

**An Intergovernmental Humanitarian Obligation:
Migration & Human Trafficking Vulnerability**

--

**A Mixed-Methods Pilot Study of Behavior Change Theory-Guided Heart Disease
Education Program in Incarcerated Men
*Rhode Island Department of Corrections (RIDOC): Heart & Sole Debate***

By
Melissa Godfrey, RN BSN
MPH, Brown University, 2019

Thesis submitted in partial fulfillment of the requirements for the
Degree of Master of Public Health in the Brown University School of Public Health

Providence, Rhode Island
May 2019

This thesis by **Melissa Godfrey** is accepted in its present form
by the Brown University School of Public Health as satisfying the
thesis requirements for the degree of Master of Public Health.

Date_____

Rosemarie Martin, PhD, Advisor

Date_____

Patricia A. Cioe, PhD, Reader

Date_____

Adam Levine, MD, MPH, FACEP Reader

Date_____

Annie Gjelsvik, PhD Associate Director, Master of Public Health Program

Approved by the Graduate Council

Date_____

Andrew G. Campbell, Dean of the Graduate School

Acknowledgements

This study was supported by Brown University and the Rhode Island Department of Corrections. Thank you to my thesis advisor, Rosemarie Martin, PhD and thesis reader, Patricia A. Cioe, PhD. Thank you to Harold Lee, PhD, you've been a consistent source of motivation and support throughout the thesis development, I cannot thank you enough. Thank you to Marten Basta, MD, and Professor John Papay, who supported the statistical analysis of this project, without you the project would not have been possible. Thank you, Eileen Stuart-Shor, PhD, ANP-BC, FAHA, FAAN, you've been an inspiration and wonderful guide throughout the years. Thank you for allowing me to adapt the Heart & Sole curriculum to reach a new population.

Big thank you kindly to all the staff at the Rhode Island Department of Corrections who supported this project. Special thanks to Deborah Davis who was a constant source of positive reinforcement, knowledge, and guidance. Your leadership inspired me to continue beyond my internship at DOC and increase my involvement in the field. Your unequivocal support allowed me to navigate the procedures at RIDOC and make this project a reality.

Thank you to my hero of a mother. You taught me to be resilient, resourceful, and perseverant. I hope my life work can serve as a reflection of all the love and passion you've instilled in me. Thank you to my sister, Brittini, you've always supported my efforts and applauded my achievements. Thank you to my darling partner, Marten, you inspire me every day through your dedication to your patients in practice and by advancing clinical research. Thank you for standing by me through the joys and challenges and always reminding me of the real goal, helping more people. I can only aspire to be as productive, efficient, and selfless as you are.

More Acknowledgements:

Deputy Warden, Kathleen Lyons
Medical Director, Jennifer Clarke, MD, MPH, FACP
Jeff Renzi
Deputy Warden Kerri McCaughey
Warden Carole Dwyer
Lieutenant Larry Ceresi
Lieutenant John Meehan
Lieutenant Albert Normandin
Captain Jack Vicino
Captain James Hollis
Ita Irizarry, MA, CIP
Celia Riccardi MS, OTR/L
Jennifer Campion, PT, DPT
Matthew J. Mimiaga, ScD, MPH
Karina Santamaria, PhD

Table of Contents

AN INTERGOVERNMENTAL HUMANITARIAN OBLIGATION: MIGRATION & HUMAN TRAFFICKING VULNERABILITY	1
ABSTRACT	2
BACKGROUND	3
RESEARCH HYPOTHESIS	7
METHODS	8
RESULTS	9
DISCUSSION	16
LIMITATIONS	16
CONCLUSIONS AND RECOMMENDATIONS	17
NEXT STEPS	18
REFERENCES.....	19
APPENDIX 1: KEY INFORMANT INTERVIEWS.....	20
APPENDIX 2: KEY INFORMANT SUGGESTED ARTICLES/VIDEOS	21
 A MIXED-METHODS PILOT STUDY ASSESSMENT OF BEHAVIOR CHANGE THEORY- GUIDED HEART DISEASE EDUCATION PROGRAM IN INCARCERATED MEN RHODE ISLAND DEPARTMENT OF CORRECTIONS (RIDOC): HEART & SOLE DEBATE	 22
LIST OF TABLES AND ILLUSTRATIONS	23
ABSTRACT.....	24
BACKGROUND	25
THEORETICAL FRAMEWORK FOR STUDY.....	27
INNOVATION OF THE CURRENT STUDY.....	32
STATEMENT OF PURPOSE.....	32
METHODS	33
METHOD: PHASE 1. PLANNING	34
METHOD: PHASE 2. QUALITATIVE FORMATIVE RESEARCH	35
<i>Procedures.....</i>	<i>35</i>
<i>Results</i>	<i>37</i>
METHOD: PHASE 3. CONDUCTING THE INTERVENTION: QUANTITATIVE RESEARCH	39
<i>Procedures.....</i>	<i>39</i>
<i>Measures.....</i>	<i>41</i>
<i>Data Analysis.....</i>	<i>43</i>
<i>Results</i>	<i>44</i>
DISCUSSION	47
LIMITATIONS	50
CONCLUSIONS	51
REFERENCES.....	52
APPENDIX 1: UNDERLYING THEORY CONSTRUCT FIGURES 1 & 2.....	54
APPENDIX 2: COURSE CURRICULUM	55
APPENDIX 3: RESULTS TABLES 1-7	56
APPENDIX 4: ASSESSMENT QUESTIONNAIRE	60
APPENDIX 5: IRB PROPOSAL	66
<i>Protocol Narrative: Lay Summary:</i>	<i>69</i>
<i>Protocol Narrative: Lay Summary:</i>	<i>69</i>
<i>Methodology:.....</i>	<i>70</i>
<i>Approach Timeline: Research Design and Methods.....</i>	<i>75</i>
<i>RIDOC Letter of Support</i>	<i>76</i>
<i>CONSENT</i>	<i>77</i>

**An Intergovernmental Humanitarian Obligation:
Migration & Human Trafficking Vulnerability**

—

Melissa Godfrey, RN BSN
MPH, Brown University, 2019

**Abstract of An Intergovernmental Humanitarian Obligation:
Migration & Human Trafficking Vulnerability**

by Melissa Godfrey, RN BSN, MPH Brown University, May 2019

--

Human trafficking is a social threat that affects millions worldwide. Situations of financial, social, physical, or mental instability serve as a precursor for potential victims. Traffickers target individuals who appear to be vulnerable and defenseless as means of control. Migrants on the move, in particular, are more susceptible to trafficking as they are leaving the familiarities of their homes. Humanitarians hold an obligation to ensure trafficking risk factors are minimized in route, migrants are aware of the predators of travel, and have methods to track migrants through transition.

In this paper, “Humanitarian” refers to Intergovernmental Organizations (IGOs) such as United Nations (including all branches), World Health Organization, and International Labor Organization.

Background

Every day millions of individuals have their rights and dignity stripped for another's personal gain; trafficking is non-discriminatory and affects people of all ages, nationalities, genders, and economic status. The official definition is: “the recruitment, transportation, transfer or harboring of persons through means of threat, coercion, fraud, or abuse with the purpose of exploiting them”¹. Traffickers prey on individuals trapped in a vulnerable situation: social rejection, displacement, risk of violence, or those with financial, physical, or mental disadvantages². Such trafficked individuals are typically minors, native women and girls, refugees, immigrants (documented/undocumented), LGBTQ, and individuals in remote, rural and urban areas; however, US and foreign-born adult individuals are also frequently trafficked³.

Individuals are manipulated to confuse trafficking with the prospect of employment, educational opportunities, refuge, transportation, and love⁴. Others are forced or coerced to work manual labor, fight as soldiers, domestic servitude, act as drug mules or conduct sexual activities⁴. Many have been used or killed for organ removal and harvesting.

International Traffickers have been categorized into four groups: organized crime syndicates, independently-owned businesses, third party labor recruiters, and community/family members³. International or local organized crime, such as drug cartels and street

gangs, typically sell drugs, guns, and humans³. Third party labor recruiters or contractors bring workers from foreign countries, most often, to provide labor for food, agriculture, construction or services (massage, nail, janitorial)³. Community or familial traffickers are typically individuals from the same community, individuals with greater social or political status, parents, siblings or extended family members³.

Survivors of domestic minor sex trafficking have mentioned there are various types of controllers/ traffickers, such as: pimp-controlled, family-controlled, gang-controlled, transgender-controlled, and crime syndicate- controlled³. In pimp-controlled trafficking there is often a targeted recruitment of minors, with a process of “grooming” to lure in unsuspecting victims then eventually “turning out” the individual to have sexual relations³. Family controlled trafficking is typically initiated through incest, then trading of the child between family members, and eventually selling to individuals outside of the family for monetary transactions³. Gang-controlled trafficking tends to have recruitment by female members seeking status within the group, where blackmail, threats, and violence play a role in capturing and keeping the victim³. Transgender-controlled trafficking is a controversial group where gay transgender and straight male minors are typically trafficked by transgender women³. Crime syndicate-controlled traffickers are traffickers with diversified portfolios, who typically start trafficking drugs and/or guns and become intrigued by the lucrative high yield from selling humans. There is a misconception that traffickers are strangers, when in actuality, individuals are usually trafficked by someone they know and trust (immediate family- 36%, boyfriends- 27%, friends of family- 14%, and employers- 14%) and only 9% are trafficked by strangers³.

As of 2016, the International Labor Organization (ILO) conservatively predicts 40.3 million adults and 152 million children, age 5-17, are trapped in modern day slavery⁵. The adult population estimates: 15.4 million in forced marriage and 24.9 million in forced labor (4.8 million in sex trafficking, 4 million in forced labor imposed by state authorities, and 16 million in domestic, construction, or agricultural work)⁵. The child population predicts 108 million work in agriculture, 18 million in industry, and 26 million in services (domestic, forced marriage, or prostitution)⁵. This data notes a higher population of enslaved humans than ever reported in history. With such vast numbers of exploited people, it is clear trafficking is not rare but rather a disturbingly well-established system.

Experts hypothesize the root causes of trafficking are situation dependent. Yet, throughout the literature, common concepts arise when assessing trafficking conditions. First, as highlighted by the #MeToo movement, systematic gender oppression of females is well ingrained throughout the global setting³. There is a pronounced normalization of devaluing, objectifying, abusing, and marginalizing women in various cultures, *some more than others*³. Second, there is a high demand, mostly male driven, for convenient and accessible commodified sex³. Exemplified in the concept of sex tourism, where sexual engagements are viewed as a means of attracting tourists to a country and a service available to accommodate. The practice is so large that countries have become known for sex tourism, most notably: Dominican Republic, Thailand, Cambodia, Netherlands, Spain, Brazil, and the Philippines⁶. High demand for sex work relies on buyer exemption from punishment. With roughly 30 million individuals forced into sex work globally, if

each has sex with 10 buyers a day, there are at least 300 million buyers purchasing sex from a trafficked person annually. This incredibly high demand is certainly propelling the trafficking system. Third, many trafficked individuals have fled their homes escaping physical, sexual, or emotional abuse/neglect, and are looking for a sense of comfort and safety- leaving them vulnerable to exploitation. Fourth, traffickers are intrigued by the high cash payouts. The ILO estimates the trafficking market generates \$150 billion USD annually, certainly acting as a main driver keeping the inhumane system alive (2016)⁵. Where individuals can only sell guns and drugs one time, they can sell a human body numerous times. It is important to note, that the younger and more attractive a trafficked individual is, the more buyers are willing to pay for sex³. Fifth, many victims who become trafficked are targeted due to their vulnerability from living in poverty. Traffickers are keen to exploit impoverished individuals and their desire to become educated or move to an area with better working options. Many traffickers create “opportunities” that appear to provide the individual with a golden ticket to escape poverty, meanwhile using a system of indebtedness to trap them in trafficking. Lastly, the demand for cheap labor in a globalized market, where businesses can have a considerable distance from supply chain processing, easily allows for individuals who are out of sight to be forced into horrible working conditions to benefit the wealthy and established³. Such a problem is challenging to control due to the secretive and criminal nature of its activity. It is imperative to assess, educate, and minimize vulnerabilities that make individuals susceptible to trafficking, as it’s easier to prevent a problem than stop it once it’s an ingrained cultural convention.

Research Hypothesis

1. Why are migrants more susceptible to trafficking? Individuals on the move are in a chronic state of stress, activated by the fight or flight response, to escape an external threat at home. Such dynamic situations threaten to put migrants in a state of desperation and high anxiety where they are more dependent on the guidance of others in new surroundings. Being in a new territory with cultural, linguistic, physical, and financial barriers can also decrease one's sense of security and autonomy.

2. What role can intergovernmental humanitarian agencies play in preventing humans from being trafficked? Humanitarian agencies were developed to “promote human welfare and social reform” and “improve lives” and “reduce suffering”^{7,8}. Migrants do not typically publicly disclose their routes and plans for movement, as a means of attempting to ensure protection and minimize interference that could prevent them from reaching their destination country. As humanitarian agencies are neutral, they have a unique opportunity to openly discuss migration with affected individuals in all stages of the journey.

Humanitarian organizations can play an integral role in assuring migrants know and understand their rights, the risks, and security measures to consider while in transit and upon arrival to a host country.

3. What role do intergovernmental humanitarian agencies play in trafficking cases? Humanitarian agencies work on multiple dimensions to assure protection, identification, and support for migrants who are at risk of/ are survivors of trafficking. They have a legacy of creating global standards of which member states will promise to uphold. However, intergovernmental agencies do not have a means of enforcement and therefore may not be able to truly create a global community prepared to protect migrants and prevent

trafficking.

Methods

In this paper I seek to address the above questions through a systematic analysis of academic and educational tools, as well as grey literature. Per suggestions of Brown

academia (Rob Blair, Nina Tannenwald, Adam Levine, and Katherine Lutz), I searched the following databases: Google Scholar (42,200 results), LexisNexis (994 results), and Brown library (694,172 results) using the following key terms:

migrants/migration/immigrants, trafficking/sex work/forced labor, humanitarian/NGOs/ intergovernmental agencies. I also used Google searches (1,070,000 results) in addition to searches on UN (434 results), WHO (1160 results) and IOM (1884 results) websites using the same key terms. I also spoke to key informants working at well-recognized and established organizations whose main tenants include protecting and advocating for survivors of human trafficking: HEAL trafficking (founder/ executive director), IOM Headquarters (Division leader of Migration Assistance Division) and Day One (Helpline Coordinator). I have volunteered at each organization and therefore have a direct line of communication with the designated informants; I requested their personal and professional opinions on a list of questions (Appendix 2). Though my key informants were unable to engage in a short interview, they each guided me to various educational materials and journal articles to read on the subject. I reviewed the below lectures referred by HEAL 1.The Modern Slave Trade: Public Health Impacts- WGBH & Harvard, 2.Human Trafficking, U.S. Violence, and Sexual Assault: Strategies to Strengthen Community Collaboration to Respond to Survivors' Needs- Office for Victims of Crime

TTA Center, 3.How to spot human trafficking- Kanani Titchen 4.Human Trafficking: Information and Resources for Healthcare Providers- Mt. Sinai Hospital 5. Understanding and Combating Human Trafficking as a Health, Social, and Economic Issue- Child Family Health International 6.Harvard Radcliffe Seminar 7.Identifying Risk Factors for Human Trafficking and Natural disasters-HHS. I closely reviewed 28 journal articles/ reports/ memos/ policy briefs regarding my topic found in the literature review and suggested by key informants. Each material reviewed (written and audio/visual) was filled with salient knowledge on human trafficking that I have used as evidence in the research paper.

Results

Why are people on the move more susceptible to trafficking? To answer this question, we must first remember why migrants leave their homes- rationales can include seeking refuge from political/ religious/ physical/ racial/ economic abuse, fleeing war, displacement due to natural disasters, or seeking an opportunity for a better life. There are multifaceted causes of susceptibility to human trafficking prior to, during and after migration. Starting in country of origin at the beginning of a disaster, physical disruption and social disorder increase emotional turmoil and separates families, making survivors easier to exploit. Traffickers may imitate first responders assisting with basic needs (such as housing, food, and water) to allow a thorough assessment of identifying whose most vulnerable in the community. During disasters, survivors are forced to use coping strategies, which increase desperation and vulnerability. Children run the risk of becoming defenseless by losing their parents, at times permanently. After disasters, the

need to quickly rebuild and cleanup land creates new demands for free/cheap labor. The disaster may cause survivors to lose their main source of income, during a time of heightened vulnerability, this increases the potential to seek last resort sources of income, including sex work. A chaotic state throughout the crisis can also weaken the existing rule of law, minimizing the institutionalized ability to protect vulnerable members of society.

Individuals who are forced to flee their country are in a “Life or Death” situation. The varying levels of security on a migration movement changes their level of vulnerability daily. Individuals on the move are outside of their comfort zone opening the door to several vulnerabilities, such as: being in a new territory, unfamiliar with the laws, unsure how to access physical/ emotional/ medical support, struggling with language barriers, and different cultural customs. Due to the rapid and desperate nature of most migrations, many individuals do not have access to their documentation (such as IDs + passports) either due to leaving it behind, losing it, or having it taken from them. Even those who do not start as vulnerable individuals can become exposed throughout the transit or once they have arrived in a destination country. The journey to seek refuge can be costly and dangerous. Individuals on the move must be prepared to pay hefty fees for travel arrangements or paperwork to mobilize. UNICEF reports the average seat on a transit boat is \$1500 USD⁹. Individuals on the move are also disadvantaged due to their inherent need to rely on the community surrounding them. With the increase of migration, there similarly is an increase in smugglers, traffickers, and opportunists seeking personal gain from the migration business². In just one year in Europe, January 2016 to January 2017,

there was an increase of nearly 20,000 smugglers- with almost 90% of migrants entering Europe with the help of a smuggler².

When people leave their homes, they are also leaving their jobs and source of income. This lack of financial stability on the move may make migrants have to choose risky or unsafe options of income for survival, such as bartering, charging for physical services, or child labor. We can see this exemplified in the Syrian refugee context. Over 5.4 million Syrians have fled the war-torn region to neighboring countries and beyond to seek refuge¹⁰. In Jordan alone, there are over 655,000 Syrian refugees, with 93% living below the poverty line¹⁰. Such detrimental poverty causes families to rely on desperate coping mechanisms. As of 2016, almost half of the Syrian families in Jordan report their child as a breadwinner¹⁰. Children being forced to work as beggars on the street or as domestic workers makes them extremely vulnerable to physical, emotional, and sexual abuse¹⁰. There are currently more migrants than ever recorded in modern history, an estimated total of 244 million migrants¹¹. Humanitarians have an integral obligation to ensure and protect human rights throughout the seek and transition to refuge.

What role can humanitarians play in preventing humans from being trafficked?

Humanitarian agencies were developed on the philosophy of humanitarianism, a purely neutral role with a core mission to relieve human suffering. The humanitarian sector has a golden opportunity to connect with migrants before, during, and after transit to ensure individuals fully understand their human rights and vulnerabilities. Where local governments may be skewed by their own cultural customs and ways of viewing

situations, humanitarian agencies can play a key role in providing culturally competent information on migrants from around the globe³. Cultural interpretations can dramatically change the vantage point in which individuals view situations. Some cultures have embedded female inferiority and abuse, which could bias an individual to normalize a trafficking situation. While some cultures have engrained distrust in police, military, and government officials- making it challenging for potential victims to seek assistance and protection. Other modest cultures may deem it inappropriate to ever talk about sexual relations, encouraging trafficked individuals to be too overcome with embarrassment to seek support. Such discussed cultural biases could affect the way trafficked individuals view the cause of their dilemma, the potential outcomes, and their role in the trafficking situation³. Humanitarian organizations can play a vital role of advocacy directly to migrants, or supporting organizations, by relaying key cultural aspects that can create vulnerabilities for trafficking and/or prevent individuals from seeking assistance to escape. Humanitarian agencies should also play a role in explaining these cultural differences to transit and host country governments and local actors, to allow for culturally competent social policy creation³. Being ignorant to such cultural considerations could drastically affect local responders' ability to provide culturally relevant services. Humanitarians can also identify gaps in services or accommodations provided. Lastly, they can inform local governments to assess societal predispositions for heightened worker demands.

Humanitarian organizations could use varying prevention responses prior to and during migration, such as: educating migrants prior to the journey, organizing safe transit

pathways, creating secure manners for migrants to report injury/violence/exploitation, and assisting with documentation and medical record distribution. Humanitarian orgs could also use surveillance methods in destination countries such as, effective id upon arrival, screening for mental/physical/emotional vulnerabilities, and referring to supportive services. Many displaced individuals bring with them experience and skills that could contribute to their new host society. Humanitarian agencies should assist displaced people to integrate their skillset into the needs of their new communities. With assisted integration, migrants would have the opportunity for economic activity and self-reliance, in-turn minimizing their vulnerability of exploitation.

What role do humanitarians play in trafficking cases? The trafficking of migrants is a global problem with various actors. For this reason- humanitarian agencies play a major role in coordinating collective action from multiple stakeholders including: “states of origin, transit, and destination; by civil society; the private sector; international organizations; academia; and by humanitarian and development actors, amongst many others”¹². Humanitarians serve a main function by creating global protocols to set international standards and guide individual countries to create evidence-informed domestic law to protect migrants before, during and after transit. The leading relevant protocols/frameworks are: Palermo Protocol, UN Convention against Transnational Organized Crime, Protocol to Prevent Suppress and Punish Trafficking in Persons especially Women, Protocol Against the Smuggling of Migrants by Land Sea and Air, Model Law against the Smuggling of Migrants, Migration Crisis Operational Framework, and most recently the Global Compact for Safe Orderly and Regular Migration. Such

protocols are accompanied by various datasets, handbooks, toolkits and workshops where nation states can learn about the topic, understand varying cultural competencies, seek guidance on national/regional/international action plans, improve strategy development, establish legislative frameworks, and get support for training and technical assistance.

Experts in the field believe there is not much need for ground-breaking laws, but rather member states of intergovernmental agencies should agree to and fully embody the commitments already made in the above protocols. Humanitarians are helping member states to fulfill their promise through individual support. For example, intergovernmental organizations (IGOs) commenced the Global Action Plan to Prevent and Address Trafficking in Persons and Smuggling of Migrants (Glo.Act), 2014-2018, to give direct guidance and support for specific countries to embed anti-trafficking services into their existing system¹². The GLO.ACT is a 4-year initiative created by the European Union(EU) and United Nations Office on Drugs and Crime (UNODC) and implemented by IOM and UNICEF¹². This project targets 13 key countries to create and implement counter-trafficking and counter-smuggling efforts with a goal to develop mechanisms to identify and screen migrants for trafficking vulnerabilities, create referral systems for protection services, and ensure survivors have access to resources according to global standards¹². With more nation-specific humanitarian guidance-based programs, such as the Glo.Act, the linkages between improved national crises responses, education/assessment of vulnerabilities, and support for migrants/ displaced individuals can be solidified and enhanced.

In addition to global and individual country guidance, the designated UN Migration Agency (IOM) serves as a leader in implementing practices in member state countries, to address trafficking among migrants. IOM country offices work with national authorities, when possible, to screen migrants for trafficking vulnerabilities and refer to local support. IOM created a phone application for migrants, that provides information on: migration routes, safe accommodations, food/water/healthcare access, human rights centers, compares pathways for sending money, allows migrants to share route information and provides news for migrants in route. IOM runs reunification programs to unite families, protect unaccompanied and separated children, by incorporating skills from local authorities, social services, and NGOs. Once trafficking survivors are identified, IOM offers comprehensive assistance packages, including psychological and medical care, support for familial reunion, safe return to countries of origin, and reintegration into society¹³. The IOM strides to improve evidence-based protocols, programs and practices as exemplified by their recent publication of the world's largest data repository on human trafficking. They also support and share reports, by other actors, that assess and rate individual countries for their anti-trafficking practices (such as United States Trafficking in Persons Report). Such feedback mechanisms allow for assessment of member states and improved training and resources to be delegation to the appropriate states.

IOM incorporates a platform to give migrants a voice to provide insight on the hardship of migration. This allows for increased access to historically marginalized survivors which has led to the modification of services, such as: multilingual translations,

identifying trends to tailor culturally relevant services, designing trauma-informed interventions, advocating for societal systems that mitigate barriers, and encouraging cultural change through community engagement strategies³. Migrants know their journey and its challenges best; IOM's model valorizes their experience to be an active creator in the system designed to help migrants.

Discussion

Due to situational influences, migrants have heightened vulnerabilities for trafficking. Humanitarians are placed in an opportune position to support migrants in route, advocate for culturally competent policy, minimize individual susceptibilities, and protect migrants from unknowingly falling into trafficking. Intergovernmental organizations serve as a mitigater between migrants and the harsh reality of a migration journey. They are the global leaders in guiding local, national, regional and international policy to valorize anti-trafficking practices. Humanitarians have an obligation to create and uphold global standards and ultimately protect migrants from human trafficking vulnerabilities.

Limitations

Various limitations arose in writing this paper. Firstly, self-serving bias, many of assessed documents were written by intergovernmental agencies, due to inability to find academic review/analysis of topic. There was also an inability to include further analysis of all pertinent concepts and case studies, for fear of exceeding page requirement. Lastly, there was an inability to evaluate efficiency of new protocols/programs.

Conclusions and Recommendations

1) Why are migrants susceptible to trafficking? Migrants are forced into survival mode to endure a dynamic migration experience. They are made vulnerable by being in a foreign territory, unfamiliar with regulations/cultural customs/ programs, leaving behind their source of income, potentially displaced from family, and reliance on the surrounding community.

2) What role can humanitarians play in preventing human trafficking? Humanitarians can assure migrants know and understand their rights, the risks, and security measures to consider while in transit and upon arrival to a host country. They can inform local policy to ensure trafficking advocacy/ support/ prevention is culturally tailored and assess societal predispositions for heightened worker demands. They can also seek resources to assure meaningful and economic integration into their host community, allowing for decreased vulnerability.

3) What role do humanitarians play in trafficking? Humanitarian agencies create evidence-informed protocols to guide national anti-trafficking policy creation. They help countries and regions to fulfill the requirements imposed by such global standards and conduct the necessary ground-work to educate, advocate for and support individuals vulnerable to/ survivors of trafficking.

Next Steps

Future research should seek independent assessment of IGO programming, procedure/program evaluations from recent policies, and expand scope to include all humanitarians (beyond IGO).

References

1. State UD of. *Trafficking In Persons Report. Office of State Publication for Civilian Security, Democracy, and Human Rights. Rep. Washington, DC.*; 2017.
2. Hodal K. Traffickers and Smugglers Exploit Record Rise in Unaccompanied Child Refugees. *the Guardian*. www.theguardian.com/global-development/2017/may/17/traffickers-smugglers-exploit-record-rise-unaccompanied-child-refugees-migrants-unicef-report. Accessed 4 May 2018.
3. Office for Victims of Crime TTA Center. *Human Trafficking, U.S. Violence, and Sexual Assault: Strategies to Strengthen Community Collaboration to Respond to Survivors' Needs*.
4. UNICEF. End Trafficking Campaign: If You Care About Trafficking, You Should Care About Refugees. , www.unicefusa.org/stories/if-you-care-about-trafficking-you-should-care-about-refugees/29851. Published 2016.
5. Organization international L. ILO Says Forced Labour Generates Annual Profits of US\$ 150 Billion. www.ilo.org/global/about-the-ilo/newsroom/news/WCMS_243201/lang--en/index.htm.
6. Huffington Post. The Most Popular Countries For Sex Tourism.www.huffingtonpost.com/oyster/the-most-popular-countrie_b_8067520.html. Published 2017.
7. Definition of: Humanitarian. Cambridge Dictionary. dictionary.cambridge.org/us/dictionary/english/humanitarian.
8. Definition of: Humanitarian. Merriam Webster Dictionary. www.merriam-webster.com/dictionary/humanitarian.
9. UNICEF. Understanding the Impacts of Pesticides on Children : A discussion paper. 2018;(January):1-26.
10. Nations U. *Syria Emergency*.; 2018.
11. International Organization for Migration. *Mediterranean Human Trafficking and Exploitation Prevalence Survey*.; 2017. www.iom.int/news/mediterranean-human-trafficking-and-exploitation-prevalence-survey-iom.
12. MICIC Brief. *Responding to Human Trafficking and Exploitation in Times of Crisis*.; 2016. [http://micicinitiative.iom.int/sites/default/files/brief/Trafficking Issue Brief final.pdf](http://micicinitiative.iom.int/sites/default/files/brief/Trafficking%20Issue%20Brief%20final.pdf).
13. International Organization for Migration. *Migrants Vulnerability to Human Trafficking and Exploitation: Evidence from the Central and Eastern Mediterranean Migration Routes*.; 2018. www.iom.int/migrant-vulnerability-human-trafficking-and-exploitation-evidence-central-and-eastern-mediterranean.

Appendix 1: Key Informant Interviews

Key Informant Interview Personnel:

- 1) IOM Headquarters Migration Assistance Division- Counter-Trafficking Staff (referred to articles in reference)
- 2) Heal Trafficking Community (referred to video lectures in reference)
- 3) Day One: Local Human Trafficking Advocates (emailed, though unable to comment)

Questions:

- How can humanitarian agencies address decrease vulnerabilities for human trafficking from migration?
- How are humanitarian agencies educating migrants on trafficking vulnerability?
- How can humanitarian agencies track migrants through transit and once in a destination country?
- What is being done to improve recognition of displaced people's professional qualifications in order to help them access and participate in the labour market and contribute most effectively in the host society?
- How can humanitarian agencies influence/ affect transit or destination countries policies regarding migrants, refugees & asylum seekers?
- How can humanitarian agencies encourage rights to work and market access in transit or destination countries?
- How can asylum systems and employers better help displaced people integrate by providing employment opportunities? Are there examples of business taking a lead in this?
- How can refugee-led social protection initiatives usefully inform policies and practice, including those which address economic livelihoods?
- How do transit or destination countries policies regarding migrants, refugees & asylum seekers affect the mobilizing population?

Appendix 2: Key Informant Suggested Articles/ Videos

Referred by IOM

- ICMPD, What are the protection concerns for migrants and refugees in Libya? November 2017, <https://www.euneighbours.eu/sites/default/files/publications/2017-11/ICMPD%20Policy%20Brief.pdf> (Referred by IOM)
- ICMPD, Targeting Vulnerabilities: The impact of the Syrian war and Refugee Situation on Trafficking in Persons | ICMPD Briefing Paper | January 2016
https://www.icmpd.org/fileadmin/ICMPD-Website/AntiTrafficking/Targeting_Vulnerabilities_Short_Version_EN_08-02_.pdf
- MICIC Brief: Responding to Human Trafficking and Exploitation in Times of Crisis (January 2016): <http://micicinitiative.iom.int/sites/default/files/brief/Trafficking%20Issue%20Brief%20final.pdf>
- Special Rapporteur Report to HR Council, May 2016. Trafficking in persons in conflict and post-conflict situations: protecting victims of trafficking and people at risk of trafficking, especially women and children http://www.un.org/ga/search/view_doc.asp?symbol=A/HRC/32/41
- Special Rapporteur, Report to UNGA, August 2016. A report that raises international awareness of the forms and nature of trafficking related to the complex situation of conflict <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N16/250/78/PDF/N1625078.pdf?OpenElement>
- The ICMPD study *Targeting Vulnerabilities: The Impact of the Syrian War and Refugee Situation on Trafficking in Persons – A Study of Syria, Turkey, Lebanon, Jordan and Iraq* assesses the effects of the Syrian conflict and refugee crisis on trafficking in persons (TIP) in Syria and the surrounding region. <https://www.icmpd.org/our-work/capacity-building/thb-and-related-forms-of-exploitation/trafficking-and-the-syrian-war/>

Referred by HEAL Trafficking

- “How to Spot Human Trafficking-Kanani Titchen” 2018, www.youtube.com/watch?v=hrxhptvEOTs
- “Human Trafficking, U.S. Violence, and Sexual Assault: Strategies to Strengthen Community Collaboration to Respond to Survivors; Needs- Office for Victims of Crime TTA Center” 2015.
www.ovcttac.gov/views/trainingmaterials/dspwebinars.cfm#strategies. Accessed 11 Apr. 2018.
- “Human Trafficking: Information and Resources for Emergency Healthcare Providers-Mt. Sinai Hospital.” 2016, www.humantraffickinged.com/. Accessed 4 May 2018.
- “Natural Disasters and Trafficking” 2017, <https://healtrafficking.org/resources/hhs-region-ii-identifying-risk-factors-for-human-trafficking-after-natural-disasters/>. Accessed 25 Mar. 2018.
- “The Modern Slave Trade: Public Health Impacts- WGBH & Harvard TH Chan School of Public Health.” 2017, theforum.sph.harvard.edu/events/the-modern-slave-trade/. Accessed 10 Apr. 2018.

**A Mixed-Methods Pilot Study Assessment of Behavior Change Theory-
Guided Heart Disease Education Program in Incarcerated Men
*Rhode Island Department of Corrections (RIDOC): Heart & Sole Debate***

By
Melissa Godfrey, RN BSN
MPH, Brown University, 2019

List of Tables and Illustrations

Figure 1 Theory of Planned Behavior & Implementation Intention Model.....	54
Figure 2 Theory of Planned Behavior & Implementation Intention Guided CVD Education in Incarcerated Population.....	54
Figure 3 Course Curriculum.....	55
Table 1 Descriptive Statistics Focus + Intervention Participants + RIDOC Population...	56
Table 2 Stress Reduction Theory of Planned Behavior Construct Responses Overtime..	57
Table 3 Stress Reduction Habits Overtime.....	57
Table 4 Exercise Theory of Planned Behavior Construct Responses Overtime.....	58
Table 5 Exercise Habits Overtime.....	58
Table 6 Practicing Heart Disease Prevention.....	59
Table 7 Personal and Social Interactions.....	59

**Abstract of A Mixed-Methods Pilot Study of Behavior Change Theory-Guided
Heart Disease Education Program in Incarcerated Men
*Rhode Island Department of Corrections (RIDOC): Heart & Sole Debate***

Prisoners suffer a higher prevalence of cardiovascular disease (CVD) relative to the general population in the United States. Communities of prisoners do not have consistent access to health care or health education for the duration of their sentences leaving them potentially more vulnerable to developing a chronic disease. Due to these gaps, prisoners may forgo timely preventative care. This presents a unique opportunity to intervene prior to the development of chronic illnesses, such as cardiovascular disease (CVD), or early in the disease state, to prevent late-stage disease which could result in higher rates of morbidity and mortality in this population. The present article describes the development and implementation of a pilot program CVD education class, *DOC Heart & Sole Debate*, for incarcerated individuals at the Rhode Island Department of Corrections Medium facility. Formative research included a focus group consisting of 17 individuals and 3 key informant interviews. The intervention was developed as a 10-session course teaching primary CVD education to 22 incarcerated individuals, guided by the Theory of Planned Behavior (TPB) and Implementation Intention (II) theory. Surveys were administered pre- and post-intervention to analyze change in behavioral intentions to improve health habits by assessing attitudes, perceived behavior control, subjective norms, plan of action, and intentions. Linear regression models evaluated behavior change. Significant improvement was noted in that 80% of participants reported practicing stress reduction and 85% of participants were exercising sufficiently post-intervention to promote heart health and minimize cardiac disease risk. We also noted significantly improved intrapersonal communication skills, suggesting heart health education may be effective in promoting positive behavior change in incarcerated males.

Background

The 1.5 million Americans currently assigned to correctional facilities suffer a higher rate of chronic illness¹, compared to the general population². Cardiovascular disease (CVD), the leading cause of death in the general population³, presents at disproportionately higher rates among prisoners along with its risk factors (overweight/obesity, stroke, diabetes, stress, and heart unhealthy diets)³. Compared to the US population in 2011-2012, the prevalence among incarcerated individuals of high blood pressure/hypertension was 26.3% vs. 13.9% (US population), stroke 2.3% vs. 0.5%, diabetes/high blood sugar 7.2% vs. 4.5%, and heart related problems 10.4% vs. 1.9%². Prisoner populations also have high rates of other CVD risk factors such as, being overweight/obese/morbidly obese 74%². The data indicates that these trends are on the rise; and compared to the prisoner population in 2004 the rate of diabetes and high blood pressure have increased by 200% and 150%, respectively². These communities of incarcerated individuals do not have consistent access to health care or health interventions during the time of their sentences, leaving them more vulnerable to developing and poorly managing a chronic disease. Heart disease is particularly dangerous for men as it is the leading cause of death for American men (causing one-quarter of deaths)⁴; 70-89% of sudden cardiac events occur in men, and half of the men who die suddenly of coronary heart disease had no previous symptoms⁵. Therefore, it is critical to develop culturally-tailored interventions to prevent CVD in male prison environments.

Several factors contribute to CVD risk among male prisoners, specifically those in Rhode Island Department of Corrections (RIDOC). A focus group among Rhode Island Inmates

in May 2017 (N=30) males in a Medium-Security Facility, conducted by Rhode Island Department of Health(DOH) and RIDOC health educator, revealed barriers to positive CVD health behaviors within the prisoner population included inconsistent access to primary healthcare, lack of options for healthy foods, lack of food nutritional labels, lack of health literacy, lack of exercise and increased stress/fear from chronically living in survival mode. The prison environment contributes to inconsistent access to preventive/primary care in that inmates only receive health services through annual health fairs and for acute conditions as needed. Prisoners do not have many options for food selection. The “chow hall” serves buffet style food that is prepared ahead of time in mass quantities, is heavily salted, and a minimal offering of vegetables and fruits is available. The lack of nutrition labels is problematic in contributing to CVD because informed health conscious food choices cannot be made. Stress/fear of survival in prison also plays a role given that the body produces cortisol in moments of stress, and chronically high levels of cortisol produces hypertension⁶. Moreover, studies have found that low health literacy is associated with behaviors linked to CVD such as lack of exercise⁷. According to the 2016 RIDOC Annual population, report male prisoners’ health literacy might be low given that “about half (51%) received a high school diploma or GED, 37% have less than a 12th grade education and only 9% have completed some college”⁸. These factors, coupled with the extended period that Rhode Island prisoners are incarcerated, average sentence 30.4 months, may be related to the high prevalence of CVD prevalence in this population⁸.

To ensure that incarceration does not act as a facilitator of or exacerbate health disparities, we must assure this population has access to information to prevent chronic disease just as the general population could attain through primary care and public media campaigns. Given the high prevalence of CVD and its risk factors in the incarcerated population, there is a potential to minimize unhealthy habits in prisoner populations by educating individuals on CVD and heart-healthy strengthening behaviors. This unmet need opportunity inspired the development and implementation of the *DOC: Heart & Sole Debate*, a pilot health education course focused on teaching Cardiovascular Education and heart healthy habits to the male prison population, guided by the Theory of Planned Behavior (TPB) and Implementation Intention (II) theory. The primary hypothesis was that an intervention that focused on improving CVD knowledge and risk perception may improve participants' engagement in heart healthy behaviors, including regular stress reduction practices and exercise.

Theoretical Framework for Study

The *Theory of Planned Behavior* of Icek Ajzen (1991) suggests increasing intention can change a person's behavior⁹. TPB posits that a person's attitude, perceived behavioral control, subjective norms, and behavioral intention can be influenced to change their behavior via behavioral intention⁹. Because intention does not always assure action, our program also incorporated the Gollwitzer's theory (1993) of *Intention Implementation*. The strategy of II includes plan formation to perform the behavior intention at a time and place⁹. Gollwitzer and Brandstatter (1997) provided evidence that plan formation increased the probability that the proposed action would be accomplished⁹. We believed that these theoretical frameworks were most appropriate to guide the intervention due to

the institutional constrictions placed on the inmate population. Within a prison setting, there is minimal ability to change an inmate's external triggering factors, due to a lack of control over daily activities, and large segments of free time with few healthful activities to engage in – both of which can serve as internal demotivators (DOH 2017 RIDOC Focus group). Prison guards are trained to address inmates generically which may lead to depersonalization and contribute to inner turmoil and increase stress. Therefore, the study targeted internal intention to improve health habits by addressing: 1) attitude, 2) perceived behavior control, 3) subjective norms, and 4) plan of intention. The targeted behavioral change model is shown in Figure 2 (Appendix1).

The *DOC Heart & Sole Debate* health classes were taught in a manner that encouraged creativity, empowerment, and an ability to defend one's actions guided by the Elaboration Likelihood Model of Persuasion. This model created by Petty (1981), suggests cognitive responses to information bring lasting attitude change, indicating that participants who can be persuaded by a message and engage in issue-relevant arguments have a higher likelihood to change their attitude⁹. Instead of teaching in a typical manner of primary lecturing, the class used multi-modality educational approaches to allow individuals of all educational, personality, and learning styles to interact with the course content. The debate portion, guided by the *Elaboration Likelihood Model of Persuasion*, was unique, in that it empowered the participant to defend the specific health behavior, debate the pros and cons of the behavior, and be an active member of the classroom. This team-building exercise also allowed for individuals of all health literacy levels, cultures

and behavior patterns to engage in the conversation regarding their health and produced a roadmap to incorporate CVD prevention into their everyday lives.

Efficacy of Theory of Planned Behavior, Implementation Intention, and Model of Persuasion in similar targeted outcomes: The *DOC Heart & Sole Debate* course pioneered a cardiovascular educational class guided by cognitive theory models to ensure improve heart-healthy behaviors in male prisoners in the Rhode Island Department of Corrections. Several meta-analyses and systematic reviews have demonstrated the efficacy of using theory-guided interventions to change behavior.

Theory of Planned Behavior (TPB): The literature supports the beneficial effect of including the TPB to facilitate behavior change interventions, specifically group-based programs¹⁰. A meta-analysis reviewing a wide array of disciplines verified the efficacy of TPB-guided interventions in changing behavior, perceived behavior control, subjective and normative beliefs, and intention¹⁰. Eighty-two studies, examining over 100 interventions, were included and outcome variables included multiple healthy behaviors: 33% physical activity, 19% healthy eating, 16% improvement in behavior/ stress management¹⁰. The age range was wide (8-82 years old) and studies from several countries were included (United States, the United Kingdom, Canada, and Australia)¹⁰. The analysis showed TPB-based interventions effectively show an average effect size of 0.50 for behavior changes and effect sizes between 0.14-0.69 for subjective norm, perceived behavioral control, intention, and attitude¹⁰. A meta-analysis and systematic review combinational article included 43 studies and demonstrated support that the TPB

was an effective intervention model for improving nutritious food choices. The article reported TPB variables had strong associations with intention and behavior; attitude and intention $r^+=0.54$, perceived behavior control and intention $r^+=0.42$, subjective norm and intention $r^+=0.37$, intention and behavior $r^+=0.45$, perceived behavior control and behavior $r^+=0.27$. This study showed the efficacy of TPB serving to empower participants to choose healthful foods, by assessed individuals who have not had and currently do not have medical conditions that could influence the food choices (ex. diabetes, anorexia, or bulimia) of participants¹¹. These two large studies demonstrated support for our use of the TPB in our program design, as *DOC Heart & Sole Debate* was designed for individuals interesting in learning about heart health and the prevention of cardiovascular disease.

Implementation Intention(II) Theory: A meta-analysis and systematic review demonstrated the effectiveness of using II theory to guide interventions which encouraged a regimented exercise routine with an effect size of 0.25.¹² This review of 13 clinical trials, had a study participant age range of 20-62 years, with 23% of participants from a healthy population and 77% of participants living with chronic diseases, including heart disease, obesity, diabetes, stress, sedentarism¹². This meta-analysis provided support for the use of II theory in the *DOC Heart & Sole Debate* intervention, in that it showed that they theory was effective in participants with and without diagnosed chronic illness, an important consideration since some of the current study participants may have unknowingly had some degree of heart disease.

Elaboration Likelihood Model of Persuasion. This theory is important to encourage systematic thinking that solidifies personal action, and has shown an impact on changing beliefs to prevent injury and promote healthy habits, such as by encouraging bicyclists to wear helmets⁹.

Use of Theory of Planned Behavior and Implementation Intention in Incarcerated

Populations: Behavioral theory models have been used with the incarcerated population before. A study in Midwest County Confinement Center used a TPB guided hand washing intervention to reduce infectious skin diseases¹³. They found the model was effective at teaching infection control and improving TPB behaviors¹³. A review of HIV Risk Prevention Interventions of adult prisoners also showed effectiveness in targeting attitude, behavior, intention, and subjective norms to improve health habits¹⁴.

Specifically, the authors reviewed fourteen articles that used various behavior theory models to guide their interventions¹⁴. Of the articles, one included TPB specifically, one use Social Cognitive Theory, another used Transtheoretical Model and Multiple Intelligence Theory, and the rest did not specify a specific theory, but addressed theoretical constructs (attitude, behaviors, intentions, self-efficacy, and intentions) to strengthen interventions and assess outcomes. The review concluded that “theory-based approaches could be an excellent fit for prisons wishing to increase knowledge and change attitudes among their inmates” and that “counseling, peer education, and group discussion interventions were all effective strategies” to improve health habits in incarcerated populations¹⁵.

Innovation of the Current Study

To our knowledge, there have been no published intervention studies guided by a behavioral change model in prisoner heart health education. Therefore, an innovative portion of our project is the incorporation of the Theory of Planned Behavior, Implementation Intention, and the Elaboration Likelihood Model of Persuasion used to guide the cardiovascular disease class content and delivery. We sought to address this gap in health education and prison health by testing a TPB and II theory-guided intervention in the Rhode Island Medium-Security Facility with male prisoners.

Statement of Purpose

The present article describes the development and implementation of a pilot program cardiovascular disease education class for incarcerated individuals at the Rhode Island Department of Corrections Medium-security facility. The main objective of the project was to examine change in inmate health CVD prevention behaviors, specifically stress reduction and cardiovascular exercise, related to heart health education. Short term, the goal was to use TPB and II guided education classes to influence attitude, intention, self-efficacy and perceived control regarding preventive CVD behaviors. During these classes the participants learned 10 stress-reduction techniques, learned the appropriate exercises for maintaining heart health, debated the benefits of CVD prevention, and planned how to incorporate the techniques into their schedules. The long-term goal was for participants to internalize healthy perceptions/ behaviors and practice them in normal daily living to prevent CVD. This article describes the study and course design, the conceptual model,

the statistical procedures of analysis, sensitivity analyses, strengths and limitations, and next steps.

Methods

The participant population was comprised of individuals currently incarcerated at the Rhode Island Department of Corrections (RIDOC), which is a state-run correctional institution, housing approximately 2,800 men and women with 13,000 intakes and releases annually¹⁵. Participants for this project were from the Medium Security John J. Moran Facility, which houses about 1000 individuals¹⁵. Private classrooms were available at RIDOC Medium Facility in the education department for recruitment, assessment, and intervention.

The Brown University institutional review board approved the prospective pilot study. Inclusion criteria for both the formative focus group and intervention were: 1) participants needed to be able to read, speak and understand English, and 2) be at least 18 years old, and 3) have at least another 6 months of their sentence, to allow for follow-up. Exclusion criteria included: 1) not being able to speak English, and 2) less than 6 months left to their sentence. Participants received no financial compensation for their time. It is reasonable to expect the following benefits from this research. Short term, the goal of the study was to use TPB and II theory-guided education classes to influence attitude, intention, self-efficacy and perceived control regarding preventive CVD behaviors. The long-term goal was that individuals would internalize healthy perceptions/ behaviors and practice them in normal daily living to prevent CVD.

The RIDOC had a supervisory role in the research project. All aspects of the research project were approved by the Medical Research Advisory Group at RIDOC. Reports, according to the standards, were maintained with the DOC Planning and Research Unit and Health Care Services regarding coordination of the project. During the health monitoring portion of the Heart & Sole Debate if the participant had an abnormal heart rate or stress-level, the primary investigator informed the RIDOC medical director of the finding.

Method: Phase 1. Planning

A Priori Manual Development: A majority of the course content and stress reduction techniques came from the original Roxbury Heart & Sole Program, a culturally competent diabetes risk factor prevention program for an at-risk population in Roxbury, Massachusetts. The course content was created by a group of multidisciplinary healthcare providers (social worker, nurse, dietitian, community health worker, physical therapist, and nurse practitioner) from Bowdin Street community health center and Beth Israel Deaconess Medical Center. Many activities and handouts in the smoking prevention section of the intervention were taken from the Rhode Island Hospital smoking prevention packet, QuitWorks Rhode Island, and QuitWorks Massachusetts. The exercise packet included exercises from Occupational and Physical Therapists of Rhode Island Hospital, strength and balance exercises¹⁶, seated strengthening exercises¹⁷, yoga basics for men¹⁸, and portions of the Prisoner Workout: bodyweight exercises for small spaces¹⁹.

Facilitators of the Intervention Class were master's students at Brown University, one studying Behavioral and Social Health Science and the other Public Health. The selected facilitators underwent orientation and training which the TPB and II concepts/principles and manners were covered; techniques to enhance facilitation of each lecture were also explained. Following training, the facilitators were expected to be able to describe the underlying premise of TPB and II, describe previous interventions guided by TPB and II efficacy, recognize curriculum modules and activities, and demonstrate an ability to support participants through positive reinforcement and therapeutic communication techniques. Orientation highlighted the importance of confidentiality with regard to participant identifiable information, personal attitudes and thoughts, course progress, and course outcomes confidential during the research period.

Method: Phase 2. Qualitative Formative Research

Procedures

Key informant interviews. We conducted individual interviews of key informants, including the deputy, the medical program director, and the health educator. The purpose of these key informant interviews was to have a deeper understanding of the prison authority's understanding, concerns, and challenges to improving health behaviors in current prisoners. Participants in the key informant interviews were queried regarding healthcare access, schedules, perceived barriers to healthy behaviors, and perceived potential facilitators to improve health literacy and healthy habits.

Focus Group Interviews. A semi-structured focus group of 17 male prisoners at RIDOC informed acceptability and feasibility of the questionnaires and intervention content. Participants were guided through proposed questions, analyzing the desire to learn health information (health literacy and motivation), obstacles to living a healthy life (access to: fruits/vegetables, nutrition labels, hygiene products, sanitation, healthcare, etc.) and the feasibility of changing health practices while incarcerated (effective forms of disseminating information, social acceptance, time allotted schedule, and ability to overcome social conditioning). Their perspectives guided the creation of a CVD prevention lecture and debate.

After the focus group was completed, one person transcribed the notes into a word document. Similar and unique findings were highlighted. Qualitative data were coded and analyzed using NVivo software²⁰, which facilitated the analysis, allowing the researchers to review response frequency and strength. The study staff created a coding scheme and reflective codebook to guide the data coding process. Results were used to modify the intervention course content.

Measures

Self-reported demographic information was collected including race, gender, age (in years), and length of sentence (in years). Results are shown in Table 1 (Appendix3).

Results

Key informant interviews indicated that the optimal time for health education would be during recreational time, which is typically 830-10a, 1230-2p, and 6-8p for individuals incarcerated in the RIDOC Medium facility. It was noted though that recreational time is when prisoners have the option of engaging in educational opportunities, going to the gym/yard to exercise, going to the barber, watching tv/playing board games in the day room, making phone calls, or having visits. For this reason, it was felt that there may always be conflicting priorities that could be a barrier to consistent participation in an multi-session educational program. Key informants noted that individuals have access to learn health information during annual medical fairs, dental clinics, medical clinics, dispensary med-lines, or during sick calls (four times a day). It was noted that inmates have access to activities that encourage motion, including full weight sets in the gym, pool tables, basketball courts, softball, and handball. There was a suggestion of including exercise packets to provide new methods and options for incarcerated individuals. Informants also suggested the use of colorful imagery, stickers, highlighters, and colorful chalk as inmates are used to having colorless environments and black and white notifications. Informants highlighted that prisoners can be put on specialized meal types (Hallah, special, kosher, allergy-specific, cardiac, house) after discussing with a dietician. The optimal method for communication of the research team with participants was suggested to be flyers/ notifications placed into individual/double cells, facilitated by the on-duty education lieutenant. It was noted that incarcerated individuals have access the following job types: cleaning, education support, yard work, maintenance, service-dog training, and industry.

Focus group participants highlighted intrinsic behaviors, abilities and challenges to make heart healthy choices while incarcerated. Individuals verified wording of questionnaires were easily understood and effective in their assessment. Focus group participants highlighted a major challenge to remaining physically active was the high cost of exercise apparel (purchasing from the RIDOC store: sneakers \$46-55, shorts \$14, t-shirts \$2.68-7.50) in comparison to their incarcerated individual's salaries (\$1-3 per day). Individuals also reported challenges to incorporating stress reduction techniques into their daily schedules due to a lack of quiet in the environment, overhead announcements until 9pm, and year-long waitlists to enter the few programs available for stress-reduction and meditation. Individuals reported feeling unsupported in exercise activities, a lack of knowledge regarding varying exercises to do, or how to use gym equipment available to them. Based on this input, an exercise packet was created and incorporated for intervention participants including guidelines and warnings regarding exercising, tips for a successful exercise program, consideration to speak with a doctor about before starting, and various cardiovascular and strength training exercises.

The focus group also noted a desire for more health education classes. Currently, there is one 5-week health education class for the entire Medium facility population. Participants noted a desire to have nutritional facts on the food they eat in the chow hall and to understand how to read such information. Our program was unable to provide such information on prepared meals served, as DOC did not have a nutritionist at the time who could discuss food preparation with *DOC Heart & Sole Debate* research team. However,

the research team created a nutritional fact sheet for all food items sold in RIDOC KEEFE store and incorporated lessons on reading nutritional labels into the lecture sessions. Participants echoed the importance of multi-modality educational requirements, specifically that colorful images were important to assure learnings of all types could absorb the lecture content. For this purpose, topic relevant images were included into the participant packets. Focus group participants highlighted the importance of having completion certifications for intervention group participants, as they found it would be valuable at parole board hearings and in general to show how their time was spent during their sentence at RIDOC.

Method: Phase 3. Conducting the Intervention: Quantitative Research

Procedures

An open pilot test of 22 participants was conducted by two trained facilitators with a facilitator manual. The *DOC Heart & Sole Debate* consisted of 10 classes: held twice weekly, for 2 hours, for 5 weeks. Each class was broken down into four sections: A) 15-minute Participant Self-Health Monitoring B) 30-minute lecture on CVD prevention topic of the day C) 15-minutes to learn/practice healthy living skill D) 45-minute participant-driven debate regarding importance of topic of the day. The remaining 15 minutes was allotted for breaks and participant questions. Course Curriculum is shown in Appendix 2.

- A) During the first 15 minutes, the participants conducted individual health monitoring techniques, where they measured their heart rate and rate stress level

(1-5) and recorded these numbers into their personal health log. The goal of the data collection session was to teach and reinforce self-measurement, symptom monitoring, and self-management skills. The expected outcome was that participants would become aware of their health data (“know their numbers”) and would feel empowered to participate in their health care.

- B) The next 30 minutes of each class integrated theory-guided interactive lectures on the proposed heart disease risk factor topic of the day. The lecture course combined active learning, discussion, and custom tailoring to increase knowledge. Topics are outlined in course curriculum in Appendix 2.
- C) The 15-minute healthy habit of the day was led by a facilitator. The entire class conducted a stress reduction technique, with the facilitators correcting participants as needed. Topics are outlined in course curriculum in Appendix 2.
- D) The remaining 45 minute of the class was a participant-driven semi-structured debate. The class was divided into two equal and randomized groups. To assign individuals to a group, facilitators instructed participants to count off numbers 1 to 22. The even numbers were Group1, the odd numbers were Group2. Each session, the facilitators assigned a different random assembly of participants to each group, by choosing seating of participants and starting the count at a different location in the room. Each Group had 11 participants, one group acted as the defender and the other group the opposer. The groups were given 10 minutes each to prepare their case, guided by the list of debate questions. With support from the facilitators, the defender group created a defense outlining the challenges to incorporating the topic of the day information learned in lecture and the stress

reduction habit in their daily lives. The opposer group produced a position that explained situations when the prisoners could overcome the challenges and engage in the healthy behavior, rationale/ importance to do so, and give examples of the time and day it would be easiest to do so. Teaching the class through a debate-style experience with arguments/persuasive communication and shifting perspectives served as a direct method to change an attitude (Petty et al. 1981). Through verbal persuasion and goal setting, the debate-style, also served to influence self-efficacy and to overcome barriers. Guided by salient knowledge gained from the formative research, the facilitator primed each group with ideas of barriers to changing, health education needs, motivation level and intentions.

Measures

Participants were asked to complete a survey (Appendix4) at three different points throughout the study period. The questionnaire included questions regarding perception of TPB affecting their risk of developing CVD, exercise and stress reduction patterns, perception of their happiness, mannerisms of reacting in intrapersonal situations, and demographics. The first survey was completed on consent day, after signing the consent forms, and was considered their pre-test questionnaire. Participants engaged in 10 intervention classes, per normal schedule. The last intervention class was shortened by 1 hour and instead of the debate portion, participants conducted their post-test questionnaire. Participants took their third questionnaire at the one-month post-intervention follow-up. Survey questionnaire found in Appendix 4.

Creation and Sensitivity Analysis of Theory Constructs: The TPB models were composed of a 10 question instrument created by modifying an existing model from the book *Changing Health Behaviors*⁹. Cronbach's Alpha analyses were run to check if the questions used for assessment accurately represent the constructs evaluated. Attitude towards using Stress Reduction habits as CVD prevention was assessed by 5-point scales (useless-helpful, don't like-like, unimportant-important, and don't believe-believe)⁹, of which questions 4-7 had a corresponding Cronbach Alpha=0.78. Attitude towards incorporating Exercise as CVD prevention was assessed by 5-point scales (useless-helpful, don't like-like, unimportant-important, and don't believe-believe)⁹, of which questions 18-21 had a corresponding Cronbach Alpha=0.25. Perceived Behavior Control towards using Stress Reduction habits as CVD prevention was assessed by 5-point scales (no control-all control, impossible-possible, I won't-I will)⁹, for which questions 8-10 had a Cronbach's Alpha of 0.61. Perceived Behavior Control towards using exercise as CVD prevention was assessed by 5-point scales (no control-all control, impossible-possible, I won't-I will)⁹, for which questions 22-24 had a related Cronbach Alpha=0.47. Subjective Norm regarding stress reduction and exercise views were assessed by 5-point scale (strongly disagree-strongly agree)⁹. Wellbeing was assessed using two happiness questions from a validated Measure of Subjective Happiness Construct²¹, they composed questions 29 and 30 with a corresponding Cronbach's Alpha score of 0.93. Improvement in communication was assessed at baseline by questions 35-37, with a corresponding Cronbach's Alpha of 0.71. Improvement in communication from debate intervention assessed by questions 33-34, with a corresponding Cronbach's Alpha of 0.88. Questions 33-37 were created by one of the facilitators as part of his MPH thesis requirements to

assess the efficacy of the interpersonal skills practiced in the debate. Intention towards CVD prevention was assessed by items: ‘In the next month, I will/will not practice stress-reduction at least 3 times a week’ ‘In the next month, I will/will not exercise at least 3 times a week’ were assessed individually⁹. As instructed by the model, the following paragraph was added to the end of questionnaires “You are more likely to practice stress-reduction techniques if you make a plan about the time and day you will do it. Sometimes people like to do 5 minutes of stress reduction when they first wake up or before going to sleep. Decide right now when and where you will exercise during the next month and then make a commitment to follow through”⁹. Participants were then asked to write out their own plan to practice CVD prevention. The effects of implementation intention were assessed by comparing participants who are equally motivated. Construct scores were created by averaging the mean answer of each question in the instrument together. Post intervention and post 1-month follow up assessments were compared to baseline values to calculate P scores.

Data Analysis

The study hypothesis was TPB & II guided health education classes teaching CVD prevention would show an effect on increased health habits (engaging in cardiovascular exercise & using stress-reduction techniques). Measures of central tendency (mean, standard deviation) examined perceived CVD risk and ability to improve health habits (through beliefs, attitudes, intentions, and motivation constructs). Change in P-values were assessed by comparing baseline scores of each variable to scores at each assessment

time point following the first session. Wellbeing questions 33 and 34, which were compared to the post intervention assessment. Evaluation assessed if results were aligned with hypothesized conceptual model and approach. We examined if potential mediators have altered. If so, we assess if these changes were associated with the primary outcome. The open pilot design did not have a control group; therefore, inferential statistics were not conducted.

Results

Demographics: Descriptive characteristics of the sample are shown in Table 1 and are compared to the overall RIDOC Prison Population as well in Table 1 (Appendix3). Participants had a mean age of 38.5 years old (SD= 11.2), with almost all identifying as male (95.5%), and an average sentence of 12.6 years (SD=0.88). Reported race was White N=7 (31.8%), Hispanics (27.3%), Blacks N=4 (18.2%), Native American N=3 (9%), Asian N=1 (4.5%), and the rest identifying as Other N=2 (9%). This is compared to the overall RIDOC demographics with a mean age of males being 65 years old, average length of sentence 1.9 years, and 100% reported as male.

Stress Reduction (SR) Outcome: Participants SR attitude showed a statistically significant improvement over the research period, from a baseline score of 3.25 to post one-month intervention score of 3.71 ($p=0.01$). SR Perceived Behavior Control increased from 3 at baseline to 3.13 post 1-month intervention ($p=0.33$). SR Subjective Norm increased from 2.68 baseline to 3.05 post 1-month intervention ($p=0.19$). Intention planning decreased from 2.00 baseline to 1.85 post 1-month intervention ($p=0.25$). Intention Implementation

increased from 3.10 baseline to 3.15 at post 1-month intervention ($p=0.24$). Table 2 (Appendix 3) reports Stress Reduction (SR) Theory of Planned Behavior Constructs.

During the baseline assessment, seven individuals (31.8%) reported “never” using stress reduction techniques, while in the post intervention and post 1 month follow up, zero individuals (0%) reported “never” using the techniques. Over time individuals increased their stress reduction practice, until 100% participants reported using stress reduction techniques “sometimes”, “a lot” or “almost every day” at 1-month follow up. Table 3 (Appendix 3) demonstrates how participants self-reported their stress reduction habits over the research period.

Exercise Outcome: Exercise Attitude increased from 3.72 baseline to 3.85 post one-month intervention ($p=0.25$). Exercise Perceived Behavior Control rose from baseline score of 3.02 to post one-month intervention score of 3.12 ($p=0.12$). Subjective Norms regarding exercise statistically significantly grew from 3.14 baseline to 3.65 post one-month intervention ($p=0.03$). Intention planning and implementation showed minor increases if at all. Similarly, to Stress Reduction TPB Constructs, Exercise TPB scores were high from baseline, therefore we do not expect to see major improvements as it appears individuals started with a firm foundational understanding of the importance of a daily exercise regimen. Table 4 (Appendix 3) showed Exercise Theory of Planned Behavior Constructs.

Overall the majority of participants regularly engage in exercise, from baseline to post 1-month intervention. At baseline 95.5% of participants reported exercising at least 1-2 times a week; this rose to 100% after post 1-month intervention assessment. Table 5 (Appendix 3) presents participants self-reported exercise regimen overtime.

CVD Prevention Health Habits: According to the American Heart Association, individuals must perform stress reduction and exercise on a regular basis to see improvement in cardiovascular health¹⁶. Table 6 shows the number of individuals conducting stress reduction sufficiently to improve their hearts health, continues to increase over time even after the intervention class has completed. We see a statistically significant increase in the amount of people reporting the use of stress reduction on a regular basis, increasing from a baseline of 40.9%, to post-intervention of 71.4%, and concluding with a post 1 month follow up of 80% of participants ($p=0.025$). Table 4 shows the majority of our study participants are engaging in exercise on a regular basis. This proportion remains fairly stable over our study period, 77.2% at baseline, 85.7% at post intervention, and 85% post 1 month engage in exercise 3-7 times a week ($p=0.770$). Therefore, we can note that our intervention class was successful in encouraging participants to incorporate stress reduction techniques into their daily lives, as it was associated with a statistically significant increase of 39.1% in class population using stress reduction techniques 3-7x week. Table 6 (Appendix 3) shows the use of stress reduction and exercise sufficiently to promote heart disease prevention and protection.

Interpersonal and Intrapersonal Wellbeing: While assessing wellbeing/happiness, we saw baseline participants self-reported themselves to be quite happy with a baseline score of 5.45 and a post intervention score of 5.92 ($p=0.25$). Participants noted a statistically significant improvement in their intrapersonal communication skills improving from a baseline score of 3.06 to a post-intervention 1-month score of 3.47 ($p=0.03^*$). Table 7 (Appendix 3) presents Personal and Social Interaction Constructs which were taught and tested during the debate section.

Discussion

This multi-method study developed and delivered a tailored intervention to improve CVD risk factor knowledge and heart-healthy behaviors in incarcerated males. The study successfully accomplished its goal of influencing participants to improve their Attitudes, Behaviors, Subjective Norms, and Intentions to make a life altering change to incorporate stress reduction and exercise into their schedules to limit their risk factors of heart disease. At the one-month intervention follow-up, 80% ($N=16/20$) of participants were practicing stress reduction and 85% ($N=17/20$) of participants exercise sufficiently to promote heart health. We also noted increased therapeutic intrapersonal communication skills within *DOC Heart & Sole Debate* participants. The improvement in participant's health behaviors provides support that behavior change theory guided interventions can be effective in improving health habits among incarcerated populations, as noted in the literature.

Scores for all constructs within Stress Reduction TPB were fairly high from baseline, therefore there was not much room for improvement from intervention. However, the improvement in participant's attitude regarding stress reductions' importance to prevent heart disease and maintain healthy lives should be considered as we assess the incorporation of techniques into daily schedules. There is a clear trend showing an increased frequency of using stress reduction techniques overtime. From baseline the N=7 (31.8%) of participants who stated they never practiced stress reduction dropped to 0 by 1-month post intervention. We also saw over time individuals continued to increase their stress reduction practice, as 100% of participant stated they practiced stress reduction "sometimes", "a lot" or "almost every day" at the 1-month post intervention assessment. It was great to see improvements continued to increase from post intervention to post 1-month intervention assessment. This suggests individuals may have become more motivated to learn on their own after the intervention course was completed. Participant packets were collected each class by facilitators, to assure individuals had them for the following class, therefore research members did not have access to reread information discussed in class throughout the study period. On the final day of class, participants were allowed to keep their packets, which may have contributed to the increased modification of TPB constructs from post intervention to follow up.

We noted improved intrapersonal communication skills within *DOC Heart & Sole Debate* participants. Emotional intelligence and mannerisms to prevent frustration during social interaction were taught and tested during the debate section. Participants noted an improvement in their abilities to have others critique their ideas, discuss varying views of

topics, and understand difference of opinions before making judgements. Such skills are important to reduce emotional outbursts and physical fights, to hopefully support individuals during their sentence and after release to reduce recidivism.

Due to participants incarceration status, their lack of choice of activities may encourage them to exercise more frequently. The baseline assessment showed participants exercise more frequently and contributed to the minimal increase in exercise frequency we witnessed, as many reported in their questionnaires they did not wish to exercise more as they felt they already exercised sufficiently. We cannot comment if our class had any effect on participant's exercise regimens overtime, though we hope the information participants learned in the class encourages them to maintain their exercise routines and engage in the most appropriate types of exercise to promote heart health.

We expect to see more differentiation between our race categories and RIDOC categories at large as their demographic information was collected differently. RIDOC records Hispanics as a race rather than ethnicity, thereby inmates identifying as Hispanic cannot also identify as white or black¹⁵. Compared to our questionnaire that allowed participants to select any and all races they identified with. There could also be a discrepancy between our race statistics compared to the overall RIDOC population, as our participants are solely from the male medium security facility, where RIDOC demographics are include a combination of all incarcerated individuals in all facilities (male and female)¹⁵. We also noted a discrepancy in gender statistics, as RIDOC solely collects biological sex data, where our questionnaire allowed individuals to choose their gender identity.

This *DOC Heart & Sole Debate* pilot program shows potential to serve as a cost-effective tool to improve cardiovascular risk factors among incarcerated individuals. The program was designed to fill a gap in preventative health knowledge that occurs in prison settings due to inconsistent primary healthcare access. The program requirements meet the strict security regulations on items that can be brought into a prison setting, as the only items required to conduct this program include a printer, clock, and writing utensils. Due to the restrictions placed on items allowed to enter a corrections facility, the innovative component of this project is in the content and method of delivery. Instead of teaching in a typical manner of primary lecturing, the class had multi-modality educational approaches to allow individuals of all educational and personality and learning styles to interact with the course content. *DOC Heart & Sole Debate* could easily be replicated in any prison in the country as a low resource solution to empower incarcerated individuals to become aware of their cardiovascular risk factors and improve health behaviors to prevent heart disease.

Limitations

Due to our inclusion criteria, we must keep in mind that our population is not representative of the entire prison population. However, we will have to assure the participants do at least represent the very specific group from which they were selected. We incorporated a narrow view of stress reduction techniques, where only activities that were done for the sole purpose of stress reduction for at least 10 minutes were considered. Other stress-reduction activities (such as praying) were not included, unless

they were specifically done to reduce stress. Also, exercise, a common form of stress-reduction, was not included as we considered it so greatly important that it had its own category for analysis. Due to a discrepancy with recruitment procedures, there may be a bias with initial participant aggregation, as DOC guards only delivered 1 sign-up sheet to each cell (for two people), therefore only one person per cell could apply for the research project. The research team remains unsure if both individuals in each cell even got the opportunity to apply to engage in the research project.

Conclusions

The evaluation assessed if the *DOC Heart & Sole Debate* was effective in changing attitude, perceived behavior control, self-efficacy and intention to incorporate cardiovascular exercise and stress reduction into their activities of daily living. We note that the course successfully encouraged participants to improve their health habits to prevent heart disease. During the conduction of the intervention, we documented the benefits and challenges of each interaction, what could have been better, what could have been more engaging, what was confusing, how individuals reacted to positive reinforcement, if this method was effective, what encouraged participants to be engaged, and how well the facilitator adhered to the manual. This data is expected to guide future research endeavors, with the goals of conducting a full RCT.

If you are interested in a copy of the facilitator packet, please kindly email the primary investigator Melissa.godfrey001@gmail.com.

References

1. Ann Carson E. Prisoners in 2016: Bulletin. *US Dep Justice Off Justice Programs Bur Justice Stat.* 2018;1-36. <https://www.bjs.gov/content/pub/>.
2. Maruschak LM, Statistician B, Berzofsky M, Unangst J. Special Report Medical Problems of State and Federal Prisoners and Jail Inmates, 2011-12. 2016;(February 2015). <https://www.bjs.gov/content/pub/pdf/mpsfpi1112.pdf>.
3. Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics—2015 Update. *Circulation.* 2015;131(4). doi:10.1161/CIR.0000000000000152
4. Kochanek KD, Xu J, Murphy SL, Minino AM, Kung H-C. National Center for Health Statistics. Deaths: Final Data for 2013. *Natl Cent Heal Stat.* 2012;60(3):1-117. doi:May 8, 2013
5. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart Disease and Stroke Statistics—2012 Update. *Circulation.* 2012;125(1):2-220. doi:10.1161/CIR.0b013e31823ac046
6. Whitworth JA, Williamson PM, Mangos G, Kelly JJ. Cardiovascular consequences of cortisol excess. *Vasc Health Risk Manag.* 2005;1(4):291-299. doi:10.2147/vhrm.2005.1.4.291
7. Safeer RS, Cooke CE, Keenan J. The impact of health literacy on cardiovascular disease. *Vasc Health Risk Manag.* 2006;2(4):457-464. doi:10.2147/vhrm.2006.2.4.457
8. Corrections RID of. Fiscal Year 2016 Annual Population Report. 2016;(October).
9. Rutter D and LQ. *Changing Health Behavior.* New York, NY, USA,: Open University Press.; 2002.
10. Steinmetz H, Knappstein M, Ajzen I, Schmidt P, Kabst R. How effective are behavior change interventions based on the theory of planned behavior?: A three-level meta analysis. *Zeitschrift fur Psychol / J Psychol.* 2016;224(3):216-233. doi:10.1027/2151-2604/a000255
11. Svenson A, Iverson D, Coltman T, et al. The theory of planned behaviour and discrete food choices: a systematic review and meta-analysis. *Int J Behav Nutr Phys Act.* 2015;12(1). doi:10.1186/s12966-015-0324-z
12. São-João TM, Brizon VC, Franco DH, Mialhe FL, Silva MAV da. Impact of implementation intentions on physical activity practice in adults: A systematic review and meta-analysis of randomized clinical trials. *PLoS One.* 2018;13(11):e0206294. doi:10.1371/journal.pone.0206294
13. Swenty CF, Rowser M. An Education Intervention in an Incarcerated Population to Reduce the Occurrence of Infectious Skin Diseases. *J Correct Heal Care.* 2014;20(4):343-352. doi:10.1177/1078345814541532
14. Senkowski V, Norris K, McGaughey A, Branscum P. A Review of the Effectiveness of HIV Sexual Risk Prevention Interventions in Adult Prison Inmates. *J Correct Heal Care.* 2016;22(4):309-321. doi:10.1177/1078345816669377
15. Goals R. Fiscal Year 2018 Annual Population Report. 2015;(October).
16. Association AHA| AS. Strength and Balance Exercises. <http://grace-sacramento.org/wp-content/uploads/2013/10/StrengthAndBalanceExercises.pdf>.

17. Ohio State University WMC. Seated Strengthening Exercises.
<https://patienteducation.osumc.edu/Documents/SeatedStrengthening.pdf>.
18. Manflowyoga. Yoga Basics for Men, An Intro to Man Flow Yoga.
<https://manflowyoga.com/wp-content/uploads/2015/04/Yoga-Basics-for-Men-2nd-Edition.pdf>.
19. Brett and Kate McKay. The Prisoner Workout: Killer Bodyweight Exercises for Small Spaces. the Art of Manliness.
20. QSR International Pty Ltd. Version 12. NVivo qualitative data analysis software. 2018.
21. Lepper HS, Lyubomirsky S. A measure of subjective happiness : Preliminary reliability and construct val ... *Soc Indic Res*. 1999;46(2):137=155.

Appendix 1: Underlying Theory Construct Figures 1 & 2

FIGURE 1: THEORY OF PLANNED BEHAVIOR & IMPLEMENTATION INTENTION MODEL

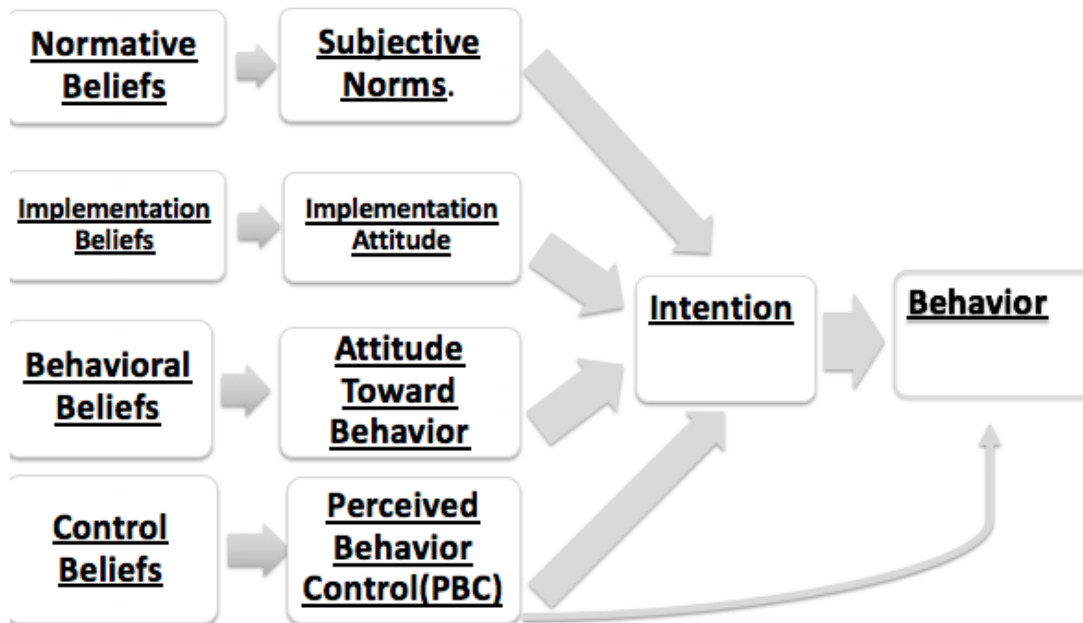
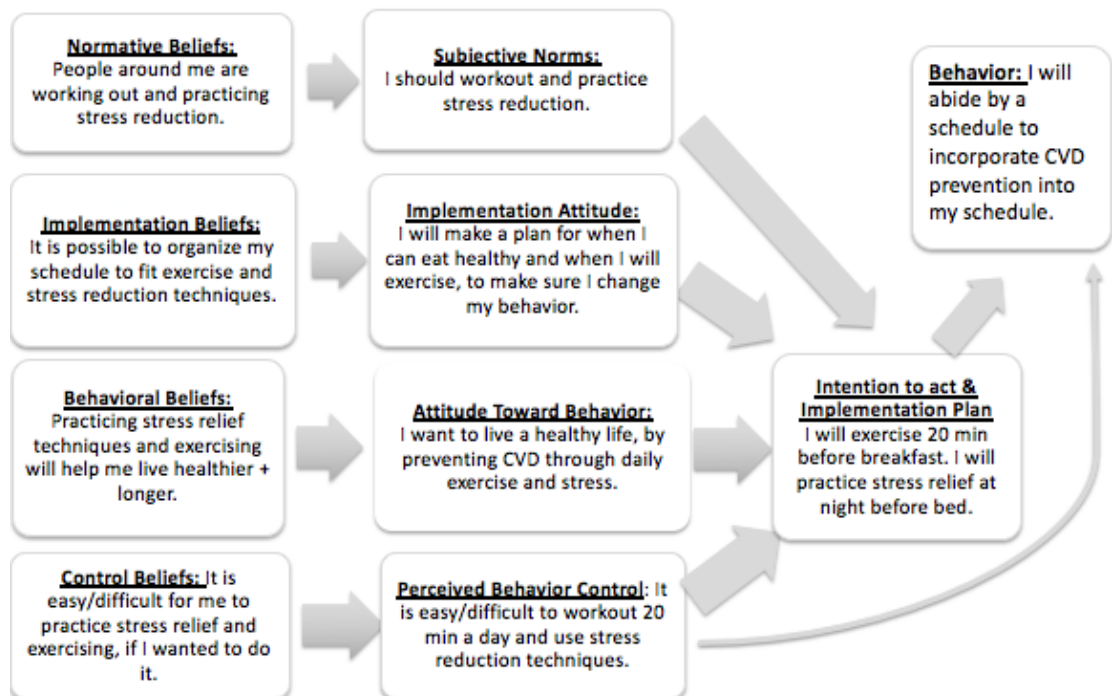


FIGURE 2: THEORY OF PLANNED BEHAVIOR & IMPLEMENTATION INTENTION GUIDED CVD EDUCATION IN INCARCERATED POPULATION



Appendix 2: Course Curriculum

	Session	1	2	3	4	5
15 min	Health Monitoring	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level
30 min	Lecture: Knowledge is Power	Welcome Cardiovascular Disease Risk Factors	Heart disease	Stress Hardiness & Resilience	Blood Pressure	Cholesterol
15 min	Practice: Healthy Living Skill	Health Monitoring & Belly Breathing (30 min)	Gratitude & Appreciation	Affirmations	Mantra Meditation	Progressive Muscle Relaxation
45 min	Debate:	<i>None</i>	Importance of Gratitude & Appreciation	Importance of Stress Hardiness	Importance of Managing BP	Importance of Understanding Cholesterol

	Session	6	7	8	9	10
20 min	Knowledge Is Power	Nutrition Balanced Plate Managing & Mindful Eating	Managing Negative Thoughts & Emotions	Smoking	Exercise: Overweight, Obesity, & Physical Inactivity	Intentional Communication & Goal Setting
5 min	Health Monitoring	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level	Measure HR & Stress-level
10 min	Healthy Living Skill	Emotional Overeating	Identifying Thinking (Cognitive) Distortions	Five Finger Exercise	Vertical Arrow Exercise	Personal Goals
45 min	Debate	Importance of Nutrition	Importance of Managing Anger	Importance of Not Smoking	Importance of Exercise	Importance of Personal Health Goals

Appendix 3: Results Tables 1-7

Table1:Descriptive Statistics: Focus + Intervention Participants + RIDOC Population			
Demographics % (N)	Focus Group, N=13-15	Intervention Participants N=22	RIDOC Prison Population:
Race:	Black: 21.4% (3) Hispanic: 21.3% (3) White: 35.7% (5) Asian + Native American + Other: 21.3% (3) N=14	Black: 18.2% (4) Hispanic: 27.3% (6) White: 31.8% (7) Asian + Native American + Other: 22.5% (5)	Black: 27.8% Hispanic: 24.7% White: 43.6% Asian + Native American + Other: 6%
Age: (in years)	18-20: 0% 21-29: 15.4% (2) 30-39: 53.8% (7) 40-49: 15.4% (2) 50-59: 0% 60+: 15.4% (2) N=13	18-20: 0% 21-29: 18.2% (4) 30-39: 50.0% (11) 40-49: 4.5% (1) 50-59: 22.7% (5) 60+: 4.6% (1)	18-20: <4% 21-29: 31.4% 30-39: 28.8% 40-49: 18.8% 50-59: 13.7% 60+: 6.4%
Sex:	Male: 100% (21) N=15	Male: 95.5% (21) Other: 4.5% (1)	Male: 100%
Length of Sentence: (in years)	<1: 7.7% (1) 1.1-3: 23.1% (3) 3.1-5: 53.8% (7) 5.1-10: 0% 10+: 15.4% (2) N=13	<1: 0% 1.1-3: 5% (1) 3.1-5: 15% (3) 5.1-10: 35% (7) 10+: 45% (9)	<1: 19.6% 1.1-3: 16.1% 3.1-5: 10.9% 5.1-10: 16.3% 10+: 35.2%

Table 2: Stress Reduction Theory of Planned Behavior Construct Responses Overtime

Stress Reduction	Questions Assessing Construct	Baseline	Post Int.	P	Post 1 Mon	P
		N=22	N=21		N=20	
Attitude	Q4: To me, practicing stress-reduction is (useless-helpful) Q5: I (don't like-like) like practicing stress-reduction Q6: To me, maintaining my stress-reduction routine is (unimportant-important) Q7: I (don't believe-believe) practicing stress reduction will help me avoid Heart Disease	3.25 (0.12)	3.45 (0.17)	0.25	3.71 (0.18)*	0.01*
Perceived Behavior Control (PBC)	Q8: How much control do you have over whether or not you practice stress reduction 3 times a week (no control- all control) Q9: For me to practice stress-reduction techniques at least three times a week, it would be (impossible-possible) Q10: I (won't-will) put stress-reduction into my day	3.00 (.09)	3.06 (0.13)	0.62	3.13 (0.13)	0.33
Subjective Norm	Q11: How much do you disagree/agree with the statement, "people in my life think practicing stress reduction is important" (strongly disagree-strongly agree)	2.68 (0.19)	2.85 (0.28)	0.55	3.05 (0.28)	0.19
Intention	Q12: In the next month, I (won't-will) practice stress-reduction at least 3 times a week	2.00 (0.09)	1.90 (0.13)	0.45	1.85 (0.13)	0.25
	Q14: Last month, I followed the plans I made to practice stress reduction (never did-always did)	-	3.10 (0.17)	-	3.15 (0.24)	0.82

Mean values of responses are listed according to time of assessment with (standard deviation). *Fisher's Exact P values are reported using first value in segment listed as comparison*, with values <0.05 significance level*

Table 3: Stress Reduction Habits Overtime

Stress-Reduction Regimen Questions:	Baseline: How much do you practice stress reduction techniques now?	Post Intervention: How much do you practice stress reduction techniques now?	Post 1 Month: How much do you practice stress reduction techniques now?
Available Answers:	Percent of Responses (N), Total N=22	Percent of Responses (N), Total N=21	Percent of Responses (N), Total N=20
<u>Never</u>	31.8% (7)	0% (0)	0% (0)
<u>Not that Much</u> (0-2 times a month/ or less)	9.1% (2)	4.7% (1)	0% (0)
<u>Sometimes</u> (1 or 2 times a week)	18.2% (4)	23.8% (5)	20% (4)
<u>A Lot</u> (3 or 4 times a week)	22.7% (5)	61.9% (13)	45% (9)
<u>Almost Every day</u> (5-7 times a week)	18.2% (4)	9.5% (2)	35% (7)

Table 4: Exercise Theory of Planned Behavior Construct Responses Overtime

Exercise	Questions Assessing Construct	Baseline	Post Int	P	Post 1 Mon	P
		N=22	N=21		N=20	
Attitude	Q18: To me, exercising is a (bad-good) idea Q19: To me, exercising is (unimportant-important) Q20: I (don't like-like) to exercise Q21: I (don't believe-believe) exercising will help me avoid Heart Disease	3.72 (0.08)	3.79 (0.11)	0.54	3.85 (0.12)	0.25
Perceived Behavior Control (PBC)	Q22: For me to exercise at least three times a week would be (difficult-easy) Q23: How much control do you have over whether or not you exercise 3 times a week (no control-all control) Q24: I (can't-can) make time for exercising	3.02 (0.08)	3.13 (0.12)	0.35	3.12 (0.12)	0.40
Subjective Norm	Q25: How much do you disagree/agree with the statement, "people in my life think exercising is important" (strongly disagree-strongly agree))	3.14 (0.16)	3.65 (0.23)	0.29	3.65 (0.23)*	0.03*
Intention	Q26: In the next month, I (won't-will) exercise at least 3 times a week	2.05 (0.09)	1.91 (0.12)	0.28	2.00 (0.35)	0.73
	Q28: Last month, I followed the plans I made to exercise (never did-always did)	-	3.29 (0.22)	-	3.35 (0.32)	0.84

Mean values of responses are listed according to time of assessment with (standard deviation). *Fisher's Exact P values are reported using first value in segment listed*, with values <0.05 significance level*

Table 5: Exercise Habits Overtime

Exercise Regimen Questions:	Baseline: How much do you exercise now?	Post Intervention: How much do you exercise now?	Post 1 Month: How much do you exercise now?
Available Answers:	Percent of Responses (N), Total N=22	Percent of Responses (N), Total N=21	Percent of Responses (N), Total N=20
<u>Never</u>	4.6% (1)	4.8% (1)	0% (0)
<u>Not that Much</u> (0-2 times a month/ or less)	0% (0)	9.5% (2)	0% (0)
<u>Sometimes</u> (1 or 2 times a week)	18.2% (4)	0% (0)	15% (3)
<u>A Lot</u> (3 or 4 times a week)	31.8% (7)	38.1% (8)	25% (5)
<u>Almost Every day</u> (5-7 times a week)	45.5% (10)	47.6% (10)	60% (12)

Table 6: Practicing Heart Disease Prevention

Practicing Stress Reduction To Prevent Heart Disease	Baseline: % (N), Total N=22	Post Intervention: % (N), Total N=21	Post 1 Month: % (N), Total N=20	Fisher's Exact P-value:
3-7x a Week	40.9% (9)	71.4% (15)	80% (16)	P = 0.025*
Exercising To Prevent Heart Disease	Baseline: % (N), Total N=22	Post Intervention: % (N), Total N=21	Post 1 Month: % (N), Total N=20	Fisher's Exact P-value:
3-7x a Week	77.2% (17)	85.7% (18)	85% (17)	P = 0.770

Fisher's Exact P values are reported with values <0.05 significance level* A binary variable was created including answers from Table2 and Table3, comparing individuals who practice Stress Reduction or Exercise frequently ("a lot" or "almost everyday") to the rest of the group.

Table 7: Personal and Social Interaction Construct Responses Overtime

Personal and Social Interaction	Questions Assessing Construct	Baseline N=22	Post Int N=21	P Value	Post 1 Mon N=20	P Value
Wellbeing	Q29: In general, I consider myself (not very happy-very happy) Q30: Compared to most of my peers, I consider myself (not very happy-very happy)	5.45 (0.28)	5.61 (0.40)	0.68	5.92 (0.40)	0.25
Communication	Q33: Did this class help you communicate better with others you do not agree with Q34: After taking this class, are you better at controlling your anger when talking to others	-	3.19 (0.19)	-	3.00 (0.28)	0.50
<i>All answer choices were (strongly disagree-strongly agree)</i>	Q35: I try to understand the other side of an argument before making any judgements. Q36: I am open to people critiquing my ideas even if I do not agree with them Q37: When I am frustrated about a topic of discussion, I try to calmly talk it over	3.06 (0.13)	3.51 (0.18)	0.02*	3.47 (0.18)	0.03*

Mean values of responses are listed according to time of assessment with (standard deviation). *Fisher's Exact P values are reported using first value in segment listed*, with values <0.05 significance level*

Appendix 4: Assessment Questionnaire

Please note for the purposes of explaining to research community, TPB & II constructs are noted in the below questionnaire; they were not noted during participant completion. Also solely for didactic purposes, all questions for pre-test and post-test were included, and extra lines for writing and spaces between questions were removed to compact the questionnaire.

Date: _____

Participant Number: _____

Time of Assessment: Control | Baseline | Course Completion | After 1 months | After 3 months

FOR THIS QUESTIONNAIRE: Stress-Reduction Techniques: are methods to calm yourself down, change your negative emotions, seek peace, or become centered. Some examples of stress-reduction techniques can be taking calming deep breaths, guided meditation, admiring the beauty in nature, and intentional thinking. **For techniques to be counted,** you must have done it for **at least 2-10 minutes** AND **done for the purpose of stress-reduction.** Even if you have never done these techniques, please still answer each question, we care about what you think.

Stress Reduction Techniques:
Meditation, Deep Breathing,
Progressive Muscle Relaxation,
Five Finger Exercise,
Purposeful Thinking:
(Affirmation/ Mantra/Gratitude)

Intervention Assessment

1. Before coming to the ACI, did you practice stress reduction techniques? Please check one box.

- A. ☐ Never
- B. ☐ Not that Much (I used techniques 0-2 times a month/ or less)
- C. ☐ Sometimes (I used techniques 1 or 2 times a week)
- D. ☐ A Lot (I used techniques 3 or 4 times a week)
- E. ☐ Almost Every day (I used techniques 5-7 times a week)

2. How much do you practice stress reduction techniques now? Please check one box.

- A. ☐ Never
- B. ☐ Not that Much (I use techniques 0-2 times a month/ or less)
- C. ☐ Sometimes (I use techniques 1 or 2 times a week)
- D. ☐ A Lot (I use techniques 3 or 4 times a week)
- E. ☐ Almost Every day (I use techniques 5-7 times a week)

3. Would you like to practice stress reductions more than you do now? Please check one box.

- A. ☐ Yes, I want to practice more stress reduction.
- B. ☐ No, I don't want to practice more stress reduction. *Please explain why you feel this way.*

- C. ☐ I don't care to practice more stress reduction. *Please explain why you feel this way.*

Attitude:

4. To me, practicing stress-reduction is useless/helpful:

0	1	2	3	4
Useless		Not Useless/ Helpful		Helpful

5. I like/don't like practicing stress-reduction:

0	1	2	3	4
Don't like		Don't like/ Like		Like

6. To me, maintaining my stress-reduction routine is important/unimportant:

0	1	2	3	4
Unimportant		Not Unimportant/Important		Important

7. I believe/ don't believe practicing stress reduction will help me avoid Heart Disease:

0	1	2	3	4
Don't Believe		Neither Don't Believe/ Believe		I Believe

Perceived Behavior Control

8. How much control do you have over whether or not you practice stress reduction 3 times a week (2-10 minutes each)?

0	1	2	3	4
No Control		Some Control		All Control

9. For me to practice stress-reduction techniques at least three times a week (2-10 minutes each), it would be possible/impossible:

0	1	2	3	4
Impossible		Not Impossible/Possible		Possible

10. I will/ won't put stress-reduction into my day:

0	1	2
I Won't	I Might	I Will

Subjective Norm:

11. How much do you agree/disagree with the following statement. People in my life think practicing stress reduction is important.

0	1	2	3	4
Strongly Disagree		Neither Disagree/Agree		Strongly Agree

Intention

12. In the next month, I will/will not practice stress-reduction at least 3 times a week (2-10 minutes each).

0	1	2
I Won't	I Might	I Will

PLEASE READ: **You are more likely to practice stress-reduction techniques if you make a plan** about the time and day you will do it. Sometimes people like to do 5 minutes of stress reduction when they first wake up or before going to sleep. Decide right now when and where you will **exercise** during the next month and then make a commitment to follow through.

13. Write your plan of when you will practice stress-reduction techniques below:

Example. I will meditate for 5 minutes when I wake up and before I go to sleep.

18. To me, exercising is a good/bad idea:

0	1	2	3	4
Bad idea		Not Good/Bad idea		Good idea

19. To me, exercising is important/unimportant:

0	1	2	3	4
Unimportant		Not Unimportant/ Important		Important

20. I like/don't like to exercise:

0	1	2	3	4
Don't like		Neither Don't Like/ Like		Like

21. I believe/ don't believe exercising (10 minutes, 3 times a week) will help me avoid Heart Disease:

0	1	2	3	4
Don't Believe		Neither Don't Believe/ Believe		I Believe

Perceived Behavior Control

22. For me to exercise at least three times a week (10 minutes each session) would be easy/difficult.

0	1	2	3	4
Difficult		Not Difficult/Easy		Easy

23. How much control do you have over whether or not you exercise 3 times a week (10 minutes each)?

0	1	2	3	4
No Control		Some Control		All Control

24. I can/can't make time for exercising.

0	1	2
I Can	I Might	I Can't

Subjective Norm

25. How much do you agree/disagree with the following statement. People in my life think exercising is important.

0	1	2	3	4
Strongly Disagree		Neither Disagree/Agree		Strongly Agree

Intention

26. In the next month, I will/won't exercise at least 3 times a week (10 minutes each).

0	1	2
I Won't	I Might	I Will

Implementation Intention

PLEASE READ: **You are more likely to exercise if you make a plan** about the time and day you will do it. Sometimes people like to do 20 minutes of exercise before breakfast or before dinner. Decide right now when and where you will exercise during the next month and then promise yourself that you will follow through.

27. Write your plan of when you will exercise below:

Example. I will work-out for 20 minutes: Monday, Wednesday, and Friday before lunch.

Post Intervention/ Follow-up Implementation Intention

28. Last month, I followed the plans I made to exercise.

0 1 2 3 4
Never Did Sometimes Did Always Did

If you answered 0/1/2. Please give reasons why you did not follow through with your plan.

Wellbeing

29. In general, I consider myself

1 2 3 4 5 6 7
Not a Very Happy Person Very Happy Person

30. Compared to most of my peers, I consider myself:

1 2 3 4 5 6 7
Not a Very Happy Person Very Happy Person

Assessment of Managing Negative Emotions

31. When I am talking to people that I do not agree with I _____. (Check all that apply.)

- A. ☐ Want to fight
- B. ☐ Want to yell
- C. ☐ Feel angry
- D. ☐ Walk away
- E. ☐ Listen
- F. ☐ Try to understand their point of view
- G. ☐ Try to compromise with them
- H. ☐ Other_____

32. Did this class help you communicate better with others you do not agree with?

0 1 2 3 4
Strongly Disagree Neither Disagree/Agree Strongly Agree

33. Did this class help you talk to others without getting upset?

0 1 2 3 4
Strongly Disagree Neither Disagree/Agree Strongly Agree

34. After taking this class, are you better at controlling your anger when talking to others?

35. I try to understand the other side of an argument before making any judgements.

36. I am open to people critiquing my ideas even if I do not agree with them.

37. When I am frustrated about a topic of discussion, I try to calmly talk it over.

Participant Information

A. ☐ Asian/Pacific Islander
B. ☐ Black/African American
C. ☐ Hispanic- or Latino-American
D. ☐ Native American / Indian American
E. ☐ Caucasian
F. ☐ Other (please specify) _____

39. How old are you? _____ Years

A. ☐ Male
B. ☐ Intersex
C. ☐ Female
D. ☐ Other
E. ☐ I'd rather not reply

41. How long have you been incarcerated: _____ Years

42. How much longer do you expect to be incarcerated: _____ Years

43. What date were you committed? _____ Day/Month/Year

44. Is there anything else you would like to tell us that we did not ask you about?

65

Appendix 5: IRB proposal

BROWN UNIVERSITY INSTITUTIONAL REVIEW BOARD HUMAN RESEARCH PROTOCOL

Protocol Title: Department of Corrections (DOC) Heart & Sole

Principal Investigator: Melissa Godfrey

Department: Brown University- School of Public Health

Funding Source (if no external funding for the project, enter "University"): University

If externally funded, Coeus Institute Proposal # for the project:

1. (1) Attach to this form the information required for a complete protocol, as outlined on the IRB Form #1 [Instructions & Information](#) pages. In addition, please review the document "[What Makes a Complete Protocol](#)."
2. (2) Select the appropriate type and category number of review. See descriptions of [expedited](#) categories. If no expedited categories completely describe the proposed research, select "Full Board.") **Expedited # Full Board**
3. (3) **Investigator Conflict of Interest Statement:**

The [Brown University Conflict of Interest Policy for Officers of Instruction and Research](#) ("COI Policy") defines the term "Investigator" as "the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research." Using this definition of "Investigator," please ensure that all Investigators on this protocol answer questions 3(a) and 3(b) below [attach additional sheets for any Investigators who are not the PI; they only need to answer 3(a) and 3(b)]:

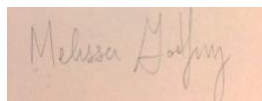
(a) Is your annual Assurance of Compliance form (and, if necessary, reporting form) accurate and up-to-date as of the time of this submission, as required by the [COI Policy](#)? (You may access the system [here](#) to confirm.)

YES NO

(b) Do you have a [significant financial interest](#) (SFI) that is related to this research protocol? "Related" could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI and/or that the SFI could be affected by the proposed research or its results. YES NO

Principal Investigator certifies to the following: (1) The rights and welfare of the participants are adequately protected. (2) The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. (3) This protocol is accurate and complete; if the project scope or design is later changed, the PI will resubmit for review. (4) All research personnel, including the PI, has been, or will be, research protections prior to beginning **Principal Investigator signature:**

adequately educated in human work on the project.



Date: 4/5/2018

Protocol Checklist and Submission Procedures

This page must be COMPLETED and INCLUDED as page #2 of your submission

To ensure the quickest turnaround time possible, please prepare your protocol for IRB review (full board or expedited) with all the following information that is applicable to your project, number the pages and note the page numbers of each item on the checklist. Refer to the following instructional pages for more information about the required elements of an IRB protocol.

IRB Form #1 (Rev. 10/18)

Protocol component	Included?	Page number(s):
1. IRB Form #1	☒ Yes	3-4
2. Lay Summary	☒ Yes	6
3. Protocol Narrative:		6-22
Aims & Methodology	☒ Yes	6-7
Informed consent procedure	☒ Yes	8-9
Consent/Assent documents/scripts	☒ Yes ☐ N/A	11-22
Risks and Benefits	☒ Yes	7
4. Attachments (if applicable):		
a) Interview/survey/focus grp instruments	☒ Yes ☐ N/A	19, 113-118
b) Letters/e-mails to participants	☒ Yes ☐ N/A	
c) Recruitment materials	☒ Yes ☐ N/A	10
d) Letters of support/permission	☒ Yes ☐ N/A	120
e) Other IRB approvals	☐ Yes ☐ N/A	
f) Data Use Agreements	☐ Yes ☐ N/A	
g) Protocol addenda/appendices, as needed	☐ Yes ☐ N/A	
h) Funding application	☒ Yes ☐ N/A	121-123

Checklist Form for Research Involving the Use of Prisoners as Study Participants

Protocol Title: Department of Corrections Heart & Sole

Investigator's Name: Melissa Godfrey, RN, MPHc

In order to satisfactorily complete a protocol that includes the use of prisoners as participants in a research study, the investigator must determine which of the following categories applies to the research study proposed. Please check the appropriate category you believe matches the protocol. The selections of the categories will be discussed at the appropriate convened IRB meeting.

 (A) The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

 X (B) The study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

 (C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

 (D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research. In addition, in order for your protocol to be complete please determine that all of the conditions below apply. Initial each condition to indicate your determination that the condition is met.

 (1) the research under review represents one of the categories of research permissible under one of the categories above;

 (2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

 (3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

 (4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless you provide to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

 (5) the information is presented in language that is understandable to the participant population;

 (6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

 (7) where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Protocol Narrative: Lay Summary:

Prisoners have higher rates of chronic diseases (44.7%) compared to the general population (gen pop) in the United States (US) (26.9%); including high blood pressure (~2x gen pop), stroke-related problems (~4x gen pop), diabetes (~1.5x gen pop), and heart-related problems (~5x gen pop) (US Department of Justice 2016). A focus group conducted among Rhode Island Department of Corrections (RIDOC) Prisoners in 2017 (N=20 males in a Medium-Security Facility, conducted by Rhode Island Department of Health and RIDOC health educator), revealed barriers to positive health behaviors relevant to CVD included inconsistent access to primary healthcare, lack of options for healthy foods, lack of food nutritional labels, lack of health literacy, lack of exercise and increased stress/fear from chronically living in survival mode. This provides a unique opportunity to minimize the prevalence of CVD in correctional populations by educating individuals on primary prevention behaviors. I propose the development and implementation of DOC Heart & Sole Debate health education courses focused on teaching primary CVD. There is minimal ability to change an inmate's external triggering factors such as lack of control over daily activities, large amounts of free time with few activities to engage in and inability to prepare their own food (2017 focus group at RIDOC). We must target behavioral intention to improve health habits by addressing: 1) attitude, 2) perceived behavior control, 3) self-efficacy, and 4) plan of intention.

Protocol Narrative: Lay Summary:

1. Conduct formative research to inform implementation, methods and content of the intervention: We will conduct focus groups to assess the following: attitude, perceived behavior control, self-efficacy, and plan of intention to engage in CVD preventive behaviors (exercise and stress-reduction). Information on needs and barriers to CVD habits will also be analyzed to understand potential challenges in the study target. The formative work also highlights if this manner of engagement is realistic and effective in this setting and population. Two focus groups (N = 8-10 per group) will be conducted in Medium-security facility (total ~20 participants). Key informants (e.g. medical personnel, correction officers, health educator) will be interviewed individually to triangulate data on relevant issues.

2. Test the feasibility and acceptability of the intervention: Conduct trial group-based educational CVD classes: The intervention pilot program will include 20 inmates taking an interactive TPB&II based CVD education course 90min/class, 2x a week, for 5 weeks. This will allow for evaluation of acceptability and impact regarding the population of interest. Will also assess feasibility to conduct an open pilot RCT.

3. Evaluation and Analysis: Hypothesis: TPB&II guided health education classes teaching CVD prevention will show an effect on increased health habits (conducting 20 min/day of cardiovascular exercise & stress-reduction techniques). All participants will take two brief initial questionnaires to assess beliefs, attitudes, intentions and motivation. Participants will retake the questionnaires after the intervention/traditional class, after three months and after six months. Allowing for effectiveness testing of theory-based CVD prevention education class vs the current practice. **Evaluate** if results are aligned with hypothesized conceptual model and approach. Examine if potential mediators have altered in cases vs controls. If so, are these changed associated with the primary outcome. Test hypothesis.

Conceptual models guiding intervention: We will use culturally competent communication in focus groups to distinguish the most appropriate information to teach in the intervention classes. In these groups, the participants will highlight intrinsic behaviors, abilities and challenges. Their perspective will guide the creation of a CVD prevention lecture and debate. The proposed lecture

will apply two theoretical frameworks, Theory of Planned Behavior and Implementation Intention, which have not previously been tested in the prisoner population. The **DOC Heart & Sole Debate** health classes will be taught in a manner that fosters participant exploration, creative problem solving, overcoming challenges/ambivalence to changing behavior practices, plan development and defending one's actions (guided by the Elaboration Likelihood Model of Persuasion).

Methodology:

Participant Population: The Rhode Island Department of Corrections (RIDOC) is a state-run

correctional institution, which houses roughly 3,000 men and women with 13,000 intakes and releases annually (RIDOC 2017 Annual Report). Participants for this project will be from the Medium Security John J. Moran Facility, which houses about 1000 individuals (RIDOC 2017 Annual Report). Private classrooms are available at RIDOC Medium Facility for recruitment, assessment and intervention.

Inclusion Criteria: (Formative focus groups & Intervention): Participants must be able to read, speak and understand English and be at least 18 years old. Participants must have at least another year of sentence, to allow for follow-up.

Exclusion Criteria: (Formative focus groups & Intervention): Anyone who cannot read/speak/understand English, are less than 18 years old, have less than a year of detention left.

Compensation: Inmate participants will receive no financial compensation for their participation.

Risks: This study involves the risk of a) breach of confidentiality, despite taking many measure to assure

confidentiality, and b) coercion. There may also be other risks that we cannot predict.

a. Breach of confidentiality is highly unlikely because all data are identified only by numeric code and are stored in a Brown University Excel Software Program. A master list of names and numbers is kept separately in a locked cabinet at Brown University to facilitate follow-up data collection. Only research staff with a need to know (for follow-ups or adverse events) or mandated auditors have access to the master list linking names and code numbers, all requests will be verified by faculty mentor Dr. Rosemarie Martin. All staff are or will be made fully conversant with relevant ethical principles, particularly around confidentiality. All intervention classes and questionnaire assessments will be closely supervised by the project's professional staff.

b. Coercion: Coercion occurs when potential participants feel compelled to participate in research for reasons such as perceived demand or the availability of large sums of reimbursement. This can be particularly true when there is little benefit to the individual for their participation. In the present study, the inclusion of a protected population and, in particular, a population who by its very nature is subject to extreme restriction in their daily freedoms, protection from coercion is of the utmost importance. That being said, we feel that there is minimal risk of potential participants being coerced to participate, as we will thoroughly train our staff, as done in previous studies with this population, to explain the absolute voluntary nature of the study to potential participants and to emphasize multiple times throughout the consenting process and all subsequent study activities that the participant has every right to choose not to participate or to withdraw from participation at any time.

Benefits: There may be no direct benefit from being in this research study. Individuals may receive benefit from the knowledge they will learn regarding Cardiovascular Disease Prevention and behavior modification. It is reasonable to expect the following benefits from this research: Short term, the goal is to use TPB and II guided education classes to influence attitude, intention, self-efficacy and perceived control regarding preventive CVD behaviors. The long-term goal is individuals internalize healthy perceptions/ behaviors and practice them in normal daily living to prevent CVD. However, we can't guarantee that each individual will personally experience benefits from participating in this study. Others may benefit in the future from the information we find in this study.

RIDOC Role in the Research Project: All aspects of the research project will be approved by the Medical Research Advisory Group at RIDOC. Reports according to the standards will be maintained with the Planning and Research Unit and Health Care Services regarding coordination of the project. During the health monitoring portion of the *Heart & Sole Debate Course* if the participant has an abnormal heart rate or stress-level, the primary investigator will inform the individual and RIDOC medical health provider about the finding.

Recruitment / Consent Procedures: Participants will be incarcerated individuals recruited from the Medium Security Facility at RIDOC. Participants will have to be able to read and understand English at an 8th grade reader level, be over 18 years older, and have at least another year of detention.

All interactions with participants (recruitment, assessment, intervention, and follow up) will be conducted in designated RIDOC Medium Facility classroom #__ (to be determined), monitored by security staff. The RIDOC staff has approved this research team to use education room #__ for this study that will be open to all inmates within Medium Security housing during the educational time on Tuesdays and Thursdays from 12:30-14:00. The Primary Investigator will identify herself as part of a non-RIDOC research team and not as a member of the RIDOC medical or security staff. All portions of study participation will occur in a group format with research staff (primary investigator and facilitator of the course).

An invitation to join the research project will be sent out in the weekly newsletter (copy below) with all inclusion and exclusion criteria, four weeks before the start of the educational course. The newsletter notice has been approved by RIDOC staff and the health educator has confirmed she will submit it to the ACI newsletter when we are prepared to recruit participants. The newsletter notification will alert interested individuals to meet the PI, Melissa Godfrey, Date to be determined @12:30-1400 in classroom #__.

First Meeting: During this 90 minute meeting, interested individuals can ask the PI any questions they may have regarding their eligibility to participate and the requirements and expectations of a participant. During this meeting individuals will be informed the second meeting will be held on a date to be determined @12:30-14:00 in Class #__ during which they will sign an informed consent for the program. During this day no research data will be collected.

The Heart & Sole Program is designed to teach healthy lifestyle skills to prevent Cardiovascular Disease which can be incorporated into life in the restricted environment and after release to the community. To assure participants are being viewed holistically as individuals who currently live in an incarcerated institution and may someday live in the community-it is important the educational material includes information for both restricted and non-restricted environments.

The facilitator will inform potential study members that participation is not associated with any extra medical or non-medical services at RIDOC and will not influence parole status or any other prison privileges. It will be explained that this is a confidential study but that if there is any information that a participant may harm himself/herself or another person, or that a child or an elderly or disabled individual is in danger, then that information will be reported. Any information which threatens the security of the RIDOC (such as plans to escape) will be reported to RIDOC staff. It will also be explained that should any abnormal health indicators be found during the research period (heart rate) the primary investigator will report it to the medical care provider for the participant. If the individual is still interested in participating, the informed consent form will be read to the participant and any questions about the study will be answered. The facilitator of the course will be instructed not to discuss study participation with any one at the RIDOC. All study staff (primary investigator and course facilitator) are certified in Human

Subjects Protection and HIPAA. We are aware of and will follow all aspects of 45 CFR part 46 Subpart C.

Consent Day: each interested individual will be handed a copy of the Informed Consent Form. The primary investigator will read out loud the informed consent, stopping at appropriate places to emphasize study procedures, aspects of consent (i.e. voluntary nature of participation, confidentiality, right to withdraw, risks and benefits of participation, study procedures, etc.), and the rights of research participants. Should questions or comments arise regarding the consent form, there will be sufficient time to discuss any concerns. Should the participants agree to enroll in the study, they will be asked to sign and date the consent form. At this moment, the primary investigator will also co-sign and date the consent form.

As part of informed consent, the primary investigator will explain the purpose of the study to the participant, i.e., that we are conducting a study to learn if

The participant will be informed that any data collected will be kept confidential and be used solely for research purposes. At no point will RIDOC staff have access to the information collected. The interested individuals will be notified of all procedures

involved in being a participant in this research project. Participants will be informed that there is no compensation available for their time spend in the education classes and follow-up assessments. Individuals will be explained that refusal to participate in this research project will in no way limit him from receiving medical or other care at the RIDOC, nor will it affect his status as an inmate with respect to flat-timing, early release, probation or parole. Potential members of the research study will be assured their participation is voluntary and refusal to participate will involve no penalty or loss of benefit.

Confidentiality Procedure: After consent is obtained, participants will be provided with two paper questionnaires. There will be written instructions provided to participants that will describe how to proceed with the survey. Only the consent form will have the participant's name on it. Participants will be assigned a number to be used on all intervention paperwork and questionnaires afterwards. I will create the cross reference, from there on out any paper work for that person is identified only by number. This means I will need to have questionnaires and any intervention paperwork numbered ahead of time and hand them to the appropriate person. Transporting paper copies is a necessity since there are not resources (space, computers, internet) to enter data on the premises at DOC. Completed paper surveys will be placed in a sealed envelope to be handed to the principal investigator who will drive in her personal vehicle to

Brown University where she will scan all paper documents to electronic files, store on an encrypted thumb drive, and shred all hard copies. A master list of names and assigned numbers will be kept in a locked filing cabinet at Brown University. Only research staff with a need to know (for follow- ups or adverse events) or mandated auditors have access to information, all requests will be verified by faculty mentor Dr. Rosemarie Martin. Participants who enroll in the study will be administered questionnaires before the intervention course, after the completion of the course, after three months and again after six months. Confidentiality must be broken if information revealed is considered a threat to the facility and/or community corrections security. Due to the group setting, confidentiality cannot be promised. The research staff will keep your information private, however we cannot promise other people in the group will.

Qualifications & Experience of Primary Investigator: The PI, Melissa Godfrey, is a registered nurse and has worked in health care services and health education for 5 years with populations who have both acute and chronic illness. Additionally, she has completed course work for an MPH degree at Brown University. The PI has provided services to the RIDOC population as health educator intern in 2017, under the supervision of the current RIDOC staff health educator Deb Davis. She has undergone the extensive RIDOC orientation to understand the population, their vulnerability and code of ethics and teaching primary CVD prevention health habit education to the prisoner population will improve health habits.

conduct of the facility. The combination of education and experience makes her qualified to carry out this research. Melissa will be at all participant meetings including: formative research, recruitment, intervention classes and follow-up assessment. The other member of the research team will be a RIDOC staff member who will be teaching the intervention course (detailed explanation of the purpose of using a RIDOC staff member can be found on pg.14).

Facilitator of Intervention Class: The PI for the project and will recruit and train, a volunteer facilitator to assist with the research project intervention delivery. The PI will be present at all meetings and classes with participants, along with the class facilitator. The hiring of a volunteer Brown Master Student intern is to make the intervention ecologically valid and delivered in the manner it is designed. The goal of the pilot project is to demonstrate that staff typically in health educator positions in this setting can teach the presented intervention materials.

The TPB and II concepts/principles and manners to enhance facilitation of each lecture will be explained. The facilitator will be able to describe the underlying premise of TPB and II, research previous interventions guided by

TPB and II efficacy, recognize curriculum modules and activities, and demonstrate an ability to support participants through positive reinforcement and therapeutic communication techniques. The facilitator will be oriented to understand for the portion of the intervention, they are serving as research health educators and will not be working as RIDOC staff. The orientation will highlight the importance of maintaining participant information and thoughts, course progress, and course outcomes confidential during the research period. The facilitator will teach the intervention course, may help with components of data analysis. The facilitator will be updated of the results of the project, but only after information has been de-identified and thoroughly analyzed by the research team.

To ensure easy replication of this research project within any Department of Corrections in the country, the facilitator of the course will be an intern with similar qualification of staff that typically work in this setting. Having an intern conduct the class will reduce bias by assuring the

facilitator has the same level of preparation + education as future facilitators. Should this program prove efficacious, the implementation process will be cost-effective, attainable, and generalizable for prisons around the country. The intern will be properly oriented and vetted through RIDOC.



STAND UP FOR YOUR HEART'S HEALTH



Join **Heart & Sole Research Study** to learn **Heart Disease Prevention!**
This Brown University study will look at Heart Disease Prevention beliefs & attitudes among people in jail.
We need 20 people for this study.

Timeframe(12 days)= 10 classes (Tuesdays & Thursdays 12:30-2pm) + 2 days follow-up:

- learn about Heart Disease, practice healthy living skills & debate the benefits of healthy habits
- take surveys on beliefs/behaviors on Heart Disease & prevention (4x)

YOU CAN JOIN IF: you can read, speak & understand English, +18 years old, have at least another year of detention

To Learn More/Join → 1st Meeting Date TBD Classroom#1 12:30-2pm

Approach Timeline: Research Design and Methods

Phase 1- Understanding the population, Intervention development and refinement:

Month 1: Facilitator orientation of Brown Intern. The TPB and II concepts/principles and manners to enhance facilitation of each lecture will be explained. Facilitators will be able to describe the underlying premise of TPB and II, research previous interventions guided by TPB and II efficacy, recognize curriculum modules and activities, and demonstrate an ability to support participants through positive reinforcement and therapeutic communication techniques.

Month 2: Formative research conducted through two semi-structured discussion focus groups (N=8-10 for each focus group; total N<=20) will assess the RIDOC prisoner's attitude, perceived behavior control, self-efficacy, and plan of intention to engage in CVD preventive behaviors (20min/day exercise and stress-reduction). We will also assess the population's barriers/ability to learn and improve their health literacy, health education needs, motivation level and intentions of the inmate population to engage in CVD preventive behaviors (exercise and stress-reduction). Key informants such as medical personnel, correction officers, and the health educator will also be interviewed individually to triangulate data on relevant issues.

Phase 2- Intervention Conduction:

Month 3 and 4: This phase consists of conducting a pilot test with ~20 participants. The course will consist of classes 2x week, 90min each, for 5 weeks (total 10 classes). The first 5 minutes, the participants will conduct individual health monitoring techniques: measure heart rate and rate stress level(1-5) and record these numbers into their personal health log. The goal of the data collection session is to teach and reinforce self-measurement, symptom monitoring and self-management skills. The expected outcome is that participants will be aware of their health data, ("know your numbers") and feel empowered to participate in their health care. The next 25 minutes of each class will incorporate theory-guided interactive lectures on the health topic of the health. The following 15 minutes the facilitator will model and lead the class in conducting a healthy living skill. The remaining 45 minutes, the participants will engage in debate-style group discussion (guided by the Elaboration Likelihood Model of Persuasion) on barriers, mannerisms of implementation and benefits of the topic of the day. All participants will take two initial questionnaires (19 questions each) to assess beliefs, attitudes, intentions and motivation regarding physical exercise and stress-reduction before the intervention, after completion of intervention, 3 months and 6 months after. Each participant will complete the form by rating questions on a Likert scale of -3 to +3 (strongly agree- strongly disagree). Participants will also complete exit interviews to gain insight into the perceived success, challenges and gaps of the program.

Phase 3- Evaluation Plan & Analysis:

Months 5 - 10: This phase includes the evaluation plan & analysis. Participants will retake the questionnaires after the intervention/traditional class, after three months and again after six months. They will also complete exit interviews to gain insight into the perceived success, challenges and gaps of the program. A control group will be comprised of 20 participants who did not engage in the intervention yet completed the questionnaires. This control group will be derived from the current individuals in the health education class run by RIDOC staff educator, Deborah Davis. Repeated measures data will be analyzed from the intervention group (N~20). Using MANOVA, TPB scales of the intervention group and control group will be compared.

RIDOC Letter of Support



RHODE ISLAND DEPARTMENT OF CORRECTIONS

Planning & Research Unit

18 Wilma Schesler Lane, Dix Bldg. 1st floor
Cranston, RI 02920

Melissa Godfrey RN BSN
Brown University
School of Public Health

February 2, 2018

Dear Melissa;

I am writing to you in my capacity of Associate Director Planning and Research, Rhode Island Department of Corrections in support of your MPH Thesis Research Project, with focus on the offender population's health needs.

The Department of Corrections encourages collaboration with local universities regarding research. There is a very positive history in working with students and faculty at Brown University for many years. Your thesis that will address cardiovascular disease prevention aimed at targeting behavioral intentions to improve health habits is most timely. Within the correctional systems across the United States, there is an ever-growing geriatric population. This also holds true in Rhode Island, with offenders sentenced to the Department fifty-five years or older. With an increasing geriatric population, health issues such as high-blood pressure and heart related problems, I would assume would be more prevalent.

A thesis paper, such as you propose that seeks to improve health habits of offenders, that can be translated upon release from incarceration, is a positive step in addressing cardiovascular disease prevention.

On behalf of the Rhode Island Department of Corrections, I support your thesis submission.

Sincerely,

Jeffrey Renzi
Associate Director Planning and Research

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
Heart & Sole Debate Course at Rhode Island Department of Corrections
Version 9, January 31th 2019

You are invited to take part in a Brown University research study. Your participation is voluntary.

- RESEARCHER: Melissa Godfrey, Dr. Rosemarie Martin & Dr. Patricia Cioe
- PURPOSE: The study is about Heart Disease Prevention among people in jail. The course will target behavior and desire to improve health habits. We hope to find 20 participants for this study. You are being asked to be in this study because you are: able to read, speak and understand English, have at least another 6 months of detention, and are in the current health education class. You also are at least 18 years old and are able to exercise 10 minutes three times a week (not prohibited by: physical, medical, cultural, or spiritual conditions).
- PROCEDURES: If you decide to join the study, you will be asked to take 2 surveys. The surveys will check your beliefs, attitudes, desires and plans about exercise, use stress-reduction habits, well-being and managing negative emotions. You may refuse to answer or skip any question at any time.
An example question is: *Keeping my exercise routine is important or unimportant to me.*
- TIME INVOLVED: The study will take 120 minutes of your time.
- COMPENSATION: You will not receive compensation for your time.
- RISKS: Failure to Keep Private Info Private. This is very unlikely because all data are identified only by given numbers. They are stored on a password-protected thumb drive. A master list of names and numbers is kept separately in a locked cabinet. This allows us to do follow-up data collection. Only research staff with a need to know (for follow-ups) or people who check records can get to the master list linking names and numbers. All staff will be taught how to keep private info private. All classes will be closely overseen by the project researcher.
Force. Force happens when people feel forced to join in research for reasons like people pressuring you or tempting you with large sums of money. This can be true when there is little benefit to the individual for being in the study. In this study, we include a protected population. Protected populations are subject to extreme limits in their daily freedoms. Protection from force is very import. We feel there is very little risk of people interested in the study being forced to join. We will train our staff to explain that you should only join the study if you want to. You do not have to. We will make this known many times through the consent process and all study activities. Anyone in the study has the right to choose not to participate. They can leave the study at any time.
There may also be other risks that we cannot predict.
- BENEFITS: You may not directly benefit from being in this research study. It is possible to get the following benefits from this research. The short term goal is to understand info taught in the classes. The long term goal is you will use healthy habits and practice them daily. This is to prevent Heart Disease. However, we can't promise that you will get benefits from participating in this study. Others may benefit in the future from the info we find in this study.

- **CONFIDENTIALITY:** We will take the steps to keep info about you private. Only this form will have your name on it. You will be given a number to be used on all paper and surveys after. Completed paper surveys will be put in a sealed envelope to be handed to the main researcher. They will drive to Brown University where she will scan all paper documents to electronic files. She will store the documents on a password-protected thumb drive and shred all hard copies. We will keep a master list of names and given numbers in a locked filing cabinet at Brown University.
However, if we think you plan to seriously harm yourself or someone else, or if there is reason to believe that you have hurt a child or older person, the info will be shared with people in charge. Privacy must be broken if info could threaten the facility and/or community corrections security. Any info which threatens the security of RIDOC (like plans to escape) will be reported to RIDOC staff. Due to the group setting, confidentiality cannot be promised. The research staff will keep your information private, however we cannot promise other people in the group will.

University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

- **VOLUNTARY:** You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.
- **CONTACT INFORMATION:** If you have any questions about your being in this study, ask the Main Researcher Melissa Godfrey. You can talk to her today before you sign this sheet, request to speak to her through the facilitators,, or during follow-up meetings. You can also contact her by mail Melissa Godfrey at 121 S Main St. Providence RI 02906.
- **YOUR RIGHTS:** If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050, email them at IRB@Brown.edu, or by mail 350 Eddy Street Box 1986, Providence, RI 02912.
- **CONSENT TO PARTICIPATE:** Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study. You will be offered a copy of this form.

Participant's Signature and Date

/

PRINTED NAME

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
Heart & Sole Debate Course at Rhode Island Department of Corrections
Version 7, July 31th 2018

You are invited to take part in a Brown University research study. Your participation is voluntary.

- RESEARCHER: Melissa Godfrey, Dr. Rosemarie Martin & Dr. Patricia Cioe
- PURPOSE: The study is about Heart Disease Prevention among people in jail. Please take time to talk about the study with your family and friends, or anyone else you wish to. The choice to join or not is up to you. In this study, we are asking questions about the worth of health education classes teaching Heart Disease prevention. The course will target behavior and desire to improve health habits. We hope to find 20 participants for this study. You are being asked to be in this study because you are: able to read, speak and understand English, have at least another year of detention, and are in the current health education class. You also are at least 18 years old and are able to exercise 10 minutes three times a week (not prohibited by: physical, medical, cultural, or spiritual conditions).
- PROCEDURES: You will be asked to, you will be asked to answer questions. The questions will check your beliefs, attitudes, desires and plans to exercise and use stress-reduction habits. We will also ask about a class that teaches those topics. You may refuse to answer or skip any question at any time.
An example question is: *Keeping my exercise routine is important or unimportant to me.*
- TIME INVOLVED: The study will take 90 minutes of your time.
- COMPENSATION: You will not receive compensation for your time.
- RISKS: Failure to Keep Private Info Private. This is very unlikely because all data are identified only by given numbers. They are stored on a password-protected thumb drive. A master list of names and numbers is kept separately in a locked cabinet. This allows us to do follow-up data collection. Only research staff with a need to know (for follow-ups) or people who check records can get to the master list linking names and numbers. All staff will be taught how to keep private info private. All classes will be closely overseen by the project researcher.

Force. Force happens when people feel forced to join in research for reasons like people pressuring you or tempting you with large sums of money. This can be true when there is little benefit to the individual for being in the study. In this study, we include a protected population. Protected populations are subject to extreme limits in their daily freedoms. Protection from force is very import. We feel there is very little risk of people interested in the study being forced to join. We will train our staff to explain that you should only join the study if you want to. You do not have to. We will make this known many times through the consent process and all study activities. Anyone in the study has the right to choose not to participate. They can leave the study at any time.

There may also be other risks that we cannot predict.

- **BENEFITS:** You may not directly benefit from being in this research study. You may get benefit from learning about Heart Disease Prevention and behavior change. It is possible to get the following benefits from this research. The short term goal is to understand info taught in the classes. The long term goal is you will use healthy habits and practice them daily. This is to prevent Heart Disease. However, we can't promise that you will get benefits from participating in this study. Others may benefit in the future from the info we find in this study.
- **CONFIDENTIALITY:** We will take the steps to keep info about you private. Only this form will have your name on it. You will be given a number to be used on all paper and surveys after. Completed paper surveys will be put in a sealed envelope to be handed to the main researcher. They will drive to Brown University where she will scan all paper documents to electronic files. She will store the documents on a password-protected thumb drive and shred all hard copies. We will keep a master list of names and given numbers in a locked filing cabinet at Brown University.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

However, if we think you plan to seriously harm yourself or someone else, or if there is reason to believe that you have hurt a child or older person, the info will be shared with people in charge. Privacy must be broken if info could threaten the facility and/or community corrections security. Any info which threatens the security of RIDOC (like plans to escape) will be reported to RIDOC staff. Due to the group setting, confidentiality cannot be promised. The research staff will keep your information private, however we cannot promise other people in the group will.

- **VOLUNTARY:** You do not have to be in this study if you do not want to be. Event if you decide to be in this study, you can change your mind and stop at any time.
- **CONTACT INFORMATION:** If you have any questions about your participation in this study, you can ask the Main Researcher Melissa Godfrey. You can talk to her today before you sign this sheet, request to speak to her through the facilitators, or during follow-up meetings. You can also contact her by mail Melissa Godfrey at 121 S Main St. Providence RI 02906.
- **YOUR RIGHTS:** If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050, email them at IRB@Brown.edu, or by mail 350 Eddy Street Box 1986, Providence, RI 02912
- **CONSENT TO PARTICIPATE:** Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date

/

PRINTED NAME

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
Heart & Sole Debate Course at Rhode Island Department of Corrections
Version 8, August 16th 2018

You are invited to take part in a Brown University research study. Your participation is voluntary.

- RESEARCHER: Melissa Godfrey, Dr. Rosemarie Martin & Dr. Patricia Cioe
- PURPOSE: The study is about Heart Disease Prevention among people in jail. Please take time to talk about the study with your family and friends, or anyone else you wish to. The choice to join or not is up to you. In this study, we are asking questions about the worth of health education classes teaching Heart Disease prevention. The course will target behavior and desire to improve health habits. We hope to find 20 participants for this study. You are being asked to be in this study because you are: able to read, speak and understand English, and have at least another 6 months of detention. You also are at least 18 years old and are able to exercise 10 minutes three times a week (not prohibited by: physical, medical, cultural, or spiritual conditions).
- PROCEDURES: You will be asked to join the research study classes. The classes are 90-minutes each, twice a week for five weeks. During these classes, you will learn about Heart Disease, practice healthy living skills, and debate the benefits of Heart Disease prevention. If you decide to join the study, you will be asked to take 1 survey. The surveys will check your beliefs, attitudes, desires and plans about exercise, use stress-reduction habits, well-being and managing negative emotions. You may refuse to answer or skip any question at any time.

An example question is: *Keeping my exercise routine is important or unimportant to me.*

- TIME INVOLVED: The study will 25 hours of your time.
- COMPENSATION: You will not receive compensation for your time.
- RISKS: Failure to Keep Private Info Private. This is very unlikely because all data are identified only by given numbers. They are stored on a password-protected thumb drive. A master list of names and numbers is kept separately in a locked cabinet. This allows us to do follow-up data collection. Only research staff with a need to know (for follow-ups) or people who check records can get to the master list linking names and numbers. All staff will be taught how to keep private info private. All classes will be closely overseen by the project researcher.

Force. Force happens when people feel forced to join in research for reasons like people pressuring you or tempting you with large sums of money. This can be true when there is little benefit to the individual for being in the study. In this study, we include a protected population. Protected populations are subject to extreme limits in their daily freedoms. Protection from force is very import. We feel there is very little risk of people interested in the study being forced to join. We will train our staff to explain that you should only join the study if you want to. You do not have to. We will make this known many times through the consent process and all study activities. Anyone in the study has the right to choose not to participate. They can leave the study at any time.

There may also be other risks that we cannot predict.

- **BENEFITS:** You may not directly benefit from being in this research study. You may get benefit from learning about Heart Disease Prevention and behavior change. It is possible to get the following benefits from this research. The short-term goal is to understand info taught in the classes. The long-term goal is you will use healthy habits and practice them daily. This is to prevent Heart Disease. However, we can't promise that you will get benefits from participating in this study. Others may benefit in the future from the info we find in this study.
- **CONFIDENTIALITY:** We will take the steps to keep info about you private. Only this form will have your name on it. You will be given a number to be used on all paper and surveys after. Completed paper surveys will be put in a sealed envelope to be handed to the main researcher. They will drive to Brown University where she will scan all paper documents to electronic files. She will store the documents on a password-protected thumb drive and shred all hard copies. We will keep a master list of names and given numbers in a locked filing cabinet at Brown University.
Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

However, if we think you plan to seriously harm yourself or someone else, or if there is reason to believe that you have hurt a child or older person, the info will be shared with people in charge. Privacy must be broken if info could threaten the facility and/or community corrections security. Any info which threatens the security of RIDOC (like plans to escape) will be reported to RIDOC staff. Due to the group setting, confidentiality cannot be promised. The research staff will keep your information private, however we cannot promise other people in the group will.

- **VOLUNTARY:** You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.
- **CONTACT INFORMATION:** If you have any questions about your participation in this study, you can ask the Main Researcher Melissa Godfrey. You can talk to her today before you sign this sheet, request to speak to her through the facilitators, or during follow-up meetings. You can also contact her by mail: Melissa Godfrey at 121 S Main St. Providence RI 02906.
- **YOUR RIGHTS:** If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050, email them at IRB@Brown.edu, or by mail 350 Eddy Street Box 1986, Providence, RI 02912.
- **CONSENT TO PARTICIPATE:** Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date

/

PRINTED NAME