Providing Trauma Informed Care for Individuals on Opioid Agonist to Increase Contraception

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PROVIDING TRAUMA INFORMED CARE FOR INDIVIDUALS ON OPIOID AGONIST TO INCREASE CONTRACEPTION

A Thesis Presented to
The Faculty of the School of Medicine
Yale University

In Candidacy for the degree of
Master of Medical Science

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**Disclaimer**: The existing literature on opioid use in pregnancy and the postpartum period focuses on cis-gendered women and mothers. In keeping with the available literature, we will utilize those terms in the same manner, while acknowledging that trans men and non-binary people with an opioid use disorder can also experience pregnancy. The extent to which the existing evidence applies to trans and non-binary people is unknown and an important area for future research.
Abbreviations

AFAB: assigned female at birth
CKA: contraception knowledge assessment
CSA: childhood sexual assault
CDC: Centers for Disease Control and Prevention
CT: Connecticut
HIPPA: Human Subjects Protection and Health Insurance and Portability and Accountability Act
ICF: informed consent form
IPV: interpersonal violence
IUD: intra-uterine device
LARC: long-acting reversible contraception
MOUD: medications for opioid use disorder
NOWS: neonatal opioid withdrawal syndrome
OAT: opioid agonist therapy
OUD: opioid use disorder
PA: Physician Associate
PTSD: post-traumatic stress disorder
SARC: short acting reversible contraception
SES: socioeconomic status
STI: sexually transmitted disease
SUD: substance use disorder
TAU: treatment as usual
TIC: trauma informed care
TISRE: trauma informed sexual and reproductive education
WHO: World Health Organization
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Table 1. Descriptive Characteristics of Study Population

Figure 1: Study Timeline
Abstract

Individuals with opioid use disorder report having less reproductive and sexual health knowledge and are at greater risk of unintended pregnancy than their peers. This has led to increased neonatal opioid withdrawal syndrome and an increased healthcare burden, yet providing contraception and trauma informed care at treatment centers for individuals engaging in medication treatment has not been emphasized. Co-locating trauma informed reproductive and sexual health education and contraception access at substance use treatment centers provides a unique opportunity to improve knowledge and access to care for this population. We propose a randomized control trial to determine whether trauma informed care and co-located services will increase the proportion of individuals obtaining long-acting reversible contraceptive methods in comparison to standard of care. We are ultimately aiming to provide insight into if trauma informed sexual health education and increased contraception access can increase reproductive autonomy and decrease unintended pregnancies in this sensitive population.
Chapter 1: Background

1.1 Background

It is estimated that in 2019, around 10.1 million people over 12 years of age misused opioids within the previous year and in 2020, 4.6 million women reported opioid misuse.\textsuperscript{1,2} Additionally, from 2010 to 2017 the rates of maternal opioid-related diagnoses and neonatal opioid withdrawal syndrome (NOWS) have increased significantly.\textsuperscript{3} Specifically, the number of neonates born with NOWS increased by 82\% and women with an opioid-related diagnosis at the time of delivery increased by 131\%.\textsuperscript{3}

Additionally, from 2017 to 2020, there was an 81\% relative increase in pregnancy-associated overdose mortality, with increases being most pronounced in 2020.\textsuperscript{4}

Contraceptive methods, including birth control pills, intrauterine devices, and hormonal injections, are widely available, yet the rates of women engaged in medication treatment for Opioid Use Disorder (OUD) who are also using effective contraceptive methods remain lower than the general population.\textsuperscript{5} The incorporation of reproductive education services in opioid treatment clinics would allow for a more holistic approach to patients of childbearing age who are receiving medications for OUD (MOUD).

The rates of unintended pregnancy in individuals with OUD are much higher than the general population, with reports ranging from 60-90\% in those with OUD compared to 40-50\% in the general population.\textsuperscript{5-8} It has also been shown that though this population is at high risk for unintended pregnancy, effective contraceptive method use is low, with only around 8\% reporting use of very effective methods and the majority using less efficacious methods such as condoms.\textsuperscript{9} Thus, though there is a high rate of unintended pregnancy in this population, effective contraception methods are underutilized.
The consequences of an unintended pregnancy affect not only the birthing parent but also the neonate and the healthcare system. Unintended pregnancies may lead pregnant capable people to halt their MOUD therapy, as it has been reported that many persons are unaware that they may continue methadone treatment while pregnant.\textsuperscript{10} This may lead to increased rates of relapse or withdrawal, both of which may cause greater harm to the birthing parent and fetus.\textsuperscript{11} Prescription misuse and illicit opioid use in pregnancy is associated with adverse pregnancy outcomes, including abruptio placenta, fetal growth restriction, intrauterine demise, and prenatal delivery, in addition to NOWS.\textsuperscript{12} When compared with illicit opioid use, medication treatment with methadone or buprenorphine has been noted to decrease the severity of NOWS and reduce complications in pregnancy that are associated with withdrawal. However, the long term effects of in-utero exposure to opioids remain inconclusive.\textsuperscript{13,14} The healthcare costs for caring for a neonate exposed to opiates in utero is estimated to be around $67,000, funds which could be used to proactively prevent NOWS by educating and empowering pregnant-capable people with OUD.\textsuperscript{15} In 2015, it was reported that neonates born with NOWS spent an elongated amount of time in the hospital after birth, resulting in around 1.5 billion in additional costs.\textsuperscript{15} Of note, treatment with buprenorphine has been associated with decreased severity of perinatal outcomes and decreased length of hospital stay when compared to treatment with methadone, thus incurring less cost.\textsuperscript{16}

There are a multitude of barriers that may in part explain the low use of contraceptive methods in this population. The barriers to receiving reproductive education and contraceptive methods for people of reproductive capacity with OUD include: fear of legal involvement, stigma and discrimination from healthcare providers, and belief in
infertility or low risk of pregnancy.\textsuperscript{5,11,17,18} Many women believe they are unable to become pregnant due to use of opioids and subsequent amenorrhea, therefore demonstrating an easily addressable gap in reproductive health education.\textsuperscript{5,7} Additional barriers include: concerns over side effects, lack of transportation, lack of insurance or payment for care, inability to find childcare, and lack of provider knowledge for this specific population. Certain populations, such as individuals of color and low-income individuals, are more likely to face barriers to accessing care, thus increasing their risk of poor perinatal outcomes.\textsuperscript{19}

Between 81-95\% of women with OUD have unmet healthcare needs.\textsuperscript{20} It is also estimated that around 50-80\% of women with a substance use disorder have previous traumatic experiences, including childhood sexual assault (CSA), interpersonal violence (IPV), and abuse which may lead to higher rates of mental illness in this population and distrust of outsiders, including healthcare providers.\textsuperscript{18,21} Reproductive coercion, meaning behavior or actions intended to exert control and power over a person’s reproductive decision making and health, is also high in this population, demonstrating the need for trauma-informed education championing autonomy.\textsuperscript{22,23} It is imperative to develop strategies to provide patient-centered, trauma aware, and compassionate care through education in this population.

There is evidence to support the role of integrating contraceptive services and education in substance use treatment settings. In 2016, Terplan et al., found that the majority of women in OUD treatment centers were supportive of incorporating reproductive education and family planning services into their treatment.\textsuperscript{20} In 2021, Heil et al. demonstrated the economic value of onsite contraceptive services with treatment for
OUD and showed increased long-acting reversible contraceptive (LARC) use and patient satisfaction. By co-locating contraceptive services alongside substance use treatment, substantial barriers faced by women and pregnant-capable people with OUD may be eliminated.

1.2 Statement of Problem

The rates of unintended pregnancy among pregnant-capable people with an OUD far exceed that of the general population. This vulnerable population also experiences low reproductive knowledge surrounding their reproductive capacity and contraceptive methods and greater barriers to receiving contraception services. These barriers include limited contact to the healthcare system outside of SUD treatment, lack of transportation or childcare services, lack of insurance, and misconceptions regarding fertility and contraception. In addition, the high rates of trauma in this population lead to increased mistrust which serves as yet another barrier to receiving appropriate sexual health education and contraception.

Delivering trauma-informed sexual health education and tools can help eliminate the stigma and mistrust experienced by this sensitive population. Trauma-informed care is a well-established practice that has been shown to be effective in multiple clinical settings. By emphasizing the five principles of trauma-informed care - safety, choice, collaboration, trustworthiness, and empowerment – providers can prevent re-traumatization of patients and promote resilience in a vulnerable population. Educating patients with trauma informed care is of the upmost importance in order to establish a strong patient provider relationship. Including trauma-informed reproductive education
and resources into OUD treatment regimens proves a unique opportunity to provide comprehensive care to a population in need and may increase the use of effective contraceptive methods along with increasing bodily autonomy and reproductive health knowledge.

1.3 Goals & Objectives

This randomized control trial aims to compare the benefit of trauma-informed sexual and reproductive education (TISRE) compared to treatment-as-usual (TAU) delivered at substance use treatment programs on the initiation of a LARC method among pregnant capable people with an OUD. Additionally, it will assess the rates of unintended pregnancy and overall reproductive and sexual health knowledge.

1.4 Hypothesis

We hypothesize that participants randomized to receive TISRE will experience a statistically significant increase in the proportion of LARC initiation compared to the group receiving TAU.

1.5 Definitions

Opioid Use Disorder (OUD): pattern of tolerance, craving, inability to control use, and continued use despite adverse consequences.

Medications for Opioid Use Disorder (MOUD): use of methadone or buprenorphine (partial opioid receptor agonists) to prevent withdrawal and decrease cravings in people with OUD.
**Long-Acting Reversible Contraception (LARC):** Intrauterine device, either copper or hormonal, or a contraceptive implant.

**People with Uteruses:** any person with an active uterus and reproductive carrying capabilities.

**Unintended Pregnancy:** any pregnancy in which the pregnant person reports not trying to become pregnant or ambivalence towards becoming pregnant.
# 1.6 References


Chapter 2: Review of the Literature

2.1 Introduction

The following section consists of a summary of current literature related to opioid use disorder and reproductive healthcare, specifically: trauma and post-traumatic stress disorder, trauma informed care, long-acting reversible contraceptives, consequences of a lack of contraception, barriers to contraception, and the integration of services. Additionally, sections regarding potential confounders and relevant methodology are included and evaluated.

A systemic search of the literature was conducted in July 2022, December 2022, and April 2023 with assistance from the Yale School of Medicine librarians. PubMed, Scopus, Cochrane Library, and Ovid were searched with the following keywords: substance use disorder, opioid agonist therapy, unintended pregnancy, neonatal opioid withdrawal syndrome, long-acting reversible contraception, and trauma informed care. Articles were selected with pertinent titles and abstracts and were reviewed for relevance. Additional resources were selected from the references list of studies selected through our systematic search. The review identified randomized control trials, cross-sectional, case-control, prospective, and retrospective studies along with secondary analyses of data, meta-analyses, and literature reviews. All selected resources were analyzed for strengths and limitations as well as to identify any gaps in current literature.

2.2 Trauma and Post-Traumatic Stress Disorder

The American College of Obstetricians and Gynecologists reports that a history of trauma is associated with an increased incidence of chronic pelvic pain, early coitarche,
unintended pregnancy, sexually transmitted infections, and experiences of sexual violence.\textsuperscript{1} As previously noted, rates of unintended pregnancy are also elevated in people with uteruses with a substance use disorder (SUD). Furthermore, individuals with SUD have been noted to have much higher rates of post-traumatic stress disorder (PTSD) than the general population, with estimates ranging from 26 to 52\%.\textsuperscript{2} Engstrom, et al. found that 58-66\% of women with a SUD had experienced childhood sexual assault and 89.8\% had experienced interpersonal violence, both leading to increased rates of PTSD.\textsuperscript{3} Women who have experienced trauma are at an increased likelihood of more severe and complex SUD, are less likely to remain on medications for opioid use disorder (MOUD), and have overall poorer outcomes compared to their non-traumatized counterparts.\textsuperscript{4} Thus, the coupling of traumatic life experiences alongside a substance use disorder places this population at an elevated risk of PTSD which necessitates the incorporation of trauma-informed care (TIC).

\section*{2.3 Trauma Informed Care}

Trauma informed care (TIC) involves incorporating the following principles into daily practice with patients: safety, trustworthiness and transparency, peer support, collaboration, and mutuality, empowerment, voice, and choice, and culture, historical and gender issues recognition.\textsuperscript{5} Approaching patients with a TIC mindset emphasizes appreciating the pervasive nature of trauma in our society, recognizing the signs and symptoms of trauma, acknowledging systemic racism and power imbalances, and actively working to prevent re-traumatization of patients.\textsuperscript{1,5,6} This approach involves
treating all patients as if they are survivors of a traumatic event and emphasizing their autonomy throughout any interaction, as well as being deliberate in the language utilized.

Additionally, incorporating trauma focused care alongside treatment for SUD can help decrease rates of PTSD and prolong engagement in treatment, as providing a safe and collaborative environment for patients has led to increased participation in autonomous reproductive decision making.\(^2,^7\) A systematic review evaluating the effectiveness of TIC with patients experiencing at least one traumatic event demonstrated statistically significant improvements in PTSD, depression, and anxiety.\(^8\) Additionally, another study found that women with a SUD whose PTSD symptoms were reduced via TIC were better able to manage their SUD in the subsequent years, including decreased return to use and utilization of MOUD.\(^4\) Furthermore, a qualitative study evaluating both providers and patients at opioid treatment centers perceived comorbid SUD and PTSD as a further barrier to care and emphasized that the incorporation of TIC was an essential step for recovery.\(^9\) The complex interplay between traumatization, substance use, and lifelong psychological impact warrants a sensitive and patient driven approach in order to support this population to the fullest extent.

### 2.4 Long-Acting Reversible Contraceptives

Long-acting reversible contraception (LARC) methods consist of both hormonal and non-hormonal options, including: copper intrauterine device, several levonorgestrel intrauterine devices, and an etonogestrel implant.\(^10,^11\) Specifically, the etonogestrel implant is a rod that is placed subdermally in the arm and acts to inhibit ovulation by preventing the luteinizing hormone surge mid-cycle.\(^10\) In contrast, intra-uterine devices
work locally rather than systemically by causing the endometrial cavity to be spermicidal thus preventing fertilization.\(^\text{10}\) The non-hormonal copper IUD decreases sperm viability and motility, while hormonal options thicken the cervical mucus to prevent penetration of sperm.\(^\text{10}\) These are all long-term options for pregnancy prevention, ranging from one to ten years, and are considered the most effective of all of the current contraception methods, aside from irreversible methods such as sterilization and tubal ligation.\(^\text{11}\) LARC are not user-dependent, like other methods such as birth control pills or condoms, thus perfect use and typical use are usually equivalent, leading to their much higher rates of efficacy.\(^\text{11}\)

Rates of LARC use in the general population were found to be roughly 18% and have been steadily increasing since 2014 (14.3 to 17.8, \(p < 0.05\)).\(^\text{12}\) Additionally, LARC and short acting reversible contraception (SARC) utilization were found to be strongly associated with access to reproductive and sexual health care. Yet, utilization of LARC methods in people with uteruses with substance use disorder has remained low, around 7%.\(^\text{13}\) Specifically, in this population it was found that individuals using SARC methods were twenty-one times more likely to have an unintended pregnancy compared to individuals using LARC methods.\(^\text{14}\)

It is also essential to note the history of reproductive coercion, especially in minority groups.\(^\text{15}\) As medical providers, it is paramount to emphasize patient preferences, bodily autonomy, and choice when discussing contraceptive methods in a collaborative manner with our patients. Of note, long-acting reversible contraception methods are highly effective and long-lasting, yet this does not translate to necessarily
being the best option for our patients. When approaching conversations regarding any contraception methods patients autonomy should always be emphasized.

2.5 Consequences of Lack of Contraception

The consequences of a lack of effective contraception extend beyond the potential birthing parent to include both the neonate and healthcare system. Without effective contraception, rates of unintended pregnancy increase which may lead to a multitude of downstream effects. This could contribute to the birthing parent stopping their opioid agonist therapy as they may perceive the medication as detrimentally harmful to the fetus.\textsuperscript{16} This can then lead to increased withdrawal and relapse, which are both more deleterious to both the parent and fetus.\textsuperscript{17}

Additionally, unintended pregnancy in individuals actively using substances may lead to neonates with more severe opioid withdrawal syndrome along with other potential adverse pregnancy outcomes such as abruptio placenta, fetal growth restriction, intrauterine demise, and pre-term delivery.\textsuperscript{17} The healthcare costs are also much higher than in the general population as neonates have extended hospital stays requiring greater interventions.\textsuperscript{18}

Unintended pregnancies may lead to abortion; between 2015-19 the proportion of unintended pregnancies decreased overall yet the proportion ending in abortion increased.\textsuperscript{19} Abortion may have further financial and psychological implications and if an unsafe abortion is preformed it may have lasting reproductive repercussions.\textsuperscript{20,21} If a woman is living in an area where abortion is not legal or she cannot afford one, she may resort to an unsafe abortion which can lead to hemorrhage, sepsis, genital trauma,
necrotic bowel, or death.\textsuperscript{20} Moreover, the financial burden of an abortion can be extremely high for both the abortion itself and any subsequent necessary medical treatment.\textsuperscript{20}

Access to reliable, long-acting contraception methods can help prevent both maternal and fetal complications and death, along with reducing the financial burden on the birthing parent and healthcare system.

\subsection{2.6 Barriers to Contraception}

Barriers to reproductive education and contraception are increased for women with substance use disorder, with one study finding that 75.8\% of women with OUD had experienced at least one barrier to care.\textsuperscript{22} These barriers may be subdivided into systemic barriers, patient specific barriers, and provider specific barriers.

\subsubsection{2.6.1 Systemic Barriers}

Systemic barriers include the cost and the difficulty of accessing reproductive education and contraception care. The most commonly reported barrier reported by women was cost, with between 52.6\% and 92\% indicating prohibitive cost discouraged them from seeking care.\textsuperscript{14,22-28} In addition to cost, appointment compliance was difficult for patients due to limitations with transportation.\textsuperscript{25} Between 20.3\% to 88.2\% of women surveyed reported lack of reliable transportation to medical appointments.\textsuperscript{24,25,27} Studies vary based on geographical location with rural patients facing the greatest difficulty with transportation to appointments.\textsuperscript{24,27}
2.6.2 Patient Specific

Patient specific barriers include misperception regarding fertility, current substance use, lack of knowledge regarding contraception, aversion to effects of contraception, fear of losing custody of children, and partner related reproductive coercion.

Substance use itself may be a barrier to care as contraception may not be a priority while someone is actively using. Additionally, others reported that they believed illicit opioid use or MOUD prevented them from pregnancy. Patients reported periods of oligo-amenorrhea or amenorrhea while using drugs thus leading them to believe they were unable to become pregnant. Others reported they believed the substances themselves prevented pregnancy or that because they had not become pregnant in the past that they were likely infertile.

Furthermore, many women on opioid agonist therapy reported they felt ill equipped to make decisions regarding contraception or that they were concerned about serious side effects. A survey of patients currently on opioid agonist therapy found a deficit in contraception knowledge, especially with material that focused on information about IUDs, emergency contraception pills, and fertility awareness. One study demonstrated that 53.8% of women reported that adverse effects were a barrier to contraception use. Additionally, beliefs that IUDs could cause life threatening infections, infertility, or other irreversible damage were common. A lack of contraceptive knowledge regarding options and their safety profile is a major barrier to care. The CHOICE study demonstrated that when women were given comprehensive contraception
counseling, up to three-quarters of participants opted for LARC, were satisfied with the option, and had higher continuation rates.31

An additional barrier for accessing reproductive healthcare is fear of losing custody of children if substance use history was disclosed.24 In a survey from Michigan, over one fourth of participants feared child protective services would become involved if they sought medical care.24 Patients also reported facing intimate partner violence (IPV) with reproductive coercion. Reproductive coercion may be defined as “behavior that interferes with the autonomous decision-making of a woman, with regards to reproductive health”.32 This may involve controlling the use of birth control methods and pregnancy outcomes.32 The rates of IPV of women with a SUD in a relationship are much higher than the general population, with rates up to around 90%.3,24 Thus, women may be unable to access care or adequate contraception due to manipulation by their partner.

2.6.3 Provider Specific

Another major barrier is negative judgement and stigmatization via healthcare providers. Fear of or previous healthcare stigmatization was among the most common reported barrier for women with SUD seeking contraception care.22-25 Studies have demonstrated providers may hold implicit biases and negative opinions on people with a SUD.33 There is also potential for inadequate knowledge regarding LARC methods among providers. Providers may hold misconceptions regarding using a LARC method in nulliparous, young, or patients with pelvic inflammatory disease.14 Furthermore, provider reproductive coercion was an additional fear for patients.23 Some reported experiencing forced treatments or unwillingness of providers to care for them.23 Additionally, there is a
long-standing history of coercion, forced sterilization, and lack of consent with medical procedures, specifically involving minorities that has led to an overall mistrust of the medical system. This has led to patients feeling unsafe around providers and a lack of trust in medical providers, along with feeling as though the medical system does not care about them as an individual. Providers need to be mindful of the history of oppression and stigmatization of people with substance use disorder and provide a non-judgmental and empathetic space for patients.

2.7 Integration of Services

Opioid agonist treatment centers have begun to provide additional services beyond medication assisted treatment, yet female specific services are still lacking. A survey of opioid treatment programs showed that only 21% had female specific programs. There also appears to be a geographic distribution of services, with female centered services from 51% in large urban areas to 19% in non-metropolitan areas with less services in the Midwest and South. Additionally, 84% of surveyed medical and program directors of opioid agonist treatment (OAT) centers indicated that women would benefit from increased and co-located services. Furthermore, most practitioners, social workers, and counselors are already trained in motivational interviewing which can be helpful for both substance use disorders and discussions regarding contraception.

The SAFE study assessed if co-located services opioid agonist treatment and reproductive education could increase contraceptive decision making. Their results showed that providing services increased the use of long-acting contraceptive methods and that the majority of women found it extremely helpful. Additionally, they noted a
high feasibility of the intervention in the clinical setting and had nearly universal adherence and follow-up with their study population. Similar studies have also shown that opioid agonist treatment centers provide an ideal opportunity to address family planning needs of their patients. A study assessed if behavioral economic theory could be useful in increasing contraception use and found that significantly more women initiated an effective contraception method with their co-located services. While screening patients they also found that the majority of women found it too time consuming or difficult to seek outside care for their contraception needs.

Survey rates for people of reproductive capacity who are interest in reproductive health care services range from 45.8-86%, demonstrating that patients are motivated to engage in reproductive and sexual health education and interventions. MOUD treatment is only one facet of recovery and programs should prioritize patients medical and psychosocial needs, including trauma informed sexual and reproductive education. By addressing the sexual and reproductive needs of women, engagement in substance use treatment may increase.

2.7 Review of Studies to Identify Possible Confounding Variables

2.7.1 Socioeconomic Factors

Lower socioeconomic status has been shown to be associated with an increased risk of unintended pregnancy and less utilization of contraception. A lower socioeconomic status refers to individuals with lower educational attainment, lower household income, and less financial security thus increasing an individual’s risk of chronic health conditions. Finer et al., showed that women with the fewest years of
education had the highest rates of unintended pregnancy and rates decreased as education level increased. Additionally, the rate of unintended pregnancy for low-income women was roughly five times the rate of high-income women. A study by Metcalfe et al., demonstrated that women with unintended pregnancies tended to be less educated and have a lower income and that low educational attainment was associated with a lack of contraception utilization. Furthermore, a study from McAfee et al., showed that women who reported substance use while pregnant were more likely to have a lower socioeconomic status based on their education and income, receive public assistance, and be younger and unmarried.

Additionally, some literature suggests that a lower socioeconomic status (SES) is associated with increased illicit substance use and that pregnant capable people who use drugs are more likely to be of a lower SES. A Swedish national cohort study with 634,284 individuals analyzed the “trajectories of poverty” to determine if childhood exposure to poverty increased one’s risk of substance abuse in the future. They found that adolescent males ‘moving into poverty’ had the highest risks of a substance use disorder (HR = 1.48, 95% CI = 1.40–1.57), with similar results for females moving into poverty in adolescence (HR = 1.63, 95% CI = 1.52–1.76). Similarly, a study based on national data showed that individuals with a maternal opioid diagnosis were more likely to reside in zip codes in the lowest income quartile. Conversely, rates of maternal opioid diagnosis and NOWS were lowest amongst those who resided in the highest income quartile. Additionally, a self-reported data via the National Survey on Drug Use and Health showed that individuals in the lowest income group were more likely to report having problems related to their substance use compared to those in the highest income
group (OR) = 1.36, 95% CI: 1.08-1.72). Socioeconomic status may be a mediating factor of both substance use and unintended pregnancy. Thus, we plan to control for SES via randomization of our participants followed by multiple logistic regression of all baseline characteristics.

2.7.2 Lifestyle

People with substance use disorder or who mis-use substances also report increased concomitant cigarette smoking. This population may also be at an increased risk of alcohol use disorder or heavy alcohol consumption. Additionally, smoking has been associated with increased alcohol usage and vice versa. Both smoking and alcohol have the potential to influence fecundity and unintended pregnancy rates.

2.7.2.1 Cigarette Smoking

A systematic review demonstrates that smoking can affect female fertility via multidirectional influence on the uterus, ovary, and oviduct with reproductive toxins being identified in the follicular fluid or ovaries of smokers. Shortened menstrual cycles have also been observed in female smokers, which could be associated with reduced fecundity in this population. Notably, it has also been shown cigarette smoking has dose-dependent adverse effects on fertility therefore with increased consumption there is decreased fertility. In one study analyzing 15,000 pregnancies it was shown that smokers had a statistically significant increased time to conception and this increased delay correlated with the number of daily cigarettes. The percentage of females with conception delay for 12 or more months was 54% higher in the smoking group vs non-
smokers. Additionally, many of the chemical additives in cigarettes are reproductively toxic, thus contributing to decreased fertility along with potential deleterious effects to the fetus. Lastly, cigarette smoking has been linked to both an increased risk of miscarriage and ectopic pregnancy along with adversely affecting the nervous, cardiovascular, and respiratory development of the fetus. Thus, smoking has been shown to increase overall time to conception, exert harmful effects on the female reproductive tract, and cause spontaneous abortion or harmful downstream effects to the fetus. These factors may contribute to decreased rates of both unintended and intended pregnancy in smokers. Importantly, a meta-analysis of 75,000 women showed that unintended pregnancy was positively and significantly associated with smoking (adjusted odds ratio [AOR]: 1.5, 95% CI: 1.4–1.6). Smoking status will be controlled for through randomization of participants.

2.7.2.2 Alcohol Usage

Data is inconclusive regarding if alcohol exerts a direct effect on female fertility. Some evidence does suggest that alcohol usage may lead to increased risky sexual behaviors, more frequent intercourse, and adolescent pregnancy. A meta-analysis and systematic review containing almost 99,000 women demonstrated that compared to non-drinkers, alcohol consumption was significantly associated with lower fecundability [0.87 (95% CI 0.78-0.95)]. Additionally, the data showed a dose-response relationship with a reduction in fertility with every 12.5 gram per day increase in alcohol (p=0.001). Alcohol usage was also shown to be associated with an increased waiting time to pregnancy [0.85 (95% CI 0.73-0.96)]. Another study analyzed alcohol consumption
throughout the menstrual cycle and the relationship with fertility. Their research demonstrated that moderate to heavy drinking during the luteal phase and ovulatory window could disturb natural hormonal cycles therefore leading to a decreased chance of successful conception.\textsuperscript{58} Additionally, their research also supported the dose response relationship showing a decrease in fecundability for even moderate alcohol consumption.\textsuperscript{58} Furthermore, the risk of unintended pregnancy is significantly elevated with heavy alcohol consumption and binge drinking.\textsuperscript{56} Those reporting heavy drinking were almost two times as likely to report unintended pregnancy.\textsuperscript{56} Overall, alcohol may have an influence on both fecundability and unintended pregnancy and will thus be controlled for via randomization.

\subsection*{2.7.3 Other Potential Confounders}

Relationship status has the potential to influence unintended pregnancy rates along with contraception usage. Data on pregnancy intention from the National Survey of Family Growth revealed differing rates of unintended pregnancy based on relationship status. The proportion of unintended pregnancies for married participants was less than half of the proportion for unmarried participants.\textsuperscript{59} Additionally, cohabitating women in long term relationships have between two to four times the rate of unintended pregnancy compared to married and non-cohabitating persons.\textsuperscript{41,59}

Prior pregnancy may also influence contraception usage and unintended pregnancy. Women with a previous birth had roughly twice the rate of unintended pregnancy compared to women who had never given birth or those with two plus births.\textsuperscript{41} Conversely, women who have given birth previously are also more likely to have been
involved in the healthcare system and offered reliable contraceptive options that can lead to a reduction in risk of unintended pregnancy.\textsuperscript{60,61}

2.9 Review of Relevant Methodology

2.9.1 Study Design and Setting

The proposed study will be a randomized controlled trial comparing trauma-informed reproductive and sexual health education (TISRE) versus treatment as usual (TAU) for pregnant capable individuals receiving MOUD delivered at substance use treatment centers. We chose a randomized controlled trial design because it is the gold standard to evaluate interventions.\textsuperscript{60} Additionally, of the five studies that have evaluated increasing access to reproductive care in pregnant capable people on MOUD, four utilized a randomized control trial study design.\textsuperscript{22,26,34,35,59} Advantages of this study design include minimization of potential biases and evidence of the effectiveness of an intervention.\textsuperscript{60}

Study settings were typically outpatient opioid use disorder clinics across varying states including North Carolina, Colorado, and Vermont. A study by Day et al., conducted a survey regarding contraception and reproductive knowledge and needs followed by a referral for contraception.\textsuperscript{29} In the Day study, a contraception clinic was established at an opioid agonist therapy center in Australia.\textsuperscript{29} Study participants were assessed for eligibility at their respective opioid treatment center and any further exposures or interventions occurred in the same location. Thus, for our study we have chosen to deliver our intervention in substance use treatment centers.
2.9.2 Selection Criteria

The inclusion criteria for the five studies discussed in this section included: assigned female at birth (AFAB), adult age of reproductive capability (typically 18-44), ability to provide informed consent, currently engaged in opioid agonist therapy, not currently pregnant, not currently utilizing contraception (besides condoms), engagement in heterosexual intercourse, no prior sterilization or tubal ligation, and no intention of pregnancy. The SAFE study additionally included verifiable locator information as an additional inclusion criteria. Additionally, the 2016 study by Heil et al., included that participants must be at least 6 months postpartum, speak and understand English, and not be facing imminent incarceration. Detailed selection criteria for our study may be found in Chapter 3.

2.9.3 Intervention

In our study participants will be randomized to TISRE or TAU, which is in keeping with prior studies evaluating reproductive health interventions in individuals on MOUD. The 2021 study by Rinehart et al., utilized either standard of care or the SHINE intervention which included two twenty-minute sessions with a peer navigator. These sessions were guided with motivational interviewing-based worksheets and sexual health pamphlets, with the main objective being to educate and connect participants with family planning services. Similarly, the SAFE study randomized patients to receive usual care, computed adapted reproductive education, or face to face reproductive and contraception education.
Heil et al., 2021 focused more on potential financial incentives of participants engaging in contraceptive education and care. Participants either received usual care, onsite contraceptive services, or onsite contraceptive services with financial incentives. Given the history of reproductive coercion in our country, the ethics of providing financial incentives in exchange for contraception utilization are debatable. However, the participants randomized to this intervention received the financial incentives independent of whether they utilized contraception or not. The 2016 study by Heil had similar exposures with participants either receiving usual care or usual care plus the WHO contraception initiation protocol with free prescription contraceptives and financial incentives for attending follow up visits. Day et al., assessed their participants via a 20-minute survey and all participants that were surveyed were assessed for clinic eligibility. Those that were eligible were provided a referral to the co-located contraception clinic.

Based on the literature review, we plan to incorporate trauma informed reproductive and sexual health education and increased access to contraception to determine if this can increase LARC. Patients will attend an educational session and have the opportunity to meet one on one with a Physician Associate regarding any questions.

2.9.4 Outcomes

Three studies assessed for the initiation of a LARC following intervention. For the SAFE trial, outcomes included intervention completion, intervention satisfaction, attendance at a contraception appointment, and receipt of LARC. The SAFE study showed higher intervention completion [face to face [means (standard error) = 0.97
higher intervention satisfaction with scoring from zero to four [FtF [M (SE) = 3.7 (0.11)] vs CA [M (SE) = 3.8 (0.11)] vs UC [M (SE) = 3.1 (0.11)], and higher LARC receipt [FtF [M (SE) = 0.77 (0.08)] vs CA [M (SE) = 0.73 (0.08)] vs UC [M (SE) = 0.23 (0.08)] for both the computer adapted and face to face interventions when compared to the usual care group. 

All outcomes were evaluated via self-reported response which could introduce response bias to results. The 2021 study conducted by Heil, et al., had similar outcomes. They assessed for verified prescription contraception use at 6 months, along with a cost-benefit analysis from a societal perspective. Their results show graded increases in contraception utilization for those assigned to usual care (10.4%; 95% CI, 3.5%-22.7%) versus contraceptive services (29.2%; 95% CI, 17.0%-44.1%) versus contraceptive services plus incentives (54.8%; 95% CI, 38.7%-70.2%) at the 6 month time point. The results were also associated with graded decreases in unintended pregnancy and demonstrated societal cost-benefits. Additionally, the 2016 Heil et al., study also assessed for the amount of participants who initiated contraception. Their results showed that significantly more women in the experimental condition group initiated prescription contraception (100% vs 29%) had higher continued use at the 1-month (63% vs 13%), 3-month (88% vs 20%), and 6-month (94% vs 13%) follow ups.

All three studies demonstrated that increased contraception utilization is feasible with co-located interventions for people of reproductive capacity on OAT.

Similarly, the Day et al., study assessed for attendance of a contraception clinic appointment following their survey. Only 2 participants of the 23 eligible attended their appointment and only one of these received a LARC method though 48% reported unmet
contraception needs. Their study demonstrates that contraception needs are unmet in this population and there may be further barriers preventing people from accessing contraceptive care.

The Rinehart et al., 2021 study focused on sexual health knowledge following their intervention. They assessed STI, LARC-specific, pregnancy, and other contraception knowledge via a true or false assessment. They found that 90% of participants found the intervention information important, 76% indicated the information was new, and 82% found working with a peer helpful. Additionally, significantly more participants receiving the intervention attended a family planning visit compared to the control. Their study highlighted that patients are motivated to learn about family planning and working with a peer may increase interest and compliance.

2.9.5 Sample Size and Statistical Tests

Within the current literature there are few results on the rates of those engaging in MOUD that are also utilizing LARC. The study conducted in 2021 by Rinehart et al., found that 3.2% of their study population was utilizing MOUD and LARC methods. Our sample size calculation will be detailed more in Chapter 3 along with specific statistical analysis techniques regarding baseline characteristics along with the primary and secondary outcomes.

2.10 Conclusion

The information contained within this chapter proves the need for increased access to trauma informed reproductive and sexual health care for people of reproductive
capacity that are engaged in opioid agonist therapy. Trauma-informed care maximizes patient autonomy, choice, safety, and privacy while dismantling stigma and many of the barriers to care faced by this marginalized community. Furthermore, co-located contraception services are supported by both patients and providers and have been shown to be financially efficacious. Additionally, the high rates of unintended pregnancy and low knowledge relating to long-acting reversible contraception methods demonstrates the need for these services. The included literature also highlights the effectiveness of LARC in ameliorating many of the downstream effects of a lack of access to contraception and how co-location of services may address many barriers faced by the study population. We aim for this study to add to the current literature regarding the advantages of trauma informed and co-located services in increasing reproductive autonomy and preventing unintended pregnancy in a sensitive and often overlooked population. Furthermore, this study may prove as a proactive initiative to decrease rates of neonatal opioid withdrawal syndrome, decreasing chronic medical complications and healthcare burden.
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Chapter 3: Study Methods

3.1 Study Design

We are proposing a multicenter randomized clinical trial involving an intervention arm that will engage in trauma-informed reproductive and sexual health education (TISRE) and a control arm that will receive treatment as usual (TAU) at opioid treatment centers across Connecticut. Throughout Connecticut, there are currently 51 certified opioid treatment centers that are further subdivided into five local mental health authorities. Within the five regions, one study site will be selected to participate in our pilots study. These sites will be invited to participate and pending acceptance, study recruitment materials will be distributed at the respective locations. Each site will be visited by a Physician Associate (PA) who will conduct educational sessions with participants randomized to the intervention group. Those in the TAU group will receive educational pamphlets regarding sexual health and contraception. Participants will attend one session 30-to-45-minute session with a PA and be provided with pamphlets and referrals for contraception. The follow up period will be 17 months in total.

3.2 Study Population and Sampling

Our source population will include all pregnant capable people receiving MOUD at selected substance use treatment centers. Inclusion criteria will be: (1) ages 18-49, (2) premenopausal and no history of hysterectomy, (3) currently stabilized on MOUD for at least 6 months, (4) not currently pregnant or < 8 weeks postpartum, (5) reports of engaging in heterosexual intercourse in the past 12 months, (6) no current LARC methods such as oral contraceptive pills, sterilization, IUD, or tubal ligation, and (7) no
plans to become pregnant in the next year, (8) able to provide informed consent, (9) able to speak English. We will utilize simple random sampling in the study population.

3.3 Subject Protection and Confidentiality

Prior to the recruitment period, the study protocol, informed consent and recruitment materials will be submitted to the Human Investigation Committee of the Yale School of Medicine to obtain Institutional Review Board approval. All study staff will be included in the submitted protocol and will complete their Human Subjects Protection and Health Insurance and Portability and Accountability Act (HIPAA) certification.

The informed consent form will detail goals of the study, time requirements, and potential risks and benefits for participants. A research assistant will orally present and review the ICF with the participants and provide them with a signed copy of the form. The research assistant will also be available to answer any questions the participants may have regarding the study process.

Any identifiable patient information will be stored via secure server with encryption. This data will only be accessible by research personnel. In order to de-identify study participants, we will utilize the Safe Harbor method to remove identifiers including: name, phone number, social security, and other identifiers. Each participant will then be assigned a unique identifier which will be used to link to their study data. Any paper files will be transferred onto the secure server and then shredded.
3.4 Recruitment

There will be a 3-month period of recruitment which will entail posting flyers and handing out pamphlets with study information at participating treatment sites. Individuals interested in participating will be screened for inclusion and exclusion criteria by research staff. If eligible, research staff will explain study expectations and obtain informed consent. Following consent, baseline demographic and substance use history data will be collected, along with baseline reproductive and sexual health knowledge. Participants will then be randomized into the intervention or control arm.

3.5 Study Variables and Measures

3.5.1 Independent Variable

The independent variable is treatment assignment. Participants will be randomly assigned in 1:1 ratio to receive TISRE or TAU. The TISRE education curriculum will be based on principles from the CDC and WHO and will incorporate TIC along with aspects of motivational interviewing. This intervention will be provided via a Physician Associate, at the opioid maintenance treatment centers during participant selected time slots. TAU will include a pamphlet with general reproduction and sexual education topics, access to condoms and the morning after pill, and a referral to an outside clinic for contraception.

3.5.2 Dependent Variable

Our primary dependent outcome will be the number of participants that obtain a LARC method throughout the follow up period. This will be measured as a dichotomous outcome, with participants responding either “yes” or “no” on follow up surveys at 1-
month, 3-months, 6-months, and 1-year time points. The primary endpoint will be at 1-month. This will be verified through electronic medical record review accessed by study staff.

Our secondary variables of interest include unintended pregnancy and knowledge surrounding reproductive and sexual health. Unintended pregnancy will be classified as a dichotomous outcome and defined as any pregnancy occurring during the follow up period for which the patient notes they were not intentionally trying to become pregnant. Participants knowledge will be classified as categorial, dependent on the number of points they receive for correct answers when completing the survey (Appendix D and F). Participants scoring 0-3 will be classified as “low”, 4-8 will be classified as “moderate”, and 9-12+ will be classified as “high”.

3.5.3 Potential Confounding Variables

Potential confounding variables we will control for include: marital status, employment, education, lifetime number of pregnancies, lifetime number of miscarriages, lifetime number of abortions, lifetime use of prescription contraception, smoking status, alcohol use, and if they are a recipient of Medicaid. Educational attainment will be used as a surrogate for socioeconomic status as income level can be hard to assess. All confounding variables will be assessed via the baseline survey.

Table 1. Descriptive Characteristics of Study Population

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<tr>
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### 3.6 Methodology Considerations

#### 3.6.1 Assignment of Intervention

Once participants have provided informed consent, they will be randomized to the intervention arm, TISRE, or control arm, TAU, via computer-generated and non-stratified allocation in a 1:1 ratio. This will be done by the trial statistician concealed to the researchers. Due to the nature of the intervention participants and staff delivering the intervention will not be blinded; however, the research staff collecting and analyzing the data will be blinded.

#### 3.6.1.1 Intervention

Research staff will be trained in providing TIC, which includes emphasizing the following principles: safety, trustworthiness and transparency, peer support, collaboration and mutuality, empowerment, voice, and choice, and culture, historical, and gender issues. Training will be conducted at the Yale School of Medicine and involve both Physicians and Physician Associates and will be based upon the Substance Abuse and
Mental Health Services Administration Trauma-Informed Care Protocol.5 Participants will meet individually with a Physician Associate on the research team to discuss RSH and contraception options. Education will be based on Guidelines for Comprehensive Sexual Education, a Guide to Trauma Informed Sex Education, along with WHO and CDC contraceptive practice recommendations and formulated into an approachable model.1-3,6 When working with patients, motivational interviewing will be implemented. Participants will also be provided with additional resources on contraceptive methods from bedsider.org (Appendix A).7 Participants will be empowered to make their own decisions regarding contraception method of choice with the help of the provider via motivational interview strategies. If interested in a LARC, the provider will either provide the contraception method on-site or schedule an appointment at a close by clinic for the participant. Research staff will send periodic reminders of the appointment and transportation will be provided at participant request.

3.6.1.2 Treatment as Usual

Our control group will receive the usual care offered at maintenance opioid treatment centers in terms of reproductive and sexual health education and intervention. This includes access to condoms and the morning after pill, along with a referral to an outside clinic for contraception. Participants will also receive a pamphlet with general reproduction and sexual education topics, including contraception facts.

3.6.2 Blinding of Intervention and Outcomes

Eligible participants will provide informed consent but will not specifically be told if they will be allocated to the intervention or control arm. Due to the nature of the
intervention following randomization participants will no longer be blinded to the their assigned study arm. Researchers involved in consenting participants, collecting baseline information, and conducting data analysis will remain blinded to the study group allocation throughout the duration of the study.

3.6.3 Adherence

Patient adherence will be recorded via study staff if the participant attends their TISRE session and stays for at least 75% of the time. By co-locating services with opioid agonist treatment, we aim to increase the adherence of our study population. After the intervention, adherence will be assessed by surveys at the 1-month, 3-month, 6-month, and 1-year time points. Participants will be provided with a reminder via their preferred method of contact 1-week before, 1-day before, and 2-days following the time point for survey completion.

3.7 Data Collection

Patient data collection will begin once participants are consented. We will use a survey to collect information on age, race, ethnicity, marital status, employment, education, lifetime number of pregnancies, lifetime number of miscarriages, lifetime number of abortions, lifetime use of prescription contraception, smoking status, alcohol use, income level, if they are currently employed, and if they are a recipient of Medicaid (Appendix B). Participants will also be given a survey to assess their substance use disorder history and current treatment (Appendix C). Additionally, all participants will complete a brief 12 question quiz to assess their reproductive and sexual health
knowledge at baseline (Appendix D). This questionnaire has been adapted from the validated contraceptive knowledge assessment, a tool to assess fertility awareness, contraceptive knowledge, and pregnancy prevention. Additionally, the survey has been determined to be at a Flesch-Kincaid 8th grade reading level, with the majority of text between a 5th and 6th grade reading level. The initial surveys will be given via study staff to answer any questions that may arise throughout the process. All data will then be de-identified, coded, and stored in an encrypted database that is only accessible via study staff.

Follow up data will also be assessed via brief survey at the 1-month, 3-month, 6-month, and 1-year time points (Appendix E). Patients will be asked to disclose any changes in their substance use, opioid maintenance therapy, initiation of a LARC method or other contraceptives, and if they have experienced an unintended pregnancy. Patients will also participate in a 13-question re-assessment of their reproductive and sexual health knowledge at the 1-month point which has also been adapted from the CKA (Appendix F).

3.8 Sample Size Calculation

Our literature search produced limited results on the rates of long-acting reversible contraceptive methods in individuals on maintenance opioid therapy. A 2021 by Rinehart, et al. found that in their study population of women on MOUD, only 3.2% of individuals were using a LARC method. Additionally, the National Survey of Family Growth found that 10.2% of women in the general population were utilizing a LARC method. This leads us to an effect size of 7% or 0.07, thus our sample size will be 151
with an \( \alpha \) of 5\% and a power of 80\%. Therefore, we will have 76 in our intervention group and 75 in our control group. *Precision and Power version 4* software was utilized to derive this calculation. Refer to Appendix G for our study sample calculation.

Prior studies focused on increasing contraceptive use in individuals on maintenance therapy had extremely low rates of participants lost to follow-up\(^9,11-13\) Thus we will anticipate a 10\% loss to follow up leading our sample size to increase to 166 individuals, thus 83 in the intervention arm and 83 in the control arm.

### 3.9 Statistical Analysis

Statistical analysis for the baseline demographic and substance use data will be analyzed for the intervention and control group. For categorial, dichotomous, and ordinal variables the proportions will be calculated and data will be compared using chi-square tests. For any continuous variables, data will be reported as a mean and standard deviation and compared using students’ t-test.

At the participant level, we plan to use chi-square tests to test our hypothesis and evaluate the difference in utilization of a LARC method (a dichotomous outcome) between the intervention and control group. Multiple logistic regression will be used for any confounding variables found to have an independent influence on the primary outcome of utilization of a LARC method. Unintended pregnancy will also be classified as a dichotomous variable and proportions will be compared via chi-square tests. Additionally, our secondary outcome of knowledge surrounding reproductive and sexual health is categorized as ordinal and thus will also be analyzed via chi-square tests. If adjusted analyses in warranted and the proportional odds assumption is met, we will
utilize ordered logistic regression. If a proportional odds assumption is not met, then we will utilize a generalized ordered logit model.

An intention-to-treat approach will be used to compare outcomes between our two study arms. For our analysis, a 5% level of significance ($p < 0.05$) will be considered significant and each estimate will be accompanied a 95% confidence interval. All analyses will be conducted using SPSS software (SPSS, Chicago, IL) and researchers will be blinded to the study condition of the participant while conducting analyses.

3.10 Timeline and Resources

This study will span 20 months in total, allowing three months for recruitment, seventeen months for follow up, and four months for data analysis. Follow up will specifically occur at 1 month, 3 months, 6 months, and 1 year. At each time point we will evaluate if the patient has obtained a LARC and if they have an unintended pregnancy. Patient reproductive and sexual health knowledge will assessed be assessed at baseline and the 1 month follow up. See Figure 1 for the proposed study timeline.

This study will require multiple researchers. One to two researchers will conduct baseline demographic, pregnancy and contraception, and substance use history survey interviews, along with the assessment of reproductive knowledge. These same researchers will conduct the follow up surveys. An additional blinded researcher will be necessary for data and statistical analysis. In addition, this study will require utilization of multiple computers for data storage, likely though RedCap. Computer software for statistical analysis will also be necessary.
### Figure 1: Study Timeline

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3.11 References

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Chapter 4: Conclusions

4.1 Advantages and Disadvantages

As rates of opioid use disorder continue to increase, it is imperative to determine appropriate and advantageous interventions for pregnant capable people to increase reproductive knowledge and autonomy and prevent unintended pregnancy. A key advantage of our study is having services co-located as it will be easier to continuously interact with our patients. Patients will be required to come to their respective clinic in order to obtain their MOUD, thus they will have sustained access to researchers and study staff for questions and to report outcomes. Moreover, loss to follow up is relatively low in this population as due to the in-person requirement for medication administration.\textsuperscript{1,2} Furthermore, a unique advantage of our study is the incorporation of trauma informed care which aims to overcome stigmatization of patients with OUD, encourage autonomous decision making, and re-instill trust in the medical system.\textsuperscript{3}

An additional advantage is the study design of a randomized control study, which will reduce bias and confounding within our results making them more generalizable and reliable. Moreover, inclusion and exclusion criteria allow us to further reduce any potential confounding that could skew results.

A major disadvantage of our study is that results will be self-reported which could lead to response bias. Additionally, due to the nature of our study participants and the physician associate providing the intervention will not be blinded. Though, as noted, any researcher engaged in data analysis will be blinded thus strengthening the internal validity of our study. Furthermore, our study is only 24 months thus we will not have long term data on participants compliance with LARC, MOUD, and rates of unintended
pregnancy. Furthermore, our study sample size is quite small and will only evaluate participants within the state of Connecticut which limits the generalizability of our results.

4.2 Clinical and Public Health Significance

Our study has the potential to create an impact on various different levels. We know that by providing increased access to reproductive education and contraception access that unintended pregnancy rates will decrease. Additionally, studies have shown that providing co-located services and trauma informed care decreases barriers to care. Thus, we assume that by co-locating and providing trauma informed sexual and reproductive education (TIRSE) and increased access to long-acting reversible contraception (LARC) methods that use of effective contraception will increase and unintended pregnancy will decrease.

By decreasing unintended pregnancy in our population we may also prevent traumatization of the birth parent, decrease rates of neonatal withdrawal syndrome that may lead to chronic health needs, and reduce healthcare cost and burden. Studies have shown that the effect of unintended pregnancy on parental stress and maternal depression is statistically significant. Additionally, women with OUD are more likely to have concomitant mental health disorders. Thus, the prevention of unintended pregnancy may decrease maternal traumatization in an already vulnerable population. Opioid use during pregnancy has been associated with fetal growth restriction, abruptio placentae, fetal death, preterm labor, and NOWS which can lead to low birth weight, respiratory distress syndrome, difficulty feeding, and seizures. Importantly, neonatal withdrawal
syndrome had a relative increase of 82% from 2010 to 2017; the increased rates along with comorbidities result in significantly longer hospitalizations with a significantly greater estimated healthcare cost.\textsuperscript{11,12} By incorporating TISRE and contraception in substance use disorder clinics, we may decrease NOWS, healthcare burden, and healthcare cost thus potentially having excess funds that may be diverted to prevention and education.

Additionally, this study provides a unique opportunity to increase autonomy and empower reproductive health decisions within a marginalized community. By incorporating co-located services we have the opportunity to educate reproductive capable people about their sexual health and contraception options, along with topics such as interpersonal violence, family planning, impacts of opioid agonist therapy on pregnancy or breastfeeding, and more.\textsuperscript{13} Power as it is related to contraceptive choice is multidimensional and multidirectional and operates at both the individual and structural levels.\textsuperscript{14} This study allows us to intervene at both levels and to motivate discourse, emphasize autonomy, and increase trust in the medical system. Substance use while pregnant will have lifelong implications for both birthing parent and fetus, by early intervention these lifelong implications may be reduced or change trajectories. By providing TISRE we aim to decrease traumatization in this sensitive population while preventing reproductive coercion and ensuring autonomous decision making.
4.3 Future Directions

If our findings are statistically significant and demonstrate efficacy of TIRSE, we plan to conduct a larger study throughout the Northeast to determine the best way to implement this intervention in all substance use treatment centers. A larger study population will allow us to evaluate the generalizability of our results and practicality of study implementation.
4.4 References


Appendix A: Resource for Patients

**BIRTH CONTROL TOP PICKS FROM BEDSIDER**

- **The Implant**
  - This tiny device is placed under the skin in the upper arm by a healthcare professional and it prevents pregnancy for up to 5 years.
  - It gives off hormones that keep ovaries from releasing eggs and has a cool sperm-blocking effect.
  - It’s so small that most people can’t even feel it—which means it can be your little secret, if you’re so inclined.
  - You can have the implant removed anytime you want and can get pregnant pretty fast after you stop using it.

- **The Shot**
  - A shot you get from a healthcare professional that keeps you from getting pregnant for 3 months at a time.
  - It contains progesterin, which keeps ovaries from producing eggs and also has an awesome sperm-blocking effect.
  - Once you get the shot, no one can tell you’re on it, so it gives you a lot of privacy.
  - It’s possible to get pregnant within 10 weeks after the last injection, but for some it can take up to 9 months.

- **The Patch**
  - A thin, beige, square piece of plastic—kind of like a Band-Aid—that you put on your skin and change once a week.
  - Gives off hormones that keep ovaries from releasing eggs and also has a fabulous sperm-blocking effect.
  - It’s less effective if you weigh more than 185 pounds (approximately 84 kg) so take that into consideration.
  - You can get pregnant pretty fast after you stop using the patch.

- **Condoms**
  - Slip a condom over the penis or insert an internal condom into the vagina to prevent pregnancy and lower the risk of sexually transmitted infections.
  - Latex or non-latex. With spermicide or without. With lube or not. There are hundreds of shapes, sizes, and types to choose from.
  - They’re chock full of non-free! and ask us to get.
  - You should use them correctly every single time if you want them to be effective.

- **Birth Control Pills**
  - Take one pill once a day and it’ll keep you from getting pregnant.
  - The pill keeps the ovaries from releasing eggs and also has an excellent sperm-blocking effect.
  - Some pills allow you to skip your period altogether. Consider the possibilities.
  - You can get pregnant pretty fast after you stop using the pill.

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**GET ON TOP OF YOUR SEX LIFE.**

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Bedsider.org

**DOWNLOAD OUR FREE REMINDERS APP**

for iOS or Android at Bedsider.org/reminders_app

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Appendix B: Demographic Survey

Age _____ Date of Birth ______________

Race
[ ] Asian American or Alaskan Native
[ ] Asian
[ ] Black or African American
[ ] Native Hawaiian or Other Pacific Islander
[ ] White
[ ] Multiracial
[ ] Unknown

Ethnicity
[ ] Hispanic or Latino
[ ] Not Hispanic or Latino
[ ] Unknown

Current Marital Status
[ ] Single
[ ] Married
[ ] Separated
[ ] Divorced
[ ] Widowed

Education Level (please indicate the highest level completed)
[ ] Did not finish high school
[ ] High school or GED
[ ] Higher education/college

Employment Status
[ ] Currently employed
[ ] Currently unemployed

Income Level
[ ] Less than $25,000
[ ] $25,000 - $34,000
[ ] $34,000 - $54,000
[ ] Greater than $54,000

Insurance Status
[ ] Self-pay
[ ] Private
[ ] Medicaid
[ ] Uninsured
Current Smoker
[ ] Yes
[ ] No

Current Alcohol Use (within last 7 days)
[ ] Yes
[ ] No

Reproductive History

Lifetime Number of Pregnancies
[ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4+

Lifetime Number of Miscarriages
[ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4+

Lifetime Number of Abortions
[ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4+

Previous Use of Prescription Contraceptives
[ ] Yes
[ ] No
### Appendix C: Substance Use History

<table>
<thead>
<tr>
<th>Substance</th>
<th>Age at First Use</th>
<th>None</th>
<th>Past Use</th>
<th>Current Use</th>
<th>Client Perceived Problem</th>
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</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
<tr>
<td>Cocaine/Crack</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
<tr>
<td>Hallucinogens</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[ ] yes  [ ] no</td>
</tr>
</tbody>
</table>

Please indicate what maintenance therapy you are currently on:
[ ] Methadone  [ ] Buprenorphine  [ ] Other _________

How long have you been on maintenance therapy? _________
Appendix D: Contraception and Reproductive Health Assessment

Select only ONE answer for each question.

1. When during a woman's cycle is she most likely to become pregnant?
   a. During her period (start of cycle)
   b. 3 days after her period ends
   c. Two weeks before her next period starts
   d. 3 days before she gets her period (end of cycle)
   e. I don't know

2. How long can sperm stay alive in a woman's body?
   a. 1–3 h
   b. 24 h
   c. 3–5 days
   d. 7–10 days
   e. I don't know

3. Which of the following choices is TRUE about pregnancy?
   a. You cannot become pregnant the first time you have sex
   b. You cannot become pregnant if you have sex standing up
   c. You cannot become pregnant if you do not have an orgasm
   d. None of the above are true
   e. I don't know

4. Which of the following choices is TRUE about withdrawal, or the “pull-out” method?
   a. Semen may be released before ejaculation
   b. Withdrawal works as well as condoms at preventing pregnancy
   c. Withdrawal can protect against some sexually transmitted diseases (STDs)
   d. Withdrawal works as well as the birth control pill at preventing pregnancy
   e. I don't know
5. Which birth control method guarantees you will not become pregnant?
   a. **None**
   b. Using a condom every time you have sex
   c. Douching, showering, or bathing immediately after sex
   d. “Pulling out” before ejaculation
   e. I don't know

6. Which is the *only* birth control method that helps prevent infections?
   a. The birth control pill
   b. **Male and female condoms**
   c. Depo-Provera (“the shot”)
   d. The IUD (intrauterine device, the “T”)
   e. I don't know

7. All of the following are TRUE about using male condoms EXCEPT:
   a. You should use water-based lubricants with spermicide
   b. **Wear two condoms to be extra safe**
   c. Prevent air bubbles by holding the condom tip when putting it on
   d. Check the expiration date and keep them in a cool and dry environment (i.e. not in a wallet or in a car)
   e. I don't know

8. Hormonal birth control comes in which of the following forms?
   a. Pills taken by mouth
   b. Patch worn on the skin
   c. Ring placed in the vagina
   d. **All of the above**
   e. I don't know

9. Which one is NOT a benefit of hormonal birth control?
a. **Improvement of diabetes**

b. Improvement of acne

c. Reduction in menstrual cramps and bleeding problems like anemia

d. Decreased risk of ovarian and uterine cancer

e. I don't know

10. How long should the vaginal ring (NuvaRing) stay in place before changing it?

a. 1 day

b. 1 week

c. **3 weeks**

d. 1 month

e. I don't know

11. Which of the following can make hormonal birth control less effective?

a. Seizure (epilepsy) medicine

b. HIV medicine

c. Herbal supplements

d. **All of the above**

e. I don't know

12. What is the main way that birth control pills work?

a. **It prevents the ovary from releasing the egg (ovulation)**

b. It prevents sperm from entering the uterus

c. It prevents the fertilized egg from implanting in the uterus

d. It prevents the embryo from growing past a certain size

e. I don't know
Appendix E: Follow-Up Survey

Have you engaged in heterosexual sex since your last visit?
[ ] Yes
[ ] No

If yes, did you use a male condom?
[ ] Yes
[ ] No

Have you initiated a contraception method since your last visit?
[ ] Yes; please indicate date if known _______
[ ] No

If yes, which method of contraception?
[ ] IUD  [ ] Implant  [ ] Injection  [ ] Birth Control Pills  [ ] Sterilization
[ ] Other ______

Have you discontinued or changed your contraception method since your last visit?
[ ] Yes; please elaborate ________________________________
_____________________________________________________________

[ ] No

Have you had any changes in your substance use since your last visit?
[ ] Yes; please elaborate ________________________________

_____________________________________________________________

[ ] No
Appendix F: Contraception and Reproductive Health Re-Assessment

1. Birth control pills can have which of the following ingredients?
   a. Testosterone
   b. **Estrogen**
   c. Magnesium
   d. Calcium
   e. I don't know

2. You should *NOT* use the birth control pill if you have any of the following:
   a. Fibroids
   b. Drink alcohol
   c. Currently taking antibiotics
   d. **None: it is safe to use the birth control pill in all of these situations**
   e. I don't know

3. How long after a woman stops using birth control can she become pregnant?
   a. **Immediately**
   b. 1 month
   c. 3 months
   d. 6 months
   e. I don't know

4. If you forget to take one birth control pill and remember the next day, what should you do?
   a. Throw the missed pill away and then continue the following day from where you left off
   b. Take the rest of the week's pills at once and then start the placebo ("reminder") week
   c. **Take two pills then continue**
d. Throw the missed pill away and wait 1 month to start a new pack

e. I don't know

5. Which of the following is FALSE about Depo-Provera (the “shot”)?
   
a. It is administered every 3 months
b. Gradual weight gain is possible
c. It might take a few months after stopping to become pregnant
d. **It cannot be used while breastfeeding**
e. I don't know

6. Which of the following birth control methods may be reversed if you decide you want to become pregnant?
   
a. Tubal ligation (“tying your tubes” or “cutting your tubes”)
b. Essure coils
c. Vasectomy
d. **IUD (intrauterine device)**
e. I don't know

7. Which birth control method is not easily noticed by a partner?
   
a. **The IUD (intrauterine device)**
b. The vaginal ring
c. Male condom
d. Female condom
e. I don't know

8. A doctor places an IUD (intrauterine device) in what part of the body?
   
a. Fallopian tube
b. **Uterus**
c. Cervix
d. Vagina
9. Which method of birth control is the best at preventing pregnancy?
   a. The IUD (intrauterine device)
   b. Depo-Provera (“the shot”)
   c. Male Condom
   d. Withdrawal (“pull-out method”)
   e. They are all equally effective
   f. I don't know

10. Which choice is FALSE about IUDs (intrauterine devices)?
   a. Women of all ages may get an IUD
   b. Women who have never had a baby may get an IUD
   c. Women can have an IUD put in right after having a baby or having an abortion
   d. Women cannot get an IUD if they have ever had a sexually transmitted disease (STD)
   e. I don't know

11. A doctor places the birth control implant (Nexplanon) in what part of the body?
   a. Thigh
   b. Vagina
   c. Arm
   d. Buttock
   e. I don't know

12. How soon after sex must the “morning after pill” (or Plan B) be used to be effective?
   a. 1 h
   b. 24 h
   c. 5 days
   d. 20 days
13. How can you get the emergency contraceptive pill called Plan B (or “the morning-after pill")?

a. If under age 18, you cannot get it, even with a prescription

b. If under age 21, you must have your parent go with you to the doctor for a prescription

c. All women must have a prescription, no matter her age

d. **You can buy it at the pharmacy, without a prescription, no matter what age**

e. I don't know
# Appendix G: Sample Size Calculation

<table>
<thead>
<tr>
<th>Group</th>
<th>Proportion Positive</th>
<th>N Per Group</th>
<th>Standard Error</th>
<th>95% Lower</th>
<th>95% Upper</th>
</tr>
</thead>
<tbody>
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<td>No Education</td>
<td>0.032</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>0.102</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate Difference</td>
<td>0.070</td>
<td>152</td>
<td>0.037</td>
<td>0.627</td>
<td>0.773</td>
</tr>
</tbody>
</table>

Alpha = 0.050; Tails = 2; Power = 0.800
Appendix H: Informed Consent Form

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Study Title: PROVIDING TRAUMA INFORMED CARE FOR INDIVIDUALS ON OPIOID AGONIST THERAPY TO INCREASE CONTRACEPTION USE

Principal Investigator: Devon Knight

Funding Source: Yale University School of Medicine – Physician Associate Program

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to increase long active reversible contraception in people of reproductive capacity on opioid agonist treatment through increased education and resources. You have been asked to participate because you are of reproductive capacity, not currently pregnant or on long-acting reversible contraception, and on maintenance opioid therapy.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible risks and benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree in participating in this randomized control study, you will be followed by research staff over the course of a year.

- Initial participant selection occurs by healthcare providers. You were selected by your provider because you meet study criteria. If you agree to participate, we will confirm your eligibility by reviewing your medical record.

- After signing the consent form, you will be contacted by a researcher to fill out a participant survey. This will ask you a number of questions on pregnancy history, social history, demographic information, and substance use history. The purpose of this is to gather baseline information that could influence study results.

- Participants will be randomized into two groups. One group will receive the usual care at their treatment center. The second group will participate in an educational session for 45 minutes.
• You will attend an educational session regarding reproductive health and contraception options with a healthcare provider. Afterwards, you will complete a survey of your knowledge. You will also be offered access to long-acting reproductive contraception.

• You will be contacted at 1-month, 3-month, 6-month, and 12-month timepoints. At these points, you will be asked about use of contraception, use of substances, and pregnancy. The purpose of this is to assess if use of contraception has increased following the intervention, and if unintended pregnancy rates have changed.

• All medical decisions will be made by your healthcare provider. Researchers will have a non-judgmental observational role only.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate. Research results will not be returned to your doctor. If research results are published, your name and other personal information will not be given.

**Risks and Inconveniences**

• There are no physical risks associated with participation in this study.

• Surveys with questions surrounding your substance use, contraception use, and pregnancy may be an inconvenience to you.

• You may be uncomfortable revealing personal information in participant surveys. Every effort will be made to keep your information confidential. A breach of confidentiality is unlikely to occur, as all study investigators are trained in research privacy.

• Research assistants will be available for questions at any time and encourage your full participation.

**Benefits**

The aim of this study is to assess if trauma informed reproductive and sexual health education can increase the use of long-acting reversible contraception in people of reproductive capacity on maintenance opioid agonist therapy. Although there may be no direct benefit for you from your participation, this research will advance our understanding of best strategies to access underserved populations.

**Economic Considerations**

Participant surveys, education sessions, and contraception will all be provided to participants free of cost.

**Confidentiality**
Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State Law. Examples of information that we are legally required to disclose include abuse of a child, which we must report to the Department of Children and Families. Information will be kept confidential by using only identification numbers on study forms, storing signed forms in locked cabinets and password protecting data stored on a computer. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific permission for this activity is obtained.

We understand that information about your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies your personal health information. This may include information that might directly identify you, such as name and address, telephone number, and email address, or mobile phone number. This information will be deidentified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you and your coded information, and this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give coded information to others to carry out this research study. The link to your personal information will be kept for 5 years, after which time the link will be destroyed and the data will be anonymous. The data will be kept in this anonymous form indefinitely.

The information about your health that will be collected in this study includes:

- Research study records, surveys, and assessments
- Records from follow up (phone calls or in person)
- Records for pregnancy or contraception

Information about your health may be used by or given to:

- The Principal Investigator, Co-Investigators, Members of the Research Team
- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Individuals at Yale who are responsible for the financial oversight of research including billings and payments

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.
All healthcare providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of information.

If you choose to participate in this study, the investigators will check your electronic medical record through EPIC to make sure you qualify. Any access to your electronic medical record will be done consistent with HIPAA regulations. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical record policies. This authorization to use and disclose your health information collected during your participation in this study will never expire.

**Voluntary Participation and Withdrawal**

You are free to choose not to participate in this study. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to participate. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. You do not give up any of your legal rights by signing this form.

**Withdrawing from the Study**

If you do not become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them you no longer want to take part. This will cancel any future appointments. The researchers may withdraw you from participating in the research if necessary.

**Withdrawing Your Authorization to Use and Disclose Your Health Information**

You may withdraw or take away permission to use and disclose your health information at any time. You do this by calling or sending written notice to the Principal Investigator. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight. *You do not give up any of your legal rights by signing this form.*
Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____________________________

Signature:____________________________________

Relationship:______________________________

Date:_______________________________________

___________________________________________

Signature of Principal Investigator Date

or

___________________________________________

Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator – Devon Knight (devon.knight@yale.edu)
If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.
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