

Women's Experiences with Relapse

by

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Dedication

This research is dedicated to those who still suffer from the disparity of substance addiction. The beauty of life is not to be seen through a haze-filled glaze. It is to be viewed with wonderment and the eyes of an infant. Those moments of darkness, they will pass. There is a way out. Reach out your hand and ask for help.

This research is dedicated to those who died so that others may live. You were loved. You are missed. Your addiction took your life, but we shall never forget your soul. Time passes, memories fade, but the spirit that once resided in you, now belongs to all of us, those who cry out for sobriety and those who struggle to maintain theirs. You are always in our hearts.

This research is dedicated to the families who watch their loved ones fade a little bit more each day. Those who know both sides of the struggle ache with you. We lift you and your loved ones up to a power greater than ourselves.

We do recover. We can recover. We can be that human we imagine ourselves to be. We can have that peace that we pray for. Never give up.

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Abstract

The purpose of this research was to examine relapse factors among women in recovery from substance abuse. Many previous substance abuse studies have excluded women from the research. The recent opioid epidemic has increased the number of drug-overdose related deaths and women comprise almost half of the approximately 72,000 people who perished in 2018. Recent studies show women face obstacles that men do not. Biological, neurological, and cultural forces direct the path of addiction women take. Motivation behind an individual's drug use is unique to the person. However, there are noted commonalities in the reasons people relapse back into substance abuse. To better understand substance use and abuse, an anonymous online survey asked questions concerning former drug use, recovery, and subsequent relapse. Participant answers were analyzed for repeated themes. Future treatment programs could benefit from the data obtained from survey participants.

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Introduction

This research project was initiated to call attention to the disturbing trend in female substance abusers who relapse following a period of recovery. Why do women relapse after they stop using alcohol and drugs? There are few social problems that spread so far as to impact most areas of society. Substance abuse is not biased when claiming victims. There is no line it will not cross: race, culture, socioeconomic status, age, gender, religion, etc. One would be hard-pressed to locate a life that has not been touched by addiction. For many, it is a loved one who battles substance abuse, for others, it is a coworker, neighbor, professor, student; countless people in our everyday lives struggle with addiction. For some, it is their own addiction that wreaks havoc upon their lives and the lives of those closest to them. Addiction in the US has become a major problem, one which requires a solution for both prevention and treatment (Becton, Chen, & Paul, 2017). It comes as no surprise that substance abuse ranks among the top ten health concerns in the US (U.S Department of Health and Human Services, 2007).

The National Institute on Drug Abuse (NIDA, 2018c) describes a substance use disorder (SUD) as the act of an individual who continues to use drugs or alcohol even after experiencing negative consequences. Many lose those things which are most important to them. They watch as their own addiction destroys their careers, friendships, and relationships, and yet, for some the pull of the substance is stronger than the tether of one's life. Substance abuse crosses gender lines, though for many years it was viewed as a man's disorder. Frequently, women were excluded or not examined in the research conducted regarding this as a genderless issue (Buccelli, Della Casa, Paternoster, Niola,

& Pierrei, 2016; NIDA, 2018d). Yet, NIDA (2018b) reported that 19.5 million females, ages 18 or older, used illicit drugs in the past year. Illicit drug use refers to the use of illegal drugs, including marijuana (according to federal law), and misuse of prescription medications (NIDA, 2018b). The nightly news is rife with accounts of men and women who have lost their battle with addiction. Bardwell, Kerr, & McNeil (2019) state, “North America is amid an overdose crisis that is showing no signs of slowing down” (p. 1). Evidence of this claim can be found in a Centers for Disease Control (CDC) report which states that the number of individuals who are dying from overdose-related deaths is steadily increasing; there were over 72,000 deaths in 2017 the last year and of those, almost half were women (CDC, 2018; Signorini, 2019). Women are losing the battle with addiction at an alarming rate. Researchers have noted that the difference in the number of women who need substance abuse treatment and those who actually receive it is a cause for concern (Fisher, Reynolds, D’Anna, Hosmer, & Hardan-Khalil, 2017). Treatment and prevention of relapse could be lifesaving. Kadam et al. (2017) explain relapse as a multifactorial phenomenon with causes being the individual, the drug, and characteristics of the environment. See, Fuchs, Ledford, & McLaughlin (2003) define relapse as the return to drug-seeking and drug-taking behavior after a period of recovery and many relapses occur following drug detoxification. Hendershot, Witkiewitz, George, & Marlatt (2011) define relapse as a change in the behavior modification of recovery where the addict returns to drug use. Although there are many definitions for relapse, for the purpose of this research it will be defined as a return to substance abuse. Alternatively, Becton, Chen, & Paul (2017) report that recovery is a process involving the change of an

individual, so that their health and wellness is directed by a life-style approach aimed at reaching their full potential and avoiding relapse.

Researchers have noted that many women must address dilemmas in their lives that are uniquely gender specific. These dilemmas can sometimes be detrimental to their recovery process (NIDA, 2018b). Biological factors related to a woman's hormonal system have been shown to play a role in the addiction cycle and recovery process (NIDA, 2018b; Riley, Hempel, & Clasen, 2019). Although the reasons behind substance abuse are unique to the individual, researchers have noted there are many similarities. Addiction is now seen as a brain disease, set in motion by the use of drugs which alter the biochemistry of neurons and how they work; at a certain point, addicts no longer abuse drugs to get high, they simply want to feel normal (Powledge, 1999).

Finally, the last obstacle discussed is perhaps the hardest one for many female addicts to overcome: the pressure society puts on them after recovery and relapse. Socially constructed gender roles demand members of society behave in ways expected of their biological sex. Should the "mother" role become overshadowed by the "addict" role, shame can impede the change that is required for successful recovery (Gueta & Addad, 2013). There is no cure for substance abuse disorder (NIDA, 2017a). However, it can be successfully treated. Effective treatment enables women to counteract addiction's disrupting effects on their brain and behavior and regain control of their lives (NIDA, 2017a). Understanding the reasons behind a woman's relapse, is a fundamental step in tackling the drug epidemic.

Women and Substance Abuse

Researchers note that substances affect women differently than they do men, especially in areas of sensitivity (Wemm & Sinha, 2019) This sensitivity can lead to addiction occurring at a much quicker rate. Substance abuse can be devastating to anyone, especially a single mother. An addict's mind is focused on nothing but obtaining the substance, this focused obsession interferes with the ability to be a present parent (Martin, Smith, Rogers, Wallen, & Boisvert, 2011). Buccelli et al. (2016) report that since addiction was until recently thought of as a male issue, most studies have been based on the male population. Since prior research has focused primarily on men (Buccelli et al.; NIDA, 2018d), society is slowly learning that women are tackling a plethora of hurdles that men do not. It is important that society recognizes these obstacles. The number of children who enter foster homes due to their substance abusing parents is on the rise (Administration for Children and Families, 2018). Substance Abuse and Mental Health Services Administration (SAMHSA) reports that in their National Survey on Drug Use, almost 8 million children live with a parent who is a substance abuser (2012). Marsh, D'Aunno, & Smith (2000) report there are many barriers women face when seeking treatment for a substance abuse disorder including too few treatment centers, lack of transportation, and lack of childcare; nor are many underlying mental health and family problems addressed at the centers once the women reach them. In a study by Martin et al. (2011), women stressed the importance of the mother role and being a good parent. There are so many roles a mother is obliged to fill: student (when applicable), mother, wife/partner, worker, cook, cleaner, a provider of love/guidance/direction, and in many cases, the drug user/addict.

In a study of substance abuse among women, women themselves describe unique reasons for using drugs, including controlling weight, fighting fatigue, coping with pain, and attempts to self-medicate to overcome mental health problems (NIDA, 2018b). Lindsay, Warren, Velasquez, & Lu (2012) found that female concern about weight loss is one of the primary factors behind their drug use. This ebb and flow of weight loss fits with the rollercoaster of addiction.

Stopping drug use is just the beginning of a long and complex recovery process. Kassani, Niazi, Hassanzadeh & Menati (2015) report that drug abuse is a chronic disorder and relapse can be a natural step in the process of getting sober. As addiction can affect every facet of a person's life, so should treatment address the whole person to be successful.

There are many paths to sobriety. Treatment approaches usually begin with detoxification and continue to cover the social, medical, personal, legal, and mental aspects of the individual's life (NIDA, 2017a). It is not uncommon for the addict to face something in their lives which drives them to seek treatment (Martin et al., 2011); the individual will have entered a period of recovery, and then an episode or occurrence will happen that triggers (initiates) the beginning of the relapse cycle. A negative or argumentative relationship can trigger relapse (Brown, Tracy, Jun, Park, & Min, 2014). In their study of incarcerated mothers, Kissman and Torres (2004) found anger was a trigger for some of the women interviewed; many of the woman found their lack of power in resolving family conflicts with their children and partners had led to self-destructive behaviors and relapse in the past. Stress is a common relapse trigger once individuals are released from incarceration (NIDA, 2014).

A mother's children can strengthen her resolve like that of no other. Many women describe their children as the motivating factor in their recovery process (Kissman & Torres, 2004). In a study by Brown et al. (2014), they found that women identified the type of relationship they had with their children as important influences on their recovery.

A majority of female addicts find that substance use is a way to deal with the many pressures of life, especially those which involve stressful relationships, finances, physical pain, or psychological distress (Martin et al, 2011). Once a newly sober woman leaves treatment, she often finds herself with no support system and no place to call home. The lucky ones have some sort of housing in place for them upon release. It is imperative that the recovery process remain slow and steady (Martin et al.). Women did not become substance abusers overnight, and it is unlikely that they will return to the life they had prior to addiction overnight. In their study on the aftercare process for substance abusers, Brown, Seraganian, Tremblay, & Annis (2002) report that while in treatment substance abusers do improve their physical, psychosocial health, and decrease their alcohol and substance use, however, the long-term is less certain. The six-month period following treatment is critical. Life hangs in the balance just in that moment of space between addiction and sobriety.

Biological Factors

Biological factors that affect relapse include those specific to the female form. There are many things which influence not only the day to day life of a woman, but also moments which arise unexpectedly and require a level of attention that is easily overlooked. Feelings, emotions, and reactions can sometimes be directed by the naturally occurring substances in a woman's body. Women must contend with such biological

influences such as hormones, menstrual cycle, fertility, breast-feeding, and menopause. Such biological factors can contribute to both initial substance use and subsequent relapse back into addiction (NIDA, 2018b; Riley, Hempel, & Clasen, 2019). When compared to male substance abuse, women's substance abuse tends to progress more quickly from the first use to a substance abuse disorder (NIAAA, 2019; NIDA, 2018b). Additionally, women may be more susceptible to craving and relapse, which are key phases of the addiction cycle (Brown, Tracy, Jun, Park, & Min, 2015).

There are those who claim addiction only hurts the user, but the impact reaches much further than the individual. Single parents, more specifically mothers, face their most difficult challenge in seeking treatment. Many women fail to seek treatment for a substance abuse disorder out of fear of repercussion because they are single parents (Kissman & Torres, 2004). Women that do seek treatment often need support for handling the burdens of work, home, childcare, and other family responsibilities. The same responsibilities for which women need support are often the reasons that lead women to relapse (Martin et al., 2011). Likewise, the stigma associated with drug addiction has been reported, in earlier research, to be detrimental to the well-being of the recovering addict. “Stigma is defined as an attribute that is deeply discrediting; it involves an individual being labelled as tainted and viewed as abnormal” (Gunn & Canada, 2015, p.281). Gunn & Canada explain that the stigma a woman may face during recovery can pose a hindrance to her recovery progress and affect her wellbeing. Goodyear, Haass-Koffler, & Chavanne (2018) describe self-stigma as an internalized negative belief that one holds about themselves; while public stigma is the beliefs that society holds concerning a stigmatized group. Becton et al.(2017) explain that recovering

individuals are often discriminated against because of the misconceptions about substance abuse. They report, some have been denied employment, advances, and health insurance after disclosing they are in recovery. Kenny & Barrington (2018) express the lack of social support afforded to women as disparaging. Thus, it is important that gender-sensitive treatment become priority (Gueta & Addad, 2012).

Research notes that the twelve-month relapse rates following alcohol cessation attempts generally range from 80-95% and evidence suggests comparable relapse trajectories across various classes of substance use (Hendershot et al.; Kadam et al., 2017). In another study by Temme & Wang (2018) they report that an estimated 60% of substance abusers will return to substance use within one year following treatment. Therefore, preventing relapse or reducing its magnitude is necessary to enable efficacious, continuing changes in addictive behaviors.

Researchers report that the relapse rate for individuals with substance abuse disorders are comparable to those of asthma and high blood pressure (American Addiction Centers, 2019; NIDA, 2018a; Thomas, 2019). Just as one must take steps to prevent an asthma attack or spike in blood pressure, an addict in recovery must work to prevent relapse back into substance addiction. Should an individual relapse, it does not mean that they have failed in their recovery. A relapse is a sign that treatment needs to be resumed, changed, or a new treatment initiated. There are some substances, such as opiates, which can lead to death if a person returns to using the same amount they used before quitting, thus effective treatment is imperative (NIDA, 2018d).

An individual's ability to recover from addiction is affected by her relationships, employment, and the stability of their housing (Brown et al., 2015). These are all factors

which, if not addressed, can weaken an individual's resolve to remain sober. Martin et al. (2011) reported, "it is important to understand how addiction can impact the performance of mothers so that effective interventions can be developed to mitigate the harmful effects on the children and the mothers themselves" (p. 153). They reported that many women sought treatment after hitting a low point and when an event or circumstance triggered a relapse, the cycle would continue.

The nature of substance abuse is marked by a compulsion to seek and use drugs even when the results are harmful (NIDA, 2018c). An individual may experience serious consequences as a result their substance use. However, the noted changes in an addict's brain significantly alters their self-control and ability to resist the urges that accompany drug use. These brain changes continue even after a person stops using drugs, which is why addiction is considered a "relapsing" disease—those in recovery from substance abuse disorders are at increased risk to return even after years of sobriety (NIDA, 2018a).

Treatment for substance abuse entails many different methods. Since addiction is a disease of the brain, it is not enough to simply stop using drugs. Changes must be incorporated into the many avenues of life. For some, detoxification is required to prevent possibly life-threatening reactions to the cessation of drug use (NIDA, 2018a). Pre-existing mental health issues should be addressed, as well. Grant, Huggins, Graham, Ernst, Whitney, & Wilson (2011) report that there is an association between treatment dropout rates and co-occurring disorders, such as a dual diagnosis of depression and substance abuse disorder. Lo, Monge, Howell, & Cheng (2013) reported the existence of a correlation between mental health and substance misuse. An individual's mental health

status should be taken into consideration when treatment for substance addiction is began.

Medication is often required for those who are addicted to alcohol or opiates. Medication is also used to help lessen the withdrawal symptoms many may experience. Depression, anxiety, and restlessness are issues which sometimes accompany withdrawal and need to be monitored (American Addiction Centers, 2019; NIDA, 2018a). Behavior modification is required to break the many habits which coincide with substance abuse. It is also important to observe the forces (people, places, things, and moods) which can lead to relapse (NIDA, 2018a; Temme & Wang, 2018).

Neurological Factors

Neurological factors that influence relapse include those associated with the neurotransmitters of the midbrain and their affect on the frontal lobe. It can be years before this brain change is noticeable. Because initial use of drugs may begin with small amounts and continue for years without ill effects; it is in later stages that the negative changes become evident (Riley, Hempel, & Clasen, 2018). In the 1930's, when scientists began to study addiction, it was viewed as a moral defect, not a health concern. We have since learned that substance abuse is not as a result of low moral character (NIDA, 2018a). The NIDA reports that using drug causes a flood of dopamine in the mid-brain (2018a). Dopamine is the neurotransmitter which drives the "reward circuit" in the brain, this motivates the repetition of behaviors necessary for survival (NIDA, 2018a). Specifically, the "reward circuit" is a component of the mid-brain, the primitive area that works unconsciously and signals the other areas of the brain that something is good for the body (MIA, 2019). More importantly, the mid-brain works with the "pleasure center,"

the force that compels the survival of the species (MIA, 2019; NIDA, 2018a). Drug use causes a surge of dopamine in the mid-brain, which will eventually lead to its depletion and increased tolerance to alcohol and drugs.

Tolerance occurs when the cells in the reward circuit no longer respond to dopamine. The user finds they can no longer experience the same high as when they first began using. As the brain changes, users derive less pleasure from things like sex, food, and social activities that once were enjoyable (MIA, 2019; NIDA, 2018a). There are long term problems that occur in the brain, as well (American Addiction Centers, 2019). The addict's learning, behavior, decision making skills, stress-related coping mechanisms, memory, and judgement are all affected by repeated substance abuse (AAA, 2019; MIA, 2019; NIDA, 2018a). Unfortunately, the user discovers that despite these harmful results, they continue to use drugs.

Cultural Factors

Cultural factors can also influence the recovery and relapse process. Becton et al. (2017) state, "in the US, drug use is routinely dealt with as a criminal offense rather than a health problem" (p. 7). We are noticing a trend in the number of women who become incarcerated due to drugs or drug-related charges (The Sentencing Project, 2016). "The female prison population has more than tripled since 1985" (Kissman & Torres, 2004, p. 217). Women offenders present with complex histories of substance use and jails are not equipped to handle them (Alemagno, 2001). The judicial system is not equipped to deal with the increase in female inmates, thus those who are granted a furlough into a rehabilitation center, find themselves waiting months longer than male inmates for an available bed (Warren, 2017). During this wait, if the women are fortunate, family will be

providing shelter, nourishment, and comfort to their children as they await their mothers return. However, many do not have such a support system, and their children are shuffled off to state's custody. It is for this reason, that many substance abusing parents do not reach out for treatment (Neger & Prinz, 2015). Virokannas (2011) explained that fear of stigmatization and losing custody of children do not make asking for help easy. Those who do enter treatment and complete a program are faced with the real world as soon as they leave the safety of the facility. Neger and Prinz report that the pressure to reunite children with their parents as soon as they leave rehab sounds wonderful on the surface. One only has to do some minor research to find that a woman who is recuperating from substance abuse must learn to care for herself before she can care for anyone else.

Drug laws in the United States are complex and their origin must be explored to better understand their enforcement. An example of such would be the different stance the federal government takes on marijuana regulation compared to some of the more accepting states. Redford and Powell (2015) explain that the laws enacted and enforced by the US government came about because of previous interventions in the drug market. The government's attempt to control drug importation, addiction, the criminal element in the drug trade, and the excessive prescribing of medication only exacerbated these issues. Current drug laws seek to punish the addict as well as the supplier. To curb opioid prescriptions, many states have enacted laws which limit the length of initial opiate prescriptions, although researchers found these laws have not accomplished their goal of curbing opiate addiction (Sacks, Hollingsworth, Nguyen, & Simon, 2019). Researchers are studying countries which have decriminalized drug use and possession in order to better understand potential benefits. Areas which have decriminalized drug use and

possession have found that there are numerous benefits such as: reduction in the number of people imprisoned, reduced criminal justice costs, and more people are entering drug treatment facilities (Clark et al., 2017).

We live in a society where an addict's first contact with the legal system results in enmeshment in that same legal system. Our society and our legal system are failing those addicts needing help; they do not need incarceration but treatment. The intricate way drug laws are enacted and enforced can be explained by various government agencies vying for budget allotment. To fund the narcotics bureaus, the government created more complex drug laws, harsher punishments for offenders, and apply prohibitions they can carry out (Redford & Powell, 2015). Opportunities for treatment as an alternative to conviction and punishment can occur at many stages in the criminal justice process, starting from initial police contact through to community reintegration after prison. Some studies suggest that outcomes for those who are legally pressured to enter treatment are as good as or better than outcomes for those who entered treatment without legal pressure (Dual Diagnosis, 2019). Individuals under legal pressure also tend to have higher attendance rates and remain in treatment for longer periods, which can also have a positive impact on treatment outcomes (Dual Diagnosis, 2019; NIDA, 2014). Clark, Dolan, & Farabee (2017) report that conviction and punishment of minor drug offenses is costly and harmful. Imprisonment uses valuable resources which could be applied to prevention and treatment.

The War on Drugs in America created sentencing policies that resulted in a growth in the number of people imprisoned for drug offenses (D'Amico, Riggs, Karstedt, & Gelb, 2015). Initiated in the 1980's, almost half a million Americans have been

incarcerated for drug charges, most have no prior history of criminal arrest for violence and are not high-level participants in the drug trade (Trends in US Corrections, 2018). Kopak, Proctor, and Hoffmann (2015) suggest that most women who have been arrested or are in jail meet the criteria for a substance abuse disorder. Harsher laws keep people who are convicted of a drug offense imprisoned for a longer time. The criminal justice system is left to deal with high levels of substance abuse and addiction. Since almost half of prison and jail inmates meet the DSM-V criteria for substance abuse, this problem requires a solution (The Sentencing Project, 2016).

Incarceration for crimes, both large and small, has for the most part, been a readily accepted form of punishment. When used to protect the public from violent offenders, there can be little doubt that punishment is an important part of a civilized society. The same cannot be said of incarceration for drug addiction, according to a growing body of evidence (Clark, Dolan, & Farabee, 2017). Clark et al. report that relapse rates for offenders who complete a prison sentence are greater than 80%. Just as prior research into substance abuse has excluded women, the judicial system is not prepared for the increase in female addicts. Twenty-five percent of female prisoners have been convicted of a drug offense and, of the women in state prisons, more than 60% have a child under the age of 18 (Warren, 2017).

At the local level, women stay in jail waiting on a bed in a treatment facility, as part of a plea agreement in their legal case, for much longer than men do (Warren, 2017). Women remain incarcerated for up to six months longer than their male counterparts and many of these women are single mothers. The Administration for Children and Families

(2018) report that almost 97,000 children were removed from their home in 2017 because one parent had a substance abuse disorder.

While the wait for an open spot in a treatment facility may be lengthy, treatment of substance abuse proves to be beneficial to the addict and society. Drug abuse and addiction cost American society more than \$740 billion annually in lost workplace productivity, healthcare expenses, and crime related costs (NIDA, 2018c; Thomas, 2019). The NIDA (2018c) reports that for every dollar invested in addiction treatment programs, there is a return between \$4 to \$7 in reduced crime, criminal justice costs, and theft. If healthcare savings are included in this, the number increases at a ratio of 12:1 (Dual Diagnosis, 2019; NIDA, 2018c). At the personal level, savings to the individual who receives substance abuse treatment includes fewer conflicts, fewer drug-related accidents, and increased job productivity (NIDA, 2018c).

To summarize, woman face hurdles that man do not when faced with the prospect of getting sober. The biological forces that can wreak havoc on a woman's system are just recently coming to light in the research being done. The brain changes caused by drug use are an added component that make sobriety even harder to attain. Add to that, the biological and neurological factors the stigmatization of a society that does not understand addiction, and a woman needs all the support she can amass if she is to overcome.

Methods

The current research study, asked women in recovery to share their relapse experiences to better understand the relapse factors associated with women who relapse back into substance abuse following a period of recovery. This research was approved by

the Middle Tennessee State University Office of Research Compliance. The Methods section provides a detailed description of the sample and the sampling design, measurement, research design, and data analysis.

Sample

40 women participated in an anonymous online survey (See Table 1). The women ranged in age from 23 to 68 years ($M = 43.13$, $SD = 10.754$). There was noted variation in the sober time of the participants: some had only been free from substances for days, while others had accrued many years of sobriety ($M = 6.19$, $SD = 6.934$; $range = 28$). Of the 40 women, one identified as Asian American (2.5%), one identified as African American (2.5%), one identified as Native American (2.5%), three identified as Latino (7.5%), and the remaining 34 participants identified as white (85%). The online survey covered participant alcohol and substance abuse from their initial use to their last, and any subsequent relapses. The women reported the substances they had used/abused, and any treatment they received for their addictions. Additionally, the women who took the survey wrote in their own words what they felt led them to relapse and how they prevented relapse today. Respondents received no compensation for completing the survey; they participated on their own volition.

Respondents answered questions concerning any legal issues that may have arisen as a result of their drug use. Questions were asked regarding education and employment status, relationship status, and age of children (if they had them). The remaining question posed to respondents was one of advice for those new to recovery. Since this was a study on the relapse stories of women, males were asked not to participate.

Research Design

A mixed methods procedure was utilized to collect data for this research. A non-probability sampling approach was taken, so that effective participants could be gathered quickly and based on survey requirements. Following approval of the Middle Tennessee State University Internal Review Board, women who frequent the same recovery group as the primary investigator were asked if they would be interested in completing an anonymous questionnaire that would cover their personal relapse and recovery stories. Snowball sampling became an useful tool during the collection of participants, as Krysik & Finn (2013) explain, “snowball sampling is useful for locating hard-to-access populations; ... this sampling method is based on the idea that people often know others in situations similar to their own” (p. 163).

The purpose of the study was explained to the respondents and contact information for the researcher handed out. Krysik & Finn (2013) explain, “as the goal of qualitative research is comprehensive understanding, sampling choices are made with the goal of yielding rich knowledge regarding the phenomenon of interest. For this reason, purposive sampling, the intentional selection of elements to be included in the sample, is the sampling method of choice” (p. 161). The mixed method of data collection continued as the participants were required to meet certain criteria to be included in the survey; they had to be 18 years of age or older, identify as female, and actively participating in recovery. Criterion sampling is useful for quality assurance because it is the selection of cases that meet the criteria of the survey (Krysik & Finn, 2013). An anonymous link was given to an online survey to those who wished to participate. The link detailed the rights

and responsibilities of the respondents and since this was an online survey, no signatures were collected. The women gave consent by continuing the anonymous survey (Appendix A).

No benefits were made available to participants; they took the survey of their own free will. The survey approach was utilized to gather qualitative and quantitative data that is sometimes hard to collect in an interview setting, as Krysik and Finn (2013) indicate, social desirability, or the pressure to answer a question in a certain way regardless if the response is true, can impede a personal interview. An online survey allows participants to exit the survey should questions of a personal nature provoke an emotional response. The debriefing section that followed the survey (Appendix B), offered to provide respondents with the numbers to access mental health resources. Participants were also encouraged to complete the survey with their Alcoholics Anonymous/Narcotics Anonymous sponsor present.

Measurement

Data were collected using a self-administered survey (Appendix C) which was designed using Qualtrics. A link to an online survey was made accessible and anonymous. After electronically signing an online consent (Appendix B), respondents could then begin the survey. The survey contained a total of 24 items. Survey items included such questions as: How long have you been sober; Have you experienced relapse; What do you feel contributed to your relapse; How do you prevent relapse now? The survey questioned respondents about their former substance abuse and current recovery. In order to better understand the respondent's history with substance abuse, questions were posed which asked about age of initial substance use and substance

abused. Respondents were also asked to identify any health issues (physical or mental) that they felt contributed to their substance abuse.

Educational background, or degree was quantified as some high school, high school or General Education Diploma, some college, college degree, graduate degree, or trade degree and relationship status was quantified as married, divorced, widowed, domestic partnership, never married, or remarried. Employment status was quantified as employed full-time, employed part-time, unemployed but looking for work, unemployed and not looking for work, disabled, retired, or employed student. This information was obtained so that an observation could be made about how past drug use affected present life.

Respondents were asked about the type of drugs/alcohol they used prior to getting sober, and what type of treatment they received, if any. They were asked about the number of children they have and their ages. Respondents were also asked if they had children who were no longer in their custody. As can occur with drug use, the women were asked if they had experienced any legal consequences as a result of their substance abuse. Open-ended (qualitative) questions were presented because substance abuse is unique to the individual. Personal accounts of addiction, an attempt to get sober, relapse struggles, the effect substance abuse may have had on the respondent's life, and any other additional information they wished to share was recorded. Finally, the only sociodemographic data obtained from respondents was their ethnicity and which state they reside in.

Data Analyses

Data were analyzed following the cessation of the survey, and no additional responses were collected. Of the 40 females who completed the online survey, two of the respondents admitted that they were still actively using drugs at the time of the survey; however, for the sake of the research, their data were collected and analyzed.

Respondents' survey answers and additional comments were analyzed for repeated themes.

IBM SPSS Statistics 26 was utilized for the analysis of quantitative data. Descriptive analyses were ran including the frequencies of respondent's responses. Measures of central tendency, mean, range, and standard deviation were evaluated when appropriate. Qualitative data was analyzed to observe reoccurring themes and better understand the women's answers.

Results

The average age of the women surveyed was 43 years; however, the variability in age groups is important to note. Forty percent of the women surveyed were between the ages of 37-45 years, and the 46-68-year-old group accounted for 40% of the participants. Table 1 notes that both the 18-25-year-old's and 26-36-year old comprised the upper and lower 10th percentiles.

A majority of the women identified as being white (82.5%). Latinas made up 7.5% of the survey group, African American women comprised 5% of the participants.

Asian Americans and Native American each comprised 2.5% of the total number of women who participated in the survey.

Table 1. lists the educational levels of the participants. Forty percent report having a High School Diploma or GED. Twenty percent have some college experience, while 2.5% report less than high school. Seventeen and a half percent have a college degree, 17.5% have a master's degree, and 2.5% earned a trade degree.

Regarding employment, 57.5% of the women worked full-time jobs, 12.5% worked part-time. 5% of the women are retired, 12.5% are disabled and 10% report they do not work. Seven and a half percent of the women both attended college and worked. Regarding domestic relationships, of the 40 women who participated in the survey, 37.5% reported being married, 5% of the respondents were widows, 7.5% were in domestic partnerships and 12.5% reported they never married. A total of 35% were divorcees or separated, and 2.5% reported being engaged.

Regarding parental status, 75% of the respondent's report being mothers. The average age of the participants children was 24 years of age, with the youngest child being one year of age and the oldest was 45. Fifteen percent of the women reported they have children who no longer reside with them.

Table 2 describes background variables on the respondent's drug use. The average age reported as the first time the respondent used alcohol/drugs was 14.5 years. Seventy-two and a half percent of the women reported they used alcohol, while 57.5% of the women first tried marijuana. Prescription medications such as Xanax and Adderall were

first used by exactly half (50%) of the women who took the survey. Methamphetamine was the drug used by 45% of the respondents, followed by 20% who tried cocaine.

The average age in which respondents first felt they had a problem with their substance use was 26 years. 20% of the women felt a pre-existing medical condition contributed to their drug use. Their responses were anxiety, depression, and one woman reported that she had a complete shoulder repair that she felt contributed to an opiate addiction. Although 95 % of the women reported current sobriety ranging from less than one year to over twenty years, 80% of the women indicated that they had experienced at least one relapse (see Table 3). The number of relapses ranged from 1(modal category 30%) to “too many to count” (5%). The average number of relapses was 3.65, with a range of 15. In comparison, the average number of respondent’s sobriety was 6.19, with a range of 28. It should be noted that 5% of the women (2) were still in the using phase of addiction.

There is some indication that four major themes represent factors which can contribute to relapse: low self-worth and its connection to intimate relationships with men, conflict and negative emotions, connection to using network (people, places, and things associated with drug use), and lack of knowledge about addiction and relapse prevention skills (An-Pyng Sun, 2007). Table 4. notes that 22.5% of the women believed their primary reason for relapse was due to the stress of life in general and/or parenting. One respondent stated, *“That it has nothing to do with loving your children enough.”* Another woman reported, *“Women are stronger than they are given credit for and they give themselves. If women are given credit for their own downfall, then they should be given credit for their own recovery as far as their own actions and mental capacity.”*

The remaining women attributed their relapse to a variety of reasons that included anxiety and depression. One participant stated, *“Depression plays a large part.”* The women also listed unresolved past trauma as a motivating factor for relapse. One woman stated, *“Sexual assault/abuse is a huge factor. After my rape my drinking escalated.”* Another woman stated, *“Sexual abuse. It's so rampant. Still today. Do you know how easy it is to forget you were raped at 10 years old when you have a substance of your choice? Why would you want to stop?”*

The participants also listed negative influences in early recovery, as well as a lack of resources and support systems. One woman explained, *“I think all folks need support. And also need a large degree of willingness. Research indicates that if there is trauma that really does need to be addressed first. If you take away alcohol/drugs and don't address trauma you suddenly taken away the traumatized persons coping/medication. This requires more than a 12-step program can do. Also, we have limited community it's mental health services to meet such needs.”*

Finally, two respondents explained that they felt their relapse was attributed to boredom and lack of will power. *“There is a million different reason why women end up relapsing. In this day and time that's what makes us all unique in our own way. The reason could be society, stress, nerves, mental and verbal abuse along with physical abuse. It could be maybe once you get sober. Get your head back on right and have clearer thinking. Then your parents won't allow you to come back home to help get back on your feet. Then it dawns on you that you've burnt a lot of bridges while was in active addiction. So, before you know it. You have been fed back to the wolves and back to into*

everything you are trying so hard to stay away from. So, you end up doing what comes naturally.”

A total of 42.5% of survey respondents indicated that detox was necessary, as was in-patient treatment, in order to get sober. One participant reported, *“It’s not easy...takes so much self-work...a person should dig deep to find the root of the problem.”* Forty-five percent of the women indicated they rely on a sponsor and a support group to maintain their sobriety. One woman reported, *“I believe core issues must be addressed as well as working a 12-step program. Both are vital for success.”* Forty-five percent of the women also indicated that they got sober by going cold turkey. One woman stated, *“Dealing with begin an addict on a daily basis is really hard at first but for me I have been an addict over twenty years now n using drugs or alcohol there is always consequences to those actions n I’ve come to the point in my life n said enough is enough, I never did rehab I myself own rehab n what’s helped me the most is to stay busy, work, n stay away from those who use n I’m going on 9 months strong n still counting!”* [sic].

Table 5 indicates the many methods that the women use to maintain their sobriety. One woman reported that it took almost all available resources for her to arrive at a point where she felt she could maintain her sobriety. *“I haven’t relapsed since receiving actual treatment for my issues - that took DBT, support, Inpatient, peers, CBT, AA and Smart Recovery. It took a village.”* Another stated, *“You have to have a good reason. And that reason is in your value. Everyone matters.”*

Respondents were questioned about any legal issues that may have arisen during their substance abuse. Forty-two and a half percent of the women experienced consequences such as arrest, jail time, probation, parole, violation of probation,

DUI/DWI, and loss of child custody. One respondent reported that she received an assault of an officer charge while intoxicated.

The survey participants were asked if they had ever been treated for any mental health issues. The women were seen for a number of concerns (Table 6). Twenty-six percent of the women were treated for depression, 14.3% were treated for anxiety and medication assistance, 7.1% (3) of the women were treated for Post-Traumatic Stress Disorder (PTSD), 4.8% (2) of the women were treated for agoraphobia. One of the women was treated for anorexia, another bipolar disorder, as well as one woman admitted herself into a mental institution, and another was treated for suicide-prevention. A total of 23.8% of the women continue either seeing a psychiatrist, therapy, or alcohol and drug counseling. One woman offered, *“I think drug abuse goes deeper than the age you first started using. I feel everything is a result of our childhoods. There is something we didn’t get as a baby or child that makes us need something to compensate for a feeling derived from needs not being met at a young age. It’s not just the addiction that needs to be dealt with but add counseling and church in with the addiction treatment and I feel that there would be more of a higher success rate in recovery.”*

Comments from Respondents

The women were asked to provide advice for those new to recovery and those who may be struggling to remain sober. Here are their responses. *“Attend meetings, try to avoid situations which would cause me to use, stay away from people who are using, find a support group/system, find new surroundings,” “12-Step meetings, sponsor, cut off anyone who would tempt me to use,” “friends in the recovery programs, spiritual*

growth, constant community involvement and communication with friends,” “therapy or counseling, methadone maintenance for opiate withdrawal,” “find other activities, set boundaries, remain active in AA, it is not worth losing my kids over,” “live everyday with intent,” “I just take it one day at a time. If I can make it to bedtime without drinking, I’ve succeeded.” “ Just keep doing the damn thing, stay plugged into AA and God,”

“Willpower and higher-powered, never give up, just keep doing the damn thing.”

Summary

In summary, this research was conducted to determine why women relapse into substance addiction following a period of recovery. To examine this issue, an anonymous link to an online survey was given to willing participants. The survey questioned the respondent’s former substance abuse, recovery and relapse. Inclusion criteria consisted of women, over the age of 18, who had experienced a relapse while in substance abuse recovery. Data were analyzed for reoccurring relapse themes. The results showed that stress concerning family members (parenting), relationships and life in general, were factors behind some of the women’s relapse. Women who were in early recovery also showed a propensity for relapse.

Discussion

The research survey results indicate that there do appear to be reoccurring relapse themes among women in recovery from substance abuse. Almost one-fourth of the survey participants indicated that stress was a major influence on their relapse. The American Addiction Centers (2019) explain that stress in an individual who does not have a substance abuse disorder may lead to frustration and anxiety but that stress in the addict can lead to relapse. Another noteworthy repeating theme was a history of

unresolved trauma, most notably, early childhood sexual abuse and rape. Peltan & Cellucci (2011) report that childhood trauma and sexual abuse have been strongly linked to substance abuse problems. Anxiety, depression, self-medicating, lack of available resources and negative influences while still in early recovery also were reasons consistently repeated by the respondents.

Other relapse factors were significant others, unsupportive family, lack of resources, and self-medicating to treat an underlying mental health issue (depression). History of a diagnosed mental health issue and legal issues as a result of drug use were recurring responses, as well. Treatment recommendations for women who suffer from substance abuse include support for the well-being of single mothers, treatment options which include care for the children and aftercare for them as well, and a plan of treatment which deals with the stress that can accompany recovery. Finally, this study was limited by the sample size and data which should have been included in the survey. Future studies could better isolate relapse themes and prepare for them.

Conclusions

Relapse prevention can save lives. It is an important component of the recovery process. Both women and men benefit from the emphasis that is placed upon identifying and preventing behaviors which can lead them back to substance abuse. While the motivation behind an individuals' first use of drugs and/or alcohol is unique to them, there are noted similarities among women who attempt to quit. Women report stress as a major force that influences their relapse back into substance addiction, followed by an unresolved history of trauma.

The growing number of women who have become involved with the judicial system due to their substance abuse is of concern. Niccols, Milligan, Smith, Sword, Thaabane, & Henderson (2012) report that for the child welfare system, maternal substance abuse is a serious problem. Women are afraid to utilize available resources for fear of losing their children, negative stigma attached to their name, and even lack of transportation” (Niccols et al.) The increase in the number of children who have substance abusing parents and enter the foster care system is alarming as well. With so many women who leave behind a child under the age of 18 to serve a drug related prison sentence, treatment versus incarceration could prevent drug-related recidivism, and that benefits everyone.

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Appendix A: Informed Consent

Primary Investigator: Angela Womack

PI Department & College: Social Welfare and Honors College

Faculty Advisor: Ariana Postlethwait PhD.

Protocol Title: Women's Experiences with Substance Abuse Relapse

Protocol ID: 19-2256

Welcome to the research study!

Information and Disclosure Section

1. Purpose: This research project is designed to help us evaluate the reasons women relapse back into substance addiction following a period of recovery (sobriety).

. Description: This project consists of an online consent form (this), a link to an online survey for participants who meet the inclusion criteria, and a debriefing form. Inclusion criteria consists of females, over the age of 18, in active recovery (not using drugs or alcohol) and having had at least one former relapse back into substance addiction. The online survey will ask participants questions regarding their former drug and alcohol use, treatment, recovery, and relapse. The debriefing form will provide the purpose of the survey and lists additional resource should the survey cause any emotional response. Because this research study is limited to women, men are asked not to participate.

2. Duration: The online survey takes about 45 minutes to complete but this can vary depending on how much or how little you write. There is no compensation for participating in this survey, but participants have the opportunity to get their story out there, anonymously. The data gathered could be beneficial to those still in active addiction (using alcohol and drugs) or those who enter recovery.

Here are your rights as a participant:

Your participation in this research is voluntary.

You may skip any item that you don't want to answer, and you may stop the experiment at any time (but see the note below) If you leave an item blank by either not clicking or entering a response, you may be warned that you missed one, just in case it was an accident. But you can continue the study without entering a response if you didn't want to answer any questions. Some items may require a response to accurately present the survey.

3. Risks & Discomforts: As stated above, there is a chance that answering questions concerning former substance and alcohol abuse may provoke an emotional response.

4. Benefits: There are no direct benefits to participants.

5. Identifiable Information: No identifiable information will be asked for. I will not know who said what only what was said.

6. Compensation: There is no compensation for participating in this study

7. Confidentiality. **NO RECORDABLE OR IDENTIFIABLE INFORMATION WILL BE ASKED.** All efforts, within reason, will be made to keep your personal information private but total privacy cannot be promised. Your information may be shared with MTSU or the government, such as the Middle Tennessee State University Institutional Review Board, Federal Government Office for Human Research Protections, if you or someone else is in danger or if we are required to do so by law.

8. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact Angela Womack (Angie) by telephone (931-743-1818) or by email (amw2ct@mtmail.mtsu.edu) OR my faculty advisor, Ariana Postlethwait by telephone (615-898-2868) or by email (ariana.postlethwait@mtsu.edu). You can also contact the MTSU Office of compliance via telephone (615 494 8918) or by email (compliance@mtsu.edu). This contact information will be presented again at the end of the survey.

By clicking below, I affirm that I freely and voluntarily choose to participate in this study. I understand I can withdraw from this study at any time without facing any consequences. I understand the risks associated with this survey.

Appendix B: Debriefing Form

Debriefing Form

Middle Tennessee State University

Thank you for your participation in our study! Your participation is greatly appreciated.

Purpose of the Study:

We previously informed you that the purpose of the study was to observe any similarities in the reason's women relapse back into alcohol and substance abuse. We realize that some of the questions asked may have provoked strong emotional reactions. As researchers, we do not provide mental health services and we will not be following up with you after the study. However, we want to provide every participant in this study with a comprehensive and accurate list of clinical resources that are available, should you decide you need assistance at any time. Please see information pertaining to local resources at the end of this form.

Confidentiality:

You may decide that you do not want your data used in this research. If you would like your data removed from the study and permanently deleted, please notify primary investigator.

Please do not disclose research procedures and/or hypotheses to anyone who might participate in this study in the future as this could affect the results of the study.

Final Report:

If you would like to receive a copy of the final report of this study (or a summary of the findings) when it is completed, please feel free to contact us.

Useful Contact Information:

If you have any questions or concerns regarding this study, its purpose or procedures, or if you have a research-related problem, please feel free to contact the researcher(s), Angela Womack 931-743-1818 or amw2ct@mtmail.mtsu.edu

If you have any questions concerning your rights as a research subject, you may contact the Middle Tennessee State University's Institutional Review Board (IRB) at irb_information@mtsu.edu

If you feel upset after having completed the study or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help. If you feel you would like assistance, please contact MTSU's Counseling Center at KUC 326-S 615-898-2670 Office Hours: 8:00am - 4:30pm Monday-Friday.

If there is an emergency outside of office hours, please call the Suicide Hotline at 1-800-273-8255, Mobile Crisis at 1-800-704-2651, or go to the nearest hospital ER.

In a serious emergency, remember that you can also call 911 for immediate assistance.

It may also be beneficial for participants to inform their sponsor prior to answering research questionnaire and following its completion.

Further Reading(s):

If you would like to learn more about women in recovery and relapse prevention, please see the following references:

<https://www.drugabuse.gov/related-topics/women-drugs>

*****Please keep a copy of this form for your future reference. Once again, thank you for your participation in this study!*****

Appendix C: Online Survey Questions

1. How do you identify yourself (female, transgender, etc.)?
2. Are you over the age of 18?
3. What year were you born?
4. Are you free from alcohol/drugs (sober) now?
5. How long have you been free from alcohol/drugs (sober)?
6. Have you experienced relapse while in recovery from alcohol/substance abuse?
7. Number of relapses?
8. What do you feel contributed to your relapse(s)?
9. Substance(s) of use and/or abuse?
10. What type of treatment have you received?
11. Have you experienced legal consequences as a result of your drug use?
12. Have you ever received treatment for mental health issues such as anxiety, depression, etc.?
13. Do you have a medical condition that you think contributed to your drug use?
14. What is your ethnicity?
15. Do you have children?
16. What are their ages?
17. Do you have children who are not in your custody?
18. What is your relationship status?
19. What is your highest level of education?
20. What is your employment status?

21. At what age did you (first) begin using alcohol/drugs?
22. What was the substance?
23. At what age did you realize you had a problem?
24. How do you prevent relapse now?
25. Where do you live (state)?
26. What else would you like me to know about factors related to relapse among women with substance abuse problems?

Table 1

Table 1.

Description of Sample (N=40)

	Mean (SD)	Percentage
<u>Age</u>	43 (10.75)	
23-25 years		10%
26-35 years		10%
36-45 years		40%
46+		40%
<u>Race</u>		
Asian American		2.5%
African American		5%
Latina		7.5%
Native American		2.5%
Mixed Race		5%
White		77.5%
<u>Education</u>		
<than High School		2.5%
High School/GED		40%
Some College		22.5%
College Degree		15%
Master's Degree		17.5%
Trade Degree		2.5%
<u>Employment</u>		
Employed		77.5%
Unemployed		10%
Disabled		12.5%
Retired		5%
<u>Marital Status</u>		
Married		37.5%
Divorced/Separated		35%
Widowed		5%
Domestic Partner		7.5%
Never Married		12.5%
Engaged		2.5%
Children	23.7 (3.92)	75%

Table 2

Table 2

Background Variables on Drug Use

Question	Mean (SD)	Percentage
What age did you begin to experiment with drugs/alcohol?	14.5 (5.73)	
What substances did you use?		
Alcohol		72.5%
Cocaine		20%
Crack		7.5%
Heroin		7.5%
Inhalants		10%
Marijuana		57.5%
Methamphetamine		45%
Prescription Meds		50%
Psychedelics		7.5%
What age did you realize you had a problem?	26 (7.56)	

Table 3

Table 3.

Use/Addiction, Tx/Relapse/Sobriety

Questions	Mean (SD)	Percent
Have you relapsed?		95%
How many times have you relapsed?	3.65 (4.51)	
Are you free from alcohol and drugs?		95%
How long have you been sober?	6.19 (6.93)	

Table 4

Table 4.

Why do you think you relapsed?

Reason	Percentage
Anxiety	5%
Stress (life and parenting)	22.5%
History Unresolved Trauma	7.5%
Early Recovery	10%
Negative Influences	7.5%
Depression	7.5%
Not Ready to Quit	5%
No Resources or Support	7.5%
Self-treating Mental Health Issues	5%
No Willpower	2.5%

Table 5

Table 5

Treatment

Tx Received for Addiction	Yes
Detox	42.5%
In-Patient	42.5%
AA/NA/12-Step	60%
Support Group	45%
Sponsor	45%
Self-Reliance/Cold Turkey	45%

Table 6

Table 6

Treatment for Mental Health

	Percent
Agoraphobia	4.8
A&D Counseling	2.4
Anorexia	2.4
Anxiety	14.3
Bipolar	2.4
Depression	26.2
Medication	14.3
Psychiatrist	9.5
PTSD	7.1
Self-Admit	2.4
Suicide prevention	2.4
Therapy	11.9

IRB
INSTITUTIONAL REVIEW BOARD
Office of Research Compliance,
010A Sam Ingram Building,
2269 Middle Tennessee Blvd
Murfreesboro, TN 37129



IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Wednesday, July 24, 2019

Principal Investigator **Angela Womack**
(Student)
Faculty Advisor Ariana Postlethwait
Co-Investigators NONE

Investigator Email(s) *amw2ct@mtmail.mtsu.edu; ariana.postlethwait@mtsu.edu*
 Department Psychology (PI) and Social Work (FA)

Protocol Title **Woman's experiences with substance abuse relapse**
 Protocol ID **19-2256**

The above identified research proposal has been reviewed by the MTSU Institutional Review Board (IRB) through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category (7) *Research on individual or group characteristics or behavior*. A summary of the IRB action and other particulars in regard to this protocol application is tabulated below:

IRB Action	APPROVED for ONE YEAR		
Date of Expiration	7/31/2020	Date of Approval	
7/24/19			
Sample Size	300 (THREE HUNDRED)		
Participant Pool	Primary Classification: Healthy Adults - 18 years or older		
	Specific Classification: Female adults in recovery from substance abuse AND experienced at least one relapse		
Exceptions	Permitted to administer online consent via Qualtrics		
Restrictions	1. Mandatory ACTIVE informed consent using MTSU template; the participants must have access to the informed consent. 2. All identifiable data/artifacts that include audio/video data, photographs, handwriting samples, and etc., must be used only for research purpose and they must be destroyed after data processing. 3. Not approved for online data collection.		
Approved Templates	MTSU templates: F024 Online Informed Consent, and F007 IRB Flyer. Non-MTSU: Web postings and verbal recruitment script		
Comments	NONE		

Post-approval

The investigator(s) indicated in this notification should read and abide by all of the post-approval conditions (<https://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php>) imposed with this approval. Any unanticipated harms to participants, adverse events or compliance breach must be reported to the Office of Compliance by calling 615-494-8918 within 48 hours of the incident. All amendments to this protocol, including adding/removing researchers, must be approved by the IRB before they can be implemented.

Institutional Review Board
 Middle Tennessee State University

Office of Compliance

Continuing Review (Follow the Schedule Below)

This protocol can be continued for up to THREE years (**7/31/2022**) by obtaining a continuation approval prior to **7/31/2020**. Refer to the following schedule to plan your annual project reports and be aware that separate **REMINDERS WILL NOT BE SENT**. Failure in obtaining an approval for continuation will result in cancellation of this protocol. Moreover, the completion of this study **MUST** be notified by filing a final report in order to close-

		48

Reporting Period	Requisition Deadline	IRB
Comments		
First year report	6/30/2020	NOT
COMPLETED	Second year report	6/30/2021
NOT	COMPLETED	Final
6/30/2022	NOT COMPLETED	report

Post-approval Protocol

Amendments:

Only two procedural amendment requests will be entertained per year. In addition, the researchers can request amendments during continuing review. This amendment restriction does not apply to minor changes such as language usage and addition/removal of research personnel. .

Date	Amendment(s)	IRB
Comments		
NONE	NONE.	NONE

Other Post-approval Actions:

Date	IRB Action(s)	IRB
Comments		
NONE	NONE.	NONE

Mandatory Data Storage Requirement: All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data must be stored for at least three (3) years after the study is closed. Subsequently, the data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.

The MTSU IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Institutional
Review Board
Middle Tennessee State
University