file will be deleted after its transcription is complete.

Table 3: Justification for Collection of Identifying Information

Identifier	Justification
Email	This will be the primary form of contact with participants to coordinate study-related assessments and intervention materials.
Telephone Number(s)	This will be a secondary form of contact with participants that will be used for screening.
Full names	This information is needed to communicate with participants.
Province of Practice	Since this study involves programs that are Canada-wide, we will be asking participants which province their practice is primarily in.
Age	This information is needed for demographic statistics.
Self-Identified Gender	
Sex at Birth	This information is needed for demographic statistics and for stratification of randomization by sex at birth.

6.2 Data Safety Measures

6.2.1. Data Access

The Research Coordinator, in collaboration with the Principal Investigator, will oversee all aspects of the data collection and management at the Offord Centre for Child Studies at the Ron Joyce Children's Health Centre located at 325 Wellington St North and 293 Wellington St North,

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both located in Hamilton. Access to data will be limited to certain members of the research team based on the type of data, listed below:

Participant treatment allocation: The list of participant's IDs with their study arm allocation after randomization will only be accessed by the facilitators and the Research Coordinator. The research assistant will not have access to study arm allocation. The facilitators of the VEGA training sessions will know which participants have been selected to complete the facilitator-led VEGA as they will be carrying out the workshops. VEGA workshop facilitators include regulated health professionals who are bound to principles and limits to confidentiality outlined by their regulatory body. All facilitators will sign a research confidentiality agreement prior to their involvement in the study.

Identifying information: The research coordinator, research assistant, and Dr. Melissa Kimber will have access to identifying information in the participant tracking document. The participant tracking document that matches all participant unique IDs will be stored on a fully encrypted document on a secure McMaster server.

The research assistant will need access to the participant tracking document to contact participants for quantitative surveys and screening calls. The research coordinator will need the participant tracking document to coordinate the training component with participants and qualitative data collection.

The VEGA team will have access to identifying information, specifically participants' names and contact information. This information will be required for registration for online modules and monitoring participant's completion of them.

Quantitative data: The research assistant will monitor the collection of quantitative data. The research coordinator will oversee storage, quality control, and management of de-identified research data (i.e., data collected by surveys and labelled with the unique participant ID only). Requests for data for analyses (e.g. by Research Team Members, graduate trainees) will be managed by the research coordinator and overseen by the PI, including Dr. Melissa Kimber.

Qualitative data: The research coordinator will monitor the collection of qualitative data via audio files and coordinate the transcription of audio files to be completed as rapidly as possible by a professional transcription service who has extensive experience working with the research team. The research coordinator will oversee storage, quality control, and management of de-identified qualitative data (i.e., transcripts). Requests for data for analyses (e.g. by Research Team Members, graduate trainees) will be managed by the research coordinator and overseen by the PIs, including Dr. Melissa Kimber.

6.2.2. Data Collection and Storage

Data collection will be completed by authorized study site personnel designated by the lead PI.

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Quantitative data will be collected in electronic format using REDCap, a secure, web-based application used for building and managing online databases and surveys. The survey will be hosted in a dedicated server for McMaster and REDCap data is stored on Canadian servers. All data will be de-identified at the point of collection. De-identified quantitative data will be downloaded from REDCap and stored on a secure McMaster server.

Qualitative data will be collected using the audio recording feature of Zoom, with video turned off. The audio file will be password-protected and stored on a secure McMaster server until transcription is complete. Once the audio files are transcribed and identifying information is removed, the research coordinator will oversee the destroying of audio files. The transcriptions will be saved as password-protected files with only the participant ID attached to them. All audio files will be deleted within one month of data collection completion for this study.

Study data and records will be maintained for 10 years post completion of the final study report or publication of the primary outcomes and then securely destroyed. Data will be kept securely in password-protected files on secure McMaster servers, or in locked storage cabinets at the Offord Centre for Child Studies. All identifying information including communication records (emails, telephone logs) will be destroyed one month after all data collection is complete. The PI will be responsible for ensuring secure storage and disposal of confidential records.

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