Appendix F: Full trial protocols

Includes the following versions:

1. HiFi Protocol January 16, 2018
2. HiFi Protocol July 7, 2017
3. HiFi Protocol September 30, 2016
4. HiFi Protocol October 26, 2015

Study Protocol

January 16, 2018

Official title: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial

Brief title: Helping Individuals with Firearm Injuries (HiFi)

Investigators: Ali Rowhani-Rahbar, MD, MPH, PhD; Lauren Whiteside, MD, MS; Kevin Haggerty, PhD; Frederick Rivara, MD, MPH

Affiliations: Department of Epidemiology, School of Public Health (Rowhani-Rahbar, Rivara); Department of Pediatrics, School of Medicine (Rowhani-Rahbar and Rivara); Department of Emergency Medicine, School of Medicine (Whiteside); School of Social Work (Haggerty); and Harborview Injury Prevention and Research Center (Rowhani-Rahbar, Whiteside, Haggerty, and Rivara)

Research team and contact information

Name	Role	E-mail
Ali Rowhani-Rahbar	Principal Investigator	rowhani@uw.edu
Lauren Whiteside	Co-Investigator	laurenkw@uw.edu
Kevin Haggerty	Co-Investigator	haggerty@uw.edu
Frederick Rivara	Co-Investigator	fpr@uw.edu
Anthony Floyd	Study Coordinator	asfloyd@uw.edu
Elizabeth Griffin	Support Specialist	davis86@uw.edu
Manal Jmaileh	Research Assistant	mjmaileh@uw.edu
Alvaro Martinez	Research Assistant	alvmarti@uw.edu
Jin Wang	Data Programmer	wangji@uw.edu
Vivian Lyons	Doctoral Student	vlyons@uw.edu
David Cheever	Medical Resident	dachee@uw.edu

Table of Contents

Significance 6
Objectives 7
Approach 8
  Study Setting and Population 8
  Eligibility 8
  Study Design 9
  HMC Usual Care for GSW Victims 9
  Trial Profile 10
  Recruitment, Disclosure of Assignment, and Consent 10
  Assignment 11
  Intervention 11
    Brief Intervention 11
    Extended Community Outreach 11
    Multi-Agency Attention 13
  Baseline and Follow-Up Assessments 13
  Measures 14
    Process Measures 14
    Outcome Measures 14
    Administrative Databases 14
    Surveys 14
  Data Management 15
    Statistical Power and Analysis 15
  Weekly Team Meetings 17
  Advisory Board 17
  Timeline 17
Protection of Human Subjects 17
  Risks to Human Subjects 17
    Psychological Risks 18
    Confidentiality Risks 18
    Vulnerable Populations 18
  Adequacy of Protection Against Risks 18
    Psychological Risks 18
    Confidentiality Risks 18
    Vulnerable Populations 18
  Potential Benefits of the Proposed Research to Human Subjects and Others 19
  Importance of the Knowledge Gained 19
Conflict of Interest 19
Dissemination 19
Appendix A 21
  Patient Identification, Approach and Engagement Protocol 21
Appendix B 25
  In-Person Recruitment Script 25
Appendix C 27
  Phone Recruitment Script 27
Appendix D 29
  Voicemail and Text Recruitment Script 29
Appendix E 30
  Phone Follow-Up Script 30
Appendix F 31

Overall Recruitment and Enrollment Flow 31
Appendix G 32
Follow-Up Timeline and Procedures 32
Appendix H 35
Safety Protocols 35
Appendix I 37
Crisis Management Protocol 37
References 40

List of Abbreviations

- **HMC**: Harborview Medical Center
- **GSW**: Gunshot Wound
- **RA**: Research Assistant
- **ED**: Emergency Department
- **MDT**: Multidisciplinary Team
- **MI**: Motivational Interviewing
- **CTI**: Critical Time Intervention

Study Synopsis

- **Title**: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial
- **Population**: Patients presenting to Harborview Medical Center with firearm injuries
- **Design**: Cluster Randomized Trial
- **Objective**: To test the effectiveness of a multicomponent intervention including brief motivational interviewing, extended community outreach services, and multiagency attention in promoting health and well-being of gunshot wound victims
- **Targeted Sample Size**: 304
- **Study Duration**: From January 1, 2016 through December 31, 2020

Significance

About 200-250 individuals present to an emergency department in King County, primarily Harborview Medical Center (HMC), for firearm-related injuries each year. Almost two-third of these patients require admission for their injuries. While the number of patients with firearm injuries who present to HMC is relatively small, these individuals are at substantially high risk of subsequent rehospitalization for another firearm or assault-related injury, arrest for firearm-related or violent crime, nonfirearm-related nonviolent crime, or firearm-related death in the five years after discharge from the hospital.[1] Thus, interventions among this group of individuals to promote their health and well-being and reduce the high risk of recidivism, morbidity, and mortality are critically needed. Such interventions may also lead to lower rates of firearm violence and its consequences in the community.

Patients with gunshot wounds (GSWs) seen at HMC receive many services. First, all patients are seen in the Emergency Department (ED) by an attending Emergency Medicine physician and resident physicians on the trauma team working in the ED. Depending on the nature and location of the GSW, these patients are often seen by specialty consulting services such as orthopedic surgery or vascular surgery. If patients have life-threatening injuries, they are seen by the trauma surgery service including an attending trauma surgeon. In addition, all patients who are victims of violence are seen by a member of the Social Work staff during their hospital stay. Currently, Level 1 trauma centers in the country including HMC are mandated by the American College of Surgeons to provide alcohol screening and brief intervention services to trauma patients, including GSW victims. Patients who are admitted and screened for substance use (e.g., alcohol and drugs) can be seen by the Harborview Addiction Intervention Service which comprises psychologists and chemical dependency counselors. Lastly, patients who present to HMC for GSWs and suicidal intent receive a comprehensive psychiatric evaluation once they are medically stable. However, currently there is no standardized intervention offered to GSW victims.

A number of hospitals across the country have created violence intervention programs to specifically help patients who sustain violent injuries. In 1996, the American Academy of Pediatrics published a report stating that while it has been routine to treat victims of child abuse, suicide attempts, and sexual assault via multidisciplinary care protocols, no care guidelines exist that address the unique needs of violently injuries adolescents.[2] In 1998, the U.S. Department of Justice's Office for Victims of Crime recommended that hospital-based counseling and prevention programs be developed. In 2009, the National Network of Hospital-based Violence Intervention Programs was formally established (http://nnhvip.org). These programs seek to engage patients in the hospital during the recovery period as a golden opportunity ("teachable moment") to change their life and reduce retaliation and recidivism. Through working groups, meetings, e-newsletter, and conferences, Network members collaborate in research and evaluation, explore opportunities for funding sustainability, develop and share best practices, and identify ways to collectively have an impact on policy. NNHVIP mainly serve individuals 15-25 years of age; however, some programs extend this range from 7 years through middle age.

While the creation of this infrastructure is a step in the right direction, rigorous research on the effectiveness of these intervention programs is needed. There exist only a few studies of the effectiveness of these programs some of which had small sample sizes and produced mixed findings.[3–20] Specifically, there have been no randomized trials evaluating the effectiveness of joint hospital-based and community-based violence intervention programs specifically offered to GSW victims. If research shows that such programs may not be effective, resources can be

better spent on other approaches to reduce gun violence and its associated morbidity and mortality.

We propose to conduct a randomized trial of an intervention program that combines a hospital-based intervention, structured community outreach program, and multi-agency attention. We will provide a brief intervention delivered at HMC to bolster the interaction that all these patients will have with the hospital Social Work staff. This intervention is derived from motivational interviewing (MI) which is a patient-centered behavioral technique based on the stages of change model and attempts to engage patients in order to find reason to change behavior.[21,22] By empathetically exploring ambivalent feelings about health-related behavior, MI encourages reduction in risky behavior. A number of investigations have demonstrated the effectiveness of providing MI-based brief interventions in the ED or inpatient wards,[23–26] primarily for alcohol use disorders[21,27–29] but also for violent behaviors.[15,30] Specifically, brief interventions utilizing principles of MI have been successful at reducing youth violence in large urban populations that sustained after one year.[13,23] Additionally, a behavioral-based intervention including MI among adolescents admitted to HMC with trauma showed a reduction in weapon carriage during the year after hospitalization.[15] This approach is appealing as its rationale is plausible and potential harms are minimal.[21]

A longitudinal intervention program provides the benefit of continued engagement. Providing GSW victims with outreach and follow-up after the healthcare encounter holds promise for reducing future violence and criminal activity. The Critical Time Intervention (CTI) approach (http://sssw.hunter.cuny.edu/cti/cti-model) can provide a strong framework for providing these patients with appropriate outreach and follow-up. Strong evidence supports CTI's effectiveness. The model meets the Coalition for Evidence-based Policy's rigorous "Top Tier" standard for interventions "shown in well-designed and implemented randomized controlled trials, preferably conducted in typical community settings, to produce sizable, sustained benefits to participants and/or society" (http://evidencebasedprograms.org/1366-2/critical-time-intervention-top-tier). CTI is a time-limited evidence-based case management practice that mobilizes support for society's most vulnerable individuals during periods of transition such as discharge from inpatient services to the community. It facilitates community integration and continuity of care by ensuring that a person has enduring ties to their community and support systems during these critical periods. CTI has been used worldwide among veterans, people with mental illness, homeless or incarcerated individuals, and many other groups.[31–35] From the beginning, CTI was thought of as an intervention that could be applied to other contexts. This approach has the potential to provide an intervention framework for a second tier outreach to GSW victims. To help the Support Specialist in delivering the CTI, a team of experts with the knowledge of available local services and how to navigate them is needed. Our proposed intervention will include such a team.

To our knowledge, this is the first randomized trial of a multicomponent dual hospital and community-based intervention exclusively focused on GSW victims. Findings of this study can directly impact practice and policy through informing the development of evidence-based programs pertaining to firearm violence in the future.

Objectives

The global goal of this study is to test the effectiveness of an intervention program for promoting health and well-being and reducing morbidity and mortality of GWS victims. The intervention program consists of a hospital-based MI, a longitudinal CTI, and multi-agency attention. We

seek to evaluate the effects of the intervention program using both process and outcome measures. Specifically, we will address the following aims:

1. What is the effect of the HiFi case management program on the proportion of GSW patients arrested over a follow-up period of up to two years after hospital discharge?

2. What is the effect of the HiFi case management program on specific outcomes other than criminal arrest (e.g., injury, mental health, substance use, aggressive behavior, health-related quality of life, social support, employment, housing, and death) over a follow-up period of up to two years after hospital discharge?

Process measures

- ☐ Reach: What proportion of patients were engaged (i.e., coverage)?
- ☐ Dosage: Did patients receive the proper dose of the intervention (i.e., dose and frequency)?
- ☐ Adherence: Did the Support Specialist adhere to the principles of case management and study protocol?
- ☐ Responsiveness: How satisfied were the patients with the intervention received?

Outcome measures

- ☐ Crime perpetration
- ☐ Injury victimization
- ☐ Death
- ☐ Impulsive and premeditated aggressive behavior
- ☐ Interpersonal violence
- ☐ Substance abuse
- ☐ Mental health
- ☐ Employment or enrollment in classes
- ☐ Physical health, happiness, and quality of life
- ☐ Availability of social support and social network

We will test the impact of the intervention on the aforementioned outcomes using usual (i.e. standard) care as the comparison. Our hypothesis is that participants in the intervention group will see greater improvements in outcomes than those who receive usual care in this setting.

Approach

Study Setting and Population

The study will be conducted at HMC located in Seattle, Washington. HMC has an annual census of about 65,000 adult patient visits per year covering a typically diverse and urban population. Based on prior data, about 200-250 GSW patients (including both ED visits and hospitalizations) are treated at HMC every year.

Eligibility

Patients can be enrolled in the study from the ED, inpatient area, or after discharge in HMC-affiliated clinics (collectively referred to as “hospital” in this document). Eligible subjects will be:

- ☐ 18 years of age or older
- ☐ Able to provide consent within 4 weeks following hospital discharge
- ☐ Able to understand and speak English
- ☐ Able to provide at least one mode of direct or alternate contact (e.g., cell phone, land line, e-mail, friend, or relative)
- ☐ Planning to live in King, Pierce, Snohomish, Thurston or Yakima counties for at least 6 months subsequent to hospital discharge
- ☐ Receiving treatment for a GSW at HMC and returning to the community, and not prison following treatment
- ☐ Being treated for gunshot wounds from assaults or accidents (self- or other-inflicted)

Patients will be ineligible to participate in this study if they are:

- ☐ 17 years of age or younger
- ☐ Unable to provide consent (including those with severe neurologic damage) within 4 weeks following hospital discharge
- ☐ Unable to understand or speak English
- ☐ Unable to provide any mode of direct or alternate contact
- ☐ Not living in King, Pierce, Snohomish, Thurston or Yakima counties, or planning to move outside of those counties within 6 months following hospital discharge
- ☐ Not receiving treatment for a GSW at HMC
- ☐ Not returning to the community following hospital discharge (e.g., being sent to a rehabilitation center, skilled nursing facility, or prison)
- ☐ Incarcerated at the time of GSW injury
- ☐ Being treated for an intentional, self-inflicted gunshot wound injuries (e.g. suicide attempts)

Study Design

We will conduct a randomized trial in which GSW victims treated at HMC either receive an intervention or treatment as usual. The unit of randomization is the calendar week; that is, the study staff will assign GSW victims to one of the two groups based on the week in which they were shot and treated at HMC. A week is defined as one starting on Monday morning at 8:00 for a duration of seven days. We will use block randomization with varying block sizes of 2 and 4 to assign each week to one of the two groups of the trial. As such, all patients admitted in the same week will be assigned to the same group. This randomization scheme will ensure that all victims in the same shooting incident will receive the same study assignment. In addition, this scheme will enhance the feasibility of study by facilitating the coordination of efforts among the study staff in delivering the intervention.

HMC Usual Care for GSW Victims

All HMC patients treated for a GSW will receive care as usual by HMC physicians and staff. For patients treated for a GSW, usual care can include the following:

- ☐ All necessary medical care and scheduled follow-up with subspecialty services
- ☐ Evaluation by Social Work during the ED or inpatient stay: Social Work staff will specifically assist with communicating with family as needed, including contact with the police if the patient desires, evaluation eligibility for the crime victims' compensation fund, referral to the Harborview Center for Sexual Assault and Traumatic Stress, and safety planning when a concern for continued violence is present.

- ☐ Screening for alcohol use: Patients who screen positive for alcohol use at the time of presentation to the HMC ED are eligible to be seen by the HMC Addiction Intervention Service. This service provides brief intervention using MI techniques that targets alcohol use. While all patients with an elevated blood alcohol levels are eligible to be contacted by the Addiction Intervention Service staff, not all patients actually receive this service.
- ☐ Discharge planning services: HMC staff will help patients with specific needs with medical devices (e.g., wheelchair, walker) or coordination of any needed home health services.
- ☐ Financial counseling services to patients, including those without insurance: Patients can access this service during their ED or hospital stay or within 14 days of their healthcare visit. Financial counseling will assist patients with applying for charity care for medically necessary services and assist with questions regarding insurance coverage. Eligibility for charity care is based on published poverty guidelines.

Trial Profile

Figure 1 illustrates participant flow through the program.

Recruitment, Disclosure of Assignment, and Consent

Potential participants will be identified electronically using the Emergency Department Board by the study research assistants (RAs) who will regularly monitor this system on a daily basis. The study RAs will not conduct any pre-screening beyond initial medical record review. We have prepared requests for HIPAA and consent waivers as well as the University of Washington Confidentiality Agreement to allow for pre-screening of patients. For recruitment purposes, the study RAs will collect patient names and other identifying information. When the study RA identifies a potentially eligible patient, she will approach the patient using an institutional review board (IRB)-approved recruitment script to determine eligibility. For patients who are hospitalized at the initial incident, the study RA will approach the patient during the hospitalization once they are stable. For patients who are treated in the emergency department and do not get admitted (i.e., discharged from the ED), the study RA will approach the patient during the ED visit or during a scheduled follow-up visit at HMC depending on the nature and location of the GSW.

The informed consent discussion will include explanations of the study's purpose, the two assignments, study procedures, all risks and benefits associated with participation as well as confidentiality procedures. The study RA will:

- ☐ Ensure that no members of the patient's healthcare team are present during the consent process.
- ☐ Present the study to the patient and conduct an informed consent conference if the patient is interested in participation.
- ☐ Emphasize that the decision to participate is voluntary and will not affect medical care at HMC.
- ☐ Prompt patients to ask questions.
- ☐ Reiterate the participant's right to refuse participation and then ask whether the patient is willing to participate at the conclusion of the informed consent process.

There will be two different consent forms, one for each study group. Following consent, the baseline survey will be completed by the patient or RA using a tablet device. For patients assigned to the usual care group, the study RA will ensure that we will have follow-up contact

information and inform the patient that they will be contacted to conduct the next follow-up assessment at month 1. For patients in the intervention group, the study RA will contact the study Support Specialist.

Assignment

Patients will receive one of the two assignments:

- ☐ Intervention: Receives a brief intervention at the start of the study followed by six months of study case management and outreach services. A multidisciplinary team of technical consultants will review cases in this group and help the study Support Specialist provide appropriate care and referrals.
- ☐ Control: Receives usual care, including any outreach services offered by or recommended at HMC.

During intervention weeks, the study RA will contact the study Support Specialist in advance of approach so that the study Support Specialist can meet the patient in the private room. The study Support Specialist will initiate the intervention at that time.

Intervention

The intervention program contains three elements: (1) Initial contact and brief intervention by the study Support Specialist; (2) Extended outreach by the study Support Specialist; and (3) Multi-agency attention.

Brief Intervention

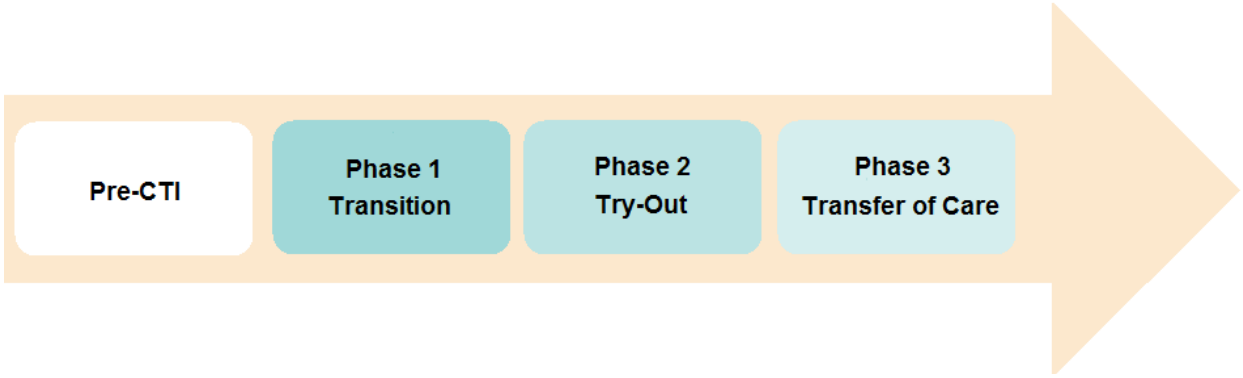
The brief intervention includes a feedback session utilizing principles of MI to elicit the goals and needs of patients. The main aim of MI in this study is to motivate the patient to be linked to the extended outreach case management. If needed, the study Support Specialist will provide a referral to community resources.

Extended Community Outreach

CTI's approach is to: (1) strengthen the individual's long-term ties to services, family, and friends; and (2) provide emotional and practical support during the critical time of transition back to the community. The six-month intervention is delivered to each participant by a single Support Specialist trained in CTI. Core components of CTI are as the following:

- ☐ Addresses a period of transition
- ☐ Time-limited
- ☐ Phased approach
- ☐ Focused
- ☐ Decreasing intensity over time
- ☐ Community-based
- ☐ No early discharge
- ☐ Small caseloads
- ☐ Harm reduction approach
- ☐ Weekly team supervision
- ☐ Regular full caseload review

Phases of CTI are as the following:



- ☐ Pre-CTI: Develop a trusting relationship with patient. Because of the brief time window of the intervention, Pre-CTI discussions must take place within 4 weeks of enrollment. Ideally the Pre-CTI discussion should take place in the hospital or emergency department, but may take place in the community briefly after discharge. Patients who do not have the Pre-CTI discussion in this time period may continue with other study procedures but will not continue with the intervention or meet with the support specialist.
- ☐ Phase 1 [Transition]: In Phase 1, the Support Specialist gets to know the patient, assesses the patient's needs, sets goals, and implements a transition plan intended to link the patient to services and supports in the community. Phase 1 should begin within 6 weeks of the Pre-CTI discussion. The plan typically includes home visits and other meetings with the patient, the patient's caregivers, and community service providers, designed to teach crisis-resolution skills, provide support and advice, and mediate any conflicts. The overarching goal is to connect the patient to people and agencies that will assume the primary role of support. Main components of this phase include:

    - ☐ Make home visits
    - ☐ Engage in collaborative assessments
    - ☐ Meet with existing supports
    - ☐ Introduce client to new supports
    - ☐ Give support and advice to patient and caregivers

- ☐ Phase 2 [Try-Out]: In Phase 2, the Support Specialist monitors and adjusts the systems of support that were developed during Phase 1. This phase involves fewer meetings with the patient, as the Support Specialist encourages the patient to problem-solve with the help of community resources and family members, and intervenes only if the patient is receiving inadequate support or if a crisis occurs. The overarching goal is to monitor and strengthen support network and patient's skills. Main components of this phase include:

    - ☐ Observe operation of support network
    - ☐ Mediate conflicts between patient and caregivers
    - ☐ Help modify network as necessary
    - ☐ Encourage patient to take more responsibility

- ☐ Phase 3 [Transfer of Care]: In Phase 3, the Support Specialist helps the patient develop and implement a plan to achieve long-term goals (e.g., employment, family reunification) and finalizes the transfer of responsibilities to caregivers and community providers. The CTI Support Specialist typically works with 10-15 patients at a time. The overarching goal is to terminate CTI services with support network safely in place. Main components of this phase include:

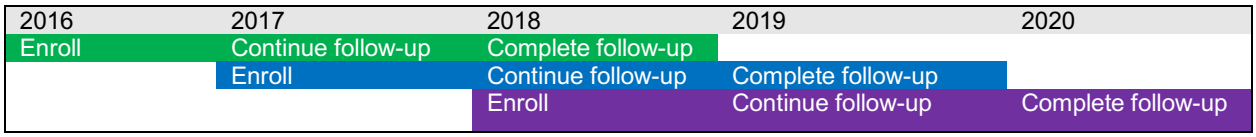
- ☐ Step back to ensure that supports can function independently
- ☐ Develop and begin to set in motion plan for long-term goals
- ☐ Hold meeting with patient and supports to mark final transfer of care
- ☐ Meet with patient for last time to review progress made

Multi-Agency Attention

The study Support Specialist will hold regular meetings with a multidisciplinary team (MDT) to seek advice about case management and service recommendations for each individual patient. It is vital for social service agencies and community-based organizations to be represented on this team. Of necessity, members of the MDT will know the identity of the individuals discussed in meetings. We do not consider MDT members to be engaged in research. They are technical consultants for the study Support Specialist. The MDT will include members from community mental health, substance abuse treatment, housing services, employment and adult education services, legal services, and law enforcement.

Baseline and Follow-Up Assessments

We plan to follow up patients for 2 years since enrollment. All participants will engage in research activities for 1 year following enrollment. The second year of follow-up will be entirely based on ascertaining outcomes in administrative databases with no patient contact as shown in the following figure:



Participants will complete surveys about their health and other outcomes at baseline, 1-month, 3-month, 6-month, 9-month, and 12-month assessments. At baseline, computer-assisted interviewing will be used to minimize skip pattern inaccuracies, missing data, ascertainment errors, and costs associated with conducting quality control and data entry on hard copy questionnaires. During the interview, the RA will read the questions to the participant and record the response using a tablet computer. For questions of sensitive nature (e.g., crime), the RA will turn the tablet to the participant so they can read the questions to themselves and key in the numeric value associated with their response choices. In addition, if a patient is unable to complete the survey electronically, the RA will read items and record responses. At follow-up assessments, the RA will send participants an email and a text with a link to the survey. Study staff will build the survey using a secure web application. If a participant cannot complete the survey electronically or does not complete the survey in one week, the study RA will call the participant to complete the survey over the phone. If the RA cannot reach the participant, she will call the alternate contact(s) listed by the participant.

A consented subject may become incarcerated at some point during participation making them an incidental prisoner subject. We will send follow-up surveys to all participants, even if they are incarcerated, with the understanding that email may be blocked during this time. A participant in the intervention group could become an incidental prisoner while receiving study case management services. If this occurs, study case management services will stop while the participant is in prison. The study Support Specialist will not make contact with the participant while incarcerated. Because participants in the intervention group are eligible for case

management services for six months, they could return to study case management if the incidental prisoner is released from prison during that six-month window.

Subjects will receive compensation for the completion of surveys. Participants can earn up to $225 if they complete all surveys. Survey time points and payment amounts are as follows:

- ☐ Month 0 baseline survey: $25
- ☐ Month 1 follow-up survey: $30
- ☐ Month 3 follow-up survey: $35
- ☐ Month 6 follow-up survey: $40
- ☐ Month 9 follow-up survey: $45
- ☐ Month 12 follow-up survey: $50

Measures

Process Measures

The following checklists will be used to gauge Reach, Dose, Adherence, and Responsiveness:

- ☐ Proportion of patients consented among those approached
- ☐ Proportion of patients in the intervention group who completed the MI and case management
- ☐ Number of contacts and sessions spent with the study Support Specialist among patients in the intervention group linked to the study Support Specialist
- ☐ Proportion of patients in the intervention group for whom the MDT discussed the case management approach
- ☐ Proportion of patients in both intervention and control groups retained in the study by time
- ☐ Adherence score using a pre-tested checklist to document whether Support Specialist is adhering to the principles of case management and study protocol
- ☐ Happiness Scale to document participant's satisfaction (see "Surveys")

Outcome Measures

Outcome measures will be collected using two different, but complementary, sources: (1) Administrative databases; and (2) Surveys.

Administrative Databases

A number of outcomes can be measured using routinely collected data. These will include:

- ☐ Washington State Administrative Office of the Courts records to identify cases of arrest and conviction
- ☐ Washington State Comprehensive Hospital Abstract Reporting System to identify hospitalizations
- ☐ Washington State Emergency Department Information Exchange to identify ED visits
- ☐ Vital records to identify cases of death

Surveys

All surveys across the assessment points contain the same scales and items. A list of those scales and items is provided below:

- ☐ Patient Health Questionnaire (PHQ-8) to measure depression
- ☐ Short Form Health Survey (SF-12) to measure health-related quality of life
- ☐ Posttraumatic Stress Disorder (PTSD) Checklist – Civilian Version (PCL-C) to measure PTSD
- ☐ The Alcohol Use Identification Test (AUDIT) to measure alcohol use
- ☐ The National Institute on Drug Abuse-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) to measure substance use
- ☐ Impulsive-Premeditated Aggression Scale (IPAS) to measure impulsive and premeditated aggressive behavior
- ☐ Conflicts Tactics Scale (CTS) to measure interpersonal violence
- ☐ Happiness Scale to measure satisfaction with specific areas of life
- ☐ Service utilization questions to measure use of physical and mental health services
- ☐ Self-Reported Delinquency (SRD) items of the Pittsburg Youth Study to measure criminal justice involvement, violence, criminal outcomes, conviction(s), and incarceration(s)
- ☐ Multidimensional Scale of Perceived Social Support (MSPSS) to measure perceived social support
- ☐ Education questions to measure educational attainment and activities
- ☐ Employment questions to measure employment status
- ☐ Housing questions to measure type of housing
- ☐ Contact information questions to increase the likelihood of reaching the subject during the follow-up
- ☐ CTI Satisfaction (3-month and 6-month interview only)

Data Management

We will use REDCap (http://project-redcap.org), a web-based data management system to input all data for the study, including each contact, intake, follow-up surveys and all chart data abstraction. It will be housed in the Virtual Private Network of the University of Washington. REDCap is highly secure with user-based access privileges. As part of the study-specific project development in REDCap, variable and value labels will be created, and aggregate scales for each instrument will be computed. The RAs will examine logical inconsistencies, correct out-of-range values, and investigate missing values. The RAs will also complete a historical narrative, detailing important events that could have affected the quality of data generated. A codebook and data dictionary will be developed including information on variable and field names, labels, values, and types. Surveys will be fully annotated to include variable and field names.

Statistical Power and Analysis

HiFi is powered based on the primary outcome of criminal arrest. Based on our previous investigations, we expect the rate of arrest after hospital discharge among GSW victims in Washington State to be about 15,528 cases per 100,000 person-years.[1,36] This translates to a 2-year cumulative incidence (i.e., proportion) of arrest at approximately $1 - \exp(-15{,}528 \times 2 / 100{,}000) = 26\%$. Assumptions for power calculations include:

- ☐ Significance level: 0.05
- ☐ Power: 80%
- ☐ Intervention-to-control ratio: 1

- ☐ Number of clusters (i.e., weeks) per year: 52
- ☐ Number of enrolled patients per cluster: 2
- ☐ Correlation between history of arrest (measured at baseline) and subsequent arrest: 0.70
- ☐ Intraclass correlation coefficient (for cluster effect): 0.10

A history of arrest is one of the strongest predictors of subsequent arrest; our previous investigations have documented relative risks of about 20 for the association between those two measures. As such, adding the history of arrest at baseline to the regression models will have the potential to notably enhance power. We will have access to the history of arrest at enrollment for all patients using both administrative databases and self-report. Based on the specifications listed above, and using 3 years of enrollment (total n = 304) and up to 2 years of follow-up, we will be able to identify a minimum detectable relative risk reduction of 29% for the primary outcome of arrest. An intervention among GSW victims that cuts the risk of arrest after hospital discharge by this extent would be of considerable interest to policy makers.

For our intent-to-treat (ITT) analysis, Subjects enrolled and assigned to the intervention group who are unable or unwilling to make initial contact with the Support Specialist will still be included in intervention group. We will obtain group-specific unadjusted estimates of the ITT cumulative incidence of arrest by 1 year following hospitalization by calculating the Kaplan-Meier estimator separately on participants randomized to the intervention versus control group using Wald-type confidence intervals. In order to relax the independent censoring assumption (required by the Kaplan-Meier method) and possibly increase statistical efficiency, for each group, we will also estimate the ITT (adjusted) cumulative incidence of an arrest by 1 year using a G-computation approach. To do so, we will first fit a Cox proportional hazards regression model including prior arrest, stable living, age, and injury intent. We will then create two versions of the HiFi study population with baseline covariates: one in which all patients had been assigned to the treatment arm, and another in which all patients had been assigned to the control arm. For each of these two new datasets, and for each study participant, we will obtain a person-specific estimate of the cumulative incidence based on the fitted Cox model and the baseline covariate values for this participant. Then, within each dataset, we will average all person-specific estimates to obtain adjusted estimates of the ITT cumulative incidence corresponding to the treatment and control groups. The relative risk will be calculated by dividing the adjusted estimate of the ITT cumulative incidence at 1 year for the intervention group to the corresponding estimate for the control group.

We will then perform a per-protocol effect (PPE) analysis to account for varying levels of participant engagement with the Support Specialist during the study. Using a parametric multi time-point G-computation approach, we will estimate the counterfactual cumulative incidence of patients with an arrest at 1 and 2 years that would have been seen (i) had all patients engaged with our Support Specialist at least 1 time per study phase for a total of 3 study meetings, and (ii) had all patients been instead assigned to the control arm. To control for potential confounding due to exposure engagement, we will adjust this analysis for stable housing, age, intent (coded as assault or not), injury severity score, prior arrest, perceived social support at baseline, and stable housing collected post-randomization at the 1 and 3-month marks. Because the intervention ends at 6 months following hospital discharge, only data from the baseline, 1 and 3-month marks can provide information on individual characteristics that would predict intervention engagement; as such, only information from these surveys (but not subsequent surveys conducted at the 6, 9 or 12-month marks) were included.

The secondary outcomes include a mixture of binary (e.g., hospitalization) and continuous (e.g., depression score) measures. For the binary outcomes, we will examine what proportion of

individuals in each arm are hospitalized over the follow-up period after their index hospital discharge. For the continuous outcomes measured on the surveys, we will use mixed effects models to take the longitudinal nature of data (baseline, 6 month, 12 month) within the same individual into account. For example, for the depression scale, mean scores at baseline and at each follow-up visit will be reported separately for the intervention and control groups. Then, to examine the difference in the trajectory of change in scores over time between the intervention and control groups, linear mixed effect models including an interaction term between time and treatment group will be used. The coefficient for this interaction term will provide an estimate of the effectiveness of the intervention on these continuous outcomes.

We do not expect much of missing data either at baseline or during the follow-up pertaining to administrative data. However, missing data for the survey items during the follow-up is inevitable. Both baseline and post-randomization missing data will be handled using multivariate imputation by chained equations. We will strive for sufficient enrollment, low attrition, close adherence to random assignment, accurate outcome measurement, and proper statistical analyses throughout the course of the project.

Weekly Team Meetings

The study team will convene two separate 1-hour weekly meetings in which the study staff will be present in person or via phone. Logistical issues, recruitment numbers, and updates to the research protocol will be discussed as needed. Successes and challenges will be reviewed and plans for the subsequent week will be finalized.

Advisory Board

Advisory Board will meet four times per year and are contacted on an ad-hoc basis as needed. The Advisory Board is essential for providing feedback and translating the knowledge required in this project. They will provide meaningful insight into the challenges the team may be encountering. At the end of the trial, results will be presented to the Advisory Board members who will in turn be actively involved in the interpretation and dissemination of those findings. The Advisory Board members will include experts in Social Work, Criminology, Trauma Surgery, and Emergency Medicine, as well as an individual with experience in implementing community-based violence prevention programs and a member of the community with a history of firearm violence and injury.

Timeline

The study duration will be 5 years from inception to completion as outlined below.

Year	2016				2017				2018				2019				2020			
Training study staff and start-up																				
Enrollment																				
Data collection																				
Data management																				
Data analysis																				
Publications and presentations																				

Protection of Human Subjects

Risks to Human Subjects

Psychological Risks

Participants may face psychological risks in participating in the study. All participants might feel stress or psychological discomfort while filling out assessments about their mental health, physical health, relationships, history of violence, and criminal activities. Participants in the intervention group may feel some stress or discomfort during interventions aimed at reducing high-risk behaviors.

Confidentiality Risks

All participants face confidentiality risks. Participants' privacy may be violated if their data are not kept confidential. Participants in the intervention group face a greater confidentiality risk, as their cases will be the subject of MDT review.

Vulnerable Populations

Some of the subjects may become incidental prisoners during the study. Participants in the intervention group may become incidental prisoners during the six-month intervention period. Also, any participant may become an incidental prisoner during follow-up surveys.

Adequacy of Protection Against Risks

Psychological Risks

The research staff (RA and Support Specialist) engaging with subjects will be trained to work with this high-risk population. They will explain the purpose of the research and will assure participants that their answers are confidential. The research staff will work to reduce any stress or psychological discomfort during assessment or outreach, and remind subjects to report any discomfort or stress. The research staff will also fully inform participants that they have the right to skips questions or activities or withdraw from the study at any time. During assessments, the study RAs may discover a subject's intentions to harm themselves or other. In that case, they will follow the Crisis Intervention Protocol.

Confidentiality Risks

Research staff will take all necessary precautions to prevent the loss of confidentiality. The research staff will keep all data in secure databases on password-protected networks. Study staff will assign study codes to participants and will record all assessment data using those study codes. The document linking participant name and study code will be password protected, and the document will be stored on a secure, password-protected computer. Assessment data will be stored in password-protected network. All paper-based data (e.g., consent forms) will be stored in a locked file cabinet. We will retain a link between study code numbers and direct identifiers after the data collection is complete, and destroy it on 1/1/2020. Members of the MDT will sign a Confidentiality Agreement to ensure that none of the shared data in the meetings are repeated or disclosed in public. The study RA will notify potential participants about information sharing with the MDT during the consent conference. We will ask patients to sign a HIPAA authorization to release medical records for the period of their study participation. This authorization is separate from the HIPAA waiver request for pre-screening.

Vulnerable Populations

We will not engage any individuals in the study procedures while they are incarcerated.

Potential Benefits of the Proposed Research to Human Subjects and Others

Participants in the intervention group will receive a brief intervention and extended case management services to reduce individual high-risk behaviors. These participants will also be referred to community agencies who can help address specific areas of need. Participants in the control group may not directly benefit from participating in the study other than monetary compensation for their participation; however, the enforcement of usual care as described above may be considered a potential benefit.

Importance of the Knowledge Gained

Gun violence affects society in many ways, including heavy medical costs, reductions in quality of life, and stresses on the criminal justice system. Gun violence prevention and intervention programs hold the potential to drastically reduce recurrent injury, readmission, retaliation and recidivism. While many hospitals have adopted violence intervention programs, few have rigorously evaluated program effectiveness. Our study has great potential to meaningfully contribute to the field of gun violence prevention.

Conflict of Interest

None

Dissemination

Upon completion of the intervention program, we will provide a report for stakeholders and prepare presentations and publications for scientific conferences and journals to disseminate the knowledge gained. The results of this trial, if proven effective, will be used to advocate for policy change within healthcare settings; the investigator team will promote the rapid translation of findings into practice. Findings will be immediately shared with member programs of the National Network of Hospital-Based Violence Intervention Programs so the evidence can be used to advocate for sustained funding for such efforts. If this intervention is successful in decreasing the risk of subsequent trauma-related morbidity, its implementation at trauma hospitals serving populations with high rates of violent trauma will be supported. If unsuccessful at reducing the risk of subsequent trauma-related morbidity, alternative models of intervention need to be investigated.

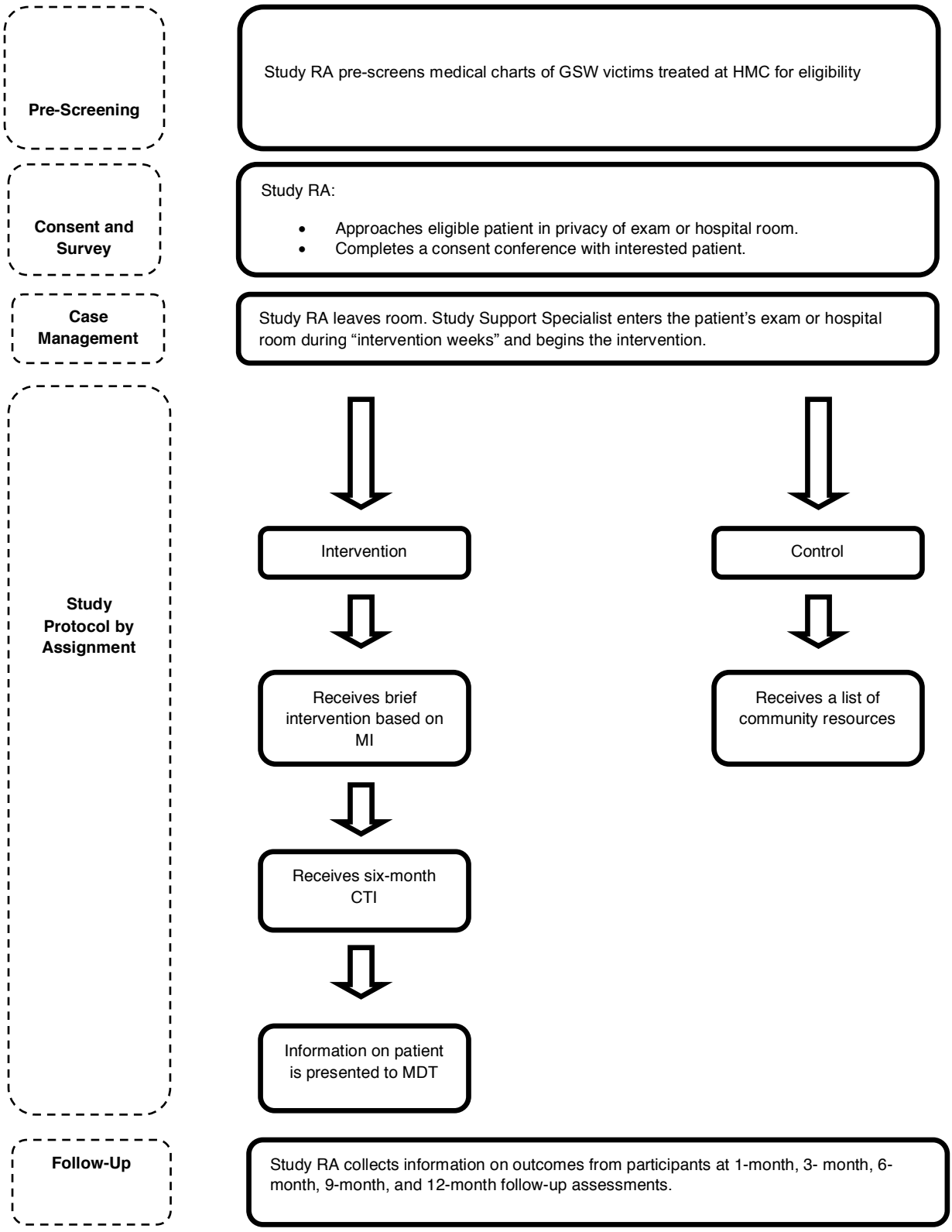


Figure 1. Trial profile. HMC: Harborview Medical Center; RA: Research Assistant; CTI: Critical Time Intervention; MDT: Multidisciplinary Team; MI: Motivational Interview

Appendix A

Patient Identification, Approach and Engagement Protocol

Step 1: Check the board for GSW patients

- ☐ SW note will have most information

Step 2: Eligibility screen via EMR (HiFi Patient Screening Survey)

- ☐ 18 years or older, not in jail, English speaking, live in King or Pierce County, neurological or cognitive impairment
    - ☐ Language can be wrong in EMR, so talk to staff or verify at approach
- ☐ Complete screener for all GSW
    - ☐ If missed, uninterested or ineligible, retain all information **except**:
        - ☐ Patient name
        - ☐ Patient H #
        - ☐ Patient location in hospital
        - ☐ Admit date
            - ☐ Keep MONTH (separate variable)
        - ☐ Discharge date
            - ☐ Keep LENGTH OF STAY (separate variable)
        - ☐ DOB
            - ☐ Keep AGE (separate variable)
- ☐ Review to see if patient has been enrolled in any other study
- ☐ Patient appears eligible per medical record review and there is no research conflict
    - ☐ Proceed to next step

Step 3: Mental status and medical acuity assessment - Pre-Approach (HiFi Patient Screening Survey)

- ☐ Intubated OR active resuscitation OR going directly to operating room
    - ☐ Notify other RA
    - ☐ Put patient on approach list in OneDrive for monitoring and leave notes for other RA
    - ☐ Continue to reassess daily - Nurse notes will have most detail
        - ☐ Check EMR - review daily surgery notes
        - ☐ Talk to staff
- ☐ Determine if patient is able to understand the research approach
    - ☐ Reasons may not understand: Intoxication, previous history of TBI, psych co-morbidity
    - ☐ Contact medical team (inpatient) or charge nurse (ED) to:
        - ☐ Introduce self and mention study clinician
        - ☐ Discuss the case
        - ☐ Determine timing of approach
- ☐ Normal mental status and not getting active medical resuscitation
    - ☐ If it is a good time to approach:
        - ☐ If an intervention week: Make a judgment call about notifying Support Specialist at this point
        - ☐ Proceed to next step

Step 4: Assemble documents needed for approach (Consent Form and HIPAA Authorization Form)

- ☐ Verify the randomization schedule on OneDrive
- ☐ Copies of stamped consent form stored at each RA desk and on OneDrive
- ☐ Select condition appropriate consent form: Intervention or Control
    - ☐ Bring two copies to the patient room:
        - ☐ One signed copy goes to patient
        - ☐ One signed copy is retained by study
- ☐ Bring two copies of HIPAA Authorization Form
    - ☐ One signed copy goes to patient
    - ☐ One signed copy is retained by study
- ☐ Bring a gift card of the appropriate value (kept by patient) AND gift card form (kept by study)
    - ☐ Mark down serial number (in OneDrive or on gift card form) **BEFORE** giving to patient
- ☐ Bring HiFi study envelop: Label with study name, study email, study cell (206-446-8914) and line to write down one month follow up date
    - ☐ Proceed to next step

Step 5: Approach patient and pitch study (5 mins)

- ☐ Tell nurse when going into room
- ☐ If patient is unable to talk to you but is willing to talk later:
    - ☐ Schedule next attempt
- ☐ If patient is willing to talk to you:
    - ☐ Proceed to next step

Step 6: Final screening questions (5 mins) (HiFi Patient Screening Survey)

- ☐ Interested? (**yes**) Live in King,Pierce, Snohomish, Thurston or Yakima Counties? (**yes**) Plans to live in King, Pierce, Snohomish, Thurston or Yakima Counties for 6 months? (**yes**) Able to provide contact? (**yes**) Going to jail? (**no**) In jail when shot? (**no**)
    - ☐ If Ineligible:
        - ☐ End interview and document (Step 9)
    - ☐ If eligible:
        - ☐ Proceed to next step

Step 7: Consent (10 mins)

- ☐ If patient does not agree to participate:
    - ☐ End interview and document (Step 9)
- ☐ If patient agrees to participate:
    - ☐ Have patient sign both copies of the consent form and HIPAA Authorization Form
    - ☐ Proceed to the next step

Step 8: Baseline Survey (30 mins) (Baseline Survey)

- ☐ If it's an intervention week AND the support specialist is working
    - ☐ Notify support specialist that that patient is eligible and that baseline is beginning

- ☐ Reminder: Be explicit with patient about why you would step out to make a call, if you make a call to Support Specialist now. "*Why: I want to get you connected as soon as possible with our support specialist, so I am going to call her to tell her you have enrolled."*
- ☐ RA completes the survey **except:**
  - ☐ If a patient would like to complete himself/herself
  - ☐ For substance Abuse and Criminal Activity questions
    - ☐ Give a prelude to these questions to neutralize and normalize them. "*We are asking every patient these private and personal questions. I will be here to answer any questions you may have."*

Step 9: End Survey

- ☐ Provide gift card and have patient sign gift card form
- ☐ Put gift card, one signed copy of HIPAA Authorization, one signed copy of consent form into study envelope
  - ☐ Mark date of 1-month follow-up on the envelope
- ☐ Intervention Patient: Hand off to Support Specialist
  - ☐ In-person if support specialist is available:
    - ☐ Provide her with any important information
  - ☐ If support specialist is not available:
    - ☐ Contact Support Specialist to discuss options
    - ☐ Update REDCap

Step 10: Complete Screener Form (HiFi Patient Screening Survey)

- ☐ Document approach outcome in REDCap record
- ☐ If ineligible, remove identifiers (listed in Step 2) from REDCap record

Step 11: File Signed Forms in Safe, Locked Area

- ☐ File signed consent forms, HIPAA Authorization and Gift Form in locked cabinet
- ☐ If daytime and no other approaches, bring to locked drawer at HIPRC
- ☐ If nighttime, lock in HMC drawer

Step 12: OneDrive Documentation (HiFi Patient Tracking on OneDrive)

- ☐ Remove patient from Approach list one determination is made
- ☐ Record patient follow-up schedule
- ☐ Input gift card information

Step 13: Follow-up (Follow Up Survey)

- ☐ RAs will contact participants via phone, text or email to complete follow-up. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone or in-person. Follow-up assessments will be done at the following times:
  - ☐ 1 month (window opens 1 week before and closes 2 weeks after 1-month date)
  - ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
  - ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)

- ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
- ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

☐ Document each time an attempt is made to contact the participant, method of contact and the outcome of the attempt.

- ☐ If contacting by phone, RAs can leave up to 2 voice messages.
- ☐ RAs can also use text as a way to contact participant or remind participant of scheduled call/meeting.
- ☐ Document on subject payment spreadsheet every time gift card is given

Step 14: Study Close Out

Appendix B

In-Person Recruitment Script

Hi, my name is [RA Name], and I am from the Helping Individuals with Firearm Injuries Study. I am here to talk to you about our study because you might be eligible to participate in it. I would like to tell you about the study and find out if you eligible to participate. The conversation should take no more than 15 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

This study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview Medical Center. We are asking you to participate because you are being treated for a gunshot wound at Harborview Medical Center. You would participate in the study for one year.

- ☐ **Intervention Group**: As part of the study, you will get all the usual services offered by the Harborview staff. In addition, you will receive outreach services from a study Support Specialist. During your one-year participation, we will ask you to complete surveys.
- ☐ **Control Group**: As part of the study, you will get all the usual services offered by the Harborview staff. During your one-year participation, we will ask you to complete surveys.

To find out if you are eligible to participate in the study, I will ask you some questions. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.
Are you interested in finding out if you are eligible to participate in the study?

- ☐ **YES**
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King, Pierce, Snohomish, Thurston or Yakima Counties?

- ☐ **YES**
- ☐ NO

Do you plan to move from King, Pierce, Snohomish, Thurston or Yakima Counties in the next six months?

- ☐ YES
- ☐ **NO**
  - If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**

☐ NO

Are you going to jail when you leave the hospital? (only ask if not in chart)

☐ YES
☐ **NO**

Were you in jail at the time of your gunshot injury? (only ask if not in chart)

☐ YES
☐ **NO**

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

☐ **YES**
☐ NO

Patient is ineligible if any responses are plain text responses.

> SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patient is eligible if **ALL** responses are underlined and bolded responses.

> SAY: Based on your responses, you are eligible to participate in the Helping Individuals with Firearm Injuries study. If you are interested in participating in the study, I will review the study consent form with you. Are you interested in learning more about the study and participation?
>
> ☐ YES (review the consent form)
> ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix C

Phone Recruitment Script

Hi, my name is [RA name], and I am calling from Harborview Medical Center about a study that you might be eligible to participate in. Am I speaking to [patient name]? Before I tell you about the study, can you confirm your age and the date/day you visited Harborview Medical Center?

[Once confirms] Thank you for confirming that information. I work for a study entitled Helping Individuals with Firearm Injuries (HiFi). The study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview. You may be eligible to participate in the study because you were treated for a gunshot wound at Harborview. Study participation is one year. During that year, you will be asked to complete 6 surveys, and you will be paid for each survey you complete. If you complete all the surveys, you will receive $225. [Read Intervention Group description below if patient is assigned to that group]

- ☐ **Intervention Group**: As part of the intervention group, you will receive outreach services from a study Support Specialist who can help you navigate your recovery. You determine what you want to work on with the Support Specialist. For example, you could set goals with her around employment, appointment management, housing, accessing mental health services, etc. She can help you connect with appropriate resources and will help you create a plan to reach your goals. The Support Specialist will work with you for 6 months.

Today's conversation will determine if you are eligible to participate. The call should take no more than 5 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

I will ask you three questions that will help me determine if you are eligible for the study. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.

Are you interested in finding out if you are eligible to participate in the study?

- ☐ YES
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King, Pierce, Snohomish, Thurston or Yakima Counties?

- ☐ **YES**
- ☐ NO

Do you plan to move from King, Pierce, Snohomish, Thurston or Yakima Counties in the next six months?

- ☐ YES
- ☐ **NO**

- ☐ If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**
- ☐ NO

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

- ☐ **YES**
- ☐ NO

Patients are ineligible if any responses are plain text responses.

SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patients are eligible if **ALL** responses are underlined and bolded responses.

SAY: Based on your responses, you are eligible to participate in the HiFi study. The next step in the process is to enroll you in the study. That process involves meeting in-person to review a consent form with a study Research Assistant. We can meet at a convenient time and location for you. The consent form review will take about 5-10 minutes. If you agree to participate upon review, we will ask you to complete a survey. The survey takes about 30 minutes to complete. So in total, the meeting would last about 45 mins. Are you interested in scheduling an in-person meeting?

- ☐ YES (Schedule an appointment with patient. If there is a follow-up appointment scheduled, ask if that is an appropriate time/location to meet. If no follow-up appointment scheduled, ask if patient is willing to come back to HMC. If not, ask for a convenient, public place to meet)
- ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix D

Voicemail and Text Recruitment Script

Hi, my name is [RA name]. I am calling from Harborview Medical Center. I am trying to reach [patient name.] [Patient name] may be eligible to participate in a study where s/he can earn up to $225 by completing surveys. Please call me back at 206-446-8914 at your earliest convenience.

Appendix E

Phone Follow-Up Script

Hi, my name is [RA name] from the Helping Individuals with Firearm Injuries study. I spoke to you at Harborview Medical Center on [Date] when you completed the baseline survey for the study. I am contacting you today to remind you the [Number]-month follow up appointment is coming up with a [Dollar amount] gift card for completing it. There are a couple different ways we can take care of this. The survey can be completed online, over the phone, or in person. Please contact me with your preferred method when you get the chance. You can either call or text (206) 446-8914; again the number is (206) 446-8914. We very much appreciate your time and participation; the information we gather for this study will go towards better helping patients in the future. Have a great day and I look forward to hearing from you.

Appendix F

Overall Recruitment and Enrollment Flow

Recruitment Flow

- ☐ Patient presents to HMC with GSW
  - ☐ Ineligible
  - ☐ Dies
  - ☐ Eligible
    - ☐ ED or Inpatient
      - ☐ RA approach while at HMC
    - ☐ Discharged before RA contact
      - ☐ Phone call to determine eligibility and schedule in-person enrollment meeting
      - ☐ Phone call schedule: 2 weeks of attempted contact with patient
        - ☐ Begin calling as soon as possible – once you start, the 2-week timer begins
        - ☐ Allowed up to 10 calls
        - ☐ Allowed 2 voicemails – after 1st and 8th call
        - ☐ Allowed 1 text – at one-week mark
        - ☐ Must use IRB approved script for call, voicemail and text
        - ☐ After 2 weeks, patient becomes "Unable to Contact"

Enrollment Flow

- ☐ Patient is eligible and interested in participation
- ☐ Sign Consent Form
- ☐ Sign HIPAA form
- ☐ Complete baseline survey
  - ☐ If baseline is not completed, complete as soon as possible
    - ☐ If completed after the 1-month survey window opening, RA to explain situation and ask patient to schedule two appointments to complete the two surveys
    - ☐ Window to complete baseline is 6 weeks after enrollment date
      - ☐ After this point, mark as "Missed"
- ☐ Provide Gift Card
- ☐ Sign Gift Card form
- ☐ For Intervention Patients:
  - ☐ Notify Support Specialist
  - ☐ Introduce her to patient
  - ☐ Tell patient Support Specialist will contact him/her

Appendix G

Follow-Up Timeline and Procedures

RAs will contact participants via phone, text, or email to complete follow-up surveys. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone, or in-person. Preferred completion mode is online or by phone. Follow-up assessments will be done at the following times:

- ☐ 1 month (window opens 1 week before and closes 3 weeks after 1-month date)
- ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
- ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)
- ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
- ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

If the participant has an email, automate REDCap notifications.

If the participant does not have an email or has been unresponsive to automated email prompts for 1 week, then contact participant by phone using the number provided at baseline or most recent survey.

- ☐ Please use study cell phone.
- ☐ You can leave up to two messages.

If participant does not respond to phone calls, call the alternative contacts provided at baseline or at most recent survey.

- ☐ At all other follow-up time points, try alternative contacts after 2 weeks of direct contact attempts with participant.
- ☐ You can leave one voicemail.
    - ☐ Do not leave any details about the study or mention the study.

If you are unable to make contact with the participants, check jail database.

- ☐ If patient is in jail, do not contact and mark that the patient is in jail on the follow-up survey.
- ☐ If you are unable to make contact with participants or alternative contacts and patient is not in the jail database, then mail a copy of the survey to the participant at the address provided at baseline or the most recent survey.
    - ☐ Include a self-addressed, stamped envelope in the mailing.

Contacting Patient by Phone

Always use the study cell phone to contact participants. The purpose of the phone call at follow-up is to:

- ☐ Remind participants about the follow-up survey and their completion options.
- ☐ Remind participants about the incentives for their completion of the surveys.
- ☐ Remind participants that it will take about 30-45 minutes to complete the survey.
- ☐ Determine the mode by which the participant wants to complete the survey:
    - ☐ If online, confirm their email address and re-send link (if sent already).

- ☐ If by phone, ask if the participant would like to complete by phone now. If not, schedule a phone call within the next 1-4 days.
- ☐ If in-person, schedule a meeting within the next 1-4 days. Ask if they are willing to come to HMC. If not, select a meeting location that is public and during daytime hours.

☐ Let them know you will give them a reminder text or leave a reminder voicemail the day/night before the phone call or in-person meeting.
☐ Thank them for their participation.

Reaching the typical study participant will require multiple calls. To be effective, you will have to try reaching them at different times of the day and different days of the week. Some people may be very easy to reach, while it may take up to 10 or more contact attempts before you are able to speak with a person. Expect and plan for multiple contact attempts, and expect to encounter some typical barriers in this process. Study participants typically have two mechanisms to help protect them from taking unwanted calls: (1) voice mail/answering machines; and (2) caller ID.

Voice Mail/Answering Machines

Many study participants use answering machines to screen their calls. To help counter this, leave a message on the machine to let them know you have called and leave the study cell phone number. The IRB has approved us to leave up to 2 voice messages. There are a few basic things to keep in mind when dealing with voice mail or answering machines:

☐ Don't leave more than 2 messages. You can make more than 2 contact attempts, but messages should be left strategically and only twice.
☐ Don't wait too long after you leave a message to call them back (1 or 2 days at most).
☐ Your message should be brief, friendly, and to-the-point. Please follow the script. Speak slowly – especially when leaving a phone number. Provide the study cell phone number in every voicemail.

Caller ID

Many study participants may have Caller ID available to them on their telephone service. This means that every time you call, your telephone number will appear and be logged into their Caller ID box. Keep this in mind when you make your calls for the day, and be careful not to call too often. They may perceive you as "harassing" them before you even make the first contact. Take careful call notes to keep track when each time a message was left and what was said in the message (e.g., "msg. left with name and #, will call back Tues. pm"). The following are several ways to address the Caller ID issue. No matter how you choose to handle this situation with a patient, keep in mind that it should facilitate interaction about survey completion.

☐ Typically, you will limit your telephone attempts to only one attempt in any day.
☐ You may have a "Line Block" placed on the telephone line that you are calling from, so that any time you call, "Anonymous" (and not your phone number) will appear on the other party's Caller ID box. To remove line block on any individual call, you can press *82 before you place the call. This will allow your name and number to be displayed to the Caller ID party on just that one call. This service is free of charge, but you must call your telephone provider to request that it be added to your line.
☐ "Per Call Blocking" allows you to block an individual call to a study participant by dialing *67 before dialing the number. When you block an individual call, "Anonymous" will be

displayed on the Caller ID party for just this one call. This service should already be available to you without you requesting to "activate" it.

Call or Meeting Reminders

Once an appointment is scheduled, you will want to do what you can ahead of time to minimize any "no-shows" or "broken appointments." The following are several ways to avoid the frustration of a "no-show" by taking these steps:

- ☐ Suggest that the study participant choose a time and place when there will be the least number of distractions and/or interruptions. HMC should be the first suggestion by RA, and if that is not possible, work with patient to identify a quiet and safe, preferably public, location.
- ☐ Set a definite time. Avoid using vague phrases like, "I'll see you around 4:00."
- ☐ In addition to having a definite time, you may want to re-state this appointment time before hanging up. "Okay, I have you down for Thursday, January 21st at 4:00 PM. Is that what you have?"
- ☐ Give a reminder call or text the day before, and depending on the participant, sometimes the day of, to confirm the appointment time. Flag your call-back time so that you are sure to follow-through and actually make the call.
- ☐ Leave contact numbers, and encourage the study participant to call you back if they need to reschedule the appointment.

Appendix H

Safety Protocols

Home or Community-Based Visits

Please do not conduct home or community visits in homes or neighborhoods in which you don't feel safe. The most important things are to use common sense, follow your gut instinct and always remember to put your own personal safety first. If you are ever in a situation where your safety feels compromised, please do whatever it takes to get out of the situation. Also, don't try to protect cash or equipment at the expense of your own safety.

Regardless of whether you are someone who is comfortable or uneasy about going to a stranger's home, you should always take precautions and make plans that will help ensure your personal safety. The more you know and are prepared for your surroundings, the more you will feel and behave more comfortably. It is helpful to visualize potential situations and plan in advance ways to maintain your safety under different circumstances.

Before calling or scheduling an appointment with a study participant, look at a map and make sure that you know something about the neighborhood. Public locations should be prioritized over private homes. Despite the perception of how "safe" a neighborhood is, you may always benefit from doing a little detective work, and learning a little about where you will be going. If you feel uncomfortable, come early and visit the neighborhood during the day. Drive around a bit and locate the nearest convenience or grocery store, fast food restaurants, a public library or gas stations (public restrooms).

Although it may be rare that you might encounter an unsafe situation or neighborhood, there will be times when you may feel uncomfortable going to a participant meeting. Take these general precautions to help you feel at ease and to guarantee your safety in a potentially dangerous situation:

Before you arrive at the meeting location:

- ☐ Where practical, research staff should travel in pairs. An ideal pairing is an RA with the Support Specialist for intervention sessions coupled with scheduled follow-up visits.
- ☐ RAs may not attend home visits alone.
- ☐ Let staff know where you are going and when to expect you back. Use Google Calendar or a shared Outlook calendar to document this.
- ☐ Know where you are going. Get directions, always have a map and plan out your route. Ask the study participant to tell you the best place to park, and which door to use.
- ☐ Call the study participant to let her know when to expect you.
- ☐ Schedule check-in times if you feel you are in a difficult place.
- ☐ Bring your charged cell phone.
- ☐ Always have sufficient gas in your car.
- ☐ Have a plan for if your car breaks down.
- ☐ Don't over-dress or carry expensive valuables. Look casual and not memorable.
- ☐ Don't leave expensive valuables in your car, especially in plain view. Lock in the trunk.

Once you are at the meeting location:

- ☐ Check it out, look around. Get a feel for what's going on around you.

- ☐ Look for a place to park that is well-lit and close to the participant's home (if applicable).
- ☐ Be aware of surroundings (including dogs).
- ☐ As much as possible, choose a clear, well-lit path to the house (if applicable).
- ☐ When walking down the street, look and walk purposefully and confidently.
- ☐ If you feel threatened by the setting, call on your cell phone (or drive to a payphone) and ask the study participant to meet you at the door.
- ☐ If you still feel unsafe, call the participant to reschedule or cancel. You may want to try to schedule a daytime appointment and/or a different location.

If you are in the home:

- ☐ Do not enter if you smell or see drugs.
- ☐ Always wear your name badge and identify yourself as soon as you arrive at the study participant's home.
- ☐ With the exception of a cell phone and iPad, never take anything into a home that you do not need for the meeting (no personal items, no extra cash, etc.)
- ☐ Ask who else is at the residence.
- ☐ Be aware of exits, and sit where you can exit easily.
- ☐ Use non-threatening body language. Remain calm and polite.
- ☐ If you feel uneasy in the study participant's home, try to suggest a location for your conversation where you would be able to leave quickly, without your path being blocked.
- ☐ Listen to your intuition/instinct. If you feel uncomfortable or have a bad feeling, cut the meeting short and politely take leave.
- ☐ If you become fearful about your safety inside the study participant's home, and feel unable to resolve it, end the conversation. You are in no way expected to stay in an unsafe situation in order to complete study activities.

If you still feel unsafe, here are some suggestions of how to end a home visit tactfully:

- ☐ Tell the study participant you are having technical difficulties and will need to reschedule the appointment.
- ☐ Tell the study participant you are not feeling well and would like to reschedule the appointment.
- ☐ Have someone call you on your cell phone 5-10 minutes after you are scheduled to arrive in case you need to use the call as an excuse to reschedule the appointment.

Please do not conduct meeting where you don't feel safe. If you still feel unsafe, consult with your supervisor about other options. Every precaution is taken to ensure your personal safety.

Report concerns to the Study Coordinator and PI upon your turn.

Appendix I

Crisis Management Protocol

Interpersonal-Harm Protocol for Crisis Intervention

- ☐ If one of the RAs discover that the patient is in imminent danger of harming another individual, they may directly ask: "Do you currently have plans to harm [Person A] or take their life?" If after asking this question, the study staff has any doubts about Person A's immediate safety, they will immediately leave the patient and call 9-1-1. The RA will then contact the Principal Investigator. To ensure the study staff's safety, the RA will not inform the patient of their plan to alert the authorities.

Suicidal ideation in patient during a hospital encounter

- ☐ If one of the Research Assistants (RAs) discovers suicidal ideation during a hospital encounter with the patient, they may directly ask:

    - Sometimes when people are [ ], and [ ], and [ ] they are thinking about suicide. Are you thinking about suicide? (Include signs or symptoms in place of blanks. For example: "Sometimes when people are feeling very anxious, hating their life, and feeling like a failure, they are thinking about suicide. Are you thinking about suicide?)

    - If after asking this question, the RA has any doubts about the patient's safety, they will first contact the patient's healthcare team immediately. Following that, the RA will notify the Support Specialist or one of the two Study Clinicians, as well as the Principal Investigator.

    - Fred Rivara (Study Clinician): 206-799-7961
    - Lauren Whiteside (Study Clinician): 773-807-8366
    - Liz Griffin (Support Specialist): 206-496-8215
    - Ali Rowhani-Rahbar (Principal Investigator): 650-213-6457

Suicidal ideation in patient during a follow-up non-hospital encounter

- ☐ If one of the RAs discovers suicidal ideation during a non-hospital encounter with the patient (i.e., during the follow-up assessment), they may directly ask:

    - Sometimes when people are [ ], and [ ], and [ ] they are thinking about suicide. Are you thinking about suicide? (Include signs or symptoms in place of blanks. For example: "Sometimes when people are feeling very anxious, hating their life, and feeling like a failure, they are thinking about suicide. Are you thinking about suicide?)

    - If after asking this question, the RA has any doubts about the patient's immediate safety, they will immediately call 9-1-1. Following that, they will notify the Support Specialist or one of the two Study Clinicians, who will speak with the patient if appropriate and possible. Finally, the RA will contact the Principal Investigator.

- ☐ If the patient would like to someone to further talk to:
    - Call National Suicide Prevention Lifeline at **1-800-273-8255** or give the subject the text Crisis Text Line to **741741**
- ☐ If the patient states that the index injury was intentional and self-inflicted during a follow-up survey, the RA will contact Designated Mental Health Professional/Crisis Team (See below) or the Support Specialist for further action.
- ☐ The RAs follow the steps from the LEARN protocol (see below) to know what to look for and what to do. DO NOT attempt to remove weapons from subjects.
- ☐ Symptoms of post-traumatic stress and trauma recovery may appear as signs of a person thinking about suicide. Stick with the delivery of the protocol and survey questions unless there is a clear indication from the subject that they may be thinking about suicide.

Tips for Talking with Youth, Adults, Friends, Family or Co-workers in Crisis

L.E.A.R.N.© intervention steps. Forefront: Innovations in Suicide Prevention (www.intheforefront.org), University of Washington

Don't assume a person is not at risk for suicide. Anyone can be…..but you can help. *Suicide IS preventable*.

1. **Look for Warning signs / ways the person is "inviting help"**: Examples: they are in pain, desperate, hopeless ("*it will never get better*"), helpless ("*there is nothing I can do*"); feeling trapped ("*there is no way out*"), like a burden, or that they try to fit in – but it never works. **Look for changes** such as isolating behavior, giving away possessions, losing interest in activities, using more alcohol or drugs, acting impulsively. Listen for threats such as: "*I won't be needing these anymore*", "*You'll miss me if I'm dead*", "*Everyone will be better off without me.*"

2. **Empathize** with them: If you think someone may be at risk for suicide, **talk to them about what is going on.** You don't have to be a therapist. **Make a connection**. **Listen… really listen**. Give full attention. Don't interrupt, minimize their situation or try to convince them everything will get better. Control your fears so you can focus on the other person. Examples of things you could say to start the conversation:

    a. "*How are things going?" "You seem upset; do you want to talk about it*?"
    b. "*I care about you. You are going through a lot. Let's talk.*"
    c. "*It sounds like you have so many problems and they feel impossible to deal with.*"
    d. "*You are in a lot of pain. I see it and I hear that you feel alone in this pain. I care. Please tell me more.*"

    Continue to **listen**, build rapport and trust. **Help them to feel understood. That is so key**. Say: "*That sounds like a very difficult situation.*" "*I would be upset about that too.*" Please understand, for some, suicide can feel like a logical way to escape pain. Don't judge, or tell them they have so much to live for or promise it will get better.

3. **ASK the person clearly, directly and compassionately about suicide**. "Are you thinking about suicide?" or "Are you thinking about ending your life?" or "When you say ___ do you mean you're thinking about killing yourself?"

    a. ***Asking the suicide question does not increase risk***. You won't cause someone to act on it by asking.
    b. Asking sincerely, compassionately and in context to what you have seen shows that someone cares.
    c. Sharing suicidal thoughts reduces feelings of isolation.
    d. Talking generally provides comfort and provides some relief.
    e. **If they say "yes" it is important to not panic**. Say: "*That took a lot of courage to tell me. Thank you.*" Demonstrate calm. Ask if they have plans (when, where, how) and means (have a gun, rope, pills etc.).

4. **Remove the danger**: In the ASK step you inquired about a suicide plan. If they have means/access to guns, ropes or excess medication. Now work with friends, family or law enforcement to secure or remove these items.

5. **Next level of care:** Let them know you are concerned and that you would like to help them. Ask if you can **help connect them with someone who has more expertise.** Say: "*Can I give you the name of a counselor who might be able to help*" or "*I'm willing to go with you to our local help center* [or school counselor etc.] or… "*Lets create a safety plan together about who you can call and what you can do if you feel at risk again in the future.*"

Free, 24/7, anonymous help is available by calling the **National Suicide Prevention Lifeline: 1-800-273-TALK (8255)**
Here in King County…. That number automatically routes you the the Crisis Clinic

In King County, **TeenLink** is a resource line for teens, staffed by trained teens. See: www.866teenlink.org or call 1-866-833-6546
MY3 is a great, free app (http://www.my3app.org/) available for iPhones or Android devices that helps create a safety plan.

If someone is in *immediate* risk for suicide, call 911…. Or take them to the nearest hospital *if it is safe for you to do so*.

Crisis Support by County

King County

Agency	Crisis and Commitment Services 401 Fifth Avenue Suite 400 Seattle, WA 98104
Contact	Diane Swanberg
Telephone	(206) 263-9202
Fax	(206) 205-5192
Crisis Line	M-F 8:30 am - 4:30 pm (206) 263-9200; After Hours (206) 461-3222; Business line-(206) 461-3210 ext 1

Pierce County

Agency	Good Samaritan Mobile Outreach Crisis Team (M.O.C.T.) 325 E. Pioneer Ave. Puyallup, WA 98374
Contact	Silvia Riley or Nate Hinrichs
Telephone	(800) 576-7764
Fax	(253) 301-5209
Crisis Line	(800) 576-7764

Snohomish County

Agency	Snohomish County Involuntary Treatment Program 3000 Rockefeller Avenue, Mail Stop 305 Everett, WA 98201
Contact	Carola Schmid or Anji Jorstad
Telephone	(425) 388-7214
Fax	(425) 388-7216
Crisis Line	(800) 584-3578 Public Line (425) 258-1352 Professional Line

Thurston-Mason County

Agency	Behavioral Health Resources Crisis Resolution Services 3436 Mary Elder Road NE Olympia, WA 98506
Contact	Tiffany Buchanan
Telephone	(360) 528-2590
Fax	(360) 528-2594
DMHP Fax	(360) 754-1194
Crisis Line	(360) 754-1338

Yakima County

Agency	Comprehensive Health Care 402 S. 4th Avenue, PO Box 959 Yakima, WA 98907
Contact	Courtney Hesla
Telephone	(509) 576-4312
Fax	(509) 574-5118
Crisis Line	(509) 575-4200 or (800) 572-8122

References

1. Rowhani-Rahbar A, Zatzick D, Wang J, et al. Firearm-related hospitalization and risk for subsequent violent injury, death, or crime perpetration. *Ann Intern Med*. 2015;162(7):492-500.
2. Adolescent assault victim needs: a review of issues and a model protocol. American Academy of Pediatrics Task Force on Adolescent Assault Victim Needs. *Pediatrics*. 1996;98(5):991-1001.
3. Aboutanos MB, Jordan A, Cohen R, et al. Brief violence interventions with community case management services are effective for high-risk trauma patients. *J Trauma*. 2011;71(1):228-36-7.
4. Becker MG, Hall JS, Ursic CM, Jain S, Calhoun D. Caught in the Crossfire: the effects of a peer-based intervention program for violently injured youth. *J Adolesc Health*. 2004;34(3):177-183.
5. Cheng TL, Haynie D, Brenner R, Wright JL, Chung S, Simons-Morton B. Effectiveness of a mentor-implemented, violence prevention intervention for assault-injured youths presenting to the emergency department: results of a randomized trial. *Pediatrics*. 2008;122(5):938-946.
6. Cheng TL, Wright JL, Markakis D, Copeland-Linder N, Menvielle E. Randomized trial of a case management program for assault-injured youth: impact on service utilization and risk for reinjury. *Pediatr Emerg Care*. 2008;24(3):130-136.
7. Cooper C, Eslinger DM, Stolley PD. Hospital-based violence intervention programs work. *J Trauma*. 2006;61(3):534-7-40.
8. Corbin TJ, Rich J a, Bloom SL, Delgado D, Rich LJ, Wilson AS. Developing a trauma-informed, emergency department-based intervention for victims of urban violence. *J Trauma Dissociation*. 2011;12(5):510-525.
9. Marcelle DR, Melzer-Lange MD. Project UJIMA: working together to make things right. *WMJ*. 2001;100(2):22-25.
10. Shibru D, Zahnd E, Becker M, Bekaert N, Calhoun D, Victorino GP. Benefits of a hospital-based peer intervention program for violently injured youth. *J Am Coll Surg*. 2007;205(5):684-689.
11. Snider C, Jiang D, Logsetty S, Strome T, Klassen T. Wraparound care for youth injured by violence: Study protocol for a pilot randomised control trial. *BMJ Open*. 2015;5(5).
12. Snider C, Lee J. Youth violence secondary prevention initiatives in emergency departments: A systematic review. *Can J Emerg Med*. 2009;11(2):161-168.
13. Walton MA, Chermack ST, Shope JT, et al. Effects of a brief intervention for reducing violence and alcohol misuse among adolescents: a randomized controlled trial. *JAMA*. 2010;304(5):527-535.
14. Watt K, Shepherd J, Newcombe R. Drunk and dangerous: a randomised controlled trial of alcohol brief intervention for violent offenders. *J Exp Criminol*. 2007;4(1):1-19.
15. Zatzick D, Russo J, Lord SP, et al. Collaborative care intervention targeting violence risk behaviors, substance use, and posttraumatic stress and depressive symptoms in injured adolescents: a randomized clinical trial. *JAMA Pediatr*. 2014;168(6):532-539.
16. Zun LS. Violence prevention in the ED: linkage of the ED to a social service agency. *Am J Emerg Med*. 2003;6757(6):454-457.
17. Zun LS, Downey L, Rosen J. The effectiveness of an ED-based violence prevention program. *Am J Emerg Med*. 2006;24(1):8-13.
18. Zun LS, Downey L, Rosen J. An emergency department-based program to change attitudes of youth toward violence. *J Emerg Med*. 2004;26(2):247-251.
19. Purtle J, Rich LJ, Bloom SL, Rich J a, Corbin TJ. Cost−Benefit Analysis Simulation of a Hospital-Based Violence Intervention Program. *Am J Prev Med*. 2015;48(2):162-169.

20. Purtle J, Dicker R, Cooper C, et al. Hospital-based violence intervention programs save lives and money. *J Trauma Acute Care Surg*. 2013;75(2):331-333.
21. Berkowitz SA, Johansen KL. Does motivational interviewing improve outcomes? *Arch Intern Med*. 2012;172(6):463-464.
22. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. *Heal Psychol*. 1994;13:39-46.
23. Cunningham RM, Chermack ST, Zimmerman M a., et al. Brief Motivational Interviewing Intervention for Peer Violence and Alcohol Use in Teens: One-Year Follow-up. *Pediatrics*. 2012;129(6):1083-1090.
24. Gentilello LM, Rivara FP, Donovan DM, et al. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Ann Surg*. 1999;230(4):473-480-483.
25. Godley MD, Godley SH, Dennis ML, Funk RR, Passetti LL, Petry NM. A randomized trial of assertive continuing care and contingency management for adolescents with substance use disorders. *J Consult Clin Psychol*. 2014;82(1):40-51.
26. Saitz R, Palfai TPA, Cheng DM, et al. Screening and brief intervention for drug use in primary care: the ASPIRE randomized clinical trial. *JAMA*. 2014;312(5):502-513.
27. Monti PM, Colby SM, Barnett NP, et al. Brief intervention for harm reduction with alcohol-positive older adolescents in a hospital emergency department. *J Consult Clin Psychol*. 1999;67(6):989-994.
28. Monti PM, Barnett NP, Colby SM, et al. Motivational interviewing versus feedback only in emergency care for young adult problem drinking. *Addiction*. 2007;102(8):1234-1243.
29. Woolard R, Baird J, Longabaugh R, et al. Project Reduce: Reducing alcohol and marijuana misuse: Effects of a brief intervention in the emergency department. *Addict Behav*. 2013;38(3):1732-1739. doi:10.1016/j.addbeh.2012.09.006.
30. Cunningham R, Knox L, Fein J, et al. Before and after the trauma bay: the prevention of violent injury among youth. *Ann Emerg Med*. 2009;53(4):490-500.
31. Lako DA, de Vet R, Beijersbergen MD, Herman DB, van Hemert AM, Wolf JR. The effectiveness of critical time intervention for abused women and homeless people leaving Dutch shelters: study protocol of two randomised controlled trials. *BMC Public Health*. 2013;13(1):555.
32. de Vet R, van Luijtelaar MJA, Brilleslijper-Kater SN, Vanderplasschen W, Beijersbergen MD, Wolf JRLM. Effectiveness of Case Management for Homeless Persons: A Systematic Review. *Am J Public Health*. 2013;103(10):e13-e26.
33. Hwang SW, Burns T. Health interventions for people who are homeless. *Lancet*. 2014;384(9953):1541-1547.
34. Angell B, Matthews E, Barrenger S, Watson AC, Draine J. Engagement processes in model programs for community reentry from prison for people with serious mental illness. *Int J Law Psychiatry*. 2014;37(5):490-500.
35. Shinn M, Samuels J, Fischer SN, Thompkins A, Fowler PJ. Longitudinal Impact of a Family Critical Time Intervention on Children in High-Risk Families Experiencing Homelessness: A Randomized Trial. *Am J Community Psychol*. 2015;56(3-4):205-216.
36. Rowhani-Rahbar A, Fan MD, Simonetti JA, et al. Violence Perpetration Among Patients Hospitalized for Unintentional and Assault-Related Firearm Injury: A Case-Control Study and a Cohort Study. *Ann Intern Med*. 2016;165(12):841-847.

Study Protocol

July 7, 2017

Official title: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial

Brief title: Helping Individuals with Firearm Injuries (HiFi)

Investigators: Ali Rowhani-Rahbar, MD, MPH, PhD; Lauren Whiteside, MD, MS; Kevin Haggerty, PhD; Frederick Rivara, MD, MPH

Affiliations: Department of Epidemiology, School of Public Health (Rowhani-Rahbar, Rivara); Department of Pediatrics, School of Medicine (Rowhani-Rahbar and Rivara); Department of Emergency Medicine, School of Medicine (Whiteside); School of Social Work (Haggerty); and Harborview Injury Prevention and Research Center (Rowhani-Rahbar, Whiteside, Haggerty, and Rivara)

Research team and contact information

Name	Role	E-mail
Ali Rowhani-Rahbar	Principal Investigator	rowhani@uw.edu
Lauren Whiteside	Co-Investigator	laurenkw@uw.edu
Kevin Haggerty	Co-Investigator	haggerty@uw.edu
Frederick Rivara	Co-Investigator	fpr@uw.edu
Anthony Floyd	Study Coordinator	asfloyd@uw.edu
Elizabeth Griffin	Support Specialist	davis86@uw.edu
Manal Jmaileh	Research Assistant	mjmaileh@uw.edu
Alvaro Martinez	Research Assistant	alvmarti@uw.edu
Jin Wang	Data Programmer	wangji@uw.edu
Vivian Lyons	Doctoral Student	vlyons@uw.edu
David Cheever	Medical Resident	dachee@uw.edu

Table of Contents

Significance 6
Objectives 7
Approach 8
  Study Setting and Population 8
  Eligibility 8
  Study Design 9
  HMC Usual Care for GSW Victims 9
  Trial Profile 10
  Recruitment, Disclosure of Assignment, and Consent 10
  Assignment 11
  Intervention 11
    Brief Intervention 11
    Extended Community Outreach 11
    Multi-Agency Attention 13
  Baseline and Follow-Up Assessments 13
  Measures 14
    Process Measures 14
    Outcome Measures 14
    Administrative Databases 14
    Surveys 14
  Data Management 15
    Statistical Power and Analysis 15
  Weekly Team Meetings 17
  Advisory Board 17
  Timeline 17
Protection of Human Subjects 17
  Risks to Human Subjects 17
    Psychological Risks 18
    Confidentiality Risks 18
    Vulnerable Populations 18
  Adequacy of Protection Against Risks 18
    Psychological Risks 18
    Confidentiality Risks 18
    Vulnerable Populations 18
  Potential Benefits of the Proposed Research to Human Subjects and Others 19
  Importance of the Knowledge Gained 19
Conflict of Interest 19
Dissemination 19
Appendix A 21
  Patient Identification, Approach and Engagement Protocol 21
Appendix B 25
  In-Person Recruitment Script 25
Appendix C 27
  Phone Recruitment Script 27
Appendix D 29
  Voicemail and Text Recruitment Script 29
Appendix E 30
  Phone Follow-Up Script 30
Appendix F 31

Overall Recruitment and Enrollment Flow 31
Appendix G 32
Follow-Up Timeline and Procedures 32
Appendix H 35
Safety Protocols 35
Appendix I 37
Crisis Management Protocol 37
References 40

List of Abbreviations

- **HMC**: Harborview Medical Center
- **GSW**: Gunshot Wound
- **RA**: Research Assistant
- **ED**: Emergency Department
- **MDT**: Multidisciplinary Team
- **MI**: Motivational Interviewing
- **CTI**: Critical Time Intervention

Study Synopsis

- **Title**: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial
- **Population**: Patients presenting to Harborview Medical Center with firearm injuries
- **Design**: Cluster Randomized Trial
- **Objective**: To test the effectiveness of a multicomponent intervention including brief motivational interviewing, extended community outreach services, and multiagency attention in promoting health and well-being of gunshot wound victims
- **Targeted Sample Size**: 304
- **Study Duration**: From January 1, 2016 through December 31, 2020

Significance

About 200-250 individuals present to an emergency department in King County, primarily Harborview Medical Center (HMC), for firearm-related injuries each year. Almost two-third of these patients require admission for their injuries. While the number of patients with firearm injuries who present to HMC is relatively small, these individuals are at substantially high risk of subsequent rehospitalization for another firearm or assault-related injury, arrest for firearm-related or violent crime, nonfirearm-related nonviolent crime, or firearm-related death in the five years after discharge from the hospital.[1] Thus, interventions among this group of individuals to promote their health and well-being and reduce the high risk of recidivism, morbidity, and mortality are critically needed. Such interventions may also lead to lower rates of firearm violence and its consequences in the community.

Patients with gunshot wounds (GSWs) seen at HMC receive many services. First, all patients are seen in the Emergency Department (ED) by an attending Emergency Medicine physician and resident physicians on the trauma team working in the ED. Depending on the nature and location of the GSW, these patients are often seen by specialty consulting services such as orthopedic surgery or vascular surgery. If patients have life-threatening injuries, they are seen by the trauma surgery service including an attending trauma surgeon. In addition, all patients who are victims of violence are seen by a member of the Social Work staff during their hospital stay. Currently, Level 1 trauma centers in the country including HMC are mandated by the American College of Surgeons to provide alcohol screening and brief intervention services to trauma patients, including GSW victims. Patients who are admitted and screened for substance use (e.g., alcohol and drugs) can be seen by the Harborview Addiction Intervention Service which comprises psychologists and chemical dependency counselors. Lastly, patients who present to HMC for GSWs and suicidal intent receive a comprehensive psychiatric evaluation once they are medically stable. However, currently there is no standardized intervention offered to GSW victims.

A number of hospitals across the country have created violence intervention programs to specifically help patients who sustain violent injuries. In 1996, the American Academy of Pediatrics published a report stating that while it has been routine to treat victims of child abuse, suicide attempts, and sexual assault via multidisciplinary care protocols, no care guidelines exist that address the unique needs of violently injuries adolescents.[2] In 1998, the U.S. Department of Justice's Office for Victims of Crime recommended that hospital-based counseling and prevention programs be developed. In 2009, the National Network of Hospital-based Violence Intervention Programs was formally established (http://nnhvip.org). These programs seek to engage patients in the hospital during the recovery period as a golden opportunity ("teachable moment") to change their life and reduce retaliation and recidivism. Through working groups, meetings, e-newsletter, and conferences, Network members collaborate in research and evaluation, explore opportunities for funding sustainability, develop and share best practices, and identify ways to collectively have an impact on policy. NNHVIP mainly serve individuals 15-25 years of age; however, some programs extend this range from 7 years through middle age.

While the creation of this infrastructure is a step in the right direction, rigorous research on the effectiveness of these intervention programs is needed. There exist only a few studies of the effectiveness of these programs some of which had small sample sizes and produced mixed findings.[3–20] Specifically, there have been no randomized trials evaluating the effectiveness of joint hospital-based and community-based violence intervention programs specifically offered to GSW victims. If research shows that such programs may not be effective, resources can be

better spent on other approaches to reduce gun violence and its associated morbidity and mortality.

We propose to conduct a randomized trial of an intervention program that combines a hospital-based intervention, structured community outreach program, and multi-agency attention. We will provide a brief intervention delivered at HMC to bolster the interaction that all these patients will have with the hospital Social Work staff. This intervention is derived from motivational interviewing (MI) which is a patient-centered behavioral technique based on the stages of change model and attempts to engage patients in order to find reason to change behavior.[21,22] By empathetically exploring ambivalent feelings about health-related behavior, MI encourages reduction in risky behavior. A number of investigations have demonstrated the effectiveness of providing MI-based brief interventions in the ED or inpatient wards,[23–26] primarily for alcohol use disorders[21,27–29] but also for violent behaviors.[15,30] Specifically, brief interventions utilizing principles of MI have been successful at reducing youth violence in large urban populations that sustained after one year.[13,23] Additionally, a behavioral-based intervention including MI among adolescents admitted to HMC with trauma showed a reduction in weapon carriage during the year after hospitalization.[15] This approach is appealing as its rationale is plausible and potential harms are minimal.[21]

A longitudinal intervention program provides the benefit of continued engagement. Providing GSW victims with outreach and follow-up after the healthcare encounter holds promise for reducing future violence and criminal activity. The Critical Time Intervention (CTI) approach (http://sssw.hunter.cuny.edu/cti/cti-model) can provide a strong framework for providing these patients with appropriate outreach and follow-up. Strong evidence supports CTI's effectiveness. The model meets the Coalition for Evidence-based Policy's rigorous "Top Tier" standard for interventions "shown in well-designed and implemented randomized controlled trials, preferably conducted in typical community settings, to produce sizable, sustained benefits to participants and/or society" (http://evidencebasedprograms.org/1366-2/critical-time-intervention-top-tier). CTI is a time-limited evidence-based case management practice that mobilizes support for society's most vulnerable individuals during periods of transition such as discharge from inpatient services to the community. It facilitates community integration and continuity of care by ensuring that a person has enduring ties to their community and support systems during these critical periods. CTI has been used worldwide among veterans, people with mental illness, homeless or incarcerated individuals, and many other groups.[31–35] From the beginning, CTI was thought of as an intervention that could be applied to other contexts. This approach has the potential to provide an intervention framework for a second tier outreach to GSW victims. To help the Support Specialist in delivering the CTI, a team of experts with the knowledge of available local services and how to navigate them is needed. Our proposed intervention will include such a team.

To our knowledge, this is the first randomized trial of a multicomponent dual hospital and community-based intervention exclusively focused on GSW victims. Findings of this study can directly impact practice and policy through informing the development of evidence-based programs pertaining to firearm violence in the future.

Objectives

The global goal of this study is to test the effectiveness of an intervention program for promoting health and well-being and reducing morbidity and mortality of GWS victims. The intervention program consists of a hospital-based MI, a longitudinal CTI, and multi-agency attention. We

seek to evaluate the effects of the intervention program using both process and outcome measures. Specifically, we will address the following aims:

1. What is the effect of the HiFi case management program on the proportion of GSW patients arrested over a follow-up period of up to two years after hospital discharge?

2. What is the effect of the HiFi case management program on specific outcomes other than criminal arrest (e.g., injury, mental health, substance use, aggressive behavior, health-related quality of life, social support, employment, housing, and death) over a follow-up period of up to two years after hospital discharge?

Process measures

- ☐ Reach: What proportion of patients were engaged (i.e., coverage)?
- ☐ Dosage: Did patients receive the proper dose of the intervention (i.e., dose and frequency)?
- ☐ Adherence: Did the Support Specialist adhere to the principles of case management and study protocol?
- ☐ Responsiveness: How satisfied were the patients with the intervention received?

Outcome measures

- ☐ Crime perpetration
- ☐ Injury victimization
- ☐ Death
- ☐ Impulsive and premeditated aggressive behavior
- ☐ Interpersonal violence
- ☐ Substance abuse
- ☐ Mental health
- ☐ Employment or enrollment in classes
- ☐ Physical health, happiness, and quality of life
- ☐ Availability of social support and social network

We will test the impact of the intervention on the aforementioned outcomes using usual (i.e. standard) care as the comparison. Our hypothesis is that participants in the intervention group will see greater improvements in outcomes than those who receive usual care in this setting.

Approach

Study Setting and Population

The study will be conducted at HMC located in Seattle, Washington. HMC has an annual census of about 65,000 adult patient visits per year covering a typically diverse and urban population. Based on prior data, about 200-250 GSW patients (including both ED visits and hospitalizations) are treated at HMC every year.

Eligibility

Patients can be enrolled in the study from the ED, inpatient area, or after discharge in HMC-affiliated clinics (collectively referred to as “hospital” in this document). Eligible subjects will be:

- ☐ 18 years of age or older
- ☐ Able to provide consent within 4 weeks following hospital discharge
- ☐ Able to understand and speak English
- ☐ Able to provide at least one mode of direct or alternate contact (e.g., cell phone, land line, e-mail, friend, or relative)
- ☐ Planning to live in King, Pierce, Snohomish, Thurston or Yakima counties for at least 6 months subsequent to hospital discharge
- ☐ Receiving treatment for a GSW at HMC and returning to the community, and not prison following treatment
- ☐ Being treated for gunshot wounds from assaults or accidents (self- or other-inflicted)

Patients will be ineligible to participate in this study if they are:

- ☐ 17 years of age or younger
- ☐ Unable to provide consent (including those with severe neurologic damage) within 4 weeks following hospital discharge
- ☐ Unable to understand or speak English
- ☐ Unable to provide any mode of direct or alternate contact
- ☐ Not living in King, Pierce, Snohomish, Thurston or Yakima counties, or planning to move outside of those counties within 6 months following hospital discharge
- ☐ Not receiving treatment for a GSW at HMC
- ☐ Not returning to the community following hospital discharge (e.g., being sent to a rehabilitation center, skilled nursing facility, or prison)
- ☐ Incarcerated at the time of GSW injury
- ☐ Being treated for an intentional, self-inflicted gunshot wound injuries (e.g. suicide attempts)

Study Design

We will conduct a randomized trial in which GSW victims treated at HMC either receive an intervention or treatment as usual. The unit of randomization is the calendar week; that is, the study staff will assign GSW victims to one of the two groups based on the week in which they were shot and treated at HMC. A week is defined as one starting on Monday morning at 8:00 for a duration of seven days. We will use block randomization with varying block sizes of 2 and 4 to assign each week to one of the two groups of the trial. As such, all patients admitted in the same week will be assigned to the same group. This randomization scheme will ensure that all victims in the same shooting incident will receive the same study assignment. In addition, this scheme will enhance the feasibility of study by facilitating the coordination of efforts among the study staff in delivering the intervention.

HMC Usual Care for GSW Victims

All HMC patients treated for a GSW will receive care as usual by HMC physicians and staff. For patients treated for a GSW, usual care can include the following:

- ☐ All necessary medical care and scheduled follow-up with subspecialty services
- ☐ Evaluation by Social Work during the ED or inpatient stay: Social Work staff will specifically assist with communicating with family as needed, including contact with the police if the patient desires, evaluation eligibility for the crime victims' compensation fund, referral to the Harborview Center for Sexual Assault and Traumatic Stress, and safety planning when a concern for continued violence is present.

- ☐ Screening for alcohol use: Patients who screen positive for alcohol use at the time of presentation to the HMC ED are eligible to be seen by the HMC Addiction Intervention Service. This service provides brief intervention using MI techniques that targets alcohol use. While all patients with an elevated blood alcohol levels are eligible to be contacted by the Addiction Intervention Service staff, not all patients actually receive this service.
- ☐ Discharge planning services: HMC staff will help patients with specific needs with medical devices (e.g., wheelchair, walker) or coordination of any needed home health services.
- ☐ Financial counseling services to patients, including those without insurance: Patients can access this service during their ED or hospital stay or within 14 days of their healthcare visit. Financial counseling will assist patients with applying for charity care for medically necessary services and assist with questions regarding insurance coverage. Eligibility for charity care is based on published poverty guidelines.

Trial Profile

Figure 1 illustrates participant flow through the program.

Recruitment, Disclosure of Assignment, and Consent

Potential participants will be identified electronically using the Emergency Department Board by the study research assistants (RAs) who will regularly monitor this system on a daily basis. The study RAs will not conduct any pre-screening beyond initial medical record review. We have prepared requests for HIPAA and consent waivers as well as the University of Washington Confidentiality Agreement to allow for pre-screening of patients. For recruitment purposes, the study RAs will collect patient names and other identifying information. When the study RA identifies a potentially eligible patient, she will approach the patient using an institutional review board (IRB)-approved recruitment script to determine eligibility. For patients who are hospitalized at the initial incident, the study RA will approach the patient during the hospitalization once they are stable. For patients who are treated in the emergency department and do not get admitted (i.e., discharged from the ED), the study RA will approach the patient during the ED visit or during a scheduled follow-up visit at HMC depending on the nature and location of the GSW.

The informed consent discussion will include explanations of the study's purpose, the two assignments, study procedures, all risks and benefits associated with participation as well as confidentiality procedures. The study RA will:

- ☐ Ensure that no members of the patient's healthcare team are present during the consent process.
- ☐ Present the study to the patient and conduct an informed consent conference if the patient is interested in participation.
- ☐ Emphasize that the decision to participate is voluntary and will not affect medical care at HMC.
- ☐ Prompt patients to ask questions.
- ☐ Reiterate the participant's right to refuse participation and then ask whether the patient is willing to participate at the conclusion of the informed consent process.

There will be two different consent forms, one for each study group. Following consent, the baseline survey will be completed by the patient or RA using a tablet device. For patients assigned to the usual care group, the study RA will ensure that we will have follow-up contact

information and inform the patient that they will be contacted to conduct the next follow-up assessment at month 1. For patients in the intervention group, the study RA will contact the study Support Specialist.

Assignment

Patients will receive one of the two assignments:

- ☐ Intervention: Receives a brief intervention at the start of the study followed by six months of study case management and outreach services. A multidisciplinary team of technical consultants will review cases in this group and help the study Support Specialist provide appropriate care and referrals.
- ☐ Control: Receives usual care, including any outreach services offered by or recommended at HMC.

During intervention weeks, the study RA will contact the study Support Specialist in advance of approach so that the study Support Specialist can meet the patient in the private room. The study Support Specialist will initiate the intervention at that time.

Intervention

The intervention program contains three elements: (1) Initial contact and brief intervention by the study Support Specialist; (2) Extended outreach by the study Support Specialist; and (3) Multi-agency attention.

Brief Intervention

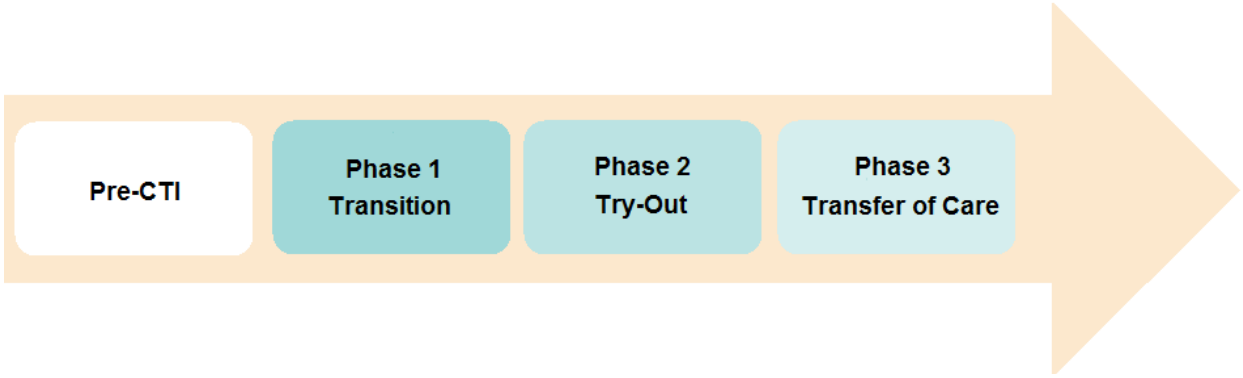
The brief intervention includes a feedback session utilizing principles of MI to elicit the goals and needs of patients. The main aim of MI in this study is to motivate the patient to be linked to the extended outreach case management. If needed, the study Support Specialist will provide a referral to community resources.

Extended Community Outreach

CTI's approach is to: (1) strengthen the individual's long-term ties to services, family, and friends; and (2) provide emotional and practical support during the critical time of transition back to the community. The six-month intervention is delivered to each participant by a single Support Specialist trained in CTI. Core components of CTI are as the following:

- ☐ Addresses a period of transition
- ☐ Time-limited
- ☐ Phased approach
- ☐ Focused
- ☐ Decreasing intensity over time
- ☐ Community-based
- ☐ No early discharge
- ☐ Small caseloads
- ☐ Harm reduction approach
- ☐ Weekly team supervision
- ☐ Regular full caseload review

Phases of CTI are as the following:



- ☐ Pre-CTI: Develop a trusting relationship with patient. Because of the brief time window of the intervention, Pre-CTI discussions must take place within 4 weeks of enrollment. Ideally the Pre-CTI discussion should take place in the hospital or emergency department, but may take place in the community briefly after discharge. Patients who do not have the Pre-CTI discussion in this time period may continue with other study procedures but will not continue with the intervention or meet with the support specialist.
- ☐ Phase 1 [Transition]: In Phase 1, the Support Specialist gets to know the patient, assesses the patient's needs, sets goals, and implements a transition plan intended to link the patient to services and supports in the community. Phase 1 should begin within 6 weeks of the Pre-CTI discussion. The plan typically includes home visits and other meetings with the patient, the patient's caregivers, and community service providers, designed to teach crisis-resolution skills, provide support and advice, and mediate any conflicts. The overarching goal is to connect the patient to people and agencies that will assume the primary role of support. Main components of this phase include:

    - ☐ Make home visits
    - ☐ Engage in collaborative assessments
    - ☐ Meet with existing supports
    - ☐ Introduce client to new supports
    - ☐ Give support and advice to patient and caregivers

- ☐ Phase 2 [Try-Out]: In Phase 2, the Support Specialist monitors and adjusts the systems of support that were developed during Phase 1. This phase involves fewer meetings with the patient, as the Support Specialist encourages the patient to problem-solve with the help of community resources and family members, and intervenes only if the patient is receiving inadequate support or if a crisis occurs. The overarching goal is to monitor and strengthen support network and patient's skills. Main components of this phase include:

    - ☐ Observe operation of support network
    - ☐ Mediate conflicts between patient and caregivers
    - ☐ Help modify network as necessary
    - ☐ Encourage patient to take more responsibility

- ☐ Phase 3 [Transfer of Care]: In Phase 3, the Support Specialist helps the patient develop and implement a plan to achieve long-term goals (e.g., employment, family reunification) and finalizes the transfer of responsibilities to caregivers and community providers. The CTI Support Specialist typically works with 10-15 patients at a time. The overarching goal is to terminate CTI services with support network safely in place. Main components of this phase include:

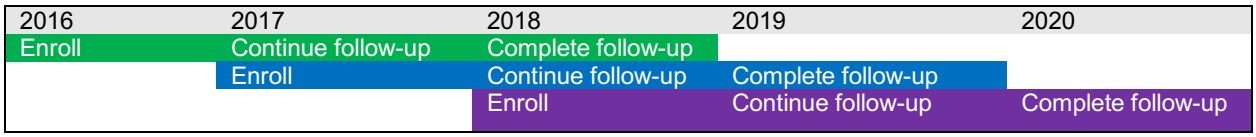
- ☐ Step back to ensure that supports can function independently
- ☐ Develop and begin to set in motion plan for long-term goals
- ☐ Hold meeting with patient and supports to mark final transfer of care
- ☐ Meet with patient for last time to review progress made

Multi-Agency Attention

The study Support Specialist will hold regular meetings with a multidisciplinary team (MDT) to seek advice about case management and service recommendations for each individual patient. It is vital for social service agencies and community-based organizations to be represented on this team. Of necessity, members of the MDT will know the identity of the individuals discussed in meetings. We do not consider MDT members to be engaged in research. They are technical consultants for the study Support Specialist. The MDT will include members from community mental health, substance abuse treatment, housing services, employment and adult education services, legal services, and law enforcement.

Baseline and Follow-Up Assessments

We plan to follow up patients for 2 years since enrollment. All participants will engage in research activities for 1 year following enrollment. The second year of follow-up will be entirely based on ascertaining outcomes in administrative databases with no patient contact as shown in the following figure:



Participants will complete surveys about their health and other outcomes at baseline, 1-month, 3-month, 6-month, 9-month, and 12-month assessments. At baseline, computer-assisted interviewing will be used to minimize skip pattern inaccuracies, missing data, ascertainment errors, and costs associated with conducting quality control and data entry on hard copy questionnaires. During the interview, the RA will read the questions to the participant and record the response using a tablet computer. For questions of sensitive nature (e.g., crime), the RA will turn the tablet to the participant so they can read the questions to themselves and key in the numeric value associated with their response choices. In addition, if a patient is unable to complete the survey electronically, the RA will read items and record responses. At follow-up assessments, the RA will send participants an email and a text with a link to the survey. Study staff will build the survey using a secure web application. If a participant cannot complete the survey electronically or does not complete the survey in one week, the study RA will call the participant to complete the survey over the phone. If the RA cannot reach the participant, she will call the alternate contact(s) listed by the participant.

A consented subject may become incarcerated at some point during participation making them an incidental prisoner subject. We will send follow-up surveys to all participants, even if they are incarcerated, with the understanding that email may be blocked during this time. A participant in the intervention group could become an incidental prisoner while receiving study case management services. If this occurs, study case management services will stop while the participant is in prison. The study Support Specialist will not make contact with the participant while incarcerated. Because participants in the intervention group are eligible for case

management services for six months, they could return to study case management if the incidental prisoner is released from prison during that six-month window.

Subjects will receive compensation for the completion of surveys. Participants can earn up to $225 if they complete all surveys. Survey time points and payment amounts are as follows:

- ☐ Month 0 baseline survey: $25
- ☐ Month 1 follow-up survey: $30
- ☐ Month 3 follow-up survey: $35
- ☐ Month 6 follow-up survey: $40
- ☐ Month 9 follow-up survey: $45
- ☐ Month 12 follow-up survey: $50

Measures

Process Measures

The following checklists will be used to gauge Reach, Dose, Adherence, and Responsiveness:

- ☐ Proportion of patients consented among those approached
- ☐ Proportion of patients in the intervention group who completed the MI and case management
- ☐ Number of contacts and sessions spent with the study Support Specialist among patients in the intervention group linked to the study Support Specialist
- ☐ Proportion of patients in the intervention group for whom the MDT discussed the case management approach
- ☐ Proportion of patients in both intervention and control groups retained in the study by time
- ☐ Adherence score using a pre-tested checklist to document whether Support Specialist is adhering to the principles of case management and study protocol
- ☐ Happiness Scale to document participant's satisfaction (see "Surveys")

Outcome Measures

Outcome measures will be collected using two different, but complementary, sources: (1) Administrative databases; and (2) Surveys.

Administrative Databases

A number of outcomes can be measured using routinely collected data. These will include:

- ☐ Washington State Administrative Office of the Courts records to identify cases of arrest and conviction
- ☐ Washington State Comprehensive Hospital Abstract Reporting System to identify hospitalizations
- ☐ Washington State Emergency Department Information Exchange to identify ED visits
- ☐ Vital records to identify cases of death

Surveys

All surveys across the assessment points contain the same scales and items. A list of those scales and items is provided below:

- ☐ Patient Health Questionnaire (PHQ-8) to measure depression
- ☐ Short Form Health Survey (SF-12) to measure health-related quality of life
- ☐ Posttraumatic Stress Disorder (PTSD) Checklist – Civilian Version (PCL-C) to measure PTSD
- ☐ The Alcohol Use Identification Test (AUDIT) to measure alcohol use
- ☐ The National Institute on Drug Abuse-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) to measure substance use
- ☐ Impulsive-Premeditated Aggression Scale (IPAS) to measure impulsive and premeditated aggressive behavior
- ☐ Conflicts Tactics Scale (CTS) to measure interpersonal violence
- ☐ Happiness Scale to measure satisfaction with specific areas of life
- ☐ Service utilization questions to measure use of physical and mental health services
- ☐ Self-Reported Delinquency (SRD) items of the Pittsburg Youth Study to measure criminal justice involvement, violence, criminal outcomes, conviction(s), and incarceration(s)
- ☐ Multidimensional Scale of Perceived Social Support (MSPSS) to measure perceived social support
- ☐ Education questions to measure educational attainment and activities
- ☐ Employment questions to measure employment status
- ☐ Housing questions to measure type of housing
- ☐ Contact information questions to increase the likelihood of reaching the subject during the follow-up
- ☐ CTI Satisfaction (3-month and 6-month interview only)

Data Management

We will use REDCap (http://project-redcap.org), a web-based data management system to input all data for the study, including each contact, intake, follow-up surveys and all chart data abstraction. It will be housed in the Virtual Private Network of the University of Washington. REDCap is highly secure with user-based access privileges. As part of the study-specific project development in REDCap, variable and value labels will be created, and aggregate scales for each instrument will be computed. The RAs will examine logical inconsistencies, correct out-of-range values, and investigate missing values. The RAs will also complete a historical narrative, detailing important events that could have affected the quality of data generated. A codebook and data dictionary will be developed including information on variable and field names, labels, values, and types. Surveys will be fully annotated to include variable and field names.

Statistical Power and Analysis

HiFi is powered based on the primary outcome of criminal arrest. Based on our previous investigations, we expect the rate of arrest after hospital discharge among GSW victims in Washington State to be about 15,528 cases per 100,000 person-years.[1,36] This translates to a 2-year cumulative incidence (i.e., proportion) of arrest at approximately $1 - \exp(-15{,}528 \times 2 / 100{,}000) = 26\%$. Assumptions for power calculations include:

- ☐ Significance level: 0.05
- ☐ Power: 80%
- ☐ Intervention-to-control ratio: 1

- ☐ Number of clusters (i.e., weeks) per year: 52
- ☐ Number of enrolled patients per cluster: 2
- ☐ Correlation between history of arrest (measured at baseline) and subsequent arrest: 0.70
- ☐ Intraclass correlation coefficient (for cluster effect): 0.10

A history of arrest is one of the strongest predictors of subsequent arrest; our previous investigations have documented relative risks of about 20 for the association between those two measures. As such, adding the history of arrest at baseline to the regression models will have the potential to notably enhance power. We will have access to the history of arrest at enrollment for all patients using both administrative databases and self-report. Based on the specifications listed above, and using 3 years of enrollment (total n = 304) and up to 2 years of follow-up, we will be able to identify a minimum detectable relative risk reduction of 29% for the primary outcome of arrest. An intervention among GSW victims that cuts the risk of arrest after hospital discharge by this extent would be of considerable interest to policy makers.

All analyses will be in accord with the intent-to-treat principle. Subjects enrolled and assigned to the intervention group who are unable or unwilling to make initial contact with the Support Specialist will still be included in intervention group. The cumulative incidence of arrest (i.e., proportion of individuals arrested) after hospital discharge over the follow-up period will be calculated in each study group. The unadjusted risk ratio will be calculated, comparing the proportion of individuals arrested in the intervention group relative to that in the control group. For example, if 15% of individuals in the intervention group, and 25% of those in the control group, are arrested over the follow-up period, the risk ratio will be 0.15/0.25 = 0.60, translating to an unadjusted intervention effect of 40%.

The intervention effect will then be examined using log-binomial regression models that will include specific covariates as described below. The exponentiated coefficient for the treatment group variable (i.e., a binary indicator of intervention or control group) in these regression models will provide the adjusted risk ratio. In these regression models, in addition to the treatment group variable, we will include a covariate capturing the baseline (i.e., pre-intervention) history of arrest to improve statistical precision. A priori, we also plan to include covariates pertaining to three demographic characteristics with strong bearing on the likelihood of outcome occurrence, namely age, sex, and race, in these models. A randomization scheme that is not on the individual level may result in imbalances in characteristics of individuals between the study groups. As such, we will carefully inspect all other individual-level characteristics and compare them between the two study groups; analyses will be further adjusted for any potential imbalances detected at baseline that exceeds a standardized difference of greater than 0.10 to minimize the likelihood of residual confounding. The interpretation of findings will be based on the results of these fully adjusted models.

Since the unit of randomization is calendar week, we will correct for any clustering by it using the cluster-robust standard error estimates. This will allow for within-week correlation, relaxing the requirement that the observations be independent. That is, the observations are independent between weeks, but not within weeks. In a secondary analysis of arrest, we will conduct survival analysis to examine time to arrest. Proportional hazards regression models will be used to provide hazard ratios estimating the effect of the program on time to arrest.

The secondary outcomes include a mixture of binary (e.g., hospitalization) and continuous (e.g., depression score) measures. For the binary outcomes, we will use the same analytic approaches described above to compare the proportion of individuals with that outcome between the two study groups. For example, we will examine what proportion of individuals in

each arm are hospitalized over the follow-up period after their index hospital discharge. For the continuous outcomes measured on the surveys, we will use mixed effects models to take the longitudinal nature of data (baseline, 6 month, 12 month) within the same individual into account. For example, for the depression scale, mean scores at baseline and at each follow-up visit will be reported separately for the intervention and control groups. Then, to examine the difference in the trajectory of change in scores over time between the intervention and control groups, linear mixed effect models including an interaction term between time and treatment group will be used. The coefficient for this interaction term will provide an estimate of the effectiveness of the intervention on these continuous outcomes.

We do not expect much of missing data either at baseline or during the follow-up pertaining to administrative data. However, missing data for the survey items during the follow-up is inevitable. Both baseline and post-randomization missing data will be handled using multivariate imputation by chained equations. We will strive for sufficient enrollment, low attrition, close adherence to random assignment, accurate outcome measurement, and proper statistical analyses throughout the course of the project.

Weekly Team Meetings

The study team will convene two separate 1-hour weekly meetings in which the study staff will be present in person or via phone. Logistical issues, recruitment numbers, and updates to the research protocol will be discussed as needed. Successes and challenges will be reviewed and plans for the subsequent week will be finalized.

Advisory Board

Advisory Board will meet four times per year and are contacted on an ad-hoc basis as needed. The Advisory Board is essential for providing feedback and translating the knowledge required in this project. They will provide meaningful insight into the challenges the team may be encountering. At the end of the trial, results will be presented to the Advisory Board members who will in turn be actively involved in the interpretation and dissemination of those findings. The Advisory Board members will include experts in Social Work, Criminology, Trauma Surgery, and Emergency Medicine, as well as an individual with experience in implementing community-based violence prevention programs and a member of the community with a history of firearm violence and injury.

Timeline

The study duration will be 5 years from inception to completion as outlined below.

Year	2016				2017				2018				2019				2020			
Training study staff and start-up																				
Enrollment																				
Data collection																				
Data management																				
Data analysis																				
Publications and presentations																				

Protection of Human Subjects

Risks to Human Subjects

Psychological Risks

Participants may face psychological risks in participating in the study. All participants might feel stress or psychological discomfort while filling out assessments about their mental health, physical health, relationships, history of violence, and criminal activities. Participants in the intervention group may feel some stress or discomfort during interventions aimed at reducing high-risk behaviors.

Confidentiality Risks

All participants face confidentiality risks. Participants' privacy may be violated if their data are not kept confidential. Participants in the intervention group face a greater confidentiality risk, as their cases will be the subject of MDT review.

Vulnerable Populations

Some of the subjects may become incidental prisoners during the study. Participants in the intervention group may become incidental prisoners during the six-month intervention period. Also, any participant may become an incidental prisoner during follow-up surveys.

Adequacy of Protection Against Risks

Psychological Risks

The research staff (RA and Support Specialist) engaging with subjects will be trained to work with this high-risk population. They will explain the purpose of the research and will assure participants that their answers are confidential. The research staff will work to reduce any stress or psychological discomfort during assessment or outreach, and remind subjects to report any discomfort or stress. The research staff will also fully inform participants that they have the right to skips questions or activities or withdraw from the study at any time. During assessments, the study RAs may discover a subject's intentions to harm themselves or other. In that case, they will follow the Crisis Intervention Protocol.

Confidentiality Risks

Research staff will take all necessary precautions to prevent the loss of confidentiality. The research staff will keep all data in secure databases on password-protected networks. Study staff will assign study codes to participants and will record all assessment data using those study codes. The document linking participant name and study code will be password protected, and the document will be stored on a secure, password-protected computer. Assessment data will be stored in password-protected network. All paper-based data (e.g., consent forms) will be stored in a locked file cabinet. We will retain a link between study code numbers and direct identifiers after the data collection is complete, and destroy it on 1/1/2020. Members of the MDT will sign a Confidentiality Agreement to ensure that none of the shared data in the meetings are repeated or disclosed in public. The study RA will notify potential participants about information sharing with the MDT during the consent conference. We will ask patients to sign a HIPAA authorization to release medical records for the period of their study participation. This authorization is separate from the HIPAA waiver request for pre-screening.

Vulnerable Populations

We will not engage any individuals in the study procedures while they are incarcerated.

Potential Benefits of the Proposed Research to Human Subjects and Others

Participants in the intervention group will receive a brief intervention and extended case management services to reduce individual high-risk behaviors. These participants will also be referred to community agencies who can help address specific areas of need. Participants in the control group may not directly benefit from participating in the study other than monetary compensation for their participation; however, the enforcement of usual care as described above may be considered a potential benefit.

Importance of the Knowledge Gained

Gun violence affects society in many ways, including heavy medical costs, reductions in quality of life, and stresses on the criminal justice system. Gun violence prevention and intervention programs hold the potential to drastically reduce recurrent injury, readmission, retaliation and recidivism. While many hospitals have adopted violence intervention programs, few have rigorously evaluated program effectiveness. Our study has great potential to meaningfully contribute to the field of gun violence prevention.

Conflict of Interest

None

Dissemination

Upon completion of the intervention program, we will provide a report for stakeholders and prepare presentations and publications for scientific conferences and journals to disseminate the knowledge gained. The results of this trial, if proven effective, will be used to advocate for policy change within healthcare settings; the investigator team will promote the rapid translation of findings into practice. Findings will be immediately shared with member programs of the National Network of Hospital-Based Violence Intervention Programs so the evidence can be used to advocate for sustained funding for such efforts. If this intervention is successful in decreasing the risk of subsequent trauma-related morbidity, its implementation at trauma hospitals serving populations with high rates of violent trauma will be supported. If unsuccessful at reducing the risk of subsequent trauma-related morbidity, alternative models of intervention need to be investigated.

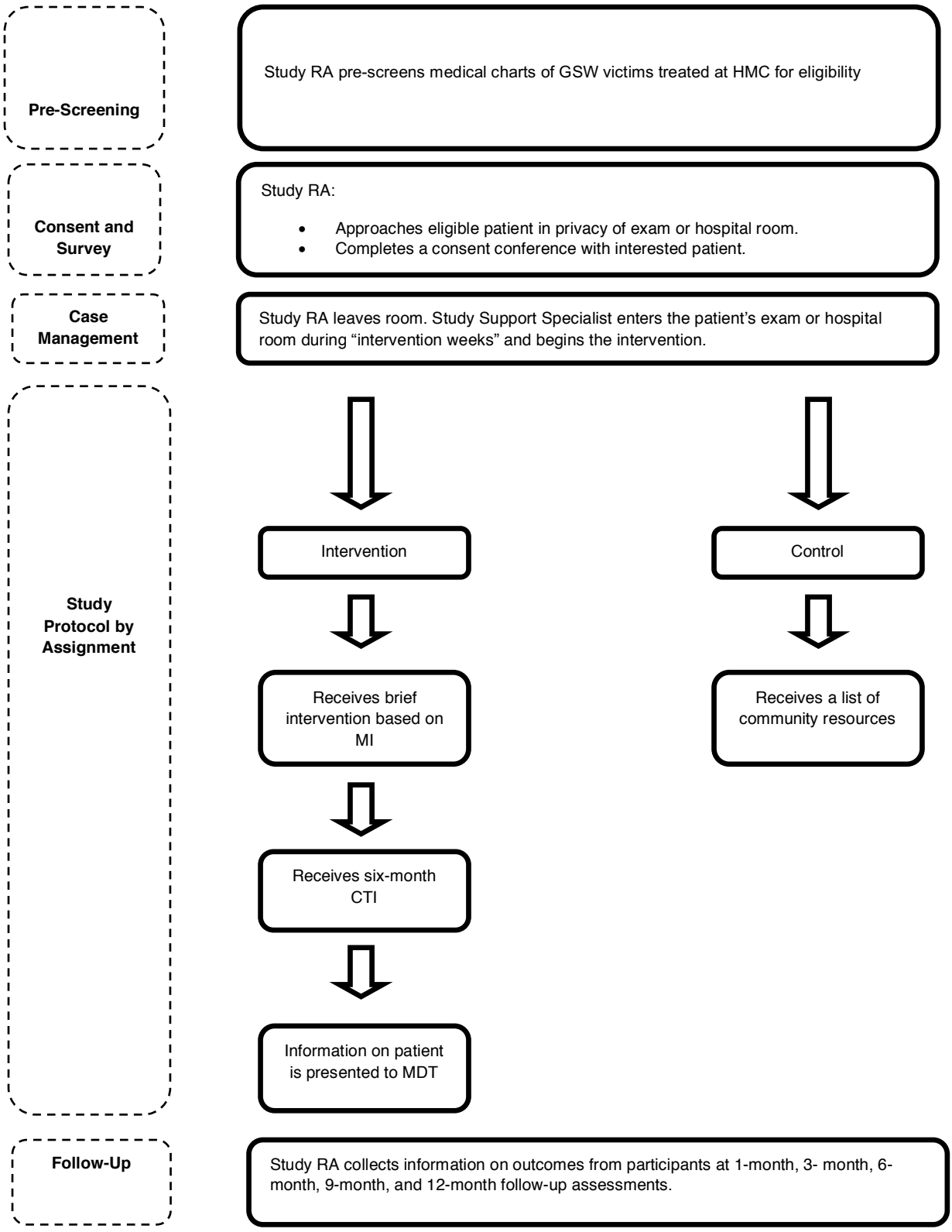


Figure 1. Trial profile. HMC: Harborview Medical Center; RA: Research Assistant; CTI: Critical Time Intervention; MDT: Multidisciplinary Team; MI: Motivational Interview

Appendix A

Patient Identification, Approach and Engagement Protocol

Step 1: Check the board for GSW patients

- ☐ SW note will have most information

Step 2: Eligibility screen via EMR (HiFi Patient Screening Survey)

- ☐ 18 years or older, not in jail, English speaking, live in King or Pierce County, neurological or cognitive impairment
    - ☐ Language can be wrong in EMR, so talk to staff or verify at approach
- ☐ Complete screener for all GSW
    - ☐ If missed, uninterested or ineligible, retain all information **except**:
        - ☐ Patient name
        - ☐ Patient H #
        - ☐ Patient location in hospital
        - ☐ Admit date
            - ☐ Keep MONTH (separate variable)
        - ☐ Discharge date
            - ☐ Keep LENGTH OF STAY (separate variable)
        - ☐ DOB
            - ☐ Keep AGE (separate variable)
- ☐ Review to see if patient has been enrolled in any other study
- ☐ Patient appears eligible per medical record review and there is no research conflict
    - ☐ Proceed to next step

Step 3: Mental status and medical acuity assessment - Pre-Approach (HiFi Patient Screening Survey)

- ☐ Intubated OR active resuscitation OR going directly to operating room
    - ☐ Notify other RA
    - ☐ Put patient on approach list in OneDrive for monitoring and leave notes for other RA
    - ☐ Continue to reassess daily - Nurse notes will have most detail
        - ☐ Check EMR - review daily surgery notes
        - ☐ Talk to staff
- ☐ Determine if patient is able to understand the research approach
    - ☐ Reasons may not understand: Intoxication, previous history of TBI, psych co-morbidity
    - ☐ Contact medical team (inpatient) or charge nurse (ED) to:
        - ☐ Introduce self and mention study clinician
        - ☐ Discuss the case
        - ☐ Determine timing of approach
- ☐ Normal mental status and not getting active medical resuscitation
    - ☐ If it is a good time to approach:
        - ☐ If an intervention week: Make a judgment call about notifying Support Specialist at this point
        - ☐ Proceed to next step

Step 4: Assemble documents needed for approach (Consent Form and HIPAA Authorization Form)

- ☐ Verify the randomization schedule on OneDrive
- ☐ Copies of stamped consent form stored at each RA desk and on OneDrive
- ☐ Select condition appropriate consent form: Intervention or Control
    - ☐ Bring two copies to the patient room:
        - ☐ One signed copy goes to patient
        - ☐ One signed copy is retained by study
- ☐ Bring two copies of HIPAA Authorization Form
    - ☐ One signed copy goes to patient
    - ☐ One signed copy is retained by study
- ☐ Bring a gift card of the appropriate value (kept by patient) AND gift card form (kept by study)
    - ☐ Mark down serial number (in OneDrive or on gift card form) **BEFORE** giving to patient
- ☐ Bring HiFi study envelop: Label with study name, study email, study cell (206-446-8914) and line to write down one month follow up date
    - ☐ Proceed to next step

Step 5: Approach patient and pitch study (5 mins)

- ☐ Tell nurse when going into room
- ☐ If patient is unable to talk to you but is willing to talk later:
    - ☐ Schedule next attempt
- ☐ If patient is willing to talk to you:
    - ☐ Proceed to next step

Step 6: Final screening questions (5 mins) (HiFi Patient Screening Survey)

- ☐ Interested? (**yes**) Live in King,Pierce, Snohomish, Thurston or Yakima Counties? (**yes**) Plans to live in King, Pierce, Snohomish, Thurston or Yakima Counties for 6 months? (**yes**) Able to provide contact? (**yes**) Going to jail? (**no**) In jail when shot? (**no**)
    - ☐ If Ineligible:
        - ☐ End interview and document (Step 9)
    - ☐ If eligible:
        - ☐ Proceed to next step

Step 7: Consent (10 mins)

- ☐ If patient does not agree to participate:
    - ☐ End interview and document (Step 9)
- ☐ If patient agrees to participate:
    - ☐ Have patient sign both copies of the consent form and HIPAA Authorization Form
    - ☐ Proceed to the next step

Step 8: Baseline Survey (30 mins) (Baseline Survey)

- ☐ If it's an intervention week AND the support specialist is working
    - ☐ Notify support specialist that that patient is eligible and that baseline is beginning

- ☐ Reminder: Be explicit with patient about why you would step out to make a call, if you make a call to Support Specialist now. "*Why: I want to get you connected as soon as possible with our support specialist, so I am going to call her to tell her you have enrolled."*
- ☐ RA completes the survey **except:**
  - ☐ If a patient would like to complete himself/herself
  - ☐ For substance Abuse and Criminal Activity questions
    - ☐ Give a prelude to these questions to neutralize and normalize them. "*We are asking every patient these private and personal questions. I will be here to answer any questions you may have."*

Step 9: End Survey

- ☐ Provide gift card and have patient sign gift card form
- ☐ Put gift card, one signed copy of HIPAA Authorization, one signed copy of consent form into study envelope
  - ☐ Mark date of 1-month follow-up on the envelope
- ☐ Intervention Patient: Hand off to Support Specialist
  - ☐ In-person if support specialist is available:
    - ☐ Provide her with any important information
  - ☐ If support specialist is not available:
    - ☐ Contact Support Specialist to discuss options
    - ☐ Update REDCap

Step 10: Complete Screener Form (HiFi Patient Screening Survey)

- ☐ Document approach outcome in REDCap record
- ☐ If ineligible, remove identifiers (listed in Step 2) from REDCap record

Step 11: File Signed Forms in Safe, Locked Area

- ☐ File signed consent forms, HIPAA Authorization and Gift Form in locked cabinet
- ☐ If daytime and no other approaches, bring to locked drawer at HIPRC
- ☐ If nighttime, lock in HMC drawer

Step 12: OneDrive Documentation (HiFi Patient Tracking on OneDrive)

- ☐ Remove patient from Approach list one determination is made
- ☐ Record patient follow-up schedule
- ☐ Input gift card information

Step 13: Follow-up (Follow Up Survey)

- ☐ RAs will contact participants via phone, text or email to complete follow-up. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone or in-person. Follow-up assessments will be done at the following times:
  - ☐ 1 month (window opens 1 week before and closes 2 weeks after 1-month date)
  - ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
  - ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)

- ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
- ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

☐ Document each time an attempt is made to contact the participant, method of contact and the outcome of the attempt.

- ☐ If contacting by phone, RAs can leave up to 2 voice messages.
- ☐ RAs can also use text as a way to contact participant or remind participant of scheduled call/meeting.
- ☐ Document on subject payment spreadsheet every time gift card is given

Step 14: Study Close Out

Appendix B

In-Person Recruitment Script

Hi, my name is [RA Name], and I am from the Helping Individuals with Firearm Injuries Study. I am here to talk to you about our study because you might be eligible to participate in it. I would like to tell you about the study and find out if you eligible to participate. The conversation should take no more than 15 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

This study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview Medical Center. We are asking you to participate because you are being treated for a gunshot wound at Harborview Medical Center. You would participate in the study for one year.

- ☐ **Intervention Group**: As part of the study, you will get all the usual services offered by the Harborview staff. In addition, you will receive outreach services from a study Support Specialist. During your one-year participation, we will ask you to complete surveys.
- ☐ **Control Group**: As part of the study, you will get all the usual services offered by the Harborview staff. During your one-year participation, we will ask you to complete surveys.

To find out if you are eligible to participate in the study, I will ask you some questions. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.
Are you interested in finding out if you are eligible to participate in the study?

- ☐ **YES**
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King, Pierce, Snohomish, Thurston or Yakima Counties?

- ☐ **YES**
- ☐ NO

Do you plan to move from King, Pierce, Snohomish, Thurston or Yakima Counties in the next six months?

- ☐ YES
- ☐ **NO**
  - If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**

☐ NO

Are you going to jail when you leave the hospital? (only ask if not in chart)

☐ YES
☐ **NO**

Were you in jail at the time of your gunshot injury? (only ask if not in chart)

☐ YES
☐ **NO**

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

☐ **YES**
☐ NO

Patient is ineligible if any responses are plain text responses.

> SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patient is eligible if **ALL** responses are underlined and bolded responses.

> SAY: Based on your responses, you are eligible to participate in the Helping Individuals with Firearm Injuries study. If you are interested in participating in the study, I will review the study consent form with you. Are you interested in learning more about the study and participation?
>
> ☐ YES (review the consent form)
> ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix C

Phone Recruitment Script

Hi, my name is [RA name], and I am calling from Harborview Medical Center about a study that you might be eligible to participate in. Am I speaking to [patient name]? Before I tell you about the study, can you confirm your age and the date/day you visited Harborview Medical Center?

[Once confirms] Thank you for confirming that information. I work for a study entitled Helping Individuals with Firearm Injuries (HiFi). The study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview. You may be eligible to participate in the study because you were treated for a gunshot wound at Harborview. Study participation is one year. During that year, you will be asked to complete 6 surveys, and you will be paid for each survey you complete. If you complete all the surveys, you will receive $225. [Read Intervention Group description below if patient is assigned to that group]

- ☐ **Intervention Group**: As part of the intervention group, you will receive outreach services from a study Support Specialist who can help you navigate your recovery. You determine what you want to work on with the Support Specialist. For example, you could set goals with her around employment, appointment management, housing, accessing mental health services, etc. She can help you connect with appropriate resources and will help you create a plan to reach your goals. The Support Specialist will work with you for 6 months.

Today's conversation will determine if you are eligible to participate. The call should take no more than 5 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

I will ask you three questions that will help me determine if you are eligible for the study. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.

Are you interested in finding out if you are eligible to participate in the study?

- ☐ YES
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King, Pierce, Snohomish, Thurston or Yakima Counties?

- ☐ **YES**
- ☐ NO

Do you plan to move from King, Pierce, Snohomish, Thurston or Yakima Counties in the next six months?

- ☐ YES
- ☐ **NO**

- ☐ If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**
- ☐ NO

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

- ☐ **YES**
- ☐ NO

Patients are ineligible if any responses are plain text responses.

SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patients are eligible if **ALL** responses are underlined and bolded responses.

SAY: Based on your responses, you are eligible to participate in the HiFi study. The next step in the process is to enroll you in the study. That process involves meeting in-person to review a consent form with a study Research Assistant. We can meet at a convenient time and location for you. The consent form review will take about 5-10 minutes. If you agree to participate upon review, we will ask you to complete a survey. The survey takes about 30 minutes to complete. So in total, the meeting would last about 45 mins. Are you interested in scheduling an in-person meeting?

- ☐ YES (Schedule an appointment with patient. If there is a follow-up appointment scheduled, ask if that is an appropriate time/location to meet. If no follow-up appointment scheduled, ask if patient is willing to come back to HMC. If not, ask for a convenient, public place to meet)
- ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix D

Voicemail and Text Recruitment Script

Hi, my name is [RA name]. I am calling from Harborview Medical Center. I am trying to reach [patient name.] [Patient name] may be eligible to participate in a study where s/he can earn up to $225 by completing surveys. Please call me back at 206-446-8914 at your earliest convenience.

Appendix E

Phone Follow-Up Script

Hi, my name is [RA name] from the Helping Individuals with Firearm Injuries study. I spoke to you at Harborview Medical Center on [Date] when you completed the baseline survey for the study. I am contacting you today to remind you the [Number]-month follow up appointment is coming up with a [Dollar amount] gift card for completing it. There are a couple different ways we can take care of this. The survey can be completed online, over the phone, or in person. Please contact me with your preferred method when you get the chance. You can either call or text (206) 446-8914; again the number is (206) 446-8914. We very much appreciate your time and participation; the information we gather for this study will go towards better helping patients in the future. Have a great day and I look forward to hearing from you.

Appendix F

Overall Recruitment and Enrollment Flow

Recruitment Flow

- ☐ Patient presents to HMC with GSW
  - ☐ Ineligible
  - ☐ Dies
  - ☐ Eligible
    - ☐ ED or Inpatient
      - ☐ RA approach while at HMC
    - ☐ Discharged before RA contact
      - ☐ Phone call to determine eligibility and schedule in-person enrollment meeting
      - ☐ Phone call schedule: 2 weeks of attempted contact with patient
        - ☐ Begin calling as soon as possible – once you start, the 2-week timer begins
        - ☐ Allowed up to 10 calls
        - ☐ Allowed 2 voicemails – after 1st and 8th call
        - ☐ Allowed 1 text – at one-week mark
        - ☐ Must use IRB approved script for call, voicemail and text
        - ☐ After 2 weeks, patient becomes "Unable to Contact"

Enrollment Flow

- ☐ Patient is eligible and interested in participation
- ☐ Sign Consent Form
- ☐ Sign HIPAA form
- ☐ Complete baseline survey
  - ☐ If baseline is not completed, complete as soon as possible
    - ☐ If completed after the 1-month survey window opening, RA to explain situation and ask patient to schedule two appointments to complete the two surveys
    - ☐ Window to complete baseline is 6 weeks after enrollment date
      - ☐ After this point, mark as "Missed"
- ☐ Provide Gift Card
- ☐ Sign Gift Card form
- ☐ For Intervention Patients:
  - ☐ Notify Support Specialist
  - ☐ Introduce her to patient
  - ☐ Tell patient Support Specialist will contact him/her

Appendix G

Follow-Up Timeline and Procedures

RAs will contact participants via phone, text, or email to complete follow-up surveys. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone, or in-person. Preferred completion mode is online or by phone. Follow-up assessments will be done at the following times:

- ☐ 1 month (window opens 1 week before and closes 3 weeks after 1-month date)
- ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
- ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)
- ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
- ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

If the participant has an email, automate REDCap notifications.

If the participant does not have an email or has been unresponsive to automated email prompts for 1 week, then contact participant by phone using the number provided at baseline or most recent survey.

- ☐ Please use study cell phone.
- ☐ You can leave up to two messages.

If participant does not respond to phone calls, call the alternative contacts provided at baseline or at most recent survey.

- ☐ At all other follow-up time points, try alternative contacts after 2 weeks of direct contact attempts with participant.
- ☐ You can leave one voicemail.
    - ☐ Do not leave any details about the study or mention the study.

If you are unable to make contact with the participants, check jail database.

- ☐ If patient is in jail, do not contact and mark that the patient is in jail on the follow-up survey.
- ☐ If you are unable to make contact with participants or alternative contacts and patient is not in the jail database, then mail a copy of the survey to the participant at the address provided at baseline or the most recent survey.
    - ☐ Include a self-addressed, stamped envelope in the mailing.

Contacting Patient by Phone

Always use the study cell phone to contact participants. The purpose of the phone call at follow-up is to:

- ☐ Remind participants about the follow-up survey and their completion options.
- ☐ Remind participants about the incentives for their completion of the surveys.
- ☐ Remind participants that it will take about 30-45 minutes to complete the survey.
- ☐ Determine the mode by which the participant wants to complete the survey:
    - ☐ If online, confirm their email address and re-send link (if sent already).

- ☐ If by phone, ask if the participant would like to complete by phone now. If not, schedule a phone call within the next 1-4 days.
- ☐ If in-person, schedule a meeting within the next 1-4 days. Ask if they are willing to come to HMC. If not, select a meeting location that is public and during daytime hours.

☐ Let them know you will give them a reminder text or leave a reminder voicemail the day/night before the phone call or in-person meeting.
☐ Thank them for their participation.

Reaching the typical study participant will require multiple calls. To be effective, you will have to try reaching them at different times of the day and different days of the week. Some people may be very easy to reach, while it may take up to 10 or more contact attempts before you are able to speak with a person. Expect and plan for multiple contact attempts, and expect to encounter some typical barriers in this process. Study participants typically have two mechanisms to help protect them from taking unwanted calls: (1) voice mail/answering machines; and (2) caller ID.

Voice Mail/Answering Machines

Many study participants use answering machines to screen their calls. To help counter this, leave a message on the machine to let them know you have called and leave the study cell phone number. The IRB has approved us to leave up to 2 voice messages. There are a few basic things to keep in mind when dealing with voice mail or answering machines:

☐ Don't leave more than 2 messages. You can make more than 2 contact attempts, but messages should be left strategically and only twice.
☐ Don't wait too long after you leave a message to call them back (1 or 2 days at most).
☐ Your message should be brief, friendly, and to-the-point. Please follow the script. Speak slowly – especially when leaving a phone number. Provide the study cell phone number in every voicemail.

Caller ID

Many study participants may have Caller ID available to them on their telephone service. This means that every time you call, your telephone number will appear and be logged into their Caller ID box. Keep this in mind when you make your calls for the day, and be careful not to call too often. They may perceive you as "harassing" them before you even make the first contact. Take careful call notes to keep track when each time a message was left and what was said in the message (e.g., "msg. left with name and #, will call back Tues. pm"). The following are several ways to address the Caller ID issue. No matter how you choose to handle this situation with a patient, keep in mind that it should facilitate interaction about survey completion.

☐ Typically, you will limit your telephone attempts to only one attempt in any day.
☐ You may have a "Line Block" placed on the telephone line that you are calling from, so that any time you call, "Anonymous" (and not your phone number) will appear on the other party's Caller ID box. To remove line block on any individual call, you can press *82 before you place the call. This will allow your name and number to be displayed to the Caller ID party on just that one call. This service is free of charge, but you must call your telephone provider to request that it be added to your line.
☐ "Per Call Blocking" allows you to block an individual call to a study participant by dialing *67 before dialing the number. When you block an individual call, "Anonymous" will be

displayed on the Caller ID party for just this one call. This service should already be available to you without you requesting to "activate" it.

Call or Meeting Reminders

Once an appointment is scheduled, you will want to do what you can ahead of time to minimize any "no-shows" or "broken appointments." The following are several ways to avoid the frustration of a "no-show" by taking these steps:

- ☐ Suggest that the study participant choose a time and place when there will be the least number of distractions and/or interruptions. HMC should be the first suggestion by RA, and if that is not possible, work with patient to identify a quiet and safe, preferably public, location.
- ☐ Set a definite time. Avoid using vague phrases like, "I'll see you around 4:00."
- ☐ In addition to having a definite time, you may want to re-state this appointment time before hanging up. "Okay, I have you down for Thursday, January 21st at 4:00 PM. Is that what you have?"
- ☐ Give a reminder call or text the day before, and depending on the participant, sometimes the day of, to confirm the appointment time. Flag your call-back time so that you are sure to follow-through and actually make the call.
- ☐ Leave contact numbers, and encourage the study participant to call you back if they need to reschedule the appointment.

Appendix H

Safety Protocols

Home or Community-Based Visits

Please do not conduct home or community visits in homes or neighborhoods in which you don't feel safe. The most important things are to use common sense, follow your gut instinct and always remember to put your own personal safety first. If you are ever in a situation where your safety feels compromised, please do whatever it takes to get out of the situation. Also, don't try to protect cash or equipment at the expense of your own safety.

Regardless of whether you are someone who is comfortable or uneasy about going to a stranger's home, you should always take precautions and make plans that will help ensure your personal safety. The more you know and are prepared for your surroundings, the more you will feel and behave more comfortably. It is helpful to visualize potential situations and plan in advance ways to maintain your safety under different circumstances.

Before calling or scheduling an appointment with a study participant, look at a map and make sure that you know something about the neighborhood. Public locations should be prioritized over private homes. Despite the perception of how "safe" a neighborhood is, you may always benefit from doing a little detective work, and learning a little about where you will be going. If you feel uncomfortable, come early and visit the neighborhood during the day. Drive around a bit and locate the nearest convenience or grocery store, fast food restaurants, a public library or gas stations (public restrooms).

Although it may be rare that you might encounter an unsafe situation or neighborhood, there will be times when you may feel uncomfortable going to a participant meeting. Take these general precautions to help you feel at ease and to guarantee your safety in a potentially dangerous situation:

Before you arrive at the meeting location:

- ☐ Where practical, research staff should travel in pairs. An ideal pairing is an RA with the Support Specialist for intervention sessions coupled with scheduled follow-up visits.
- ☐ RAs may not attend home visits alone.
- ☐ Let staff know where you are going and when to expect you back. Use Google Calendar or a shared Outlook calendar to document this.
- ☐ Know where you are going. Get directions, always have a map and plan out your route. Ask the study participant to tell you the best place to park, and which door to use.
- ☐ Call the study participant to let her know when to expect you.
- ☐ Schedule check-in times if you feel you are in a difficult place.
- ☐ Bring your charged cell phone.
- ☐ Always have sufficient gas in your car.
- ☐ Have a plan for if your car breaks down.
- ☐ Don't over-dress or carry expensive valuables. Look casual and not memorable.
- ☐ Don't leave expensive valuables in your car, especially in plain view. Lock in the trunk.

Once you are at the meeting location:

- ☐ Check it out, look around. Get a feel for what's going on around you.

- ☐ Look for a place to park that is well-lit and close to the participant's home (if applicable).
- ☐ Be aware of surroundings (including dogs).
- ☐ As much as possible, choose a clear, well-lit path to the house (if applicable).
- ☐ When walking down the street, look and walk purposefully and confidently.
- ☐ If you feel threatened by the setting, call on your cell phone (or drive to a payphone) and ask the study participant to meet you at the door.
- ☐ If you still feel unsafe, call the participant to reschedule or cancel. You may want to try to schedule a daytime appointment and/or a different location.

If you are in the home:

- ☐ Do not enter if you smell or see drugs.
- ☐ Always wear your name badge and identify yourself as soon as you arrive at the study participant's home.
- ☐ With the exception of a cell phone and iPad, never take anything into a home that you do not need for the meeting (no personal items, no extra cash, etc.)
- ☐ Ask who else is at the residence.
- ☐ Be aware of exits, and sit where you can exit easily.
- ☐ Use non-threatening body language. Remain calm and polite.
- ☐ If you feel uneasy in the study participant's home, try to suggest a location for your conversation where you would be able to leave quickly, without your path being blocked.
- ☐ Listen to your intuition/instinct. If you feel uncomfortable or have a bad feeling, cut the meeting short and politely take leave.
- ☐ If you become fearful about your safety inside the study participant's home, and feel unable to resolve it, end the conversation. You are in no way expected to stay in an unsafe situation in order to complete study activities.

If you still feel unsafe, here are some suggestions of how to end a home visit tactfully:

- ☐ Tell the study participant you are having technical difficulties and will need to reschedule the appointment.
- ☐ Tell the study participant you are not feeling well and would like to reschedule the appointment.
- ☐ Have someone call you on your cell phone 5-10 minutes after you are scheduled to arrive in case you need to use the call as an excuse to reschedule the appointment.

Please do not conduct meeting where you don't feel safe. If you still feel unsafe, consult with your supervisor about other options. Every precaution is taken to ensure your personal safety.

Report concerns to the Study Coordinator and PI upon your turn.

Appendix I

Crisis Management Protocol

Interpersonal-Harm Protocol for Crisis Intervention

- ☐ If one of the RAs discover that the patient is in imminent danger of harming another individual, they may directly ask: "Do you currently have plans to harm [Person A] or take their life?" If after asking this question, the study staff has any doubts about Person A's immediate safety, they will immediately leave the patient and call 9-1-1. The RA will then contact the Principal Investigator. To ensure the study staff's safety, the RA will not inform the patient of their plan to alert the authorities.

Suicidal ideation in patient during a hospital encounter

- ☐ If one of the Research Assistants (RAs) discovers suicidal ideation during a hospital encounter with the patient, they may directly ask:

    - Sometimes when people are [ ], and [ ], and [ ] they are thinking about suicide. Are you thinking about suicide? (Include signs or symptoms in place of blanks. For example: "Sometimes when people are feeling very anxious, hating their life, and feeling like a failure, they are thinking about suicide. Are you thinking about suicide?)

    - If after asking this question, the RA has any doubts about the patient's safety, they will first contact the patient's healthcare team immediately. Following that, the RA will notify the Support Specialist or one of the two Study Clinicians, as well as the Principal Investigator.

    - Fred Rivara (Study Clinician): 206-799-7961
    - Lauren Whiteside (Study Clinician): 773-807-8366
    - Liz Griffin (Support Specialist): 206-496-8215
    - Ali Rowhani-Rahbar (Principal Investigator): 650-213-6457

Suicidal ideation in patient during a follow-up non-hospital encounter

- ☐ If one of the RAs discovers suicidal ideation during a non-hospital encounter with the patient (i.e., during the follow-up assessment), they may directly ask:

    - Sometimes when people are [ ], and [ ], and [ ] they are thinking about suicide. Are you thinking about suicide? (Include signs or symptoms in place of blanks. For example: "Sometimes when people are feeling very anxious, hating their life, and feeling like a failure, they are thinking about suicide. Are you thinking about suicide?)

    - If after asking this question, the RA has any doubts about the patient's immediate safety, they will immediately call 9-1-1. Following that, they will notify the Support Specialist or one of the two Study Clinicians, who will speak with the patient if appropriate and possible. Finally, the RA will contact the Principal Investigator.

- ☐ If the patient would like to someone to further talk to:
    - Call National Suicide Prevention Lifeline at **1-800-273-8255** or give the subject the text Crisis Text Line to **741741**
- ☐ If the patient states that the index injury was intentional and self-inflicted during a follow-up survey, the RA will contact Designated Mental Health Professional/Crisis Team (See below) or the Support Specialist for further action.
- ☐ The RAs follow the steps from the LEARN protocol (see below) to know what to look for and what to do. DO NOT attempt to remove weapons from subjects.
- ☐ Symptoms of post-traumatic stress and trauma recovery may appear as signs of a person thinking about suicide. Stick with the delivery of the protocol and survey questions unless there is a clear indication from the subject that they may be thinking about suicide.

Tips for Talking with Youth, Adults, Friends, Family or Co-workers in Crisis

L.E.A.R.N.© intervention steps. Forefront: Innovations in Suicide Prevention (www.intheforefront.org), University of Washington

Don't assume a person is not at risk for suicide. Anyone can be…..but you can help. *Suicide IS preventable*.

1. **Look for Warning signs / ways the person is "inviting help"**: Examples: they are in pain, desperate, hopeless ("*it will never get better*"), helpless ("*there is nothing I can do*"); feeling trapped ("*there is no way out*"), like a burden, or that they try to fit in – but it never works. **Look for changes** such as isolating behavior, giving away possessions, losing interest in activities, using more alcohol or drugs, acting impulsively. Listen for threats such as: "*I won't be needing these anymore*", "*You'll miss me if I'm dead*", "*Everyone will be better off without me.*"

2. **Empathize** with them: If you think someone may be at risk for suicide, **talk to them about what is going on.** You don't have to be a therapist. **Make a connection**. **Listen… really listen**. Give full attention. Don't interrupt, minimize their situation or try to convince them everything will get better. Control your fears so you can focus on the other person. Examples of things you could say to start the conversation:

    a. "*How are things going?" "You seem upset; do you want to talk about it*?"
    b. "*I care about you. You are going through a lot. Let's talk.*"
    c. "*It sounds like you have so many problems and they feel impossible to deal with.*"
    d. "*You are in a lot of pain. I see it and I hear that you feel alone in this pain. I care. Please tell me more.*"

    Continue to **listen**, build rapport and trust. **Help them to feel understood. That is so key**. Say: "*That sounds like a very difficult situation.*" "*I would be upset about that too.*" Please understand, for some, suicide can feel like a logical way to escape pain. Don't judge, or tell them they have so much to live for or promise it will get better.

3. **ASK the person clearly, directly and compassionately about suicide**. "Are you thinking about suicide?" or "Are you thinking about ending your life?" or "When you say ___ do you mean you're thinking about killing yourself?"

    a. ***Asking the suicide question does not increase risk***. You won't cause someone to act on it by asking.
    b. Asking sincerely, compassionately and in context to what you have seen shows that someone cares.
    c. Sharing suicidal thoughts reduces feelings of isolation.
    d. Talking generally provides comfort and provides some relief.
    e. **If they say "yes" it is important to not panic**. Say: "*That took a lot of courage to tell me. Thank you.*" Demonstrate calm. Ask if they have plans (when, where, how) and means (have a gun, rope, pills etc.).

4. **Remove the danger**: In the ASK step you inquired about a suicide plan. If they have means/access to guns, ropes or excess medication. Now work with friends, family or law enforcement to secure or remove these items.

5. **Next level of care:** Let them know you are concerned and that you would like to help them. Ask if you can **help connect them with someone who has more expertise.** Say: "*Can I give you the name of a counselor who might be able to help*" or "*I'm willing to go with you to our local help center* [or school counselor etc.] or… "*Lets create a safety plan together about who you can call and what you can do if you feel at risk again in the future.*"

Free, 24/7, anonymous help is available by calling the **National Suicide Prevention Lifeline: 1-800-273-TALK (8255)**
Here in King County…. That number automatically routes you the the Crisis Clinic

In King County, **TeenLink** is a resource line for teens, staffed by trained teens. See: www.866teenlink.org or call 1-866-833-6546
MY3 is a great, free app (http://www.my3app.org/) available for iPhones or Android devices that helps create a safety plan.

If someone is in *immediate* risk for suicide, call 911…. Or take them to the nearest hospital *if it is safe for you to do so*.

Crisis Support by County

King County

Agency	Crisis and Commitment Services 401 Fifth Avenue Suite 400 Seattle, WA 98104
Contact	Diane Swanberg
Telephone	(206) 263-9202
Fax	(206) 205-5192
Crisis Line	M-F 8:30 am - 4:30 pm (206) 263-9200; After Hours (206) 461-3222; Business line-(206) 461-3210 ext 1

Pierce County

Agency	Good Samaritan Mobile Outreach Crisis Team (M.O.C.T.) 325 E. Pioneer Ave. Puyallup, WA 98374
Contact	Silvia Riley or Nate Hinrichs
Telephone	(800) 576-7764
Fax	(253) 301-5209
Crisis Line	(800) 576-7764

Snohomish County

Agency	Snohomish County Involuntary Treatment Program 3000 Rockefeller Avenue, Mail Stop 305 Everett, WA 98201
Contact	Carola Schmid or Anji Jorstad
Telephone	(425) 388-7214
Fax	(425) 388-7216
Crisis Line	(800) 584-3578 Public Line (425) 258-1352 Professional Line

Thurston-Mason County

Agency	Behavioral Health Resources Crisis Resolution Services 3436 Mary Elder Road NE Olympia, WA 98506
Contact	Tiffany Buchanan
Telephone	(360) 528-2590
Fax	(360) 528-2594
DMHP Fax	(360) 754-1194
Crisis Line	(360) 754-1338

Yakima County

Agency	Comprehensive Health Care 402 S. 4th Avenue, PO Box 959 Yakima, WA 98907
Contact	Courtney Hesla
Telephone	(509) 576-4312
Fax	(509) 574-5118
Crisis Line	(509) 575-4200 or (800) 572-8122

References

1. Rowhani-Rahbar A, Zatzick D, Wang J, et al. Firearm-related hospitalization and risk for subsequent violent injury, death, or crime perpetration. *Ann Intern Med*. 2015;162(7):492-500.
2. Adolescent assault victim needs: a review of issues and a model protocol. American Academy of Pediatrics Task Force on Adolescent Assault Victim Needs. *Pediatrics*. 1996;98(5):991-1001.
3. Aboutanos MB, Jordan A, Cohen R, et al. Brief violence interventions with community case management services are effective for high-risk trauma patients. *J Trauma*. 2011;71(1):228-36-7.
4. Becker MG, Hall JS, Ursic CM, Jain S, Calhoun D. Caught in the Crossfire: the effects of a peer-based intervention program for violently injured youth. *J Adolesc Health*. 2004;34(3):177-183.
5. Cheng TL, Haynie D, Brenner R, Wright JL, Chung S, Simons-Morton B. Effectiveness of a mentor-implemented, violence prevention intervention for assault-injured youths presenting to the emergency department: results of a randomized trial. *Pediatrics*. 2008;122(5):938-946.
6. Cheng TL, Wright JL, Markakis D, Copeland-Linder N, Menvielle E. Randomized trial of a case management program for assault-injured youth: impact on service utilization and risk for reinjury. *Pediatr Emerg Care*. 2008;24(3):130-136.
7. Cooper C, Eslinger DM, Stolley PD. Hospital-based violence intervention programs work. *J Trauma*. 2006;61(3):534-7-40.
8. Corbin TJ, Rich J a, Bloom SL, Delgado D, Rich LJ, Wilson AS. Developing a trauma-informed, emergency department-based intervention for victims of urban violence. *J Trauma Dissociation*. 2011;12(5):510-525.
9. Marcelle DR, Melzer-Lange MD. Project UJIMA: working together to make things right. *WMJ*. 2001;100(2):22-25.
10. Shibru D, Zahnd E, Becker M, Bekaert N, Calhoun D, Victorino GP. Benefits of a hospital-based peer intervention program for violently injured youth. *J Am Coll Surg*. 2007;205(5):684-689.
11. Snider C, Jiang D, Logsetty S, Strome T, Klassen T. Wraparound care for youth injured by violence: Study protocol for a pilot randomised control trial. *BMJ Open*. 2015;5(5).
12. Snider C, Lee J. Youth violence secondary prevention initiatives in emergency departments: A systematic review. *Can J Emerg Med*. 2009;11(2):161-168.
13. Walton MA, Chermack ST, Shope JT, et al. Effects of a brief intervention for reducing violence and alcohol misuse among adolescents: a randomized controlled trial. *JAMA*. 2010;304(5):527-535.
14. Watt K, Shepherd J, Newcombe R. Drunk and dangerous: a randomised controlled trial of alcohol brief intervention for violent offenders. *J Exp Criminol*. 2007;4(1):1-19.
15. Zatzick D, Russo J, Lord SP, et al. Collaborative care intervention targeting violence risk behaviors, substance use, and posttraumatic stress and depressive symptoms in injured adolescents: a randomized clinical trial. *JAMA Pediatr*. 2014;168(6):532-539.
16. Zun LS. Violence prevention in the ED: linkage of the ED to a social service agency. *Am J Emerg Med*. 2003;6757(6):454-457.
17. Zun LS, Downey L, Rosen J. The effectiveness of an ED-based violence prevention program. *Am J Emerg Med*. 2006;24(1):8-13.
18. Zun LS, Downey L, Rosen J. An emergency department-based program to change attitudes of youth toward violence. *J Emerg Med*. 2004;26(2):247-251.
19. Purtle J, Rich LJ, Bloom SL, Rich J a, Corbin TJ. Cost−Benefit Analysis Simulation of a Hospital-Based Violence Intervention Program. *Am J Prev Med*. 2015;48(2):162-169.

20. Purtle J, Dicker R, Cooper C, et al. Hospital-based violence intervention programs save lives and money. *J Trauma Acute Care Surg*. 2013;75(2):331-333.
21. Berkowitz SA, Johansen KL. Does motivational interviewing improve outcomes? *Arch Intern Med*. 2012;172(6):463-464.
22. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. *Heal Psychol*. 1994;13:39-46.
23. Cunningham RM, Chermack ST, Zimmerman M a., et al. Brief Motivational Interviewing Intervention for Peer Violence and Alcohol Use in Teens: One-Year Follow-up. *Pediatrics*. 2012;129(6):1083-1090.
24. Gentilello LM, Rivara FP, Donovan DM, et al. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Ann Surg*. 1999;230(4):473-480-483.
25. Godley MD, Godley SH, Dennis ML, Funk RR, Passetti LL, Petry NM. A randomized trial of assertive continuing care and contingency management for adolescents with substance use disorders. *J Consult Clin Psychol*. 2014;82(1):40-51.
26. Saitz R, Palfai TPA, Cheng DM, et al. Screening and brief intervention for drug use in primary care: the ASPIRE randomized clinical trial. *JAMA*. 2014;312(5):502-513.
27. Monti PM, Colby SM, Barnett NP, et al. Brief intervention for harm reduction with alcohol-positive older adolescents in a hospital emergency department. *J Consult Clin Psychol*. 1999;67(6):989-994.
28. Monti PM, Barnett NP, Colby SM, et al. Motivational interviewing versus feedback only in emergency care for young adult problem drinking. *Addiction*. 2007;102(8):1234-1243.
29. Woolard R, Baird J, Longabaugh R, et al. Project Reduce: Reducing alcohol and marijuana misuse: Effects of a brief intervention in the emergency department. *Addict Behav*. 2013;38(3):1732-1739. doi:10.1016/j.addbeh.2012.09.006.
30. Cunningham R, Knox L, Fein J, et al. Before and after the trauma bay: the prevention of violent injury among youth. *Ann Emerg Med*. 2009;53(4):490-500.
31. Lako DA, de Vet R, Beijersbergen MD, Herman DB, van Hemert AM, Wolf JR. The effectiveness of critical time intervention for abused women and homeless people leaving Dutch shelters: study protocol of two randomised controlled trials. *BMC Public Health*. 2013;13(1):555.
32. de Vet R, van Luijtelaar MJA, Brilleslijper-Kater SN, Vanderplasschen W, Beijersbergen MD, Wolf JRLM. Effectiveness of Case Management for Homeless Persons: A Systematic Review. *Am J Public Health*. 2013;103(10):e13-e26.
33. Hwang SW, Burns T. Health interventions for people who are homeless. *Lancet*. 2014;384(9953):1541-1547.
34. Angell B, Matthews E, Barrenger S, Watson AC, Draine J. Engagement processes in model programs for community reentry from prison for people with serious mental illness. *Int J Law Psychiatry*. 2014;37(5):490-500.
35. Shinn M, Samuels J, Fischer SN, Thompkins A, Fowler PJ. Longitudinal Impact of a Family Critical Time Intervention on Children in High-Risk Families Experiencing Homelessness: A Randomized Trial. *Am J Community Psychol*. 2015;56(3-4):205-216.
36. Rowhani-Rahbar A, Fan MD, Simonetti JA, et al. Violence Perpetration Among Patients Hospitalized for Unintentional and Assault-Related Firearm Injury: A Case-Control Study and a Cohort Study. *Ann Intern Med*. 2016;165(12):841-847.

Study Protocol

September 30, 2016

Official title: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial

Brief title: Helping Individuals with Firearm Injuries (HIFI)

Investigators: Ali Rowhani-Rahbar, MD, MPH, PhD; Lauren Whiteside, MD, MS; Kevin Haggerty, PhD; Frederick Rivara, MD, MPH

Affiliations: Department of Epidemiology, School of Public Health (Rowhani-Rahbar, Rivara); Department of Pediatrics, School of Medicine (Rowhani-Rahbar and Rivara); Department of Emergency Medicine, School of Medicine (Whiteside); School of Social Work (Haggerty); and Harborview Injury Prevention and Research Center (Rowhani-Rahbar, Whiteside, Haggerty, and Rivara)

Research team and contact information

Name	Role	E-mail
Ali Rowhani-Rahbar	Principal Investigator	rowhani@uw.edu
Lauren Whiteside	Co-Investigator	laurenkw@uw.edu
Kevin Haggerty	Co-Investigator	haggerty@uw.edu
Frederick Rivara	Co-Investigator	fpr@uw.edu
Anthony Floyd	Study Coordinator	asfloyd@uw.edu
Elizabeth Davis	Support Specialist	davis86@uw.edu
Manal Jmaileh	Research Assistant	mjmaileh@uw.edu
Emma Bent	Research Assistant	ecbent@uw.edu
Jin Wang	Data Programmer	wangji@uw.edu

Table of Contents

Significance 6
Objectives 7
Approach 8
  Study Setting and Population 8
  Eligibility 8
  Study Design 9
  HMC Usual Care for GSW Victims 9
  Trial Profile 10
  Recruitment, Disclosure of Assignment, and Consent 10
  Assignment 10
  Intervention 11
    Brief Intervention 11
    Extended Community Outreach 11
    Multi-Agency Attention 12
  Baseline and Follow-Up Assessments 12
  Measures 13
    Process Measures 13
    Outcome Measures 14
    Administrative Databases 14
    Surveys 14
  Data Management 15
    Statistical Analysis and Power 15
  Weekly Team Meetings 15
  Advisory Board 15
  Timeline 16
Protection of Human Subjects 16
  Risks to Human Subjects 16
    Psychological Risks 16
    Confidentiality Risks 16
    Vulnerable Populations 16
  Adequacy of Protection Against Risks 16
    Psychological Risks 16
    Confidentiality Risks 17
    Vulnerable Populations 17
  Potential Benefits of the Proposed Research to Human Subjects and Others 17
  Importance of the Knowledge Gained 17
Conflict of Interest 17
Dissemination 17
Appendix A 20
  Patient Identification, Approach and Engagement Protocol 20
Appendix B 24
  In-Person Recruitment Script 24
Appendix C 26
  Phone Recruitment Script 26
Appendix D 28
  Voicemail and Text Recruitment Script 28
Appendix E 29
  Phone Follow-Up Script 29
Appendix F 30

Overall Recruitment and Enrollment Flow 30
Appendix G 31
Follow-Up Timeline and Procedures 31
Appendix H 34
Safety Protocols 34
Appendix I 36
Crisis Management Protocol 36
References 37

List of Abbreviations

- **HMC**: Harborview Medical Center
- **GSW**: Gunshot Wound
- **RA**: Research Assistant
- **ED**: Emergency Department
- **MDT**: Multidisciplinary Team
- **MI**: Motivational Interviewing
- **CTI**: Critical Time Intervention

Study Synopsis

- ☐ **Title**: Helping Individuals with Firearm Injuries: A Cluster Randomized Trial
- ☐ **Population**: Patients presenting to Harborview Medical Center with firearm injuries
- ☐ **Design**: Cluster Randomized Trial
- ☐ **Objective**: To test the effectiveness of a multicomponent intervention including brief motivational interviewing, extended community outreach services, and multiagency attention in promoting health and well-being of gunshot wound victims
- ☐ **Targeted Sample Size**: 200
- ☐ **Study Duration**: From January 1, 2016 through December 31, 2018

Significance

About 200-250 individuals present to an emergency department in King County, primarily Harborview Medical Center (HMC), for firearm-related injuries each year. Almost two-third of these patients require admission for their injuries. While the number of patients with firearm injuries who present to HMC is relatively small, these individuals are at substantially high risk of subsequent rehospitalization for another firearm or assault-related injury, arrest for firearm-related or violent crime, nonfirearm-related nonviolent crime, or firearm-related death in the five years after discharge from the hospital.[1] Thus, interventions among this group of individuals to promote their health and well-being and reduce the high risk of recidivism, morbidity, and mortality are critically needed. Such interventions may also lead to lower rates of firearm violence and its consequences in the community.

Patients with gunshot wounds (GSWs) seen at HMC receive many services. First, all patients are seen in the Emergency Department (ED) by an attending Emergency Medicine physician and resident physicians on the trauma team working in the ED. Depending on the nature and location of the GSW, these patients are often seen by specialty consulting services such as orthopedic surgery or vascular surgery. If patients have life-threatening injuries, they are seen by the trauma surgery service including an attending trauma surgeon. In addition, all patients who are victims of violence are seen by a member of the Social Work staff during their hospital stay. Currently, Level 1 trauma centers in the country including HMC are mandated by the American College of Surgeons to provide alcohol screening and brief intervention services to trauma patients, including GSW victims. Patients who are admitted and screened for substance use (e.g., alcohol and drugs) can be seen by the Harborview Addiction Intervention Service which comprises psychologists and chemical dependency counselors. Lastly, patients who present to HMC for GSWs and suicidal intent receive a comprehensive psychiatric evaluation once they are medically stable. However, currently there is no standardized intervention offered to GSW victims.

A number of hospitals across the country have created violence intervention programs to specifically help patients who sustain violent injuries. In 1996, the American Academy of Pediatrics published a report stating that while it has been routine to treat victims of child abuse, suicide attempts, and sexual assault via multidisciplinary care protocols, no care guidelines exist that address the unique needs of violently injuries adolescents.[2] In 1998, the U.S. Department of Justice's Office for Victims of Crime recommended that hospital-based counseling and prevention programs be developed. In 2009, the National Network of Hospital-based Violence Intervention Programs was formally established (http://nnhvip.org). These programs seek to engage patients in the hospital during the recovery period as a golden opportunity ("teachable moment") to change their life and reduce retaliation and recidivism. Through working groups, meetings, e-newsletter, and conferences, Network members collaborate in research and evaluation, explore opportunities for funding sustainability, develop and share best practices, and identify ways to collectively have an impact on policy. NNHVIP mainly serve individuals 15-25 years of age; however, some programs extend this range from 7 years through middle age.

While the creation of this infrastructure is a step in the right direction, rigorous research on the effectiveness of these intervention programs is needed. There exist only a few studies of the effectiveness of these programs some of which had small sample sizes and produced mixed findings.[3–20] Specifically, there have been no randomized trials evaluating the effectiveness of joint hospital-based and community-based violence intervention programs specifically offered to GSW victims. If research shows that such programs may not be effective, resources can be

better spent on other approaches to reduce gun violence and its associated morbidity and mortality.

We propose to conduct a randomized trial of an intervention program that combines a hospital-based intervention, structured community outreach program, and multi-agency attention. We will provide a brief intervention delivered at HMC to bolster the interaction that all these patients will have with the hospital Social Work staff. This intervention is derived from motivational interviewing (MI) which is a patient-centered behavioral technique based on the stages of change model and attempts to engage patients in order to find reason to change behavior.[21,22] By empathetically exploring ambivalent feelings about health-related behavior, MI encourages reduction in risky behavior. A number of investigations have demonstrated the effectiveness of providing MI-based brief interventions in the ED or inpatient wards,[23–26] primarily for alcohol use disorders[21,27–29] but also for violent behaviors.[15,30] Specifically, brief interventions utilizing principles of MI have been successful at reducing youth violence in large urban populations that sustained after one year.[13,23] Additionally, a behavioral-based intervention including MI among adolescents admitted to HMC with trauma showed a reduction in weapon carriage during the year after hospitalization.[15] This approach is appealing as its rationale is plausible and potential harms are minimal.[21]

A longitudinal intervention program provides the benefit of continued engagement. Providing GSW victims with outreach and follow-up after the healthcare encounter holds promise for reducing future violence and criminal activity. The Critical Time Intervention (CTI) approach (http://sssw.hunter.cuny.edu/cti/cti-model) can provide a strong framework for providing these patients with appropriate outreach and follow-up. Strong evidence supports CTI's effectiveness. The model meets the Coalition for Evidence-based Policy's rigorous "Top Tier" standard for interventions "shown in well-designed and implemented randomized controlled trials, preferably conducted in typical community settings, to produce sizable, sustained benefits to participants and/or society" (http://evidencebasedprograms.org/1366-2/critical-time-intervention-top-tier). CTI is a time-limited evidence-based case management practice that mobilizes support for society's most vulnerable individuals during periods of transition such as discharge from inpatient services to the community. It facilitates community integration and continuity of care by ensuring that a person has enduring ties to their community and support systems during these critical periods. CTI has been used worldwide among veterans, people with mental illness, homeless or incarcerated individuals, and many other groups.[31–35] From the beginning, CTI was thought of as an intervention that could be applied to other contexts. This approach has the potential to provide an intervention framework for a second tier outreach to GSW victims. To help the Support Specialist in delivering the CTI, a team of experts with the knowledge of available local services and how to navigate them is needed. Our proposed intervention will include such a team.

To our knowledge, this is the first randomized trial of a multicomponent dual hospital and community-based intervention exclusively focused on GSW victims. Findings of this study can directly impact practice and policy through informing the development of evidence-based programs pertaining to firearm violence in the future.

Objectives

The global goal of this study is to test the effectiveness of an intervention program for promoting health and well-being and reducing morbidity and mortality of GWS victims. The intervention program consists of a hospital-based MI, a longitudinal CTI, and multi-agency attention. We

seek to evaluate the effects of the intervention program using both process and outcome measures. Specifically, we will test the following measures:

- **Process measures**
  - Reach: What proportion of patients were engaged (i.e., coverage)?
  - Dosage: Did patients receive the proper dose of the intervention (i.e., dose and frequency)?
  - Adherence: Did the Support Specialist adhere to the principles of case management and study protocol?
  - Responsiveness: How satisfied were the patients?

- **Outcome measures**
  - Crime perpetration
  - Injury victimization
  - Death
  - Impulsive and premeditated aggressive behavior
  - Interpersonal violence
  - Substance abuse
  - Mental health
  - Employment or enrollment in classes
  - Physical health, happiness, and quality of life
  - Availability of social support and social network

We will test the impact of the intervention on the aforementioned outcomes using usual (i.e. standard) care as the comparison. Our hypothesis is that participants in the intervention group will see greater improvements in outcomes than those who receive usual care in this setting.

Approach

Study Setting and Population

The study will be conducted at HMC located in Seattle, Washington. HMC has an annual census of about 65,000 adult patient visits per year covering a typically diverse and urban population. Based on prior data, about 200-250 GSW patients (including both ED visits and hospitalizations) are treated at HMC every year.

Eligibility

Patients can be enrolled in the study from the ED, inpatient area, or after discharge in HMC-affiliated clinics (collectively referred to as “hospital” in this document). Eligible subjects will be:

- 18 years of age or older
- Able to provide consent within 4 weeks following hospital discharge
- Able to understand and speak English
- Able to provide at least one mode of direct or alternate contact (e.g., cell phone, land line, e-mail, friend, or relative)
- Planning to live in King or Pierce County for at least 6 months subsequent to hospital discharge
- Receiving treatment for a GSW at HMC and returning to the community, and not prison following treatment

Patients will be ineligible to participate in this study if they are:

- ☐ 17 years of age or younger
- ☐ Unable to provide consent (including those with severe neurologic damage) within 4 weeks following hospital discharge
- ☐ Unable to understand or speak English
- ☐ Unable to provide any mode of direct or alternate contact
- ☐ Not living in King or Pierce County, or planning to move outside of those counties within 6 months following hospital discharge
- ☐ Not receiving treatment for a GSW at HMC
- ☐ Not returning to the community following hospital discharge (e.g., being sent to a rehabilitation center, skilled nursing facility, or prison)
- ☐ Incarcerated at the time of GSW injury

Study Design

We will conduct a randomized trial in which GSW victims treated at HMC either receive an intervention or treatment as usual. The unit of randomization is the calendar week; that is, the study staff will assign GSW victims to one of the two groups based on the week in which they were shot and treated at HMC. A week is defined as one starting on Monday morning at 8:00 for a duration of seven days. We will use block randomization with varying block sizes of 2 and 4 to assign each week to one of the two groups of the trial. As such, all patients admitted in the same week will be assigned to the same group. This randomization scheme will ensure that all victims in the same shooting incident will receive the same study assignment. In addition, this scheme will enhance the feasibility of study by facilitating the coordination of efforts among the study staff in delivering the intervention.

HMC Usual Care for GSW Victims

All HMC patients treated for a GSW will receive care as usual by HMC physicians and staff. For patients treated for a GSW, usual care can include the following:

- ☐ All necessary medical care and scheduled follow-up with subspecialty services
- ☐ Evaluation by Social Work during the ED or inpatient stay: Social Work staff will specifically assist with communicating with family as needed, including contact with the police if the patient desires, evaluation eligibility for the crime victims' compensation fund, referral to the Harborview Center for Sexual Assault and Traumatic Stress, and safety planning when a concern for continued violence is present.
- ☐ Screening for alcohol use: Patients who screen positive for alcohol use at the time of presentation to the HMC ED are eligible to be seen by the HMC Addiction Intervention Service. This service provides brief intervention using MI techniques that targets alcohol use. While all patients with an elevated blood alcohol levels are eligible to be contacted by the Addiction Intervention Service staff, not all patients actually receive this service.
- ☐ Discharge planning services: HMC staff will help patients with specific needs with medical devices (e.g., wheelchair, walker) or coordination of any needed home health services.
- ☐ Financial counseling services to patients, including those without insurance: Patients can access this service during their ED or hospital stay or within 14 days of their healthcare visit. Financial counseling will assist patients with applying for charity care for medically necessary services and assist with questions regarding insurance coverage. Eligibility for charity care is based on published poverty guidelines.

Trial Profile

Figure 1 illustrates participant flow through the program.

Recruitment, Disclosure of Assignment, and Consent

Potential participants will be identified electronically using the Emergency Department Board by the study research assistants (RAs) who will regularly monitor this system on a daily basis. The study RAs will not conduct any pre-screening beyond initial medical record review. We have prepared requests for HIPAA and consent waivers as well as the University of Washington Confidentiality Agreement to allow for pre-screening of patients. For recruitment purposes, the study RAs will collect patient names and other identifying information. When the study RA identifies a potentially eligible patient, she will approach the patient using an institutional review board (IRB)-approved recruitment script to determine eligibility. For patients who are hospitalized at the initial incident, the study RA will approach the patient during the hospitalization once they are stable. For patients who are treated in the emergency department and do not get admitted (i.e., discharged from the ED), the study RA will approach the patient during the ED visit or during a scheduled follow-up visit at HMC depending on the nature and location of the GSW.

The informed consent discussion will include explanations of the study's purpose, the two assignments, study procedures, all risks and benefits associated with participation as well as confidentiality procedures. The study RA will:

- ☐ Ensure that no members of the patient's healthcare team are present during the consent process.
- ☐ Present the study to the patient and conduct an informed consent conference if the patient is interested in participation.
- ☐ Emphasize that the decision to participate is voluntary and will not affect medical care at HMC.
- ☐ Prompt patients to ask questions.
- ☐ Reiterate the participant's right to refuse participation and then ask whether the patient is willing to participate at the conclusion of the informed consent process.

There will be two different consent forms, one for each study group. Following consent, the the baseline survey will be completed by the patient or RA using a tablet device. For patients assigned to the usual care group, the study RA will ensure that we will have follow-up contact information and inform the patient that they will be contacted to conduct the next follow-up assessment at month 1. For patients in the intervention group, the study RA will contact the study Support Specialist.

Assignment

Patients will receive one of the two assignments:

- ☐ Intervention: Receives a brief intervention at the start of the study followed by six months of study case management and outreach services. A multidisciplinary team of technical consultants will review cases in this group and help the study Support Specialist provide appropriate care and referrals.
- ☐ Control: Receives usual care, including any outreach services offered by or recommended at HMC.

During intervention weeks, the study RA will contact the study Support Specialist in advance of approach so that the study Support Specialist can meet the patient in the private room. The study Support Specialist will initiate the intervention at that time.

Intervention

The intervention program contains three elements: (1) Initial contact and brief intervention by the study Support Specialist; (2) Extended outreach by the study Support Specialist; and (3) Multi-agency attention.

Brief Intervention

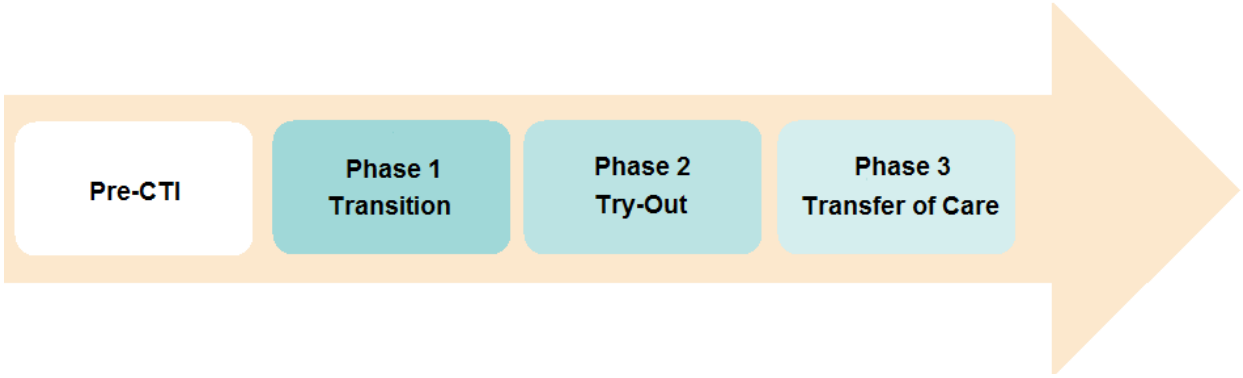
The brief intervention includes a feedback session utilizing principles of MI to elicit the goals and needs of patients. The main aim of MI in this study is to motivate the patient to be linked to the extended outreach case management. If needed, the study Support Specialist will provide a referral to community resources.

Extended Community Outreach

CTI's approach is to: (1) strengthen the individual's long-term ties to services, family, and friends; and (2) provide emotional and practical support during the critical time of transition back to the community. The six-month intervention is delivered to each participant by a single Support Specialist trained in CTI. Core components of CTI are as the following:

- ☐ Addresses a period of transition
- ☐ Time-limited
- ☐ Phased approach
- ☐ Focused
- ☐ Decreasing intensity over time
- ☐ Community-based
- ☐ No early discharge
- ☐ Small caseloads
- ☐ Harm reduction approach
- ☐ Weekly team supervision
- ☐ Regular full caseload review

Phases of CTI are as the following:



- ☐ Pre-CTI: Develop a trusting relationship with patient

- ☐ Phase 1 [Transition]: In Phase 1, the Support Specialist gets to know the patient, assesses the patient's needs, and implements a transition plan intended to link the patient to services and supports in the community. The plan typically includes home visits and other meetings with the patient, the patient's caregivers, and community service providers, designed to teach crisis-resolution skills, provide support and advice, and mediate any conflicts. The overarching goal is to connect the patient to people and agencies that will assume the primary role of support. Main components of this phase include:

  - ☐ Make home visits
  - ☐ Engage in collaborative assessments
  - ☐ Meet with existing supports
  - ☐ Introduce client to new supports
  - ☐ Give support and advice to patient and caregivers

- ☐ Phase 2 [Try-Out]: In Phase 2, the Support Specialist monitors and adjusts the systems of support that were developed during Phase 1. This phase involves fewer meetings with the patient, as the Support Specialist encourages the patient to problem-solve with the help of community resources and family members, and intervenes only if the patient is receiving inadequate support or if a crisis occurs. The overarching goal is to monitor and strengthen support network and patient's skills. Main components of this phase include:

  - ☐ Observe operation of support network
  - ☐ Mediate conflicts between patient and caregivers
  - ☐ Help modify network as necessary
  - ☐ Encourage patient to take more responsibility

- ☐ Phase 3 [Transfer of Care]: In Phase 3, the Support Specialist helps the patient develop and implement a plan to achieve long-term goals (e.g., employment, family reunification) and finalizes the transfer of responsibilities to caregivers and community providers. The CTI Support Specialist typically works with 10-15 patients at a time. The overarching goal is to terminate CTI services with support network safely in place. Main components of this phase include:

  - ☐ Step back to ensure that supports can function independently
  - ☐ Develop and begin to set in motion plan for long-term goals
  - ☐ Hold meeting with patient and supports to mark final transfer of care
  - ☐ Meet with patient for last time to review progress made

Multi-Agency Attention

The study Support Specialist will hold regular meetings with a multidisciplinary team (MDT) to seek advice about case management and service recommendations for each individual patient. It is vital for social service agencies and community-based organizations to be represented on this team. Of necessity, members of the MDT will know the identity of the individuals discussed in meetings. We do not consider MDT members to be engaged in research. They are technical consultants for the study Support Specialist. The MDT will include members from community mental health, substance abuse treatment, housing services, employment and adult education services, legal services, and law enforcement.

Baseline and Follow-Up Assessments

All participants will engage in research activities for one year following enrollment. Participants will complete surveys about their health and other outcomes at baseline, 1-month, 3-month, 6-month, 9-month, and 12-month assessments. At baseline, computer-assisted interviewing will be used to minimize skip pattern inaccuracies, missing data, ascertainment errors, and costs associated with conducting quality control and data entry on hard copy questionnaires. During the interview, the RA will read the questions to the participant and record the response using a tablet computer. For questions of sensitive nature (e.g., crime), the RA will turn the tablet to the participant so they can read the questions to themselves and key in the numeric value associated with their response choices. In addition, if a patient is unable to complete the survey electronically, the RA will read items and record responses. At follow-up assessments, the RA will send participants an email and a text with a link to the survey. Study staff will build the survey using a secure web application. If a participant cannot complete the survey electronically or does not complete the survey in one week, the study RA will call the participant to complete the survey over the phone. If the RA cannot reach the participant, she will call the alternate contact(s) listed by the participant.

A consented subject may become incarcerated at some point during participation making them an incidental prisoner subject. We will send follow-up surveys to all participants, even if they are incarcerated, with the understanding that email may be blocked during this time. A participant in the intervention group could become an incidental prisoner while receiving study case management services. If this occurs, study case management services will stop while the participant is in prison. The study Support Specialist will not make contact with the participant while incarcerated. Because participants in the intervention group are eligible for case management services for six months, they could return to study case management if the incidental prisoner is released from prison during that six-month window.

Subjects will receive compensation for the completion of surveys. Participants can earn up to $225 if they complete all surveys. Survey time points and payment amounts are as follows:

- ☐ Month 0 baseline survey: $25
- ☐ Month 1 follow-up survey: $30
- ☐ Month 3 follow-up survey: $35
- ☐ Month 6 follow-up survey: $40
- ☐ Month 9 follow-up survey: $45
- ☐ Month 12 follow-up survey: $50

Measures

Process Measures

The following checklists will be used to gauge Reach, Dose, Adherence, and Responsiveness:

- ☐ Proportion of patients consented among those approached
- ☐ Proportion of patients in the intervention group who completed the MI and case management
- ☐ Number of contacts and sessions spent with the study Support Specialist among patients in the intervention group linked to the study Support Specialist
- ☐ Proportion of patients in the intervention group for whom the MDT discussed the case management approach
- ☐ Proportion of patients in both intervention and control groups retained in the study by time

- ☐ Adherence score using a pre-tested checklist to document whether Support Specialist is adhering to the principles of case management and study protocol
- ☐ Happiness Scale to document participant's satisfaction (see "Surveys")

Outcome Measures

Outcome measures will be collected using two different, but complementary, sources: (1) Administrative databases; and (2) Surveys.

Administrative Databases

A number of outcomes can be measured using routinely collected data. These will include:

- ☐ Washington State Patrol and Administrative Office of the Courts records to identify cases of arrest and conviction
- ☐ Harborview Medical Center medical records, Washington State trauma registry, Washington State Comprehensive Hospital Abstract Reporting System, and Washington State Emergency Department Information Exchange to identify cases of injury
- ☐ Vital records to identify cases of death

Surveys

All surveys across the assessment points contain the same scales and items. A list of those scales and items is provided below:

- ☐ Patient Health Questionnaire (PHQ-8) to measure depression
- ☐ Short Form Health Survey (SF-12) to measure health-related quality of life
- ☐ Posttraumatic Stress Disorder (PTSD) Checklist – Civilian Version (PCL-C) to measure PTSD
- ☐ The Alcohol Use Identification Test (AUDIT) to measure alcohol use
- ☐ The National Institute on Drug Abuse-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) to measure substance use
- ☐ Impulsive-Premeditated Aggression Scale (IPAS) to measure impulsive and premeditated aggressive behavior
- ☐ Conflicts Tactics Scale (CTS) to measure interpersonal violence
- ☐ Happiness Scale to measure satisfaction with specific areas of life
- ☐ Service utilization questions to measure use of physical and mental health services
- ☐ Self-Reported Delinquency (SRD) items of the Pittsburg Youth Study to measure criminal justice involvement, violence, criminal outcomes, conviction(s), and incarceration(s)
- ☐ Multidimensional Scale of Perceived Social Support (MSPSS) to measure perceived social support
- ☐ Education questions to measure educational attainment and activities
- ☐ Employment questions to measure employment status
- ☐ Housing questions to measure type of housing
- ☐ Contact information questions to increase the likelihood of reaching the subject during the follow-up
- ☐ CTI Satisfaction (3-month and 6-month interview only)

Data Management

We will use REDCap (http://project-redcap.org), a web-based data management system to input all data for the study, including each contact, intake, follow-up surveys and all chart data abstraction. It will be housed in the Virtual Private Network of the University of Washington. REDCap is highly secure with user-based access privileges. As part of the study-specific project development in REDCap, variable and value labels will be created, and aggregate scales for each instrument will be computed. The RAs will examine logical inconsistencies, correct out-of-range values, and investigate missing values. The RAs will also complete a historical narrative, detailing important events that could have affected the quality of data generated. A codebook and data dictionary will be developed including information on variable and field names, labels, values, and types. Surveys will be fully annotated to include variable and field names.

Statistical Analysis and Power

The study will be powered on the basis of the primary outcome of arrest. Our previous investigation among GSW victims in Washington State and King County indicated that the rate of subsequent arrest following hospital discharge among these individuals is about 15,528 cases per 100,000 person-years. This translates to a one-year cumulative incidence of arrest at about 14% (i.e., $1 - \exp[-15{,}528/100{,}000]$). Assuming a significance level of 0.05, a power of 80%, an intervention-to-control ratio of 1, 52 clusters (i.e., weeks) per group during the two-year enrollment phase, a sample size of about 2 patients per cluster (for a total of about 200 GSW patients during the two-year enrollment phase), and an intraclass correlation coefficient of 0.01, we will be able to identify a minimally detectable risk difference of 11 percentage point for the primary outcome of arrest.

All analyses will be in accord with the intent-to-treat principle. Survival analysis techniques will be used to examine both single and multiple failure times while taking competing risks (e.g., death) into account. Since the unit of randomization is calendar week, clustering by calendar week will be taken into account in all analyses. A randomization scheme that is not on the individual level may result in imbalances in characteristics of individuals (e.g., age, race) in the two groups. As such, we will carefully inspect all individual-level characteristics and compare them between the two groups; all analyses will be adjusted for any potential imbalances detected at baseline.

Weekly Team Meetings

The study team will convene two separate 1-hour weekly meetings in which the study staff will be present in person or via phone. Logistical issues, recruitment numbers, and updates to the research protocol will be discussed as needed. Successes and challenges will be reviewed and plans for the subsequent week will be finalized.

Advisory Board

Advisory Board will meet four times per year and are contacted on an ad-hoc basis as needed. The Advisory Board is essential for providing feedback and translating the knowledge required in this project. They will provide meaningful insight into the challenges the team may be encountering. At the end of the trial, results will be presented to the Advisory Board members who will in turn be actively involved in the interpretation and dissemination of those findings. The Advisory Board members will include experts in Social Work, Criminology, Trauma Surgery, and Emergency Medicine, as well as an individual with experience in implementing community-

based violence prevention programs and a member of the community with a history of firearm violence and injury.

Timeline

The study duration will be 3 years from inception to completion as outlined below.

Year	1				2				3			
Training study staff and start-up												
Enrollment												
Data collection												
Data management												
Data analysis												
Preparing publications and presentations												

Protection of Human Subjects

Risks to Human Subjects

Psychological Risks

Participants may face psychological risks in participating in the study. All participants might feel stress or psychological discomfort while filling out assessments about their mental health, physical health, relationships, history of violence, and criminal activities. Participants in the intervention group may feel some stress or discomfort during interventions aimed at reducing high-risk behaviors.

Confidentiality Risks

All participants face confidentiality risks. Participants' privacy may be violated if their data are not kept confidential. Participants in the intervention group face a greater confidentiality risk, as their cases will be the subject of MDT review.

Vulnerable Populations

Some of the subjects may become incidental prisoners during the study. Participants in the intervention group may become incidental prisoners during the six-month intervention period. Also, any participant may become an incidental prisoner during follow-up surveys.

Adequacy of Protection Against Risks

Psychological Risks

The research staff (RA and Support Specialist) engaging with subjects will be trained to work with this high-risk population. They will explain the purpose of the research and will assure participants that their answers are confidential. The research staff will work to reduce any stress or psychological discomfort during assessment or outreach, and remind subjects to report any discomfort or stress. The research staff will also fully inform participants that they have the right to skips questions or activities or withdraw from the study at any time. During assessments, the

study RAs may discover a subject's intentions to harm themselves or other. In that case, they will follow the Crisis Intervention Protocol.

Confidentiality Risks

Research staff will take all necessary precautions to prevent the loss of confidentiality. The research staff will keep all data in secure databases on password-protected networks. Study staff will assign study codes to participants and will record all assessment data using those study codes. The document linking participant name and study code will be password protected, and the document will be stored on a secure, password-protected computer. Assessment data will be stored in password-protected network. All paper-based data (e.g., consent forms) will be stored in a locked file cabinet. We will retain a link between study code numbers and direct identifiers after the data collection is complete, and destroy it on 1/1/2020. Members of the MDT will sign a Confidentiality Agreement to ensure that none of the shared data in the meetings are repeated or disclosed in public. The study RA will notify potential participants about information sharing with the MDT during the consent conference. We will ask patients to sign a HIPAA authorization to release medical records for the period of their study participation. This authorization is separate from the HIPAA waiver request for pre-screening.

Vulnerable Populations

We will not engage any individuals in the study procedures while they are incarcerated.

Potential Benefits of the Proposed Research to Human Subjects and Others

Participants in the intervention group will receive a brief intervention and extended case management services to reduce individual high-risk behaviors. These participants will also be referred to community agencies who can help address specific areas of need. Participants in the control group may not directly benefit from participating in the study other than monetary compensation for their participation; however, the enforcement of usual care as described above may be considered a potential benefit.

Importance of the Knowledge Gained

Gun violence affects society in many ways, including heavy medical costs, reductions in quality of life, and stresses on the criminal justice system. Gun violence prevention and intervention programs hold the potential to drastically reduce recurrent injury, readmission, retaliation and recidivism. While many hospitals have adopted violence intervention programs, few have rigorously evaluated program effectiveness. Our study has great potential to meaningfully contribute to the field of gun violence prevention.

Conflict of Interest

None

Dissemination

Upon completion of the intervention program, we will provide a report for stakeholders and prepare presentations and publications for scientific conferences and journals to disseminate the knowledge gained. The results of this trial, if proven effective, will be used to advocate for policy change within healthcare settings; the investigator team will promote the rapid translation

of findings into practice. Findings will be immediately shared with member programs of the National Network of Hospital-Based Violence Intervention Programs so the evidence can be used to advocate for sustained funding for such efforts. If this intervention is successful in decreasing the risk of subsequent trauma-related morbidity, its implementation at trauma hospitals serving populations with high rates of violent trauma will be supported. If unsuccessful at reducing the risk of subsequent trauma-related morbidity, alternative models of intervention need to be investigated.

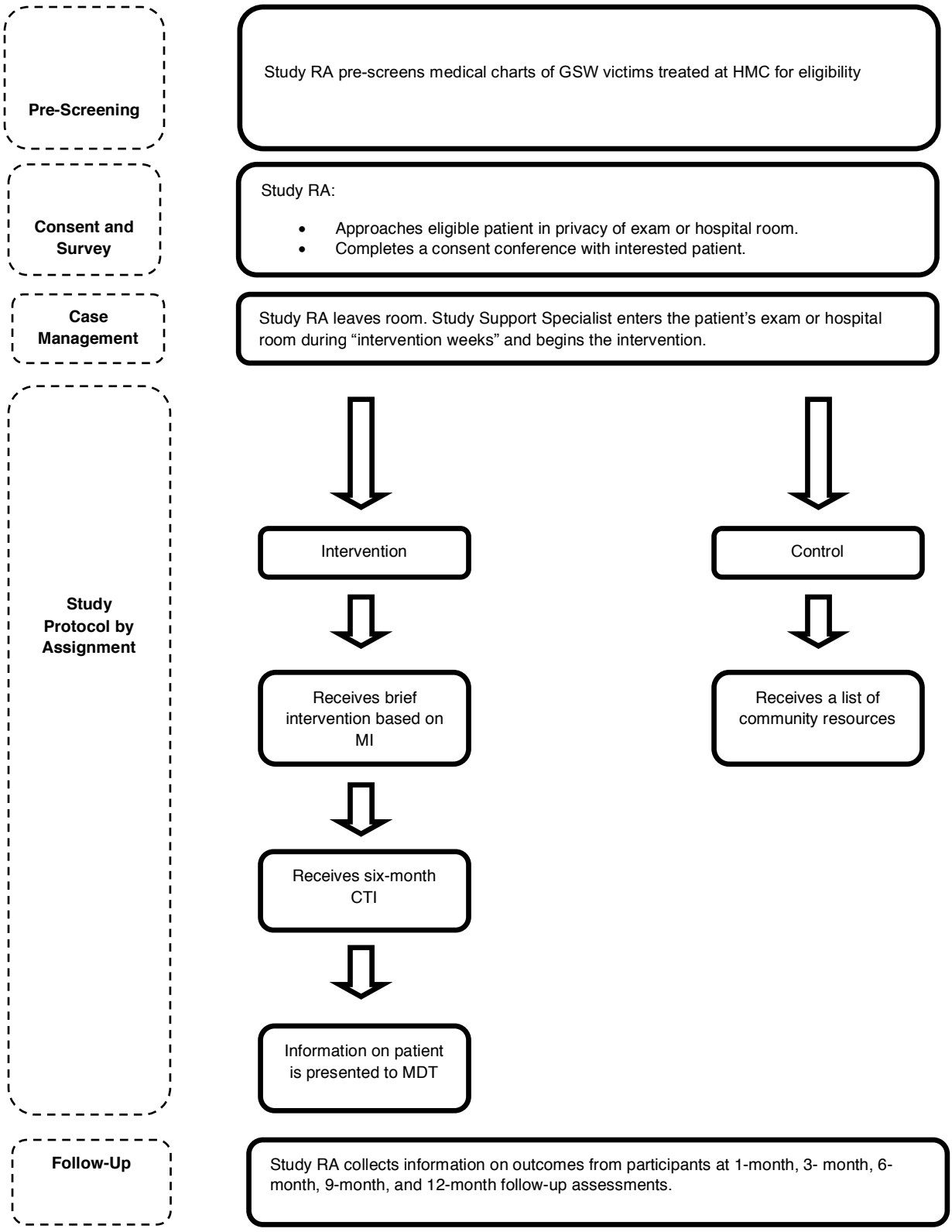


Figure 1. Trial profile. HMC: Harborview Medical Center; RA: Research Assistant; CTI: Critical Time Intervention; MDT: Multidisciplinary Team; MI: Motivational Interview

Appendix A

Patient Identification, Approach and Engagement Protocol

Step 1: Check the board for GSW patients

- ☐ SW note will have most information

Step 2: Eligibility screen via EMR (HIFI Patient Screening Survey)

- ☐ 18 years or older, not in jail, English speaking, live in King or Pierce County, neurological or cognitive impairment
    - ☐ Language can be wrong in EMR, so talk to staff or verify at approach
- ☐ Complete screener for all GSW
    - ☐ If missed, uninterested or ineligible, retain all information **except**:
        - ☐ Patient name
        - ☐ Patient H #
        - ☐ Patient location in hospital
        - ☐ Admit date
            - ☐ Keep MONTH (separate variable)
        - ☐ Discharge date
            - ☐ Keep LENGTH OF STAY (separate variable)
        - ☐ DOB
            - ☐ Keep AGE (separate variable)
- ☐ Review to see if patient has been enrolled in any other study
- ☐ Patient appears eligible per medical record review and there is no research conflict
    - ☐ Proceed to next step

Step 3: Mental status and medical acuity assessment - Pre-Approach (HIFI Patient Screening Survey)

- ☐ Intubated OR active resuscitation OR going directly to operating room
    - ☐ Notify other RA
    - ☐ Put patient on approach list in OneDrive for monitoring and leave notes for other RA
    - ☐ Continue to reassess daily - Nurse notes will have most detail
        - ☐ Check EMR - review daily surgery notes
        - ☐ Talk to staff
- ☐ Determine if patient is able to understand the research approach
    - ☐ Reasons may not understand: Intoxication, previous history of TBI, psych co-morbidity
    - ☐ Contact medical team (inpatient) or charge nurse (ED) to:
        - ☐ Introduce self and mention study clinician
        - ☐ Discuss the case
        - ☐ Determine timing of approach
- ☐ Normal mental status and not getting active medical resuscitation
    - ☐ If it is a good time to approach:
        - ☐ If an intervention week: Make a judgment call about notifying Support Specialist at this point
        - ☐ Proceed to next step

Step 4: Assemble documents needed for approach (Consent Form and HIPAA Authorization Form)

- ☐ Verify the randomization schedule on OneDrive
- ☐ Copies of stamped consent form stored at each RA desk and on OneDrive
- ☐ Select condition appropriate consent form: Intervention or Control
    - ☐ Bring two copies to the patient room:
        - ☐ One signed copy goes to patient
        - ☐ One signed copy is retained by study
- ☐ Bring two copies of HIPAA Authorization Form
    - ☐ One signed copy goes to patient
    - ☐ One signed copy is retained by study
- ☐ Bring a gift card of the appropriate value (kept by patient) AND gift card form (kept by study)
    - ☐ Mark down serial number (in OneDrive or on gift card form) **BEFORE** giving to patient
- ☐ Bring HIFI study envelop: Label with study name, study email, study cell (206-446-8914) and line to write down one month follow up date
    - ☐ Proceed to next step

Step 5: Approach patient and pitch study (5 mins)

- ☐ Tell nurse when going into room
- ☐ If patient is unable to talk to you but is willing to talk later:
    - ☐ Schedule next attempt
- ☐ If patient is willing to talk to you:
    - ☐ Proceed to next step

Step 6: Final screening questions (5 mins) (HIFI Patient Screening Survey)

- ☐ Interested? (**yes**) Live in King or Pierce County? (**yes**) Plans to live in King or Pierce County for 6 months? (**yes**) Able to provide contact? (**yes**) Going to jail? (**no**) In jail when shot? (**no**)
    - ☐ If Ineligible:
        - ☐ End interview and document (Step 9)
    - ☐ If eligible:
        - ☐ Proceed to next step

Step 7: Consent (10 mins)

- ☐ If patient does not agree to participate:
    - ☐ End interview and document (Step 9)
- ☐ If patient agrees to participate:
    - ☐ Have patient sign both copies of the consent form and HIPAA Authorization Form
    - ☐ Proceed to the next step

Step 8: Baseline Survey (30 mins) (Baseline Survey)

- ☐ If it's an intervention week AND the support specialist is working
    - ☐ Notify support specialist that that patient is eligible and that baseline is beginning

- ☐ Reminder: Be explicit with patient about why you would step out to make a call, if you make a call to Support Specialist now. "*Why: I want to get you connected as soon as possible with our support specialist, so I am going to call her to tell her you have enrolled."*
- ☐ RA completes the survey **except:**
  - ☐ If a patient would like to complete himself/herself
  - ☐ For substance Abuse and Criminal Activity questions
    - ☐ Give a prelude to these questions to neutralize and normalize them. "*We are asking every patient these private and personal questions. I will be here to answer any questions you may have."*

Step 9: End Survey

- ☐ Provide gift card and have patient sign gift card form
- ☐ Put gift card, one signed copy of HIPAA Authorization, one signed copy of consent form into study envelope
  - ☐ Mark date of 1-month follow-up on the envelope
- ☐ Intervention Patient: Hand off to Support Specialist
  - ☐ In-person if support specialist is available:
    - ☐ Provide her with summary scores and any important information
  - ☐ If support specialist is not available:
    - ☐ Contact Support Specialist to discuss options
    - ☐ Update OneDrive

Step 10: Complete Screener Form (HIFI Patient Screening Survey)

- ☐ Document approach outcome in REDCap record
- ☐ If ineligible, remove identifiers (listed in Step 2) from REDCap record

Step 11: File Signed Forms in Safe, Locked Area

- ☐ File signed consent forms, HIPAA Authorization and Gift Form in locked cabinet
- ☐ If daytime and no other approaches, bring to locked drawer at HIPRC
  - ☐ If Study Coordinator is there, bring to her locked cabinet
  - ☐ If Study Coordinator is not there, temporarily store in the locked cabinet at your desk
- ☐ If nighttime, lock in HMC drawer
  - ☐ On next day shift, file at HIPRC following the above protocol

Step 12: OneDrive Documentation (HIFI Patient Tracking on OneDrive)

- ☐ Remove patient from Approach list one determination is made
- ☐ Record patient follow-up schedule
- ☐ Input gift card information

Step 13: Follow-up (Follow-Up Survey)

- ☐ RAs will contact participants via phone, text or email to complete follow-up. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone or in-person. Follow-up assessments will be done at the following times:
    - ☐ 1 month (window opens 1 week before and closes 2 weeks after 1-month date)
    - ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
    - ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)
    - ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
    - ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

- ☐ Document each time an attempt is made to contact the participant, method of contact and the outcome of the attempt.
    - ☐ If contacting by phone, RAs can leave up to 2 voice messages.
    - ☐ RAs can also use text as a way to contact participant or remind participant of scheduled call/meeting.
    - ☐ Document on subject payment spreadsheet every time gift card is given

Step 14: Study Close Out

Appendix B

In-Person Recruitment Script

Hi, my name is [RA Name], and I am from the Helping Individuals with Firearm Injuries Study. I am here to talk to you about our study because you might be eligible to participate in it. I would like to tell you about the study and find out if you eligible to participate. The conversation should take no more than 15 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

This study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview Medical Center. We are asking you to participate because you are being treated for a gunshot wound at Harborview Medical Center. You would participate in the study for one year.

- ☐ **Intervention Group**: As part of the study, you will get all the usual services offered by the Harborview staff. In addition, you will receive outreach services from a study Support Specialist. During your one-year participation, we will ask you to complete surveys.
- ☐ **Control Group**: As part of the study, you will get all the usual services offered by the Harborview staff. During your one-year participation, we will ask you to complete surveys.

To find out if you are eligible to participate in the study, I will ask you some questions. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.
Are you interested in finding out if you are eligible to participate in the study?

- ☐ **YES**
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King or Pierce County?

- ☐ **YES**
- ☐ NO

Do you plan to move from King or Pierce County in the next six months?

- ☐ YES
- ☐ **NO**
  - If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**
- ☐ NO

Are you going to jail when you leave the hospital? (only ask if not in chart)

- ☐ YES
- ☐ **NO**

Were you in jail at the time of your gunshot injury? (only ask if not in chart)

- ☐ YES
- ☐ **NO**

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

- ☐ **YES**
- ☐ NO

Patient is ineligible if any responses are plain text responses.

> SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patient is eligible if **ALL** responses are underlined and bolded responses.

> SAY: Based on your responses, you are eligible to participate in the Helping Individuals with Firearm Injuries study. If you are interested in participating in the study, I will review the study consent form with you. Are you interested in learning more about the study and participation?
>
> - ☐ YES (review the consent form)
> - ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix C

Phone Recruitment Script

Hi, my name is [RA name], and I am calling from Harborview Medical Center about a study that you might be eligible to participate in. Am I speaking to [patient name]? Before I tell you about the study, can you confirm your age and the date/day you visited Harborview Medical Center?

[Once confirms] Thank you for confirming that information. I work for a study entitled Helping Individuals with Firearm Injuries (HIFI). The study is testing a program designed to improve the health and well-being of individuals treated for gunshot wounds at Harborview. You may be eligible to participate in the study because you were treated for a gunshot wound at Harborview. Study participation is one year. During that year, you will be asked to complete 6 surveys, and you will be paid for each survey you complete. If you complete all the surveys, you will receive $225. [Read Intervention Group description below if patient is assigned to that group]

- ☐ **Intervention Group**: As part of the intervention group, you will receive outreach services from a study Support Specialist who can help you navigate your recovery. You determine what you want to work on with the Support Specialist. For example, you could set goals with her around employment, appointment management, housing, accessing mental health services, etc. She can help you connect with appropriate resources and will help you create a plan to reach your goals. The Support Specialist will work with you for 6 months.

Today's conversation will determine if you are eligible to participate. The call should take no more than 5 minutes. Is now an OK time to talk?

- ☐ YES (If yes, begin screening script)
- ☐ NO (If no, reschedule with patient, if s/he is interested)

I will ask you three questions that will help me determine if you are eligible for the study. I will record your answers to these questions. However, your name will not be associated with any of the answers you give me during this screening. The study will keep your anonymous answers, even if you are not interested in participating or if you are ineligible to participate.

Are you interested in finding out if you are eligible to participate in the study?

- ☐ YES
- ☐ NO (If no, thank him/her for his/her time)

Do you live in King or Pierce County?

- ☐ **YES**
- ☐ NO

Do you plan to move from King or Pierce County in the next six months?

- ☐ YES
- ☐ **NO**

- ☐ If not sure, ask patient to rate the likelihood of moving on a scale of 1 to 10 with 1 being the least likely to move and 10 being the most likely to move. If patient reports a 5 or above, s/he is not eligible.

Are you able to give at least one mode of direct or alternative contact (e.g. cell phone, land line, email, friend or relative)?

- ☐ **YES**
- ☐ NO

Are you planning to return to the community after you are discharged from the hospital? That means not a rehabilitation center, skill nursing facility, or prison.

- ☐ **YES**
- ☐ NO

Patients are ineligible if any responses are plain text responses.

SAY: Unfortunately, you are not eligible to participate in this study. Thank you so much for talking with me today.

Patients are eligible if **ALL** responses are underlined and bolded responses.

SAY: Based on your responses, you are eligible to participate in the HIFI study. The next step in the process is to enroll you in the study. That process involves meeting in-person to review a consent form with a study Research Assistant. We can meet at a convenient time and location for you. The consent form review will take about 5-10 minutes. If you agree to participate upon review, we will ask you to complete a survey. The survey takes about 30 minutes to complete. So in total, the meeting would last about 45 mins. Are you interested in scheduling an in-person meeting?

- ☐ YES (Schedule an appointment with patient. If there is a follow-up appointment scheduled, ask if that is an appropriate time/location to meet. If no follow-up appointment scheduled, ask if patient is willing to come back to HMC. If not, ask for a convenient, public place to meet)
- ☐ NO (Say: Thank you for taking the time to talk with me today)

Appendix D

Voicemail and Text Recruitment Script

Hi, my name is [RA name]. I am calling from Harborview Medical Center. I am trying to reach [patient name.] [Patient name] may be eligible to participate in a study where s/he can earn up to $225 by completing surveys. Please call me back at 206-446-8914 at your earliest convenience.

Appendix E

Phone Follow-Up Script

Hi, my name is [RA name] from the Helping Individuals with Firearm Injuries study. I spoke to you at Harborview Medical Center on [Date] when you completed the baseline survey for the study. I am contacting you today to remind you the [Number]-month follow up appointment is coming up with a [Dollar amount] gift card for completing it. There are a couple different ways we can take care of this. The survey can be completed online, over the phone, or in person. Please contact me with your preferred method when you get the chance. You can either call or text (206) 446-8914; again the number is (206) 446-8914. We very much appreciate your time and participation; the information we gather for this study will go towards better helping patients in the future. Have a great day and I look forward to hearing from you.

Appendix F

Overall Recruitment and Enrollment Flow

Recruitment Flow

- ☐ Patient presents to HMC with GSW
  - ☐ Ineligible
  - ☐ Dies
  - ☐ Eligible
    - ☐ ED or Inpatient
      - ☐ RA approach while at HMC
    - ☐ Discharged before RA contact
      - ☐ Phone call to determine eligibility and schedule in-person enrollment meeting
      - ☐ Phone call schedule: 2 weeks of attempted contact with patient
        - ☐ Begin calling as soon as possible – once you start, the 2-week timer begins
        - ☐ Allowed up to 10 calls
        - ☐ Allowed 2 voicemails – after 1st and 8th call
        - ☐ Allowed 1 text – at one-week mark
        - ☐ Must use IRB approved script for call, voicemail and text
        - ☐ After 2 weeks, patient becomes "Unable to Contact"

Enrollment Flow

- ☐ Patient is eligible and interested in participation
- ☐ Sign Consent Form
- ☐ Sign HIPAA form
- ☐ Complete baseline survey
  - ☐ If baseline is not completed, complete as soon as possible
    - ☐ If completed after the 1-month survey window opening, RA to explain situation and ask patient to schedule two appointments to complete the two surveys
    - ☐ Window to complete baseline is 6 weeks after enrollment date
      - ☐ After this point, mark as "Missed"
- ☐ Provide Gift Card
- ☐ Sign Gift Card form
- ☐ For Intervention Patients:
  - ☐ Notify Support Specialist
  - ☐ Introduce her to patient
  - ☐ Tell patient Support Specialist will contact him/her

Appendix G

Follow-Up Timeline and Procedures

RAs will contact participants via phone, text, or email to complete follow-up surveys. The follow-up assessments can be done via web-link as a computer assisted self-interview, over the phone, or in-person. Preferred completion mode is online or by phone. Follow-up assessments will be done at the following times:

- ☐ 1 month (window opens 1 week before and closes 3 weeks after 1-month date)
- ☐ 3 months (window opens 2 weeks before and closes 4 weeks after 3-month date)
- ☐ 6 months (window closes 2 weeks before and closes 4 weeks after 6-month date)
- ☐ 9 months (window opens 2 weeks before and closes 4 weeks after 9-month date)
- ☐ 12 months (window opens 2 weeks before and closes 4 weeks after 12-month date)

If the participant has an email, automate REDCap notifications.

If the participant does not have an email or has been unresponsive to automated email prompts for 1 week, then contact participant by phone using the number provided at baseline or most recent survey.

- ☐ Please use study cell phone.
- ☐ You can leave up to two messages.

If participant does not respond to phone calls, call the alternative contacts provided at baseline or at most recent survey.

- ☐ At all other follow-up time points, try alternative contacts after 2 weeks of direct contact attempts with participant.
- ☐ You can leave one voicemail.
    - ☐ Do not leave any details about the study or mention the study.

If you are unable to make contact with the participants, check jail database.

- ☐ If patient is in jail, do not contact and mark that the patient is in jail on the follow-up survey.
- ☐ If you are unable to make contact with participants or alternative contacts and patient is not in the jail database, then mail a copy of the survey to the participant at the address provided at baseline or the most recent survey.
    - ☐ Include a self-addressed, stamped envelope in the mailing.

Contacting Patient by Phone

Always use the study cell phone to contact participants. The purpose of the phone call at follow-up is to:

- ☐ Remind participants about the follow-up survey and their completion options.
- ☐ Remind participants about the incentives for their completion of the surveys.
- ☐ Remind participants that it will take about 30-45 minutes to complete the survey.
- ☐ Determine the mode by which the participant wants to complete the survey:
    - ☐ If online, confirm their email address and re-send link (if sent already).

- ☐ If by phone, ask if the participant would like to complete by phone now. If not, schedule a phone call within the next 1-4 days.
- ☐ If in-person, schedule a meeting within the next 1-4 days. Ask if they are willing to come to HMC. If not, select a meeting location that is public and during daytime hours.

- ☐ Let them know you will give them a reminder text or leave a reminder voicemail the day/night before the phone call or in-person meeting.
- ☐ Thank them for their participation.

Reaching the typical study participant will require multiple calls. To be effective, you will have to try reaching them at different times of the day and different days of the week. Some people may be very easy to reach, while it may take up to 10 or more contact attempts before you are able to speak with a person. Expect and plan for multiple contact attempts, and expect to encounter some typical barriers in this process. Study participants typically have two mechanisms to help protect them from taking unwanted calls: (1) voice mail/answering machines; and (2) caller ID.

Voice Mail/Answering Machines

Many study participants use answering machines to screen their calls. To help counter this, leave a message on the machine to let them know you have called and leave the study cell phone number. The IRB has approved us to leave up to 2 voice messages. There are a few basic things to keep in mind when dealing with voice mail or answering machines:

- ☐ Don't leave more than 2 messages. You can make more than 2 contact attempts, but messages should be left strategically and only twice.
- ☐ Don't wait too long after you leave a message to call them back (1 or 2 days at most).
- ☐ Your message should be brief, friendly, and to-the-point. Please follow the script. Speak slowly – especially when leaving a phone number. Provide the study cell phone number in every voicemail.

Caller ID

Many study participants may have Caller ID available to them on their telephone service. This means that every time you call, your telephone number will appear and be logged into their Caller ID box. Keep this in mind when you make your calls for the day, and be careful not to call too often. They may perceive you as "harassing" them before you even make the first contact. Take careful call notes to keep track when each time a message was left and what was said in the message (e.g., "msg. left with name and #, will call back Tues. pm"). The following are several ways to address the Caller ID issue. No matter how you choose to handle this situation with a patient, keep in mind that it should facilitate interaction about survey completion.

- ☐ Typically, you will limit your telephone attempts to only one attempt in any day.
- ☐ You may have a "Line Block" placed on the telephone line that you are calling from, so that any time you call, "Anonymous" (and not your phone number) will appear on the other party's Caller ID box. To remove line block on any individual call, you can press *82 before you place the call. This will allow your name and number to be displayed to the Caller ID party on just that one call. This service is free of charge, but you must call your telephone provider to request that it be added to your line.
- ☐ "Per Call Blocking" allows you to block an individual call to a study participant by dialing *67 before dialing the number. When you block an individual call, "Anonymous" will be

displayed on the Caller ID party for just this one call. This service should already be available to you without you requesting to "activate" it.

Call or Meeting Reminders

Once an appointment is scheduled, you will want to do what you can ahead of time to minimize any "no-shows" or "broken appointments." The following are several ways to avoid the frustration of a "no-show" by taking these steps:

- ☐ Suggest that the study participant choose a time and place when there will be the least number of distractions and/or interruptions. HMC should be the first suggestion by RA, and if that is not possible, work with patient to identify a quiet and safe, preferably public, location.
- ☐ Set a definite time. Avoid using vague phrases like, "I'll see you around 4:00."
- ☐ In addition to having a definite time, you may want to re-state this appointment time before hanging up. "Okay, I have you down for Thursday, January 21st at 4:00 PM. Is that what you have?"
- ☐ Give a reminder call or text the day before, and depending on the participant, sometimes the day of, to confirm the appointment time. Flag your call-back time so that you are sure to follow-through and actually make the call.
- ☐ Leave contact numbers, and encourage the study participant to call you back if they need to reschedule the appointment.

Appendix H

Safety Protocols

Home or Community-Based Visits

Please do not conduct home or community visits in homes or neighborhoods in which you don't feel safe. The most important things are to use common sense, follow your gut instinct and always remember to put your own personal safety first. If you are ever in a situation where your safety feels compromised, please do whatever it takes to get out of the situation. Also, don't try to protect cash or equipment at the expense of your own safety.

Regardless of whether you are someone who is comfortable or uneasy about going to a stranger's home, you should always take precautions and make plans that will help ensure your personal safety. The more you know and are prepared for your surroundings, the more you will feel and behave more comfortably. It is helpful to visualize potential situations and plan in advance ways to maintain your safety under different circumstances.

Before calling or scheduling an appointment with a study participant, look at a map and make sure that you know something about the neighborhood. Despite the perception of how "safe" a neighborhood is, you may always benefit from doing a little detective work, and learning a little about where you will be going. If you feel uncomfortable, come early and visit the neighborhood during the day. Drive around a bit and locate the nearest convenience or grocery store, fast food restaurants, a public library or gas stations (public restrooms).

Although it may be rare that you might encounter an unsafe situation or neighborhood, there will be times when you may feel uncomfortable going to a participant meeting. Take these general precautions to help you feel at ease and to guarantee your safety in a potentially dangerous situation:

Before you arrive at the study participant's home:

- ☐ Let staff know where you are going and when to expect you back.
- ☐ Know where you are going. Get directions, always have a map and plan out your route. Ask the study participant to tell you the best place to park, and which door to use.
- ☐ Call the study participant to let her know when to expect you.
- ☐ Schedule check-in times if you feel you are in a difficult place.
- ☐ Bring your cell phone.
- ☐ Always have sufficient gas in your car.
- ☐ Have a plan for if your car breaks down.
- ☐ Don't over-dress or carry expensive valuables. Look casual and not memorable.
- ☐ Don't leave expensive valuables in your car, especially in plain view. Lock in the trunk.

Once you are in the study participant's neighborhood:

- ☐ Check it out, look around. Get a feel for what's going on around you.
- ☐ Look for a place to park that is well-lit and close to the participant's home.
- ☐ Be aware of surroundings (including dogs).
- ☐ As much as possible, choose a clear, well-lit path to the house.
- ☐ When walking down the street, look and walk purposefully and confidently.

- ☐ If you feel threatened by the setting, call on your cell phone (or drive to a payphone) and ask the study participant to meet you at the door.
- ☐ If you still feel unsafe, call the participant to reschedule or cancel. You may want to try to schedule a daytime appointment and/or a different location.

While you are in the home:

- ☐ Do not enter if you smell or see drugs.
- ☐ Always wear your name badge and identify yourself as soon as you arrive at the study participant's home.
- ☐ With the exception of a cell phone, never take anything into a home that you do not need for the meeting (no personal items, no extra cash, etc.)
- ☐ Ask who else is at the residence.
- ☐ Be aware of exits, and sit where you can exit easily.
- ☐ Use non-threatening body language. Remain calm and polite.
- ☐ If you feel uneasy in the study participant's home, try to suggest a location for your conversation where you would be able to leave quickly, without your path being blocked.
- ☐ Listen to your intuition/instinct. If you feel uncomfortable or have a bad feeling, cut the meeting short and politely take leave.
- ☐ If you become fearful about your safety inside the study participant's home, and feel unable to resolve it, end the conversation. You are in no way expected to stay in an unsafe situation in order to complete study activities.

If you still feel unsafe, here are some suggestions of how to end a home visit tactfully:

- ☐ Tell the study participant you are having technical difficulties and will need to reschedule the appointment.
- ☐ Tell the study participant you are not feeling well and would like to reschedule the appointment.
- ☐ Have someone call you on your cell phone 5-10 minutes after you are scheduled to arrive in case you need to use the call as an excuse to reschedule the appointment.

Please do not conduct meeting where you don't feel safe. If you still feel unsafe, consult with your supervisor about other options. Every precaution is taken to ensure your personal safety.

Report concerns to the Study Coordinator and PI upon your turn.

Appendix I

Crisis Management Protocol

Suicidal ideation in patient during a hospital encounter

- ☐ If one of the Research Assistants (RAs) discovers suicidal ideation during a hospital encounter with the patient, she may directly ask: “Do you currently have plans to harm yourself or take your own life?” If after asking this question, the RA has any doubts about the patient’s safety, she will first contact the patient’s healthcare team immediately. Following that, she will notify the Support Specialist or one of the two Study Clinicians, as well as the Principal Investigator.

    - ☐ Fred Rivara (Study Clinician): 206-799-7961
    - ☐ Lauren Whiteside (Study Clinician): 773-807-8366
    - ☐ Liz Davis (Support Specialist): 206-496-8215
    - ☐ Ali Rowhani-Rahbar (Principal Investigator): 650-213-6457

Suicidal ideation in patient during a follow-up non-hospital encounter

- ☐ If one of the RAs discovers suicidal ideation during a non-hospital encounter with the patient (i.e., during the follow-up assessment), she may directly ask: “Do you currently have plans to harm yourself or take your own life?” If after asking this question, the RA has any doubts about the patient’s safety, she will immediately call 9-1-1. Following that, she will notify the Support Specialist or one of the two Study Clinicians, who will speak with the patient if appropriate and possible. Finally, she will contact the Principal Investigator.

Interpersonal-Harm Protocol for Crisis Intervention

- ☐ If one of the RAs discover that the patient is in imminent danger of harming another individual, she may directly ask: “Do you currently have plans to harm [Person A] or take their life?” If after asking this question, the study staff has any doubts about Person A’s immediate safety, she will immediately leave the patient and call 9-1-1. She will then contact the Principal Investigator. To ensure the study staff’s safety, she will not inform the patient of her plan to alert the authorities.

References

1. Rowhani-Rahbar A, Zatzick D, Wang J, et al. Firearm-related hospitalization and risk for subsequent violent injury, death, or crime perpetration. *Ann Intern Med*. 2015;162(7):492-500.
2. Adolescent assault victim needs: a review of issues and a model protocol. American Academy of Pediatrics Task Force on Adolescent Assault Victim Needs. *Pediatrics*. 1996;98(5):991-1001.
3. Aboutanos MB, Jordan A, Cohen R, et al. Brief violence interventions with community case management services are effective for high-risk trauma patients. *J Trauma*. 2011;71(1):228-236; discussion 236-237.
4. Becker MG, Hall JS, Ursic CM, Jain S, Calhoun D. Caught in the Crossfire: the effects of a peer-based intervention program for violently injured youth. *J Adolesc Health*. 2004;34(3):177-183.
5. Cheng TL, Haynie D, Brenner R, Wright JL, Chung S, Simons-Morton B. Effectiveness of a mentor-implemented, violence prevention intervention for assault-injured youths presenting to the emergency department: results of a randomized trial. *Pediatrics*. 2008;122(5):938-946.
6. Cheng TL, Wright JL, Markakis D, Copeland-Linder N, Menvielle E. Randomized trial of a case management program for assault-injured youth: impact on service utilization and risk for reinjury. *Pediatr Emerg Care*. 2008;24(3):130-136.
7. Cooper C, Eslinger DM, Stolley PD. Hospital-based violence intervention programs work. *J Trauma*. 2006;61(3):534-537; discussion 537-540.
8. Corbin TJ, Rich J a, Bloom SL, Delgado D, Rich LJ, Wilson AS. Developing a trauma-informed, emergency department-based intervention for victims of urban violence. *J Trauma Dissociation*. 2011;12(5):510-525.
9. Marcelle DR, Melzer-Lange MD. Project UJIMA: working together to make things right. *WMJ*. 2001;100(2):22-25.
10. Shibru D, Zahnd E, Becker M, Bekaert N, Calhoun D, Victorino GP. Benefits of a hospital-based peer intervention program for violently injured youth. *J Am Coll Surg*. 2007;205(5):684-689.
11. Snider C, Jiang D, Logsetty S, Strome T, Klassen T. Wraparound care for youth injured by violence: Study protocol for a pilot randomised control trial. *BMJ Open*. 2015;5(5).
12. Snider C, Lee J. Youth violence secondary prevention initiatives in emergency departments: A systematic review. *Can J Emerg Med*. 2009;11(2):161-168.
13. Walton MA, Chermack ST, Shope JT, et al. Effects of a brief intervention for reducing violence and alcohol misuse among adolescents: a randomized controlled trial. *JAMA*. 2010;304(5):527-535.
14. Watt K, Shepherd J, Newcombe R. Drunk and dangerous: a randomised controlled trial of alcohol brief intervention for violent offenders. *J Exp Criminol*. 2007;4(1):1-19.
15. Zatzick D, Russo J, Lord SP, et al. Collaborative care intervention targeting violence risk behaviors, substance use, and posttraumatic stress and depressive symptoms in injured adolescents: a randomized clinical trial. *JAMA Pediatr*. 2014;168(6):532-539.
16. Zun LS. Violence prevention in the ED: linkage of the ED to a social service agency. *Am J Emerg Med*. 2003;6757(6):454-457.
17. Zun LS, Downey L, Rosen J. The effectiveness of an ED-based violence prevention program. *Am J Emerg Med*. 2006;24(1):8-13.
18. Zun LS, Downey L, Rosen J. An emergency department-based program to change attitudes of youth toward violence. *J Emerg Med*. 2004;26(2):247-251.
19. Purtle J, Rich LJ, Bloom SL, Rich J a, Corbin TJ. Cost−Benefit Analysis Simulation of a Hospital-Based Violence Intervention Program. *Am J Prev Med*. 2015;48(2):162-169.

20. Purtle J, Dicker R, Cooper C, et al. Hospital-based violence intervention programs save lives and money. *J Trauma Acute Care Surg*. 2013;75(2):331-333.
21. Berkowitz SA, Johansen KL. Does motivational interviewing improve outcomes? *Arch Intern Med*. 2012;172(6):463-464.
22. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. *Heal Psychol*. 1994;13:39-46.
23. Cunningham RM, Chermack ST, Zimmerman M a., et al. Brief Motivational Interviewing Intervention for Peer Violence and Alcohol Use in Teens: One-Year Follow-up. *Pediatrics*. 2012;129(6):1083-1090.
24. Gentilello LM, Rivara FP, Donovan DM, et al. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Ann Surg*. 1999;230(4):473-480; discussion 480-483.
25. Godley MD, Godley SH, Dennis ML, Funk RR, Passetti LL, Petry NM. A randomized trial of assertive continuing care and contingency management for adolescents with substance use disorders. *J Consult Clin Psychol*. 2014;82(1):40-51.
26. Saitz R, Palfai TPA, Cheng DM, et al. Screening and brief intervention for drug use in primary care: the ASPIRE randomized clinical trial. *JAMA*. 2014;312(5):502-513.
27. Monti PM, Colby SM, Barnett NP, et al. Brief intervention for harm reduction with alcohol-positive older adolescents in a hospital emergency department. *J Consult Clin Psychol*. 1999;67(6):989-994.
28. Monti PM, Barnett NP, Colby SM, et al. Motivational interviewing versus feedback only in emergency care for young adult problem drinking. *Addiction*. 2007;102(8):1234-1243.
29. Woolard R, Baird J, Longabaugh R, et al. Project Reduce: Reducing alcohol and marijuana misuse: Effects of a brief intervention in the emergency department. *Addict Behav*. 2013;38(3):1732-1739. doi:10.1016/j.addbeh.2012.09.006.
30. Cunningham R, Knox L, Fein J, et al. Before and after the trauma bay: the prevention of violent injury among youth. *Ann Emerg Med*. 2009;53(4):490-500.
31. Lako DA, de Vet R, Beijersbergen MD, Herman DB, van Hemert AM, Wolf JR. The effectiveness of critical time intervention for abused women and homeless people leaving Dutch shelters: study protocol of two randomised controlled trials. *BMC Public Health*. 2013;13(1):555.
32. de Vet R, van Luijtelaar MJA, Brilleslijper-Kater SN, Vanderplasschen W, Beijersbergen MD, Wolf JRLM. Effectiveness of Case Management for Homeless Persons: A Systematic Review. *Am J Public Health*. 2013;103(10):e13-e26.
33. Hwang SW, Burns T. Health interventions for people who are homeless. *Lancet*. 2014;384(9953):1541-1547.
34. Angell B, Matthews E, Barrenger S, Watson AC, Draine J. Engagement processes in model programs for community reentry from prison for people with serious mental illness. *Int J Law Psychiatry*. 2014;37(5):490-500.
35. Shinn M, Samuels J, Fischer SN, Thompkins A, Fowler PJ. Longitudinal Impact of a Family Critical Time Intervention on Children in High-Risk Families Experiencing Homelessness: A Randomized Trial. *Am J Community Psychol*. 2015;56(3-4):205-216.

Study Protocol
26 October 2015

Title: Helping Patients with Firearm Injuries

Investigators: Ali Rowhani-Rahbar, MD, MPH, PhD; Lauren Whiteside, MD, MS; Kevin Haggerty, PhD; Frederick Rivara, MD, MPH

Affiliations: Department of Epidemiology, School of Public Health (Rowhani-Rahbar, Rivara); Department of Pediatrics, School of Medicine (Rowhani-Rahbar and Rivara); Department of Emergency Medicine, School of Medicine (Whiteside); School of Social Work (Haggerty); and Harborview Injury Prevention and Research Center (Rowhani-Rahbar, Whiteside, Haggerty, and Rivara)

Research Team and Contact Information

Name	Role	E-mail
Ali Rowhani-Rahbar	Principal Investigator	rowhani@uw.edu
Lauren Whiteside	Co-Investigator	laurenkw@uw.edu
Kevin Haggerty	Co-Investigator	haggerty@uw.edu
Frederick Rivara	Co-Investigator	fpr@uw.edu
TBD	Project Coordinator	
TBD	Case Manager 1	
TBD	Case Manager 2	
TBD	Research Assistant 1	
TBD	Research Assistant 2	
TBD	Data Programmer	

Contents

1. Significance 5
2. Objectives 6
3. Approach 7
3.1. Study setting and population 7
3.2. Eligibility 7
3.3. Study design 8
3.4. HMC usual care for GSW Victims 8
3.5. Trial profile 9
3.6. Recruitment, disclosure of assignment, and consent 9
3.5. Assignment 10
3.6. Intervention 10
3.6.1. Brief intervention 10
3.6.2. Extended outreach 10
3.6.3. Multiagency Attention 12
3.7. Baseline and follow-up assessments 13
3.8. Measures 13
3.8.1. Vital, criminal, and medical records 14
3.8.2. Surveys 14
3.9. Statistical analysis and power 14
3.10. Timeline 15
4.1. Risks to human subjects 15
4.1.1. Psychological risks 15
4.1.2. Confidentiality risks 15
4.1.3. Vulnerable populations 16
4.2. Adequacy of protection against risks 16
4.2.1. Psychological risks 16
4.2.2. Confidentiality risks 16
4.2.3. Vulnerable populations 16

List of Abbreviations

HMC: Harborview Medical Center
GSW: Gunshot wound
RA: Research Assistant
CM: Case Manager
ED: Emergency Department
MDT: Multidisciplinary Team
MI: Motivational Interviewing
CRA: Community Reinforcement Approach

Research Synopsis

Study Title: Helping Patients with Firearm Injuries
Study Population: Patients presenting to Harborview Medical Center with firearm injury
Study Design: Randomized Controlled Trial
Study Objectives: To examine the effectiveness of a multicomponent intervention including brief motivational interviewing, extended outreach services using community reinforcement approach, and multiagency attention.
Targeted Sample Size: 150 total
Study Duration: Two years (one year of recruitment and one year of follow-up).

1. Significance

About 150 individuals present to an emergency department in King County (primarily Harborview Medical Center [HMC]) for firearm-related injuries each year. About two-third of these patients require admission for these injuries. While this number is relatively small, these individuals are at greatly increased risk of subsequent rehospitalization for another firearm or assault-related injury, arrest for firearm-related or violent crime, nonfirearm-related nonviolent crime, or firearm-related death in the five years after discharge from the hospital.[1] Thus, interventions among this group of individuals have the potential to reduce the high risk of recidivism, morbidity, and mortality among them, and lead to lower rates of firearm violence and its consequences in the community.

Patients with gunshot wounds (GSWs) seen at HMC receive many services. First, all patients are seen in the Emergency Department (ED) by an attending Emergency Medicine physician and resident physicians on the trauma team working in the ED. Depending on the nature and location of the GSW, these patients are often seen by specialty consulting services such as orthopedic surgery or vascular surgery. If patients have life-threatening injuries they are seen by the trauma surgery service including an attending trauma surgeon. In addition, all patients that are victims of violence are seen by a member of the Social Work staff during their hospital stay. Currently, Level 1 trauma centers in the country including HMC are mandated by the American College of Surgeons to provide alcohol screening and brief intervention services to trauma patients, including GSW victims. Patients who are admitted and screened for substance use (e.g., alcohol and drugs) can be seen by the Harborview Addiction Intervention Service which is comprised of psychologists and chemical dependency counselors. Lastly, patients who present to HMC for GSWs and suicidal intent will receive a comprehensive psychiatric evaluation once they are medically stable. However, currently there is no standardized intervention offered to GSW victims.

A number of hospitals across the country have created violence intervention programs to specifically help patients who sustain violent injury. A network, the National Network of Hospital-based Violence Intervention Programs, has formed (http://nnhvip.org). These programs seek to engage patients in the hospital during the recovery period as a golden opportunity (“teachable moment”) to change their life and reduce retaliation and recidivism. Through working groups, meetings, e-newsletter and conferences, Network members collaborate in research and evaluation, explore opportunities for funding sustainability, develop and share best practices, and identify ways to collectively have an impact on policy. While the creation of this infrastructure is a step in the right direction, researchers have not rigorously tested the effectiveness of these intervention programs. Specifically, there have been no trials evaluating the effectiveness of hospital-based violence intervention programs offered to GSW victims. If research shows that such programs may not be effective, resources might be better spent on other approaches to reduce gun violence.

We aim to conduct a randomized controlled trial (RCT) of an intervention program that combines a hospital-based intervention and a structured outreach program. We will provide a

brief intervention delivered at HMC to bolster the interaction that all these patients will have with hospital Social Work staff. This intervention is derived from motivational interviewing (MI) which is a patient-centered behavioral technique based on the stages of change model and attempts to engage patients in order to find reason to change behavior.[2,3] By empathetically exploring ambivalent feelings about health-related behavior, MI encourages reduction in risky behavior. A number of investigations have demonstrated the effectiveness of providing MI-based brief interventions in the ED or inpatient wards, primarily for alcohol use disorders[4,5] but also for violent behaviors.[6,7] Specifically, brief intervention utilizing principles of MI have been successful at reducing youth violence in large urban populations with a decrease in violence sustained after one year.[8,9] Additionally, a behavioral-based intervention including MI among adolescents admitted to HMC with trauma showed a reduction in weapon carriage during the year after hospitalization.[6] This approach is appealing as its rationale is plausible and potential harms are minimal.[2]

A longitudinal intervention program provides the added benefit of continued engagement. Providing outreach and follow-up after the healthcare encounter to GSW victims holds promise for reducing future violence and criminal activity. The Community Reinforcement Approach (CRA) may provide a strong framework for providing outreach and follow-up to these patients. CRA is derived from a social ecological/systems model that believes behavioral trajectories and outcomes are the result of activities defined by or in response to the demands of specific social systems: people behave in accordance to the setting or environment they inhabit. This includes their friends and family, as well as the actual physical location where they live. Following this ecological framework, there are two ways to change a person's behavior: (1) Change the settings in which individuals conduct everyday activities; or (2) Change the way individuals respond to influences from that particular setting. CRA aims to place GSW victims in positive settings that promote a healthy lifestyle and safe behavior. The CRA model involves one-on-one sessions with clients to build skills to prevent relapse, increase engagement in prosocial activities, and strengthen social support. The model has shown evidence of effectiveness in randomized trials with adolescent populations for substance abuse treatment.[10] The Washington State Institute for Public Policy has determined that the approach with adolescence is cost-beneficial. For every dollar invested in the approach, there is a $5.09 savings to the community. The treatment model has also been implemented with fidelity and effectiveness in community agencies that serve young adults ages 18-24 in King County and there is some but limited infrastructure for providing services to King County residents. This approach has the potential to provide an intervention framework for a second tier outreach to GSW victims in King County.

2. Objectives

The goal of this study is to test the effectiveness of an intervention program for reducing morbidity and mortality among GWS victims. Specifically, the intervention program consists of hospital-based MI about behavior change, a longitudinal CRA program, and multiagency attention. We seek to evaluate the effects of the intervention program on the following outcomes:

Primary

- Crime: Official reports of arrests and self-reports of criminal activity
- Injury: Official reports of injury and self-reports of injury
- Death: All-cause and cause-specific mortality

Secondary

- Gun carrying: Official reports of arrests for weapon carrying; self-reports of weapon carrying
- Intimate partner violence: official reports of protection orders or police calls; self-reports of intimate partner violence
- Substance abuse: Use of alcohol or other drugs; treatment for substance use
- Mental health: Depression, PTSD, and treatment received for mental health problems
- Employment or enrollment in classes
- Physical health, happiness, and quality of life
- Availability of social support and social network
- Use of study case manager (process measure)

We will test the impact of the intervention against usual (i.e. standard) care, and we anticipate that participants in the intervention condition will see greater improvements in the above outcomes compared to those who receive usual care in this setting.

3. Approach

3.1. Study setting and population

The study will be conducted at HMC located in Seattle, Washington. HMC has an annual census of about 65,000 adult patient visits per year treating a typically diverse and urban population. Based on prior data, about 150 GSW patients (including both ED visits and hospitalizations) are treated at HMC every year.

3.2. Eligibility

Patients can be enrolled in the study from the ED, inpatient area, or in HMC-affiliated clinics after discharge. Eligible subjects will be:

- Over the age of 18 years
- Able to provide consent
- Able to understand and speak English
- Able to provide at least one mode of contact (e.g., cell phone, land line, e-mail, friend or relative)
- Living in King County

- Receiving treatment for a GSW at HMC and returning to the community, and not prison following treatment

Patients will be ineligible to participate in this study if they are:

- 18 years of age or younger
- Unable to provide consent including those with severe neurologic damage
- Unable to understand or speak English
- Unable to provide any mode of contact
- Living outside of King County, or planning to move outside of King County within six months following discharge
- Sent to prison upon hospital discharge
- Incarcerated at the time of GSW injury

3.3. Study design

We will conduct a randomized controlled trial in which GSW victims injured in Seattle and treated at HMC either receive an intervention or treatment as usual. The unit of randomization is by week of treatment; that is, the study staff will assign GSW victims to a one of the two groups based on the week in which they were shot and treated at HMC. A week is defined as one starting on Monday morning at 8:00 for a duration of seven days. We will use block randomization with varying block sizes of 2 and 4 to assign each week to one of the two groups of the trial. As such, all patients admitted in the same week will be assigned to the same group. This randomization scheme will ensure that all victims in the same shooting incident will receive the same study assignment.

3.4. HMC usual care for GSW Victims

All HMC patients treated for a GSW will receive care as usual by HMC physicians and staff. For patients treated for a GSW, usual care can include the following:

- All necessary medical care and scheduled follow-up with subspecialty services.

- Evaluation by Social Work during the ED or inpatient stay: Social Work staff will specifically assist with communicating with family as needed, including contact with police if the patient desires, evaluation eligibility for the crime victims compensation fund, referral to the Harborview Center for Sexual Assault and Traumatic Stress, and safety planning when a concern for continued violence is present.

- Screening for alcohol use: Patients who screen positive for alcohol use at the time of presentation to the HMC ED are eligible to be seen by the HMC Addiction Intervention Service. This service provides brief intervention using MI techniques that targets alcohol use. While all patients with an elevated blood alcohol levels are eligible to be contacted by the Addiction Intervention Service staff, not all patients actually receive this service.

- Discharge planning services: HMC staff will help patients with specific needs with medical devices (e.g., wheelchair, walker) or coordination of any needed home health services.

- Financial counseling services to patients, including those without insurance: Patients can access this service during their ED or hospital stay or within 14 days of their healthcare visit. Financial counseling will assist patients with applying for charity care for medically necessary services and assist with questions regarding insurance coverage. Eligibility for charity care is based on published poverty guidelines.

3.5. Trial profile

Figure 1 illustrates participant flow through the program.

3.6. Recruitment, disclosure of assignment, and consent

The study research assistant (RA) will review HMC medical records to identify GSW patients and determine study eligibility.

The study RA will not conduct any pre-screening beyond medical record review. We have prepared requests for HIPPA and consent waivers as well as the University of Washington Confidentiality Agreement to allow for pre-screening of patients. The study RA will review medical records to identify eligible GSW patients treated at HMC. For recruitment purposes, the study RA will collect patient names and other identifying information; (s)he will retain the names of patients who decline participation so as to re-approach them they are admitted for future GSW injury and/or treatment. When the study RA identifies an eligible patient, s/he will approach the patient using an institutional review board (IRB)-approved recruitment script. For patients who are hospitalized at the initial incident, the study RA will approach the eligible patient during the hospitalization once they are stable. For patients who are treated in the emergency department and do not get admitted (i.e., discharged from the ED), the study RA will approach the eligible patient during the ED visit or during a scheduled follow-up visit at HMC depending on the nature and location of the GSW.

The informed consent discussion will include explanations of the study's purpose, the two assignments, study procedures, all risks and benefits associated with participation as well as confidentiality procedures. The study RA will:

- Ensure that no members of the patient's healthcare team are present during the consent process
- Present the study to the patient and conduct an informed consent conference if the patient is interested in participation
- Emphasize that the decision to participate is voluntary and will not affect medical care at HMC

- Prompt patients to ask questions.
- Reiterate the participant's right to refuse participation and then ask whether the patient is willing to participate at the conclusion of the informed consent process

There will be two different consent forms, one for each study group (see Assignments). Following consent, the study RA will administer the baseline survey (see Baseline and Follow-up Assessments) to the patient. For patients assigned to the usual care group, the study RA will ensure that we will have follow-up contact information and inform the patient that they will be contacted to conduct the next follow-up assessment at month 1. For patients in the intervention group, the RA will contact the study Case Manager (CM).

3.5. Assignment

Patients will receive one of the two assignments:

- Intervention: Receives a brief intervention at the start of the study followed by 6 months of study case management and outreach services. A multidisciplinary team of technical consultants will review cases in this group and help the study CM provide appropriate care and referrals.
- Control: Receives usual care, including any outreach services offered by or at HMC.

During intervention weeks, the study RA will contact the study CM, in advance of approach, so that the study CM can meet the patient in the private room after the RA has left. The study CM will initiate the intervention at that time (see Intervention).

3.6. Intervention

The intervention program contains three elements: (1) Initial contact and brief intervention with the study CM; (2) Extended outreach services by study CM; and (3) Multi-agency attention.

3.6.1. Brief intervention

The brief intervention includes a feedback session utilizing principles of MI to elicit the goals and needs of patients. If needed, the study CM will provide a referral to community resources.

3.6.2. Extended outreach

The extended outreach includes a formal needs assessment and self-assessment of functioning. Based on these evaluations, the study CM will use the CRA to address problematic areas. CRA is derived from a social ecological/systems model that believes behavioral trajectories and outcomes are the result of activities defined by or in response to the demands of specific social systems: people behave in accordance to the setting or environment they inhabit. These systems include friends and family, as well as the actual physical community in which they live. Following this ecological framework, there are two ways to change a person's

behavior: change the settings in which individuals conduct everyday activities or change the way individuals respond to influences from that particular setting. In this study, CRA aims to place GSW victims in positive settings that promote a healthy lifestyle and safe behavior.

The duration of the CRA intervention is 12 sessions, which will occur over a 6-month period. Each session will occur at a mutually agreeable location for both the participant and study CM. The study CM will write case summaries of sessions, and those summaries will be study data. GSW victims in the Intervention group will undergo a needs assessment and complete a self-assessment of functioning in multiple areas. Based on these evaluations, the study CM will choose from a "menu" of CRA procedures that address problematic areas, including stress, problem-solving and communication skills, as well as participation in prosocial activities. Role-playing and behavioral rehearsal is a crucial element of CRA skills training, as these exercises teach communication and relapse-prevention skills. Participants will receive homework assignments to practice skills learned during sessions and are encouraged to take part in positive leisure activities. CRA Core Procedures are as the following:

- Procedure 1: Functional Analysis of Substance Use Behavior
- Procedure 2: Functional Analysis of Prosocial Behaviors
- Procedure 3: Happiness Scale and Goals of Counseling
- Procedure 4: Trauma and Mental Health Counseling Referral
- Procedure 5: Increasing Prosocial Recreation
- Procedure 6: Relapse Prevention Skills (if applicable)
- Procedure 7: Communication Skills
- Procedure 8: Problem-Solving Skills
- Procedure 9: Treatment Closure

CRA Additional Procedures are as the following:

- Additional Procedure 2: Job-Seeking Skills
- Additional Procedure 3: Anger Management
- Additional Procedure 4: Sobriety Sampling
- Additional Procedure 5: Systematic Encouragement
- Additional Procedure 6: Medication Adherence and Monitoring
- Additional Procedure 7: Couples Relationship Skills

The study CM will deliver 12 CRA sessions to all intervention-assigned participants as the following:

- Session 1: In the first session, the study CM discusses CRA treatment success, philosophy, and sessions. S/he provides information about the length of treatment sessions, number and type of sessions, disclosure of information policy. The study participant is encouraged to ask questions at any point during their work together. The study CM's goal for the session is to develop rapport. S/he can use the Happiness Scale

(Procedure 3) as a basis for conversation and a mechanism for determining areas of importance to the participant. If time permits, the study CM and participant can begin the functional analysis of substance use (Procedure 1).

- Sessions 2–4: During these sessions, the study CM will complete a Functional Analysis of Substance Use Behavior (Procedure 1, if appropriate), a Functional Analysis of Prosocial Behaviors (Procedure 2), and at least one Happiness Scale form and a Goals of Counseling form (Procedure 3). During these sessions, the study CM encourages Prosocial Recreation (Procedure 5). Other procedures may be used depending on the needs of the participant.

- Sessions 5–10: These sessions follow a similar format. The study CM does not need to teach skills in a standard sequence. Standard parts of each session will include the following:

    - Begin with rapport-building interchanges
    - Check on homework completion
    - Ask about social activities or encouraging healthy social activities
    - Ask about progress in completion of goals listed on the Goals of Counseling form
    - Ask about relationships with friends
    - Ask about relationships with family members
    - Ask about other problems
    - End with a homework assignment related to the session content
    - Reinforce attendance at the present session and encourage future attendance
    - Schedule the time and location for the next session

    Topics and skills covered in each session will include the following:

    - Relapse Prevention Skills (if applicable) (Procedure 6)
    - Communication Skills (Procedure 7)
    - Problem-Solving Skills (Procedure 8)

- Session 11: This session focuses on the skills previously presented. The study CM may have introduced these skills earlier but may review with participant.

- Session 12: This last session includes the review of treatment goals and termination of services (Procedure 9).

3.6.3. Multiagency Attention

The Study CM will hold regular meetings with a multidisciplinary team (MDT) to seek advice about care management and service recommendations for each individual case. Of necessity, members of the MDT will know the identity of the individuals discussed in meetings. We do not consider MDT members to be engaged in research. They are technical consultants for the study

CM. The MDT will include members from community mental health, substance abuse treatment, housing services, employment and adult education services, legal services as well as law enforcement.

3.7. Baseline and follow-up assessments

All participants will engage in research activities for one year following enrollment. Participants will complete a baseline survey at consent and follow-up surveys at 1-month, 3-month, 6-month, 9-month, and 12-month follow-up assessments. The baseline survey will be a self-administered assessment on a tablet computer. If a patient is unable to complete the survey electronically, the study RA will read items and record responses. At follow-up assessments, the study RA will send participants an email and a text with a link to the survey. Study staff will build the survey using a secure web application. If a participant cannot complete the survey electronically or does not complete the survey in one week, the study RA will call the participant to complete the survey over the phone. If the study RA cannot reach the participant, (s)he will call the alternative contacts listed by the participant.

A consented subject may become incarcerated at some point during participation, making them an incidental prisoner subject. We will send follow-up surveys to all participants, even if they are incarcerated, with the understanding that email may be blocked during this time. A participant in the intervention group could become an incidental prisoner while receiving study case management services. If this occurs, study case management services will stop while the participant is in prison. The study CM will not make contact with the participant while incarcerated. Because participants in the intervention group are eligible for case management services for 6 months, they could return to study case management if the incidental prisoner is released from prison during that 6-month window.

Subjects will receive payment completion of surveys. Participants can earn up to $225 if they complete all surveys. Survey time points and payment amounts are as follows:

- Baseline survey: $25
- 1-month follow-up survey: $30
- 3 month follow-up survey: $35
- 6-month follow-up survey: $40
- 9-month follow-up survey: $45
- 12-month follow-up survey: $50

3.8. Measures

Outcomes will be measured using two different, but complementary, sources: (1) Vital, criminal, and medical records; and (2) Survey.

3.8.1. Vital, criminal, and medical records

A number of outcomes can be measured using routinely collected data. These will include:

- Washington State Patrol records to identify cases of arrest
- Harborview Medical Center medical records, Washington State trauma registry, and Washington State Emergency Department Information Exchange to identify cases of injury
- Vital records to identify cases of death

3.8.2. Surveys

All surveys contain the same scales and items. Copies of the baseline and follow-up survey are enclosed. A list of those scales and items is provided below:

- Patient Health Questionnaire (PHQ-9) to measure depression
- Short Form Health Survey (SF-12) to measure health-related quality of life
- Posttraumatic Street Disorder (PTSD) Checklist – Civilian Version (PCL-C) to measure PTSD
- The Alcohol Use Identification Test (AUDIT) to measure alcohol use
- The National Institute on Drug Abuse-modified Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) to measure substance use
- Conflicts Tactics Scale (CTS) to measure interpersonal violence
- Happiness Scale to measure satisfaction with specific areas of life
- Service Utilization Questions to measure use of physical and mental health services
- Criminal Activity Questions to measure criminal justice involvement, violence, criminal outcomes, conviction(s), and Incarceration(s)
- Multidimensional Scale of Perceived Social Support to measure perceived social support
- Education Questions to measure educational attainment and activities
- Employment Questions to measure employment status
- Housing Questions to measure type of housing
- Contact Information Questions to increase the likelihood of reaching the subject during the follow-up

3.9. Statistical analysis and power

The study will be powered on the basis of the primary outcome of arrest. Our previous investigation among GSW victims in Washington State and King County indicated that the rate of subsequent arrest following hospital discharge among these individuals is about 15,528 cases per 100,000 person-years. This translates to a one-year cumulative incidence of arrest at about 15% (i.e., 1 – exp[–15,528/100,000]). Assuming that the intervention will reduce the risk of subsequent arrest to 5% (i.e., 10% absolute reduction; 67% relative reduction), a significance level of 0.05, a power of 80%, and an intervention-to-control ratio of 1, we need to enroll at least

140 patients in the intervention arm and 140 patients in the control arm in this study. Considering the number of patients presenting to HMC with GSWs each year (i.e., about 150), we need to enroll patients for at least two years to provide effect sizes with sufficient precision.

All analyses will be in accord with the intent-to-treat principle. Cox proportional hazards regression models will be used to examine both single and multiple failure (i.e., event) times. Since the unit of randomization is calendar week, clustering by calendar week will be taken into account in all analyses. A randomization scheme that is not on the individual level may result in imbalances in characteristics of individuals in different arms (e.g., age, race). As such, we will carefully inspect all individual characteristics and compare them between the two arms; all analyses will be adjusted for any potential imbalances detected at baseline.

3.10. Timeline

The team of investigators and staff will meet in person on a weekly basis to track progress and address issues that may arise over the course of the follow-up.

Year	**1**				**2**			
Training study staff and start-up								
Enrollment								
Data collection								
Data management								
Data analysis								
Preparing publications and presentations								

4. Protection of Human Subjects

4.1. Risks to human subjects

4.1.1. Psychological risks

Participants may face psychological risks in participating in the study. All participants might feel stress or psychological discomfort while filling out assessments about their mental health, physical health, relationships, history of violence, and criminal activities. Participants in the intervention group may feel some stress or discomfort during CRA interventions aimed at reducing high risk behaviors.

4.1.2. Confidentiality risks

All participants face confidentiality risks. Participants' privacy may be violated if their data is not kept confidential. Participants in the intervention group face a higher confidentiality risk, as their cases will be the subject of MDT review.

4.1.3. Vulnerable populations

Some of the subjects may become incidental prisoners during the study. Participants in the intervention group may become incidental prisoners during the 6-month intervention period. Also, any participant may become an incidental prisoner during follow-up surveys.

4.2. Adequacy of protection against risks

4.2.1. Psychological risks

The research staff (RA and CM) engaging with subjects will be trained to work with this high-risk population. They will explain the purpose of the research and will assure participants that their answers are confidential. The research staff will work to reduce any stress or psychological discomfort during assessment or outreach, and remind subjects to report any discomfort or stress. The research staff will also fully inform participants that they have the right to skips questions or activities or withdraw from the study at any time. During assessments, the study RA or study CM may discover a subject's suicidal intentions. The research staff will immediately refer the subject to Mental Health services at HMC and contact the study PI.

4.2.2. Confidentiality risks

Research staff will take all necessary precautions to prevent the loss of confidentiality. The research staff will keep all data in secure databases on password-protected networks. Study staff will assign study codes to participants and will record all assessment data using those study codes. The document linking participant name and study code will be password protected, and the document will be stored on a secure, password-protected computer. Assessment data will be stored in password-protected network. All paper-based data (consent forms) will be stored in a locked file cabinet. We will retain a link between study code numbers and direct identifiers after the data collection is complete, and destroy it on 1/1/2020. Members of the MDT will sign a Confidentiality Agreement to ensure that none of the shared data in the meetings are repeated or disclosed in public. The study RA will notify potential participants about information sharing with the MDT during the consent conference. We will ask patients to sign a HIPAA authorization to release medical records for the period of their study participation. This authorization is separate from the HIPAA waiver request for pre-screening.

4.2.3. Vulnerable populations

We have prepared a Vulnerable Populations Supplement to address the engagement of incidental prisoners and request a prisoner advocate be present at full committee review.

4.3. Potential Benefits of the Proposed Research to Human Subjects and Others

Participants in the intervention group will receive a brief intervention and extended case management services to reduce individual high-risk behaviors. These participants will also be referred to community agencies who can help address specific areas of need. Participants in the control group will not directly benefit from participating in the study; however, the enforcement of usual care as described above may be considered a potential benefit.

4.4. Importance of the Knowledge Gained

Gun violence affects society in many ways, including greater medical costs, reductions in quality of life, and stresses on the criminal justice system. Gun violence prevention and intervention programs hold the potential to drastically reduce reinjury, readmission, retaliation and recidivism. While many hospitals have adopted violence intervention programs, very few have rigorously evaluated program effectiveness. Our study will contribute to the field of gun violence prevention.

5. Conflict of Interest

None

6. Publications and Presentations

Upon completion of the program, we will provide a report for stakeholders as well as presentations and publications for scientific conferences and journal, respectively, to disseminate the knowledge gained.

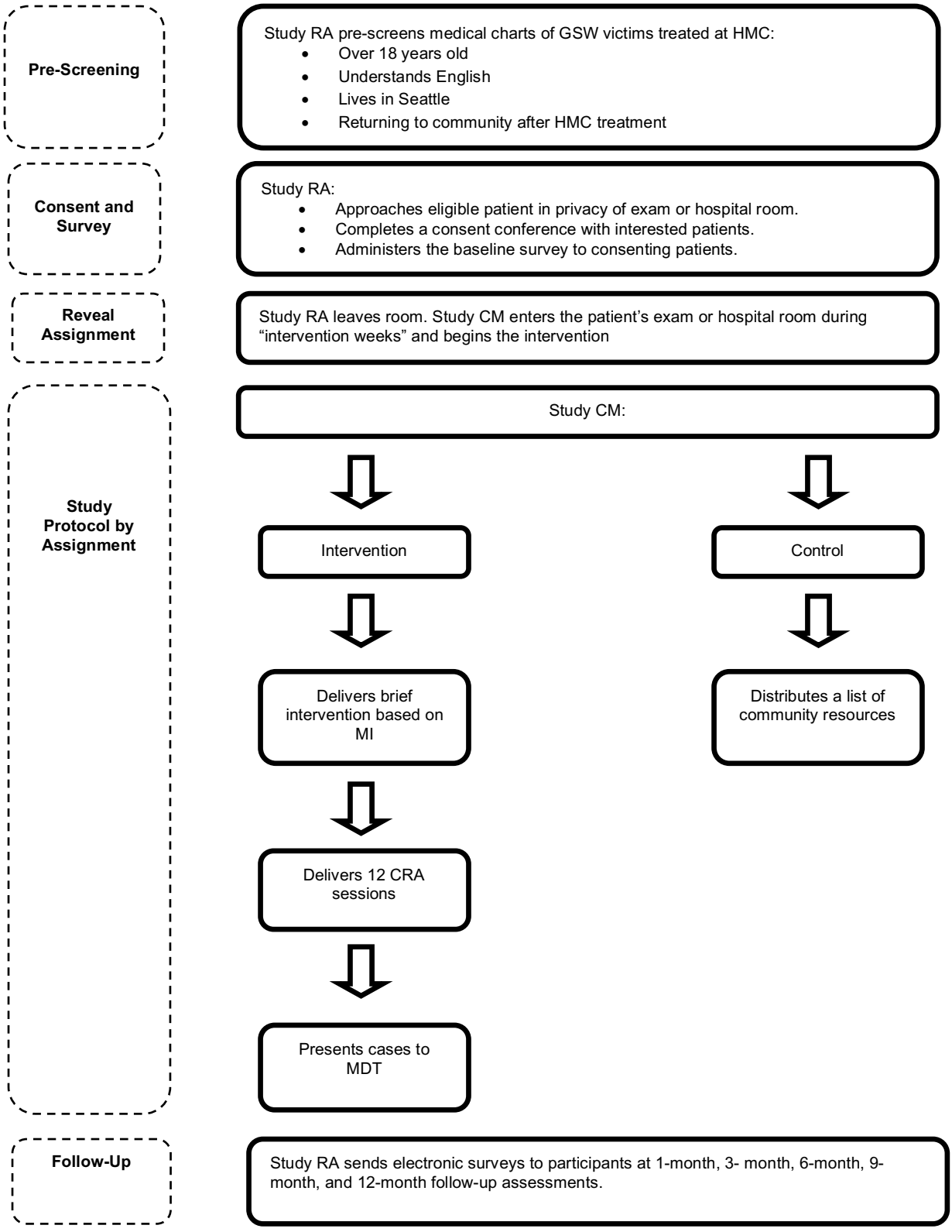


Figure 1. Trial profile. HMC: Harborview Medical Center; RA: Research Assistant; CM: Case Manager; MDT: Multidisciplinary Team; MI: Motivational Interview

7. References

1. Rowhani-Rahbar A, Zatzick D, Wang J, et al. Firearm-Related Hospitalization and Risk for Subsequent Violent Injury, Death, or Crime Perpetration. Ann Intern Med 2015;162(7):492–500.

2. Berkowitz SA, Johansen KL. Does motivational interviewing improve outcomes? Arch Intern Med 2012;172(6):463–4.

3. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. Heal Psychol 1994;13:39–46.

4. Monti PM, Barnett NP, Colby SM, et al. Motivational interviewing versus feedback only in emergency care for young adult problem drinking. Addiction 2007;102(8):1234–43.

5. Woolard R, Baird J, Longabaugh R, et al. Project Reduce: Reducing alcohol and marijuana misuse: Effects of a brief intervention in the emergency department. Addict Behav 2013;38(3):1732–9.

6. Zatzick D, Russo J, Lord SP, et al. Collaborative care intervention targeting violence risk behaviors, substance use, and posttraumatic stress and depressive symptoms in injured adolescents: a randomized clinical trial. JAMA Pediatr 2014;168(6):532–9.

7. Cunningham R, Knox L, Fein J, et al. Before and after the trauma bay: the prevention of violent injury among youth. Ann Emerg Med 2009;53(4):490–500.

8. Cunningham RM, Chermack ST, Zimmerman M a., et al. Brief Motivational Interviewing Intervention for Peer Violence and Alcohol Use in Teens: One-Year Follow-up. Pediatrics 2012;129(6):1083–90.

9. Walton MA, Chermack ST, Shope JT, et al. Effects of a brief intervention for reducing violence and alcohol misuse among adolescents: a randomized controlled trial. JAMA 2010;304(5):527–35.

10. Godley MD, Godley SH, Dennis ML, Funk RR, Passetti LL, Petry NM. A randomized trial of assertive continuing care and contingency management for adolescents with substance use disorders. J Consult Clin Psychol 2014;82(1):40–51.