INTEGRATED PSYCHOSOCIAL GROUP TREATMENT (IPGT): A RANDMIZED PILOT TRIAL OF A HARM REDUCTION AND PREVENTATIVE APPROACH FOR CHRONIC PAIN PATIENTS AT RISK FOR OPIOID MISUSE

by

Valerie Jean Hruschak

B.S.W., University of British Columbia. 2008

M.S.W., University of British Columbia. 2010

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This dissertation was presented

by

Valerie Hruschak

It was defended on

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and approved by

Dr. Shaun Eack, PhD, MSW, James and Noel Browne Endowed Chair, Associate Dean for Research, and Professor of Social Work and Professor of Psychiatry

Dr. Ajay Wasan, MD, MSc, Professor of Anesthesiology and Perioperative Medicine and Psychiatry Vice Chair for Pain Medicine

Dissertation Chair: Dr. Gerald Cochran, PhD, MSW, Internal Medicine, Associate Professor, Psychiatry Adjunct Associate Professor, Adult Psychiatry and Epidemiology at the University of Utah

Dissertation Co-Chair: Dr. Daniel Rosen, PhD, MSW, Professor of Social Work

INTEGRATED PSYCHOSOCIAL GROUP TREATMENT (IPGT):

A RANDMIZED PILOT TRIAL OF A HARM REDUCTION AND PREVENTATIVE APPROACH FOR CHRONIC PAIN PATIENTS AT RISK FOR OPIOID MISUSE

Valerie Hruschak, Ph.D.

University of Pittsburgh

The United States is experiencing an interrelated public health crisis, involving the management of chronic pain and the risks associated with opioid misuse. A fundamental challenge for healthcare is to achieve a balance between decreasing the misuse of opioids and associated harms while optimizing pain care. This dissertation conducted a pilot randomized control trial (RCT) for an integrated psychosocial group treatment (IPGT) model for patients with chronic pain who are at risk for opioid misuse. A primary aim of this study was to examine the feasibility and acceptability of IPGT for chronic pain patients at risk for opioid misuse. This dissertation also investigated the preliminary efficacy of IPGT in chronic pain patients at risk for opioid misuse.

Recruitment occurred from June 2018 until November 2018. All intervention components were delivered to 87% (n=13) of the participants, successfully achieving the goal of 75% or higher. IPGT recipients reported a high level of satisfaction with the intervention. Regarding preliminary efficacy, results showed that the IPGT intervention group made nonsignificant improvements in pain severity compared to the TAU control group (β =0.22, 95% CI= -0.24, 0.66, $p = 0.35$). However, we observed significant treatment by time interactions on the outcome of pain interference (β =3.32, 95% CI= 0.01, 6.65, $p = 0.05$) and pain catastrophizing (β =2.74,

95% CI= 0.49, 4.99, $p = 0.02$). We detected no significant differences in opioid misuse between participants who received the IPGT intervention and those patients in the control group (AOR= 069, 95% CI=-0.26, 1.64, p=0.16).

This dissertation provides initial support for IPGT being acceptable and feasible for delivery in chronic pain patients at risk for opioid misuse in which preliminary efficacy was demonstrated in both pain interference and pain catastrophizing. To better establish these findings, future studies should expand on these data by further investigating this intervention within a fully powered clinical trial framework. The preliminary findings of this dissertation support the next steps of the development of a novel treatment model (IPGT) which includes the social work lens to address chronic pain patients at risk for opioid misuse while providing greater insight into strategies to address this public health crisis.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

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"The roots of all goodness lie in the soil of appreciation for goodness." —Dalai Lama

Chapter One: Introduction

Problem Statement

The United States is experiencing an interrelated public health crisis, involving the management of chronic pain and the risks associated with opioid misuse. Opioid analgesics are a class of drugs that may result in pain relief and produce euphoric properties when ingested, and include drugs such as: oxycodone, hydrocodone, and morphine. Opioids are widely recognized as a legitimate source to treat pain but are associated with risks such as: misuse, opioid use disorder, diversion, and overdose fatalities (Gostin, Hodge, & Noe, 2017). Opioid misuse includes aberrant drug taking behaviors such as: early refills, taking medications at higher doses or more frequently than prescribed, doctor shopping, and using medications to cope with problems or for psychoactive effects (Knisely, Wunsch, Cropsey, & Campbell, 2008; Sullivan et al., 2010). Opioid misuse has become a major concern for health care providers among patients with chronic pain, which has primarily stemmed from the epidemic, prompting increased efforts to better understand this phenomenon and to develop preventative measures (Martel, Dolman, Edwards, Jamison, & Wasan, 2014; ,Brady, McCauley, & Back, 2015).

Within the United States, there is an unprecedented increase of opioid related morbidity and mortality where overdose deaths involving prescription opioids have quadrupled since 1999 (Chen, Hedegaard, & Warner, 2014). The Centers for Disease Control and Prevention (CDC) reported that in 2015, drug overdoses accounted for 52,404 fatalities in which 33,091 involved opioids (Rudd, 2016). Since 1999, the number of overdose deaths involving both prescription prescribed opioids and heroin have quadrupled (Control & Prevention, 2013). Within general population samples, the prevalence of chronic pain and opioid misuse is 11% to 19% (Nahin, 2015); (Schopflocher, Taenzer, & Jovey, 2011). Chronic pain and opioid misuse exact a heavy

toll on patients, physicians, and society as the annual mean of health care costs for patients who misuse opioids is 8.7 times greater than individuals who do not misuse (Ruetsch, 2010). According to the Centers for Disease Control and Prevention (CDC) more people die in the United States from opioid related overdosed than from motor vehicle accidents. The opioid epidemic takes roughly 44 lives daily, while a significant amount of individuals develop opioid misuse or addiction (Deborah Dowell, Tamara M Haegerich, & Roger Chou, 2016a). However, opioid overdoses are amenable to intervention given that risk factors are well understood, therefore harm reduction approaches such as providing overdose prevention and naloxone to individuals who are at risk is essential (Bowman, Eiserman, Beletsky, Stancliff, & Bruce, 2013). A fundamental challenge is to achieve a balance between decreasing the risks of opioid misuse, and associated harms, while optimizing pain care, including the provision of multidisciplinary treatments, which is pertinent to the social work profession (Lavigne, 2016).

Relevance to the Social Work Profession

Social workers are integral in various settings across the continuum of pain care and provide services to individuals and families throughout the lifespan, addressing the full range of biopsychosocial issues that impact well-being. Social workers play a critical role in advocating for policies that reduce health disparities and improve access to health care, especially for vulnerable populations. Unfortunately, inadequately treated pain is increasingly common in marginalized individuals (Institute of Medicine Committee on Advancing Pain Research & Education, 2011) and symptomology often complicates the trajectory of care (Gatchel, 2004). Inadequate treatment of pain depicts a problem demanding advocacy, and the social work profession is well positioned to address this issue given the profession's commitment to social justice. Social work has historically applied a biopsychosocial, strengths-based approach of

assessing a person within their environment while acknowledging the subjective nature of the individual's experience (Simpson, Williams, & Segall, 2007). This perspective is an essential platform allowing practitioners to attend to the social, cultural, political, ethical, psychological and spiritual aspects of pain care. Additionally, this approach is patient and family-centered, and moves beyond the medical model to a multidimensional focus, including political, regulatory, and legislative arenas which is pertinent to chronic pain (Mendenhall, 2003).

Healthcare in the United States is burdened with significant disparities associated with a variety of factors such as: insurance status, income, race, and ethnicity. Chronic pain can be understood as a public health challenge due to various reasons associated with prevalence, disparities, vulnerable populations, the utility of population health strategies, and the need of prevention at the population and individual level. While the risk for developing chronic pain is universal, there are particular populations who are disproportionately susceptible to chronic pain conditions and often are composed of vulnerable individuals which include both racial and ethnic minorities (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, & Riley, 2009; Meghani et al., 2012). Community-based studies of nationally representative samples have demonstrated individuals from racial and ethnic minorities are at a higher risk of more serious or activity-limiting pain (Reyes-Gibby, Aday, Todd, Cleeland, & Anderson, 2007). For instance, results from the 2000 Health and Retirement Study, indicated African Americans and Hispanic whites (27%) were more likely than non-Hispanic whites (17%) to report severe pain (Riley, Wade, Myers, Sheffield, Papas, & Price, 2002). Findings from the Wave 1 Public Use Files of the National Epidemiologic Survey suggested that Blacks were 1.40 (95% confidence interval [CI], 1.39–1.41) and Hispanics 1.25 (95% CI, 1.24–1.25) times more likely than non-Hispanic whites to report pain in the past four weeks that interfered with their activities ("quite a bit" or

"extremely") (Stinson, Grant, Dawson, Ruan, Huang, & Saha, 2005). However, what determines the prevalence of pain in a population is the extent to which it is assessed and treated. Regrettably, there is emerging literature which suggests there are lower rates of assessment in pain and higher rates of untreated or undertreated pain in African Americans (Riley, Wade, Myers, Sheffield, Papas, & Price, 2002). To address the complex needs of this vulnerable population, healthcare practitioners must recognize the social determinants of health, including biological, social, and psychological dimensions, which aligns strongly to the values and mandate of the social work profession.

Chronic pain often can precipitate physical and cognitive impairment, including psychiatric issues, disability and social isolation, which in return contributes to stigmatization. There is no standard approach to treat chronic pain and given the subjective and individualized nature of the condition, it can often produce invalidating experiences (Gilles J. Lavigne, 2016). The stigma associated with chronic pain has amplified given the effects of the opioid epidemic, as the rise in opioid misuse, abuse and overdose fatalities has made many patients with chronic pain feel ostracized and believed to be seen as drug seeking or 'addicts'. Stigma is harmful, distressing, and marginalizing, but can also result in barriers to accessing treatment, misdiagnosis, and inadequate treatment, and therefore it is fundamental for the chronic pain patient that this stigma is reversed. The personal, social, and economic consequences of stigmatizing behavior requires greater research understanding and innovative intervention strategies such as harm reduction, opioid overdose prevention, and naloxone distribution (De Ruddere & Craig, 2016) which social work is well situated to address given the profession's mission, core values, and focus on social justice (Parrott, 2016).

Definitions and Conceptual Terms

This section will be used to define the operational and conceptual definitions that will be used regularly throughout this dissertation.

Pain: Acute vs. Chronic

Opioid misuse often complicates the treatment trajectory for individuals with chronic pain, although better understanding the nature of pain offers additional insight into an individual's prognosis and the appropriate course of action (Savage, Kirsh, & Passik, 2008). The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described by the patient in terms of such damage." Chronic pain has been defined as pain typically lasting longer than three months or past the time of normal tissue healing and can be the outcome of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (H. E. Merskey, 1986). There are three dimensions generally evaluated in chronic pain, which are: severity, duration, and impact, including quality of life, disability and overall functionality (Wahl et al., 2009). Pain affects multiple facets of an individual's functioning and thus an interdisciplinary approach that incorporates various health care providers is essential for successful patient management (Dennis C Turk et al., 2010). The social work profession is fundamental when treating psychosocial elements of chronic pain. For instance, social workers typically conduct biopsychosocial assessments, which provides insight into cultural, psychological, social, and familial dynamics, helping to better understand a patient's overall pain experience and how best to intervene. Additionally, the profession's ability to address communication challenges, healthcare beliefs, and access to treatment can also potentially mediate healthcare disparities (Pasquale, Seehaus, & Horton, 2011).

Opioid Misuse vs. Opioid Use Disorder

The revisions of the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) includes several modifications for prescription opioid-use disorder. These changes incorporated the exclusion of tolerance and withdrawal symptoms for individuals taking opioid medications under appropriate medical supervision (Boscarino, Hoffman, & Han, 2015). In addition, due to the conceptual issues in the DSM-4 between abuse and dependence, recommendations in the DSM-5 included consolidating these symptom clusters into one distinct disorder with graded severity (Hasin et al., 2013).

Table 1. Differentiation Between Opioid Misuse and Opioid Use Disorder

Prescription Opioid Misuse Index: Misuse Behaviors	
Misuse Behaviors	• Taking more medication than prescribed • Taking medication too often • Early refills • Medication buzz • Medications to cope with emotional problems • Doctor Shopping
DSM-5 Diagnostic Categories and Criteria for Opioid Use Disorder	
Category	Criteria
Impaired Control	• Opioids used in larger amounts or for longer than intended • Cravings to use opioids • Unsuccessful efforts or desire to cut back or control opioid use • Excessive amount of time spent obtaining, using or recovering from opioid
Social Impairment	• Failure to fulfill major role obligations at work, school, or home as a result of recurrent opioid use • Persistent or recurrent social or interpersonal problems that are exacerbated by opioids or continued use of opioids despite these problems • Reduced social, occupational, or recreational activities because of opioid use
Risky Use	• Opioid use in physically hazardous situations • Continued opioid use despite knowledge of persistent psychological problem that is likely caused by opioid use • Continued use despite physical consequences of opioid use
Pharmacological Properties	• Tolerance: increased amounts of opioids needed to achieve desired effect • Withdrawal as demonstrated by symptoms of opioid withdrawal syndrome • Opioids taken to relieve or avoid withdrawal

The DSM does not diagnosis opioid misuse however the DSM approaches conceptualizing misuse, abuse, and addiction as related entities that differ in regards to the severity of presenting symptoms, behaviors, intent, and consequences. There is often some confusion around the terms opioid misuse as opposed to opioid use disorder. Further, the use of DSM criteria in the diagnosis of opioid use disorders in patients with chronic pain is often unclear especially in patients who are taking opioid analgesics for their pain condition. Table 1. demonstrates the differentiation between opioid misuse and opioid use disorder and further illustrates possible indicators specific to chronic pain patients. Better understanding the continuum of misuse and opioid use disorders helps to inform points of prevention and early intervention for chronic pain patient (S. C. Miller & Frankowski, 2012).

Harm Reduction, Naloxone, and the Opioid Epidemic

Harm Reduction can be defined as any program or policy that is aimed at reducing drug-related harm without necessarily requiring the cessation of drug use. With the growing opioid epidemic, there are many established and emerging harm reduction strategies to prevent opioid overdose-related mortalities, including overdose education and naloxone distribution, safe injection sites, drug checking services, opioid substitution therapy, and drug adherence therapies (Wermeling, 2010). This dissertation primarily focused on Naloxone which can be defined as a synthetic drug that blocks opiate receptors in the nervous system. Naloxone has a longstanding history in being used for the treatment of opioid overdose as it counteract life-threatening depression of the respiratory system and the central nervous system. Naloxone has no potential for abuse and may also induce withdrawal symptoms for those with physical dependency (Mueller, Walley, Calcaterra, Glanz, & Binswanger, 2015). Harm reduction is a valuable strategy

in addressing the opioid epidemic and should be considered for patients with chronic pain who are at risk for opioid misuse and overdose (Weinrib et al., 2017).

Theoretical Framework

There have been several theoretical frameworks that have been proposed to better understand the physiological basis of pain and when incorporated with theories specific to social work, can be an effective approach in conceptualizing evidenced based social work in the field of pain. This section will include two prominent theories in pain, the specificity theory and gate control theory, which help to inform the evolution of the etiology of pain. The ecological perspective and systems theory are well known to the field of social work and will be used to examine chronic pain and issues associated with opioid misuse, specifically from the lens of the profession. Lastly, the biopsychosocial model was applied to examine etiological factors that are pertinent to the social work profession and further how to integrate these theoretical notions into research and practice. It is a combination of blending theory with empiricism and fostering the development of social work theories that will serve to expand the profession's knowledge base to provide optimal multidisciplinary patient care (Adams et al., 2007; Barr, 2013)

The Initial Conceptualization of Pain: The Specificity Theory

During the 16th century, René Descartes, a French writer and 'Father of Modern Philosophy', adopted one of the first major contributions to the pain field. Descartes offered a theoretical drawing (Figure 1.) which revealed the transmission of pain information through the peripheral nerves and the spinal cord to the ventricles of the brain and the pineal organ where the conscious perception of a painful stimulus was believed to have been produced.

Figure 1. Descartes' Pain Pathway

Moayedi, M., & Davis, K. D. (2012). Theories of pain: from specificity to gate control. Journal of neurophysiology, 109(1), 5-12

This drawing helped to explain the specificity theory which considers pain as an independent sensation with specialized peripheral sensory receptors responding to damage and sending signals through pathways in the nervous system to target brain centers (H. Merskey, Loeser, & Dubner, 2005). This theory challenged previous beliefs that saw pain as a punishment inflicted by the Gods and helped to shape societal perspectives and the overall field of pain in the first half of the twentieth century (Reynolds, 1993).

Gate Control Theory: Liberalization of Pain Care

As time progressed, theories such as Descartes' specificity theory were no longer sufficient in explaining the whole experience of pain. While there were previous discoveries in the field since that time, one of the next ground breaking theories was developed by Ronald Melzack and Patrick Wall in 1965 and referred to as the gate control theory. The theory indicated that pain perception differs within each individual according to his or her emotional condition and prior pain experiences. According to the theory, pain signals do not necessarily reach the brain as soon as they are generated at the injured tissues or sites. They need to encounter certain 'neurological gates' at the spinal cord and these gates determine whether the pain signals reach

the brain or not. This theory significantly influenced the field's interpretation and understanding of pain, including overall management of care (Melzack & Wall, 1967).

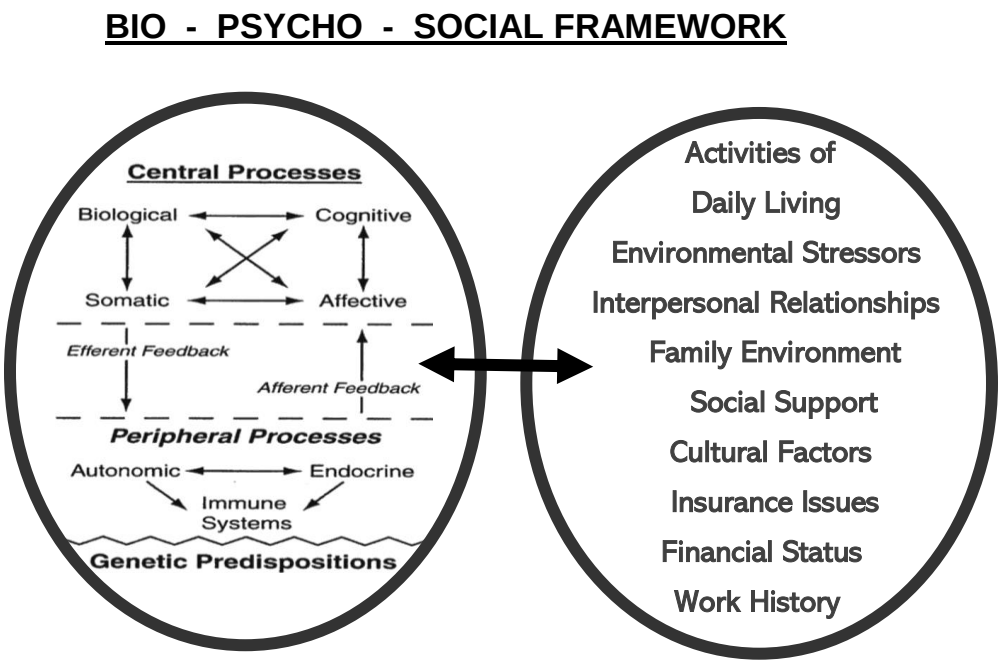
Gate control theory has been described as a sociological critique of entrenched power and practice. It was suggested that pain was being controlled by economic interests such as surgeons, drug companies, and psychiatrists who approached patients in pain with costly drugs and harmful neurosurgery when alternative methods would have sufficed. However, the gate control theory referenced ideas about the personality and psyche of the individual, which helped to argue that these patients were not necessarily a product of indulgence but rather a response to social oppression (Kugelmann, 1997). This motivated the field to consider alternative remedies and supported the liberalization of pain medicine (Wailoo, 2014). The gate control theory eventually transformed into what is largely accepted as the biopsychosocial model of pain care. This ultimately led to the growth of the field of behavioral medicine, health psychology, and social work which has been largely influential in the developments of social policy (Engel, 1977).

Biopsychosocial Perspective, Chronic Pain Management and Opioid Misuse

The biopsychosocial perspective was developed in the late 1970's by Drs. George Engel and John Romano in an attempt to offer medical practitioners a framework to systematically attend to the biological, psychological, and social dimensions of illness (Engel, 1997). Pain research has traditionally focused on sensory modalities and the neurological transmissions identified solely on a biological level. Although with interdisciplinary advancements in the field, there has been an emergence to look beyond the biomedical domains of chronic pain and the condition is now commonly accepted as a biopsychosocial phenomenon (Gatchel, 2004). The model acknowledges that pathology consists of inter-related mechanisms categorized into:

biological, psychological, and environmental or social causes as depicted in Figure 2. (M. J. Sullivan, Feuerstein, Gatchel, Linton, & Pransky, 2005).

Figure 2: Biopsychosocial Perspective of Chronic Pain



From "Comorbidity of Chronic Mental and Physical Health Conditions: The Biopsychosocial Perspective," by R. J. Gatchel, American Psychologist, 59, 792– 805. Copyright 2004 by the American Psychological Association.

The biopsychosocial model is extensively recognized in the addiction field and with regard to opioid misuse, the US, Canada, European, and UK guidelines for opioid management in chronic pain recommend incorporating multidisciplinary, psychosocial or behavioral approaches into patient care plans (Nicholas, Molloy, & Brooker, 2006). The interrelationships among biological changes, psychological status, substance use patterns, and the sociocultural context must be considered to fully understand an individual's perception and response to pain. Furthermore, any model that focuses solely on one of these dimensions is largely inadequate and will be problematic in the assessment and treatment of the patient (Robert J Gatchel, Yuan Bo Peng, Madelon L Peters, Perry N Fuchs, & Dennis C Turk, 2007). This frequently has occurred

within the recent opioid epidemic where opioid analgesics become the primary means of treatment and nonpharmacologic therapies are underutilized or dismissed completely. Despite evidence-based guidelines, which suggest interdisciplinary care reduces pain and improves functionality, exclusively focusing on pharmacological therapy will continue to perpetuate the escalation of opioid prescriptions for this patient population, potentially increasing rates of misuse and inadequate management of pain (Taylor, 2004).

Systems Theory and Ecological Perspective in Chronic Pain

Systems theory and ecological perspective is complementary to the biopsychosocial model, given that each ideological lens embraces a transactional relational multifaceted understanding of the situation. In the application of systems theory to address the etiology of pain, the individual is viewed in a larger context where other systems exist and is further situated in an encapsulating system where the interactions influence the infrastructure and its parts (Chapman, Tuckett, & Song, 2008). Pain can in part be explained by the concept of allostasis which the essence of the stress response is. When a stressor such as tissue damage persists for an extended period of time, or when other internal or external and environmental stressors occur in a rapid or persistent manner, allostasis may use resources quicker than the body can replenish them (Chapman et al., 2008). In this transactional process, when encountered with a stressor, the individual modifies their level of metabolic activity to adapt to environmental demands that inhibit what is referred to as an allostatic load. This can potentially lead to maladaptive responses inducing a series of stress-related pathophysiological strains which in turn can trigger the amplification and the persistence of the pain state, having the potential to lead to chronicity (Juster, McEwen, & Lupien, 2010).

There are heritable individual differences to the stress response which originates from two causal mechanisms: genetics and epigenetics, which jointly influences system interactions and also contributes to the development of chronic pain (Von Bertalanffy, 1968). The psychosocial system surrounding the individual is a potential source of stressors that demand an allostatic response. In the presence of psychosocial stressors, acute stress responses can fail to resolve appropriately and fundamentally can lead to the onset of chronic pain (Chapman et al., 2008). To further explicate this transactional relationship, the concept of plasticity is examined as the brain's capacity to change as a result of input given its exposed environment. Despite common misconceptions, genetics are not a fixed entity, rather their expression can change due to psychosocial and environmental factors (Kim et al., 2004). For instance, a hypersensitive stress response can eventually overtime manifest a mental health problem such as anxiety or pain catastrophizing behavior, both which can pose as the means of a coping mechanism (McEwen & Gianaros, 2011). An individual's reactions to stress, and how they perceive the stimulus can either promote or inhibit practices supporting health, has the potential to shape an individual's experience of pain. Unhealthy coping such as substance abuse and/or opioid misuse can also be a maladaptive way of attempting to overcome such problems (M. J. Sullivan et al., 2001). Moderating factors including social supports also influences a person's capacity to adapt and effectively respond to stress (Lyon, 2000).

Both systems theory and the ecological perspective offers an alternative approach from medical and disease orientated frameworks (De Hoyos & Jensen, 1985) which is pertinent to chronic pain and issues pertaining to opioid misuse (Guzman et al., 2002). Chronic pain and opioid misuse are recognized as a biopsychosocial condition in which assessment and development of effective intervention strategies requires consideration of the individual in

relation to their biological, psychological and social context (Wahl et al., 2009). Blending systems theory and ecological perspective with the biopsychosocial model, provides a rich and effective framework for analyzing complex systems with the goal of enhancing the "goodness of fit" between an individual and their environment (Allen & Friedman, 2010). Pain management transactions have often been described as problematic due to traditional health care models which are often medically driven and not reflective of psychosocial origins of pathology. Patients who do not "fit" the system, often experience either problems with access to care or inadequate treatment, with some patients even being blamed for their condition (Mendenhall, 2003). Stigma and common misconceptions about pain and substance use disorders, often further complicates optimal care. This is particularly representative of chronic pain patients who elicit challenging behaviors associated with either mental health or substance use issues and can often be seen as drug seeking (Dersh, Polatin, & Gatchel, 2002).

Patients with chronic pain and aberrant drug-related behaviors are often discontinued from opioid treatment as a result of their misuse behaviors (Jamison et al., 2010; Sehgal, Manchikanti, & Smith, 2012) rather than being prescribed adherence interventions. As a result, their risk for increased rates of substance use or relapse are significantly heightened, and incongruously, their pain remains problematic. Inadequate treatment of opioid misuse can lead to a vicious cycle that negatively affects the patient's physical and psychological functionality, pain severity, and overall quality of life (Howe & Sullivan, 2014). Consequently, worsening psychological, social, and physiological processes interact to negatively affect perception, transmission, and evaluation of pain. Heightened psychological symptoms, such as anxiety, depression and pain catastrophizing, also create additional challenges in pain management (Melzack, 1999). These psychological impacts underscore the importance of recognizing all

facets within the biopsychosocial model and how each system interacts, which is fundamental to consider when treating an individual with chronic pain and opioid misuse. From a theoretical position, systems theory and ecological perspective strive for an understanding of the multidimensional transactions in understanding and rigorously treating the chronic pain patient. This combined within a biopsychosocial framework is particularly beneficial in understanding the intricate psychosocial factors of individuals with comorbid opioid misuse. Approaching the problem with such a multidimensional lens is patient-centered as it validates the individual and their environment and is more reflective of the biopsychosocial elements of both pain management and opioid misuse which is also complementary of the social work profession (Mendenhall, 2003).

Empirical Support of Theoretical Frameworks

The research examining specificity theory, gate control theory, the biopsychosocial model and systems theory are limited. Initially, evidence for the specificity theory came from Schiff and Woroschiloff's findings of pain pathways in the spinal cord in a series of experiments from 1854 to 1859. However as new research emerged this theory became outdated and there was room for advancement (Rey, 1995). Melzack and Wall (1965) initially discussed the shortcomings of the specificity theory and attempted to expand on this theory with a framework based on the aspects corroborated by physiological data. However, there is less empirical research on the biopsychosocial model, systems theory and the ecological perspective given the subjective nature of these theories. While the empirical research is limited, there have been various review articles or observational studies which address these theories which include: the biopsychosocial framework (Gatchel, 2004; Hatala, 2012; Wahl et al 2009), systems theory (Chapman, Tuckett, & Song, 2008; Dersh, 2002), and the ecological perspective (Germain, 1979; Gitterman, &

Germain, 2008; Mendenhall, 2003). There have been less empirical efforts which blend these theoretical viewpoints in an attempt to better understand the issues pertaining to chronic pain and opioid misuse. Although, there have been some scholars in the field who have acknowledged that the unification of these perspectives provides a rich and effective framework for analyzing these complex systems (Friedman & Allen, 2010).

Each of the pain theories discussed in this dissertation describes a series of observations about the nociceptive system and pain perception. However, it is important to note that none of the theories sufficiently account for the complexity of the pain system. There is a large amount of subjectivity when attempting to provide explanation for something as intricate as human behavior, which makes it challenging to provide robust support for such theories (Montano & Kasprzyk, 2015). Empirical evidence and theory should not be seen as competing forces but as a seamless entity, integrating deductive and inductive elements into the scientific process. While practice requires a strong evidence base, if this is derived from the collection of empirical evidence alone, there is a risk that the focus will remain strictly on the 'proven' interventions (Green, 2000). Similarly, theory in isolation is insufficient in attempting to advance social work practice; it is vital that this process is well documented and published. Evidence about the use of theory to guide practice will help to strengthen the knowledge base for the profession and better serve the diverse needs of this population (Van den Broucke, 2012).

Theoretical Applications of Integrated Psychosocial Group Treatment (IPGT)

There is a common understanding that theory should be used to help inform the development of clinical interventions (Steinmo et al., 2016), and specifically in the field of pain (Apkarian, Baliki, & Geha, 2009). Unfortunately, often theory can be viewed as "abstract, intimidating, irrelevant" (Craig et al., 2013), and dismissed throughout the intervention design.

This lack of explicit behavioral theory within the design stage often results in outcomes that are poor in efficacy (Improved Clinical Effectiveness through Behavioural Research, 2006; Michie et al., 2005) which underscores the significance of incorporating a strong theoretical framework into behavioral health research. This dissertation utilizes the gate control theory, ecological perspectives, systems theory and the biopsychosocial model to help inform the design of IPGT.

The gate control theory has initiated a drastic revolution in the field of pain as the theory suggests that pain management can be achieved by selectively influencing the larger nerve fibers that carry non-pain stimuli. The theory has also helped to expand and support behavioral health research on cognitive and behavioral approaches to pain care (Mendell, 2014) which is particularly relevant to the conceptual basis of the IPGT model. The gate control theory underscores that emotions and thoughts determine the way how pain is perceived. For instance, patients with chronic pain who are anxious or depressed can often feel intense pain and have issues with coping. This is because the brain sends messages through descending fibers that stop, reduce or amplify the transmission of pain signals through the gate, depending on the thoughts and emotions of that patient. Positive emotions, distraction, and deep relaxed breathing can act to partially close the gate while strong emotions like fear, anxiety, and catastrophizing open the gate. Therefore, IGPT recognizes that "closing the gate" refers to the reduction in pain perception and the intervention predominately targets the emotional and cognitive components of the pain experience. IPGT utilizes emotional and cognitive factors which include: psychoeducation, cognitive behavioral therapy, mindfulness-based strategies and relaxation techniques while also allowing for emotional and peer support. Topics covered include: pacing and goal setting, negative thinking, coping with stress and anxiety, managing set-backs, treatment adherence, and quality of life.

The social work perspective helps to contribute in the development of an innovative approach in the design of IPGT by using two social work theories which are built into the conceptual foundation of the intervention. Systems theory and ecological perspective acknowledge that behavior is influenced by a variety of factors that function together as a whole system (Adams et al., 2007). In the application of systems theory, a social worker must examine all systems that contribute to an individual's behavior, and work to strengthen those systems. IPGT considers the various parts of systems that a pain patient encounter and aims to target these individual factors in order to enhance pain outcomes. An individual's response to stress can either promote or inhibit actions that shape an individual's experience of pain. Unhealthy coping such as opioid misuse can also be a maladaptive way of attempting to overcome such problems (M. J. Sullivan et al., 2001). IPGT preemptively incorporates strategies to mitigate individual risk factors of opioid misuse which overtime if not addressed could perpetuate into opioid use disorder. IPGT aims to assess individual risk factors of the pain patient's larger system, and responds by using various psychosocial interventions that are best fitted to the patient, with an aim of enhancing pain outcomes while decreasing risk for opioid misuse (Lyon, 2000). Both systems theory and the ecological perspective offer an alternative approach from medical models (De Hoyos & Jensen, 1985) which is pertinent to chronic pain, issues related to opioid misuse (Guzman et al., 2002) and that encompass core social work values (Pasquale et al., 2011).

IPGT acknowledges that chronic pain and opioid misuse are a biopsychosocial condition which require intervention strategies that consider the individual in relation to their biological, psychological and social context (Wahl et al., 2009). The intervention design of IPGT encompasses the theoretical notions that psychological, social, and physiological processes interact to affect perception, transmission, and evaluation of pain. For instance, psychological

symptoms, such as anxiety, depression and pain catastrophizing, in addition to social factors such as poor support systems create challenges in the management of pain (Melzack, 1999). Therefore, IPGT aims to assertively and simultaneously target each of these psychosocial factors which are fundamental to the pain experience while also addressing risk factors associated with opioid misuse. IPGT blends systems theory, ecological perspective, along with the biopsychosocial model, which provides a robust framework for analyzing and addressing pain systems which is fundamental to consider with chronic patients who are at risk for opioid misuse. IPGT is particularly relevant and complementary to the social work field as it approaches treatment from a multidimensional lens which is patient-centered and is reflective of the biopsychosocial elements of both pain and opioid misuse (Mendenhall, 2003).

Statement of Purpose and Research Questions:

At the center of the opioid public health crisis, concerning the management of chronic pain and the risks associated with opioid misuse, exists an emphasis for both prevention and treatment. From a biopsychosocial, systems theory and ecological perspective, chronic pain is seen as a multifaceted experience emerging from the dynamic interplay of a patient's physiological state, thoughts, emotions, behaviors, and sociocultural influences (Roditi & Robinson, 2011). The field has made significant progress in the realm of chronic pain management through the applications of biopsychosocial treatments (Robert J Gatchel, Yuan Bo Peng, Madelon L Peters, Perry N Fuchs, & Dennis C Turk, 2007). However, with the devastating effects of the opioid epidemic, there has been less advances in preventative approaches targeting chronic pain patients who are at risk for opioid misuse and associated harms such as overdose.

A pilot randomized controlled trial (RCT) was conducted to investigate an IPGT model targeting patients with chronic pain who are at risk for opioid misuse. The primary objective was

to assess IPGT's feasibility and acceptability in patients with chronic pain who are at risk for opioid misuse. In addition to examining feasibility and acceptability, this study also conducted an exploratory analysis of the preliminary efficacy of the intervention. The exploratory research questions included, does this behavioral intervention, when applied to patients with chronic pain who are at risk for opioid misuse, potentially produce: (1) a reduction in the number of opioid misuse behaviors; (2) a decrease in pain severity, interference, and catastrophizing; (3) and enhanced knowledge of opioids, overdose, overdose response, and naloxone administration. To the author's knowledge, a behavioral intervention and risk reduction model that incorporates overdose education and training on naloxone administration has not been tested within chronic pain patients who are at risk for opioid misuse. This pilot project was a necessary first step in exploring this novel intervention in which the study results have helped to inform preliminary efficacy and both feasibility and acceptability, which is instructive in that it points to modifications needed in the planning and design of a larger efficacy trial.

Chapter Two: Literature Review

As opioid misuse and corresponding rates of opioid use disorders and overdose deaths exceed epidemic proportions, there is an urgent need for research in this area. The objective of this section is to review the literature on both macro and micro levels of intervention on chronic pain and opioid misuse. This offers a unique contribution to the field given that the majority of the current literature explicitly focuses on either chronic pain or substance use disorders. In the development of effective clinical interventions, it becomes imperative to have a strong knowledge of evidence-based practices in addition to current policies, guidelines, and other governing bodies that help to inform both pain care and issues pertaining to the opioid crisis.

Chronic Pain and Opioid Misuse: Macro Level Initiatives

When addressing the social problems associated with chronic pain and the opioid epidemic, it is essential to examine macro levels of intervention to better understand how they help to inform evidenced based practices, including prevention and early intervention. Various target areas that are particularly important include: administration, research, policy and education or curriculum development. The objective of this section is to review some of the larger macro initiatives addressing chronic pain and opioid misuse, and particularly how they influence and inform clinical practice. The following macro level initiatives will be examined: prevention and intervention strategies to decrease misuse of prescription pain medication, overdose education and naloxone distribution (OEND), and prevention and promotion through advancing pain care.

The Culture of Opioid Prescribing

The number of opioid prescriptions for chronic pain has increased substantially in the United States over the past two decades (Chou et al., 2009) and with this rise in prescribing patterns, opioids have garnished a large amount of attention in issues of misuse, abuse, and

overdose fatality (Califf, Woodcock, & Ostroff, 2016). Physicians are often conflicted about their decisions to prescribe opioid medications as the complexities of this enigma can be summarized in the following quote: "*Opioids play a unique role in society. They are a widely feared compound, associated with abuse, addiction and diversion, but are also the most effective drugs for the relief of pain and suffering*" (A. Rosenblum, Marsch, L., Joseph, H., Portenoy, R. , 2008). Despite advances in pain care, there is still significant controversy regarding prescription opioids including: type of conditions that should be treated, treatment efficacy in specific patient populations, and well defined clinical objectives including duration and dosage of the prescription (Ballantyne & LaForge, 2007). Amongst this ambiguity, there are various factors that contribute to the culture of prescribing. Physician concern about misuse and abuse of opioid medications is a detrimental factor that influences both attitudes and prescribing behaviors. This is especially relevant with the recent pressures of the opioid epidemic, which has been largely promoted by the media (Wallwork, Chipidza, & Stern, 2016). There has been a historical practice of inappropriate prescribing which is believed to have contributed to the increase in prescription opioids and consequently the proliferations of opioid misuse, diversion, and overdose. However, on the opposite continuum, with the vagueness in prescription guidelines, some physicians act with caution and prescribe reluctantly. Beyond the pressures caused by the opioid crisis, physicians can encounter serious legal sanctions including: malpractice liability, medical board discipline, and criminal convictions (Dineen & DuBois, 2016). It has been suggested that some of these factors have helped to curb the opioid epidemic however in other instances have compromised the quality of care provided with more of an emphasis needing to be placed on multidisciplinary treatments (Dineen & DuBois, 2016; Teo & Bal, 2016).

The long-term administration of opioid treatment for chronic non-cancer pain is controversial as there are trepidations regarding the effectiveness, safety, and abuse liability of the drug (Rosenblum, Marsch, Joseph, & Portenoy, 2008). While management of chronic pain with opioids is applied to this population, there is the potential for individuals' pain to exacerbate, despite aggressive therapy. There has been a growing amount of literature to support the conclusion that this increase in pain can be due to a condition called opioid-induced hyperalgesia (OIH). OIH may be more formally defined as increased nociceptive sensitization caused by long-term exposure to opioids, though the clinical prevalence of OIH continues to remain unknown (Marion Lee, Sanford Silverman, Hans Hansen, & Vikram Patel, 2011). Published guidelines for future opioid pharmacotherapy research have called for action the need for increased investigation into OIH. The authors noted that specific clinical guidelines for OIH are lacking which perpetuates the unnecessary prescription of the medication and particularly with regard to chronic pain, resulting an unfortunate aftermath (Tompkins & Campbell, 2011).

Further complicating the decision regarding long term opiate prescribing is the extensive proliferation in the diversion and abuse of the drug. In addition to their addictive potential, high doses of opiate analgesics can also cause profound respiratory depression, which has been the leading cause of death from these drugs. Given these reasons, opioid diversion has been magnified by the parallel growth of emergency room visits and deaths due to prescription opioid overdose (Fields, 2011). A number of historical factors have influenced the growth of opioid misuse in the United States, however it is believed that the past increased availability of the drug has been a main contributor to this profound issue. In particular, past marketing and promotion by the pharmaceutical industry has significantly amplified the prescription sales and availability of opioids, further propagating this social problem (Van Zee, 2009). The interface between the

legitimate use to provide analgesia and the occurrences associated with misuse and diversion continues to poses challenges to the field which has led to uncertainty about the appropriate role of these drugs in the treatment of pain and in particular, chronic pain (Rosenblum et al., 2008). Within best practices of management of chronic pain, appropriate opioid prescribing is essential in order to: achieve adequate pain control, to minimize patient risk of abuse, addiction, and fatal toxicity, and to minimize societal harms from diversion (Ballantyne & Mao, 2003). Given the complicating factors of opioid use for chronic pain, it is important to acknowledge that chronic pain is not only influenced by somatic pathology, but also by psychological and social factors, and thus multidisciplinary interventions must be considered at the policy level.

There is a current movement of policymakers and stakeholders attempting to explore opportunities and obstacles to change the culture of prescribing opioid medications. The Center for Disease Control (CDC) analyzed retail prescription data from QuintilesIMS to assess opioid prescribing in the US from 2006 to 2015. This included rates, amounts, dosages, and duration of opioid medications prescribed. The quantity of opioids prescribed in the US peaked in 2010 and then declined each year through to 2015. Variations in prescribing practices were examined and it was found that half of US counties had a decline in the amount of opioids prescribed per person from 2010 to 2015, although the morphine milligram equivalents (MME) prescribed per person in 2015 was about 3 times as high as in 1999. County-level characteristics, such as rural versus urban, income level, and demographics, only accounted for approximately one third of the differences. Furthermore, the variation in opioid prescribing at the county level suggests inconsistent practices and problems with the application of guidelines for prescribing opioids. To effectively address the opioid epidemic, it is essential to increase access to evidence-based treatment for chronic pain and opioid misuse. The proper identification of those who are at risk

or already misusing their medications allows for appropriate referrals to address both pain management and issues pertaining to medication adherence (Alan D Kaye et al., 2017).

Pain as the Fifth Vital Sign: An Attempt to Improve Pain Care?

International efforts have occurred to improve pain assessment and management, with significant developments in 1995 when the American Pain Society (APS) introduced the phrase "pain as the fifth vital sign". This phrase emphasized that pain assessment was just as imperative as the standard four vital signs and that practitioners are required to take action when patients report pain (Mularski et al., 2006). Shortly after this phrase was introduced, Purdue Pharma released OxyContin, a form of oxycodone in a patented time-released form, which exploded the market (Laxmaiah Manchikanti, Sairam Atluri, & Hans Hansen, 2014). Following this movement, legislators were encouraging state medical and nursing boards to develop guidelines for pain and symptom management. These guidelines placed a requirement on licensed health care facilities and educational programs to integrate pain as the fifth vital sign into their curriculum (Walid, Donahue, Darmohray, Hyer Jr, & Robinson Jr, 2008). Unfortunately, the legislation for 'the right to pain relief' were misunderstanding of the consequences of inappropriate opioid use in chronic pain, including misuse, abuse, and overdose fatalities. In conjunction with increased efforts to improve pain care, studies regarding substance use trends in the US reported that non-medical use of prescription opioids has increased over threefold since 1990, (Hall et al., 2008) with tripled rates of overdose fatalities (Cobaugh et al., 2014). Over a decade later, in 2012, sales of prescription opioids totaled more than $9 billion a year. In 2007, Purdue Pharma pleaded guilty to misbranding OxyContin as less addictive when compared to other pain medicines and as a result, they paid $635 million in fines (Laxmaiah Manchikanti et al., 2014).

There are various speculations as to the reasons for the opioid epidemic, but specifically pertaining pain as the fifth vital sign, there was some concern that this movement created practitioner awareness without preparedness. Additionally, it can be projected that the increase in prescription opioids highlights the misconception that pain is a unidimensional problem requiring solely medical treatments. Chronic pain is a complex issue and attempting to box it into a vital sign may inadvertently decrease the value of a comprehensive pain assessment. While the fifth vital sign helps to recognize when a patient is in pain, this information alone is not complete and requires further action for appropriate care (Morone & Weiner, 2013). The interface between the legitimate use of opioids to provide analgesia and the occurrences associated with misuse continues to pose challenges to the field which has led to uncertainty about the appropriate role of these drugs in the treatment of pain and in particular, Chronic pain (Rosenblum et al., 2008). Issues associated with risk for misuse in conjunction with inadequate treatment of pain, underscores the importance for the provisions of interdisciplinary treatments that in the social work profession is uniquely positioned to offer strong contributions to the field.

Chronic Pain, Prevalence, and Risk Factors for Misuse and Opioid Use Disorder

Opioid abuse and misuse occur for a number of reasons, including purposes of self-medication, maladaptive coping, and use to achieve reward and euphoric properties. However, the trajectory of misuse and opioid use disorder within chronic pain patients is unique which often poses differences in motivations for the development, prevalence rates, and risk factors for the co-occurrence (Alan D. Kaye et al., 2017). In 2015, of the 91.8 million adults in the United States who used prescription opioids, it has been estimated that 12.5% misused the medications (Han et al., 2017) and specifically within general population samples, the prevalence of chronic pain and opioid misuse is 11% to 19% (Nahin, 2015); (Schopflocher, Taenzer, & Jovey, 2011).

There is literature that suggests individuals without opioid use disorders reported pain as a main reason for misuse behaviors (63%), whereas over half of the individuals with opioid use disorder and other substance use disorders reported different reasons such as misusing opioids for achieving euphoric states. Prescription opioid misuse among individuals entering substance abuse treatment was reported to be due to withdrawal prevention and taking the drug 'to get high', however there was somewhat of a larger rate in the subgroup of heroin users that misused opioids for pain relief (Trafton, Oliva, Horst, Minkel, & Humphreys, 2004).

Typically, it has been presumed that chronic pain precedes the onset of misuse and opioid use disorders, however there has been research that suggest that opioid use disorders often occur prior to the onset of chronic pain. In the National Comorbidity Survey Replication (NCS-R), among those with pain and opioid use disorder, the opioid use disorder preceded pain in 58.2%, and pain preceded the opioid use disorder in 35.4% (Ilgen, Perron, Czyz, McCammon, & Trafton, 2010). Patients with chronic pain and co-occurring substance use disorders and/or mental health disorders, are often at a higher risk for misuse of prescribed opioids (Sehgal et al., 2012). Additionally, there have been various demographic and historical factors such as history of substance abuse, legal problems, trauma, and presence of mood disorder which have been associated with increased risk for misuse of opioids (Dennis C. Turk, Swanson, & Gatchel, 2008). The Opioid Risk Tool (ORT), is a commonly used opioid risk assessment measure, and it screens for family and personal history, age, trauma, and psychological diagnosis (Lynn R. Webster & Rebecca M. Webster, 2005). There have been various psychological factors that have also been associated with increased risk for misuse and offer some advantage in addressing potentially modifiable mechanisms that underlie risk. In particular, pain-catastrophizing has been associated with increased risk of opioid misuse (Martel, Wasan, Jamison, & Edwards, 2013), in

addition to various pain-related outcomes such as depression and disability (Arnow et al., 2011). Pain catastrophizing can be defined as an exaggerated negative reaction or response to pain, and includes: rumination and magnification of pain, as well as feelings of helplessness (Sullivan, Bishop, & J. Pivik, 1995). In addition, catastrophizing has been shown to be associated with craving for opioid medications, even after accounting for depression, pain severity and duration, patient history of substance use problems, and opioid dosage (Marc, Martel, Jamison, Wasan, & Edwards, 2014). Distress intolerance is another psychological construct that has been associated with increased risk for opioid misuse in chronic pain patients. Among individuals with chronic pain, those who were less likely to tolerate physical or emotional distress had an increased likelihood to misuse opioid medications. It was hypothesized that this likely occurs because individuals who are unable to effectively regulate their pain or distressing emotions may seek instant stress relief through behaviors such as substance use, risk taking, avoidance, and escapism (McHugh et al., 2016). Identifying risk factors associated with possible misuse is critical among healthcare providers, and requires regular screening protocols (Bowman et al., 2013; Chou et al., 2015b; Dowell, Haegerich, & Chou, 2016b).

Currently, screening for opioid misuse includes assessment of premorbid and comorbid substance abuse; assessment of aberrant drug-related behaviors; risk stratification; opioid screening tools; urine drug testing; prescription monitoring programs; opioid treatment agreements; and utilization of universal precautions (Sehgal et al., 2012). Prevention and early intervention is pivotal, and treatment often only occurs once a problem is identified and therefore screening and identifying patients who are at risk for misuse will help to facilitate direct referral pathways to appropriate care (Moore, Jones, Browder, Daffron, & Passik, 2009). This is an under-examined subject, as studies investigating opioid misuse screening, assessment, and

intervention protocols are nearly non-existent (Bowman et al., 2013). Given the deleterious consequences of the opioid crisis, there is a critical need for this work.

The Changing Face of the Opioid Epidemic

Overcoming the opioid crisis requires that the field has a thorough understanding of opioid use patterns that have occurred throughout the epidemic, as more recently there has been some significant shifts which are fundamental to consider. From 2010 to 2013, there was a substantial reduction of opioid medication abuse and a concurrent increase in abuse of heroin (Dart et al., 2015). Additionally, the Centers for Disease Control and Prevention has indicated that there has been 10,574 heroin overdose deaths in 2014, which is more than a fivefold increase of the heroin death rate from 2002 to 2014 (Al-Tayyib, Koester, & Riggs, 2017). According to the National Institute on Drug Abuse, it has been projected that 4 to 6% of individuals who misuse prescription opioids transition to heroin. A study in 2016, found that over a 36-month period, 27 (7.5%) out of 362 participants who were initially abusing prescription opioids initiated heroin use, with the rate of heroin initiation at 2.8 % per year (Carlson, Nahhas, Martins, & Daniulaityte, 2016). Another study in 2017, demonstrated that about 1 in 13 participants (7.7%) who were abusing prescription opioids, later initiated heroin (Surratt et al., 2017). Until more data are available, the most recent evidence proposes a less than 10% incidence of individuals abusing opioid medications transitioning to heroin use. However, on the opposite continuum, one study predicted about 80 percent of current heroin users reported that they began their drug use with prescription opioids (Jones, 2013). The demographics of heroin use have also dramatically changed over time. Typically, those who used heroin in the 1960s were mostly racially heterogeneous young people, however those who used heroin in subsequent decades were often mostly older Caucasian men who started their drug use with prescription opioids (Cicero, Ellis,

Surratt, & Kurtz, 2014; Martins et al., 2017). Although, this trend seems to be reversing, for instance from 2005 to 2013, opioid initiation with prescription opioids among treatment-seeking heroin users decreased from 84% to 52%, but opioid initiation with heroin rose from 8.7% to 33% (Cicero et al., 2014). Given that the use of prescription opioids alone is declining among those with opioid use disorder, their concurrent use with heroin is in general progressively increasing (Cicero, Ellis, & Harney, 2015).

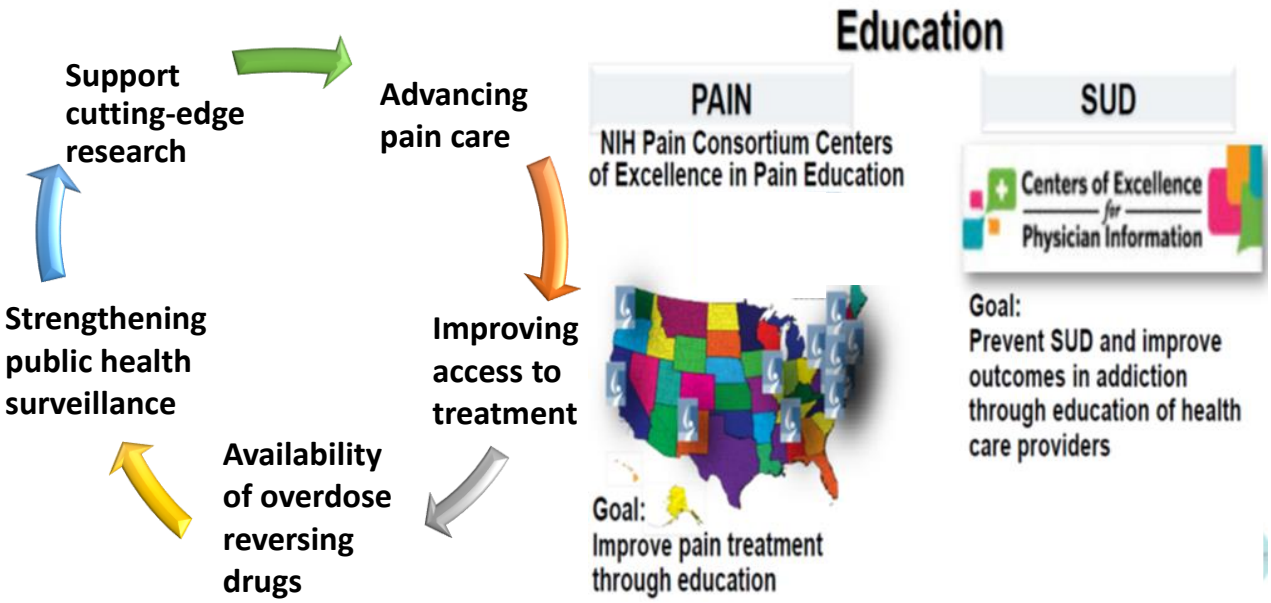
The factors contributing to the changing face of the opioid epidemic are not well established as studies that examine patterns of heroin use in nonmedical users of prescription opioids are primarily observational and descriptive, posing uncertainty of cause and effect. Although, consistent findings of a positive association between nonmedical use of prescription opioids and heroin use are conceivable, due to the common pharmacologic principles (Compton, Jones, & Baldwin, 2016). Given that prescription opioid analgesics are legal, and the dose is clearly specified on a distinctive tablet, it has been speculated that this can help to create the perception that these drugs are safer to use than other illicit substances (Cicero et al., 2015). Trajectory analysis of patterns of opioid and heroin use disorders suggests that individuals often start with oral nonmedical use of opioids. Next, they progress to more efficient routes of administration, including insufflation, smoking, or injection, as tolerance to opioids develops and it becomes more costly to maintain their level of use. Once an individual is to initiate heroin, it can often be viewed as consistently available, more potent, easier to manipulate for nonoral routes, and more cost-effective than prescription opioids (Cicero et al., 2014; Lankenau et al., 2012; Siegal, Carlson, Kenne, & Swora, 2003). Individuals who inject drugs are not only at risk to the harms related to the drug itself but also to the harms related to injection, such as: risk of abscesses, tissue infections, ulcers at the site of injection, and endocarditis (Smith, Robinowitz,

Chaulk, & Johnson, 2014). For individuals who share injection equipment, they also encounter risk of contracting bloodborne infections such as hepatitis C virus and HIV (Rich, Bia, Altice, & Feinberg, 2018). Recognizing that the public health effects of prescription opioids and heroin are intertwined, helps to underscore that combatting the epidemic will require an approach that includes prevention and harm reduction strategies. This dissertation ascribes to an upstream framework by targeting a demographic, which are patients with chronic pain who are at risk of opioid misuse through applying a psychosocial intervention aimed at preventing potential misuse of opioid medications and in the extreme form, heroin initiation.

National Efforts to Curb the Prescription Opioid Epidemic

In response to the opioid crisis as depicted in Figure 3., the US Human Health and Services (HHS) is focusing its efforts on five major priorities which include: (1) strengthening our understanding of the epidemic through public surveillance; (2) support for cutting-edge research on pain and addiction; (3) advancing practices for pain management; (4) improving access to treatment and recovery services; and (5) promoting use of overdose-reversing drugs (Macrae, Hyde, & Slavitt, 2016).

Figure 3. The US Human Health and Services' (HHS) Opioid Crisis Strategy



Adapted from: Macrae J, Hyde P, Slavitt A. HHS Launches Multi-pronged Effort to Combat Opioid Abuse Washington, DC: US Department of Health & Human Services; July 27, 2015. 2016.

The four macro levels of intervention explored in this dissertation include: (1) Prevention of decreasing opioid misuse and harms associated; (2) overdose education and naloxone distribution (OENDS); and (3) primary prevention through a cultural transformation of pain care.

Prevention: Decreasing Opioid Misuse and Harms Associated

More recently, there has been an urgent need to better understand the scale of the opioid epidemic and to further implement various risk mitigation strategies. Efforts to address the opioid epidemic have primarily focused on the reduction of nonmedical opioid medication use. However, the NIH is currently launching an initiative in the following areas: (1) developing better overdose-reversal and prevention interventions to reduce mortality; (2) saving lives for future treatment and recovery; (3) finding new medications and technologies to treat misuse and opioid use disorders; and (4) finding safe, effective, nonaddictive approaches to manage chronic pain, including behavioral health interventions (Volkow & Collins, 2017). Identifying evidence-

based preventive measures for opioid misuse continues to be an ongoing effort that will require more documentation of how prevention can best ameliorate the opioid crisis. A multifaceted approach that utilizes primary, secondary, and tertiary prevention strategies is needed to successfully decrease opioid-related morbidity and mortality (Hawk, Vaca, & D'Onofrio, 2015). Prevention strategies should focus on preventing new cases of opioid misuse, the identification of early cases of opioid use disorder, and to ensure access to effective pain management and addiction treatment. The aim of prevention is to screen patients who are at risk for opioid misuse before it causes serious complications. Efforts to identify and treat misuse and opioid use disorder early on are likely to reduce the risk of overdose, psychosocial deterioration, transition to injection opioid use, and medical complications (Kolodny et al., 2015).

A challenge for health care is to reduce the harm associated with opioids, including the prevention of misuse, abuse, and overdose fatality, while providing chronic pain patients with access to optimal treatments, including: physical, psychological, and pharmacological interventions (Roditi & Robinson, 2011). The prevention of opioid misuse requires careful screening by educated prescribers, increased safety education to patients and population, and increased access to mental health and substance use services with to access to pain management (Gilles & Lavigne, 2016). Stratification of patients into different risk categories is fundamental when identifying patients who are at risk for opioid misuse. This requires the use of screening tools designed specifically to screen for opioid misuse, such as the Opioid Risk Tool (Webster & Rebecca M Webster, 2005). Once risk level is identified, the patient can be matched with appropriate resources and interventions in order to address the corresponding risk. It is fundamental that patients receive appropriate education on: opioid medications and chronic pain, both risk and protective factors for misuse and opioid use disorders, and information pertaining

to overdose education and naloxone distribution (Dowell et al., 2016a). There is a pressing need for behavioral health research for patients with chronic pain who are at risk for opioid misuse as approaching this issue upstream will not only help reverse the opioid crisis but also enhance patient outcomes (Volkow & Collins, 2017).

Access to Overdose Education and Naloxone Distribution Programs

There has been an increase in the literature to support mezzo/macro level approaches to prevent opioid overdose fatalities through various harm reduction strategies. These strategies have focused on training on how to respond to opioid overdose through overdose education and naloxone distribution (OEND) programs. Training has primarily targeted individuals using opioids, their friends and family, and bystanders who are more likely to encounter an overdose (Green, Dauria, Bratberg, Davis, & Walley, 2015). The content of OEND programs have consisted of: how to respond to an opioid overdose including the emergency administration of naloxone, which is an opioid antidote to revive individuals experiencing an overdose (Mueller et al., 2015). A recent study suggests brief education is adequate in improving both comfort and capability in recognizing and managing overdose. Participants in the study completed a standardized 5 to 10-minute education on overdose and naloxone distribution. Results of the study found participants demonstrated comfort with recognition of, response to, and administration of naloxone following brief education among first-time recipients (Behar, Santos, Wheeler, Rowe, & Coffin, 2015). Thus, instigating routine overdose education and naloxone distribution in treatment settings, has the ability to offer a relatively simple method of addressing the escalating problem of opioid overdose fatalities (Lott & Rhodes, 2016).

Naloxone is not defined as a controlled substance as it has no potential for abuse and has been used by medical practitioners in the US for over 40 years as the best practice treatment for

opioid overdose (Sporer, 1999). In the early 1990's, health professionals first called for the provision of naloxone outside of the medical setting and by the mid-1990s, naloxone was being distributed to heroin users in Italy, Germany, and the UK (Green et al., 2015). In the US, the first programs to dispense naloxone was in the early 1990's, and nearly 10 years later, OEND programs were in several US states including: New Mexico, Massachusetts, and New York (Coffin et al., 2003). In 2012, the United Nations Commission on Narcotic Drugs recognized overdose as a global health concern that required attention from the World Health Organization, and resolutions focused on naloxone for the prevention of opioid overdose (Walley et al., 2013). As of June 2014, 644 community-based OEND programs were in operation in the US, and participants reported reversing more than 26,463 overdose events (Wheeler, Jones, Gilbert, & Davidson, 2015). These interventions have been endorsed by the United Nations Office on Drugs and Crime (UNODC) jointly with the World Health Organization (WHO), US President's Emergency Plan For AIDS Relief (PEPFAR), the American Public Health Association (APHA), state legislatures, and public health departments and national programs. To maximize identification of opportunities for intervention, initiatives focusing on prevention, access to effective treatment, and harm reduction are fundamental (Doe-Simkins et al., 2014).

There is a fair amount of literature to support the efficacy and cost-effectiveness of OEND. For instance, there was a large scale analysis of OEND programs conducted between 2006 and 2009 in Massachusetts communities with high opioid overdose rates which demonstrated a significant reduction in overdose mortality (Walley et al., 2013). Cost-effectiveness studies found among heroin users, that naloxone prevented 6.5% of fatal overdoses for every 20% of the population that the intervention reached. Such measures have been determined to be cost-effective, with an incremental cost-effectiveness ratio of $438 per quality-

adjusted life-year gained (Coffin & Sullivan, 2013). In order to effectively respond to the opioid crisis, it is essential to increase access to naloxone for those who are most at risk. As of September, 2015 there were 43 states which have passed laws to increase access to naloxone; although unfortunately the laws vary between states, and research is needed to determine what best practices are. It has been recommended that states with legislative barriers to expand naloxone distribution should be encouraged by their state medical societies and health department officials, addiction services, and the public in an attempt to support legislation to eliminate such obstacles. Additional research is needed to incorporate overdose education and naloxone distribution with chronic pain patients who are at risk for opioid misuse within an outpatient setting (Davis, Carr, Southwell, & Beletsky, 2015).

Prevention: Cultural Transformation in Pain Care

The United States is facing a major public health issue of poorly managed pain. The combination of poor health outcomes and inappropriate use of opioid medications has resulted in a substantial increase of opioid-related deaths (Bowman et al., 2013). First line treatments for chronic pain include non-drug strategies such as physiotherapy or exercise physiology, mind-body relaxation techniques such as breathing techniques and mindfulness meditation, hypnosis and other behavior therapies. Lifestyle changes such as: stretching, walking, pacing activity, nutrition changes, improving sleep hygiene and addressing relationship problems can also help to manage pain. If these approaches are not effective, non-opioid analgesics are safer and may be more effective in treating chronic pain (Dowell et al., 2016a). The public would benefit from a better understanding of pain, knowledge translation of best practices regarding opioid medications, and the risks of misuse, overdose, and diversion associated with inappropriate prescribing practices. Increased knowledge on chronic pain management could essentially help

to facilitate appropriate linkages to care supporting a preventative framework for individuals with chronic pain who are at risk of misuse (Slomski, 2011). Given that pain is a biopsychosocial condition, it requires an integrated, multimodal, and interdisciplinary approach, which a national strategy is needed to reflect these evidence based components (Gatchel, Peng, Peters, Fuchs, & Turk, 2007). It is vital that this strategy also underscores the importance of efforts needed to garner upstream activities in the prevention of opioid misuse and overdose such as inclusion of harm reduction strategies (Gourlay, Heit, & Almahrezi, 2005).

Chronic Pain and Opioid Misuse: Micro Level of Interventions

Opioid misuse in the context of chronic pain is a multifaceted and complex issue. As misuse and corresponding rates of addiction and overdose deaths continue to escalate, there is a critical need for research in this area. The objective of this section is to review the literature focusing on chronic pain, opioid misuse and micro level practice. A search was conducted for psychosocial interventions targeting patients with chronic pain who are at risk for opioid misuse, however there were no behavioral health interventions found with a focus on prevention, suggesting that there is a significant void in the literature. The NIH's National Center for Complementary and Integrative Health have endorsed that there is currently no evidence demonstrating that opioids are effective for chronic pain and has allotted approximately 30% of its budget to researching pain and nondrug approaches to pain management. Thus, it is evident that research is needed to increase the knowledgebase on psychosocial interventions for managing chronic pain, with an emphasis on prevention of misuse and opioid use disorders and adherence to treatment (NCCIH, 2018b). Given this large gap in the literature, a review was completed on psychosocial interventions on chronic pain and misuse and opioid use disorders. This approach was taken to establish a broad foundation of what is available within the literature

and further, to determine if certain concepts or themes could be transposed specifically to patients with chronic pain and who are at risk of opioid misuse.

Psychosocial Interventions for Chronic Pain and Opioid Misuse

Better understanding the research supporting psychosocial interventions for chronic pain and opioid misuse will help to inform the development of novel interventions needed to address chronic pain and issues pertaining to opioid misuse. The literature on psychosocial interventions addressing chronic pain and comorbid opioid misuse is also underdeveloped (Hruschak, Cochran, & Wasan, 2018). There are currently only two studies (Table 2.) that have investigated psychosocial interventions exclusively targeting chronic pain and comorbid opioid misuse and one study that examine the psychosocial variable of pain acceptance. The first study examined an intervention referred to as Mindfulness-Oriented Recovery Enhancement (MORE), in 115 chronic pain patients with opioid misuse randomized to 8 weeks of MORE or a support group (SG). MORE participants reported significantly greater reductions in pain severity and interference compared with SG participants. MORE also demonstrated significantly less stress arousal and desire for opioids, and were more likely to not meet criteria for opioid use disorder immediately following treatment (Garland et al., 2014). The second study was a randomized control trial of 42 patients with non-cancer back pain who demonstrated opioid misuse or who were at- risk for misuse. The experimental treatment consisted of: monthly urine screens, compliance checklists, and individual and group motivational counselling. The findings demonstrated that no participants receiving the psychosocial intervention were discharged due to aberrant behaviors, and that opioid treatment adherence improved as opposed to those who did not receive the experimental treatment (Jamison et al., 2010).

Table 2. Studies examining psychosocial interventions addressing comorbid chronic pain and opioid misuse

Study (Author & year)	Methods	Psychosocial Intervention	Results and Conclusion
(Garland, 2014) UT, United States	**RCT**: (N=115); participants were randomized to 8 weeks of MORE or a support group. Pain severity, pain interference, changes in opioid use, desire for opioids, stress, reinterpretation of pain sensations, and reappraisal were evaluated. Outcomes were pre and post and at 3-month follow-up.	Mindfulness-Oriented Recovery Enhancement (MORE) unites aspects of mindfulness training, third-wave cognitive behavioral therapy (CBT), and principles from positive psychology into an integrative intervention strategy.	**Results:** MORE participants reported significantly greater reductions in pain severity (p .038) and interference (p .003) than SG participants. MORE participants evidenced significantly less stress arousal (p .034) and desire for opioids (p .027), and were significantly more likely not to meet criteria for opioid use disorder immediately following treatment (p .05). **Conclusions**: Findings demonstrate preliminary feasibility and efficacy of MORE as a treatment for chronic pain and comorbid opioid misuse.
(Jamison, 2010) MA, United States	**RCT**: (N=66); participants were randomized to either high-risk control (n= 21) or high-risk experimental (n= 21). 20 additional participants were recruited to a low-risk control group and followed for 6 months with pre and post outcome measures.	(1) Monthly electronic diaries; (2) monthly urine screens; (3) monthly completion of the Opioid Compliance Checklist; (4) monthly group education sessions; (5) motivational compliance counseling	**Results:** Significant differences were found between groups: 73.7% of the High-Risk Control patients demonstrating positive scores on the drug misuse index (DMI) compared with 26.3% from the High-Risk Experimental group and 25.0% from the Low-Risk Controls ($p < 0.05$). **Conclusion:** results support brief behavioral intervention in the management of opioid compliance among chronic back pain patient at high-risk for prescription opioid misuse.
(Lin, 2015) MI, United States	(N=501); Participants were stratified into low, moderate and high severity of opioid use. Demographic and clinical characteristics were compared across opiate severity categories.	The Chronic Pain Acceptance Questionnaire (CPAQ) used for pain acceptance. The CPAQ yields separate factor scores for activity engagement and pain willingness.	**Results:** Lower pain acceptance were associated with higher severity of opioid use, where pain intensity was not. Higher pain acceptance was associated with lower odds of severe prescription opioid (AOR 0.50, 95% CI 0.38–0.68 for a one SD increase in pain acceptance). **Conclusions:** Lower pain acceptance is related to greater opiate use and should be considered as an intervention for chronic pain and opioid misuse.

Adapted from: Hruschak, V., Cochran, G., & Wasan, A. D. (2018). Psychosocial interventions for chronic pain and comorbid opioid misuse: a narrative review of the literature. Journal of Opioid Management, (In Press).

Review for Chronic Pain and Opioid Misuse

Given that there are only three identified studies examining this topic, the author expanded the literature search and conducted two additional reviews that included: 1) psychosocial interventions for chronic pain and; 2) psychosocial interventions for opioid misuse or opioid use disorder. Each psychosocial intervention that was found addressing either pain or opioid misuse or opioid use disorder, was further examined for efficacy. This method has allowed for a more global analysis in the identification of any patterns or themes between chronic pain and opioid misuse, while also exploring any data relevant to prevention. Patients with chronic pain and opioid misuse are frequently classified into a "one fits all" category despite that often these two issues are closely interconnected and thus requires an integrated and unique response (Chou et al., 2015a) which this review will help to define. Each of the psychosocial interventions listed in this review have been considered in the development of the IPGT model being investigated within this dissertation.

Psychosocial Interventions for Chronic Pain

Studies included for psychosocial interventions for chronic pain include: 1) cognitive behavioral therapy; 2) acceptance and commitment therapy; 3) mindfulness based cognitive therapy and mindfulness-based stress reduction; and 4) chronic pain self-management programs.

Cognitive Behavioral Treatment

The primary objective of CBT is to help patients identify maladaptive cognitive and behavioral responses and to replace them with healthier coping skills through the use of cognitive restructuring, behavioral activation, behavioral goal setting, activity pacing and relaxation (Kaiser, Mooreville, & Kannan, 2015). Currently, CBT is a first-line psychological treatment for individuals with chronic pain including: back pain, headache, arthritis, and

fibromyalgia. There have been various studies which have examined CBT interventions for chronic pain and which have obtained empirical support (Ehde, Dillworth, & Turner, 2014). A recent systematic review of CBT interventions targeting non-specific lower back pain (LBP) included 23 studies with a total of 3359 participants. Findings suggested a small to moderate effect sizes in support of CBT on a range of patient reported outcomes when compared to no treatment arm or a guideline-based active treatment (Richmond et al., 2015). These results are consistent with the findings of previous systematic reviews and meta analyses of CBT for LBP, which also concluded moderate effects in support of CBT on both pain and disability. (Henschke et al., 2010; Hoffman, Papas, Chatkoff, & Kerns, 2007). A wider review of meta-analyses on CBT interventions targeting chronic pain in adults also concluded that CBT produced moderate effect sizes for chronic pain (Kaiser et al., 2015). While the Cochrane Library review suggested that CBT can help reduce mood problems and disability associated with pain, the treatment modality showed to have weak effects in the improvement of pain. Although there is evidence to support the efficacy of CBT for chronic pain, the data to determine which specific treatment is most effective for which condition is limited (Eccleston, Morley, & Williams, 2013).

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is a newer form of behavioral treatment, which differs from CBT in that it puts an emphasis on the acknowledgement and acceptance of events, rather than attempting to change them. The conceptual understanding of the modality is that being aware of an individual's thoughts and emotions indirectly modifies their behavior to align with their treatment goals (Hofmann & Asmundson, 2008; Song, Lu, Chen, Geng, & Wang, 2014). There are various RCTs that offer support for the use of ACT for chronic pain (Buhrman et al., 2013; Dahl, Wilson, & Nilsson, 2004; Wetherell et al., 2011; Wicksell,

Ahlqvist, Bring, Melin, & Olsson, 2008; Wicksell et al., 2013). In addition there are a number of uncontrolled trials (Johnston, Foster, Shennan, Starkey, & Johnson, 2010; McCracken, Vowles, & Eccleston, 2005; Vowles, Wetherell, & Sorrell, 2009) and a series of effectiveness studies (McCracken & Gutiérrez-Martínez, 2011; Vowles & McCracken, 2008). The effectiveness studies demonstrated consistent positive effects of ACT on increased physical and social functionality and decreased pain-related medical visits. A meta-analysis examining ACT for chronic pain that examined 22 studies concluded that ACT is at least equally effective as traditional CBT (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). Results from these analyses indicate there is a correlation between high levels of acceptance of pain and decreased anxiety, depression, and disability (McCracken et al., 2005; Vowles & McCracken, 2008).

Mindfulness Based Cognitive Therapy and Mindfulness-Based Stress Reduction

Mindfulness-based cognitive therapy (MBCT) is another cognitive treatment that integrates Buddhist mindfulness meditation with contemporary Western psychology approaches, including CBT. Mindfulness-based stress reduction (MBSR) was developed based on principles of MBCT. MBSR is another mindfulness based intervention that includes a structured 8-week group program of weekly 2.5-hour sessions, which includes: sitting meditation, walking meditation, hatha yoga, and body scan (Bawa et al., 2015). A recent systematic review found limited evidence that MBSR provided short-term relief of pain and back-related disability in patients with LBP. While single studies reported effects on physical or emotional well-being, overall there were minimal effects on quality of life reported (Cramer, Haller, Lauche, & Dobos, 2012). These results were comparable with another meta-analysis on mindfulness-based interventions for chronic pain that found MBSR was superior to controls in decreasing pain intensity and increasing well-being; however, it was not significant in increasing quality of life

(Veehof et al., 2011). Despite this evidence, it is questionable if pain intensity is an appropriate outcome measure given that pain reduction is not a primary objective of mindfulness-based interventions. Pain is a multidimensional experience and includes: sensory, affective, and cognitive components (Reiner, Tibi, & Lipsitz, 2013). Consequently, larger effect sizes should not be anticipated and future recommendations should incorporate pain measures such as interference of pain with daily life activities (Veilleux, Colvin, Anderson, York, & Heinz, 2010).

Chronic Pain Self-Management Program

Self-management has become a widely accepted practice in the management of chronic conditions (Lorig & Holman, 2003). The Chronic Pain Self-Management Program, known as the CPSMP, was derived from Stanford's Arthritis Self-Management Program and the Chronic Disease Self-Management Program. CPSMP empowers the individual in pain to be an active participant in their own treatment through teaching effective symptom management and practical skills. Topics covered within CPSMP include: (1) techniques to deal with fatigue, isolation, and poor sleep; (2) appropriate exercise for maintaining and improving strength, flexibility, and endurance; (3) adherence of medications; (4) communicating effectively with family, friends, and health professionals; (5) nutrition, (6) pacing activities; and (7) how to evaluate new treatments (LeFort, Gray-Donald, Rowat, & Jeans, 1998). CPSMP has been rigorously evaluated in two RCTs which concluded individuals who participated in CPSMP had more vitality, less pain, less dependence on others, improved mental health, enhanced social capital, and improved life satisfaction compared to those who had not taken the program (McGillion, LeFort, Webber, & Stinson, 2011). Expanding on the results of the single site trials, LeFort and colleagues developed a larger scale (n=279) multisite effectiveness trial with long-term follow-up. Evaluation of the program found participants had enhanced coping skills, education, and overall

quality of life which were retained 12 months following post program completion (M. H. McGillion, LeFort, & Stinson, 2008). While there has been a significant amount of attention focused on CPSMP, increased efforts to establish evidence for individual and online self-management programs is starting to occur (Blyth, March, Nicholas, & Cousins, 2005).

Psychosocial Interventions for Misuse and Opioid Use Disorders

The misuse of and addiction to opioid medications is a public health crisis which demands sustained efforts from researchers and health professionals to implement evidence-based prevention and treatment strategies. There has been an emphasis for research to examine the efficacy of behavioral health interventions, while also focusing on prevention and adherence to treatment (Reiner et al., 2013). As previously noted, while this dissertation is examining a behavioral intervention for chronic pain patients at risk for opioid misuse, given the lack of literature on preventative interventions, this section will broadly examine psychosocial interventions for misuse and opioid use disorders. Studies for psychosocial interventions for opioid misuse included: 1) cognitive behavioral therapy and relapse prevention; 2) motivational interviewing and stages of change; 3) contingency management; and 4) peer support groups such as Narcotics Anonymous.

Cognitive Behavioral Therapy and Relapse Prevention

CBT addressing substance abuse generally emphasizes a functional analysis of cues for drug use and engages the patient in a systematic training of alternative responses to such cues. Relapse Prevention (RP) is a form of CBT specialized for substance use and primarily focuses on the identification and prevention of high-risk situations, increasing the likelihood of when a patient is more susceptible to use alcohol or drugs (Marlatt & Donovan, 2005). RP includes a broad range of psychoeducation, cognitive reappraisal, skills training, and other behavioral

strategies (R Kathryn McHugh, Hearon, & Otto, 2010). Researchers have suggested that increased frequency of CBT enhances patient outcomes, including extended periods of abstinence for chronic substance users. The format of CBT for substance use disorders is typically in the setting of individual (Vedel, Emmelkamp, & Schippers, 2008) or group sessions (Watkins et al., 2011). Individual sessions generally focus more on individualized treatment plans whereas group settings providing an avenue for sharing experiences and peer-support (Pan et al., 2015).

The literature examining RP and opioid misuse are limited however, there were various meta-analyses that reviewed RP and substance use other than opioid misuse. One meta-analysis reviewed the efficacy of RP in 26 studies with 70 hypothesis tests representing a sample of 9,504 participants which examined alcohol and drug use disorders as well as smoking. The findings of the meta-analysis found RP was most effective when applied to alcohol or polysubstance use disorders, combined with the adjunctive use of medication (Irvin, Bowers, Dunn, & Wang, 1999). Additional evidence for the efficacy of CBT for substance use disorders was also supported in meta-analytic reviews, with effect size estimations in the low moderate range using heterogeneous comparison conditions (Dutra et al., 2008) and large effect sizes compared to no-treatment control groups (Magill & Ray, 2009). An additional systematic review investigating the use of psychosocial interventions in conjunction with medications for the treatment of opioid use disorders was included in the review. The study found evidence to support the application of CBT in conjunction with contingency management in methadone maintenance therapy. The authors concluded by indicating that there is little empirical evidence suggesting what psychosocial treatments work best in conjunction with what medication-assisted treatment (Drummond & Perryman, 2007). The empirical base addressing CBT and opioid misuse is

insufficient; future research is needed, specifically regarding CBT protocols to address specific characteristics of opioid misuse.

Stages of Change and Motivational Interviewing

Stages of Change are often linked to patient motivation and the likelihood of their ability to make changes in their drug use. There are 6 stages of change which include: precontemplation, contemplation, preparation, action, maintenance, and termination (DiClemente, Schlundt, & Gemmell, 2004). Conceptually, an individual can be seen as moving along a continuum marked by these stages through such techniques as motivational interviewing. The principles of this behavioral technique are used to strengthen motivation and develop a plan for change in which the therapist monitors the patient's progress, reviews cessation strategies, and continues to encourage commitment to either change or sustained abstinence (Miller, Yahne, & Tonigan, 2003). Interventions based on motivation interviewing can be utilized as either a stand-alone therapy or in combination with other treatment strategies (Kathryn McHugh et al., 2010). There have been 32 trials demonstrating that motivational interviewing improves treatment adherence in which the results show a small to medium effect size with variability across settings and providers (Brown & Miller, 1993; Hettema, Steele, & Miller, 2005). Additionally, a Cochrane review in 2011 concluded that motivational interviewing can reduce the extent of drug use, including opioid misuse as compared to no intervention (Smedslund et al., 2011). While there is a larger body of evidence examining motivational interviewing on substance use disorders, the literature specifically addressing motivational interviewing in misuse and opioid use disorders is limited.

Contingency Management Interventions

Contingency Management (CM) principles are based on behavioral therapies, classical conditioning and positive reinforcement, offering patients tangible rewards to reinforce behaviors such as abstinence. Studies conducted in both methadone programs and psychosocial counseling programs demonstrated that incentive-based interventions are highly effective in increasing treatment retention and promoting abstinence from drugs. There have been several literature reviews (Higgins & Silverman, 1999; Silverman, 2004) and two meta-analyses investigating CM treatment. One meta-analysis (Griffith, Rowan-Szal, Roark, & Simpson, 2000) focused on the use of CM within the context of methadone maintenance treatment and the second, more recent meta-analysis (Lussier, Heil, Mongeon, Badger, & Higgins, 2006) examined the most commonly used approach to CM, voucher-based reinforcement therapy. Both of these meta-analyses found CM to be effective, with a small to medium effect size; CM was also found to be promising for opioid-dependent patients receiving methadone maintenance (Petry, Alessi, Hanson, & Sierra, 2007; Petry & Martin, 2002; Petry, Martin, & Simcic Jr, 2005) and buprenorphine (Kosten et al., 2003; Schottenfeld et al., 2005).

Additional support included a secondary analysis which reviewed data from a large, multi-site effectiveness trial seeking to determine if a web-based behavioral treatment, with principles of CBT and CM, differed by participants' self-identified primary drug of choice. The results of the study suggested that opioid users did not benefit from the web-based treatment and that this population experiences the best outcomes with medication-assisted therapies, as a base treatment upon which psychosocial interventions can be more closely examined (Cochran et al., 2015). This was highlighted in a RCT examining CM and opioid use disorders which found improvement in compliance with naltrexone (Carroll, Sinha, Nich, Babuscio, & Rounsaville,

2002). These findings suggest that targeted behavioral interventions can play a significant role in broadening the utility of available pharmacotherapies.

Self-Help Models

Participation in self-help groups can be an adjunct to professional interventions, or a treatment in itself. The most prominent self-help groups include: Alcoholics Anonymous (AA), Narcotics Anonymous (NA), and Cocaine Anonymous (CA), all which are based on the 12-step model (Ferri, Amato, & Davoli, 2006). There are alternative self-help models for special interest groups such as the Secular Organizations for Sobriety and Self-Management And Recovery Training (SMART) (Timko & DeBenedetti, 2007). While this is not applicable for those with opioid misuse, with regard to opioid use disorders, individuals on methadone maintenance are typically not permitted to openly share their experiences at 12-step meetings as in these environments, methadone is often viewed as a drug (McGonagle, 1994; Ronel, Gueta, Abramsohn, Caspi, & Adelson, 2011). However, in 1991, Methadone Anonymous, a group-based model was created to address stigma in an attempt to include individuals on prescribed methadone who wished to pursue recovery through a 12-step approach. (L. Glickman, Galanter, Dermatis, Dingle, & Hall, 2005). Despite that 12-step and AA programmes for substance use problems are promoted worldwide, vigorous research is still needed in order to support their efficacy and with opioid misuse in particular, including the therapeutic value of peer support in a group setting (Ferri et al., 2006; Kownacki & Shadish, 1999).

Chronic Pain and Opioid Misuse Review: Discussion

Studies that examined psychosocial interventions for chronic pain, included: CBT, ACT, MBCT/MBSR, and CPSMP. The psychosocial interventions for opioid misuse included: CBT and RP, Motivational Interviewing and Stages of Change, CM, and self-help, and peer support-

based groups. While the purpose of this review was to provide a summary and critical analysis of research addressing psychosocial interventions targeting chronic pain and opioid misuse, overall, the literature provided either limited or mixed evidence to offer direction in this area primarily due to the fact that targeted behaviors, such as misuse and opioid use disorder were varied. This review has demonstrated there is strong conceptual commitment to the biopsychosocial model and an interdisciplinary approach to chronic pain and opioid misuse, in which there is ample opportunity to contribute from a social work perspective. Recent data has indicated that chronic pain patients who are either at risk for or have an active substance use disorder, often require more comprehensive treatment options (Alford et al., 2016) and are best served by a multidisciplinary team, including a specialist in addictions (Sehgal et al., 2012). Treating chronic pain among co-occurring opioid misuse is a complex phenomenon as practitioners must not only treat the pain, but also need to consider issues of medication safety, misuse, diversion, and other emergent psychosocial factors (Upshur, Luckmann, & Savageau, 2006). Early identification of psychosocial risk factors within chronic pain translates to the potential of prevention and positive impacts on the trajectory of the chronicity of pain (Bérubé et al., 2017). However, little empirical data are available to guide practitioners in the appropriate methods for treating this patient population and particularly from a psychosocial perspective. Research on behavioral interventions are greatly needed to improve our understanding of treatment approaches in patients with chronic pain who are at risk for opioid misuse.

When attempting to evaluate the research being conducted in a subject area, it can be informative to analyze patterns and trends in the current studies of that field. Upon completion of the review for psychosocial interventions for chronic pain and opioid misuse (Hruschak et al., 2018), which was conducted July, 2017, exclusion of records indicated that 252 studies of the

486 reviewed, exclusively focused on medical management. Therefore, 52% of the studies investigated either medical management or pharmacological approaches and were not concerned with psychosocial factors. Furthermore, 171 or 35% of the studies were epidemiology studies which examined predictors of opioid misuse, medication adherence, or various pain measures and were not concerned with treatment or interventions. Together these two categories consist of 87% of the literature, which is a staggering number and is particularly insightful, given that only 3 studies (6%) examined psychosocial interventions in chronic pain and comorbid opioid misuse which underscores that there is a significant void in the literature. This is perplexing given the recent acknowledgement through the Centers for Disease Control & Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain (Dowell et al., 2016a) which emphasizes that opioids are not first-line or routine therapy for chronic pain and that non-pharmacologic and non-opioid therapy are preferred. Despite the recommendations that psychosocial interventions are rudimentary in the management of chronic pain, the literature dictating best practices for what therapies is nearly non-existent. Given the alarming rate of opioid overdose fatalities and the emotional and physical suffering of people in pain, it is essential to ask the question: why has this important area of research been neglected? A fundamental challenge for healthcare is to achieve a balance between decreasing the misuse of opioids and harms associated while optimizing patient care, including the provision of interdisciplinary treatments for chronic pain, which is pertinent to the social work profession.

Research Methodologies and Implications for Future Research

Understanding chronic pain has evolved drastically over the past decade, however with the recent opioid epidemic there has been additional pressure to more effectively address patients with chronic pain who are either at risk of opioid misuse or already have misuse or opioid use

disorders. With this pressure, there has been increased efforts to improve research methods, expand research targets, and encourage interdisciplinary collaboration amongst research teams (Steglitz, Buscemi, & Ferguson, 2012). The purpose of this section is to provide an overview of research methodologies that have examined psychosocial interventions for chronic pain and issues pertaining to opioid misuse, and to provide recommendations for future research.

Research Methodologies for Chronic Pain and Opioid Misuse

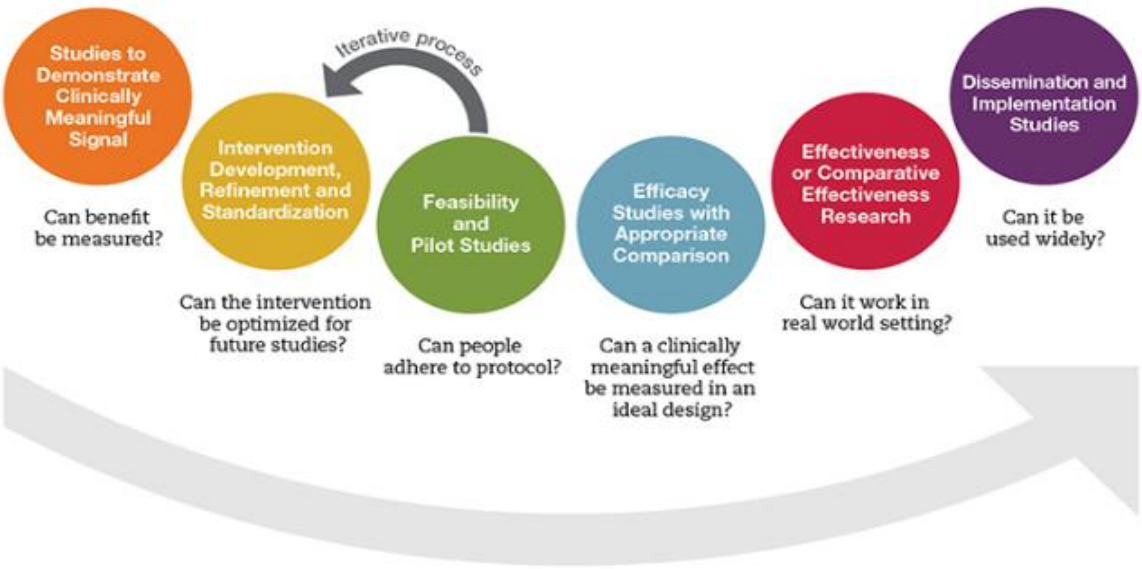
The majority of research methodologies examining this subject are quantitative and predominately experimental research in design, while there are also systematic reviews and meta-analyses providing various summaries of research findings. An article published on advances in clinical research methodology for pain proposed that it is important to consider the individualization and subjectivity of pain, when designing and conducting a study in pain care. The article also recommended a randomized, double-blind clinical trial as the primary methodology utilized to assess treatment efficacy (Farrar, 2010). The RCT is also known as the gold standard in addiction research, partly due to its potential for maximizing internal validity. While clinical trials most commonly are used to test treatment effects, some trials focus on treatment interactions with client characteristics or with other treatments (Del Boca & Darkes, 2007). However, full scale RCTs are costly and time consuming, and therefore pilot studies are often crucial in producing information which can inform planning and justification for RCTs (Thabane et al., 2010).

Pilot studies have a critical role in health research, and can be defined as ‘a small-scale test of the methods and procedures to be used on a larger scale’ (Arain, Campbell, Cooper, & Lancaster, 2010). Prior to conducting a full scale RCT to test the efficacy of a novel intervention, it is essential to demonstrate the feasibility and acceptability of the intervention and test the study

methods with the population of interest (NCCIH, 2018a) as depicted in Figure 4. Feasibility can be understood as whether research procedures and the intervention can be delivered with high fidelity; whereas acceptability is whether the intervention or research design are appropriate from the participants' perspective (Lancaster, Dodd, & Williamson, 2004).

The analysis of pilot studies should be primarily descriptive or focus on estimation of confidence interval and hypothesis testing should be treated as preliminary and interpreted with caution. It is advised that sample size calculation is not mandatory for publishing and should not necessarily be done. Given that the effect size estimated from a pilot study is unstable, it does not offer an accurate estimation for power calculations. Rather, the proposed pilot study sample size should be based on practical considerations including patient flow, budgetary constraints, and the number of patients to reasonably evaluate feasibility goals (Arain et al., 2010). Pilot studies have different objectives as compared to RCTs and patients involved should be informed that they are in a pilot study and there is a possibility that there may not be a larger study following completion (Lancaster et al., 2004). A pilot study is beneficial in testing recruitment and retention methods which helps to demonstrate that the enrollment criteria is appropriate for the patient population. Ultimately pilot studies are used to determine whether a subsequent larger fully powered study can successfully be executed, and provide robust and clinically useful evidence regarding efficacy of the intervention (NCCIH, 2018a).

Figure 4. National Center for Complementary and Integrative Health's Framework (NCCIH) Framework for Developing and Testing Mind and Body Interventions



From: NCCIH, (2018a). Framework for Developing and Testing Mind and Body Interventions. Retrieved from https://nccih.nih.gov/grants/mindbody/framework

Gaps in Research Methodologies

Clinical trials in the field of chronic pain and opioid misuse that have evaluated psychosocial interventions vary widely in both their format (group vs. individual, in-person vs. online) and content. For instance, CBT for chronic pain is typically a multicomponent treatment with no standard treatment manual and for those studies that do incorporate manuals, most are crafted by the investigators and seldom are published, which makes comparisons across different studies extremely difficult (Morley, Shapiro, & Biggs, 2004). Additional research is required to determine the ideal frequency of treatment, length and number of sessions, and mode (in-person, telephone) of each session (Ehde, Dillworth, & Turner, 2014). Most of the psychosocial treatments that target either chronic pain or opioid misuse are very general and broad-based therapies however chronic pain and comorbid opioid misuse are very specialized problems; there is a lack of research guiding how this therapy should be adapted to this patient population. There have been some studies that have examined module-based therapy in chronic pain which is a

treatment strategy to target symptom specific problems of pain, such as depression, catastrophizing, inactivity, or fear-avoidance (Williams, Eccleston, & Morley, 2012). Several promising module-based CBT treatments for chronic pain have been developed but there is still more work that needs to be done to match patient characteristics to treatment modules, in addition to including topics on prevention of opioid misuse and treatment adherence (Ruehlman, Karoly, & Enders, 2012).

With regard to the results from studies on opioid use disorder, there was generally significance for the efficacy of psychosocial interventions in combination with medications for the treatment of opioid use disorder. However, it is important to note that the incremental efficacy of combining psychosocial interventions to medically assisted treatment, varied for different outcomes, across different studies, and within psychosocial intervention types (Amato, Minozzi, & Davoli, 2011). It can be proposed that this is likely due to the fact that the comparison groups were not consistent across the studies that were reviewed. In the majority of the studies, control groups did not include medications alone and the medication management control group conditions may have been more intensive than in clinical practice; for instance, more frequent and longer physician visits. It can be speculated that the effects would have been stronger and more consistent if the comparison conditions offered medication alone or at least demonstrated the level of medication management that occurred (Dugosh, Abraham, Seymour, McLoyd, Chalk, & Festinger, 2016). However, it is important to acknowledge if the patient population is either at risk for opioid misuse or has opioid misuse behavior, but not opioid use disorder, MAT is not relevant (McElrath & Joseph, 2018).

Given the severity of the opioid epidemic, it is fundamental that the field continues to advance the body of empirical knowledge that can guide practitioners in determining the most

appropriate psychosocial intervention for patients with chronic pain who are at risk for opioid misuse, are engaging in medication misuse, or have opioid use disorder. As millions of individuals continue to suffer with chronic pain and as misuse and opioid use disorders and overdose fatalities continue to escalate, the need to advance evidenced based research on best practices in prevention and behavioral health research is critical (Dugosh, et al., 2016).

Treatment Mechanisms and Moderators

The identification of specific cognitive and behavioral variables that mediate the effects of psychosocial interventions on patient outcomes could possibly facilitate the alteration of more effective treatment models. However, there have been very few studies that have investigated the mechanisms as to which psychosocial interventions are effective. Changes in chronic pain related beliefs and coping have demonstrated association with concurrent improvements in both symptoms and functionality (Burns, Johnson, Mahoney, Devine, & Pawl, 1998; Nielson & Jensen, 2004). One study reported decreases in pain catastrophizing mediated the relationships between three treatments for chronic low back pain (CBT, active physical treatment, and CBT plus active physical therapy) and improvements in disability, functional limitations, and pain (Smeets, Vlaeyen, Kester, & Knottnerus, 2006). Another study demonstrated that decreased pain catastrophizing and increased perceived personal control over pain, mediated reduction in pain behavior and depression levels with operant-behavioral treatment (Spinhoven, Ter Kuile, Kole-Snijders, Hutten Mansfeld, Den Ouden, & Vlaeyen, 2004). Despite these findings, conclusions pertaining to causal and sequential relationships are precluded given that the outcome and process variables were assessed concurrently. In an RCT of CBT compared to education for chronic pain, Turner et al. (2007) demonstrated that patients who reported increased pain, depression, physical issues, rumination, catastrophizing, and stress

prior to treatment had less desirable outcomes at one year regardless of their treatment (Ehde et al., 2014). A meta-analysis of psychosocial interventions for chronic pain and low back pain (Hoffman et al., 2007) also found minimal support that psychosocial interventions effects vary by patient characteristics. It should be emphasized that the low statistical power of these studies in addition to the small sample of participants from racial and ethnic minority groups underrepresented in RCTs, do not adequately address the issue of moderators. Additional research is needed to better understand why the intervention work and for who, and under which circumstances. There is also a need for improved data of mediators, moderators, therapist characteristics, and therapeutic factors that are valuable for specific outcomes which can guide effective psychosocial treatment models for chronic pain and opioid misuse (Ehde et al., 2014). While it is not feasible to include this within the analysis of this dissertation given that it is a pilot study, these issues should be considered within the planning of a larger efficacy trial.

Quality of Clinical Trials in Chronic Pain and Opioid Misuse

Quality in clinical trials of psychosocial interventions pertains to the study design, methods, and quality of the treatment and its delivery. Chronic pain and opioid misuse treatment quality indicators include: manualization, adherence to the manual, therapist training, treatment content, treatment duration, and patient engagement (Yates, Morley, Eccleston, & Williams, 2005). Poor quality of study design and treatment is a recurring criticism in the systematic reviews of CBT for chronic pain (Aggarwal et al., 2011; Macea et al., 2010; Palermo et al., 2010). Williams and co-investigators (2012) used a quality rating scale in their meta-analysis of studies of psychological treatments for chronic pain published through 2011. Their findings suggested the quality and reporting of the study methods improved over time, although they noted the quality of psychosocial factors and reporting of information had not, preventing the

ability to replicate and extend findings to future studies. In order to advance future research, it must be recognized that knowledge pertaining to the efficacy of chronic pain and opioid misuse is reliant on the quality and reporting of the research. Therefore, there is a need for more rigorous design and study methods in addition to standardization of measures across clinical trials (Ehde, et al., 2014).

Integrated Psychosocial Group Treatment: Advancements in the Literature

Despite the recommendations of the National Pain Strategy (Committee, 2015) for improving patient access to quality, multidisciplinary care, in addition to the CDC Guideline for Prescribing Opioids for Chronic Pain (Dowell et al., 2016a), the knowledge base supporting these interventions are limited. This research study has provided the knowledge and experience necessary to progress toward a fully powered RCT. This study provides data on the feasibility, acceptability, and preliminary efficacy on the integration of treatment and delivery of a behavioral health care model for patients with chronic pain who are at risk for opioid misuse. The research conducted on IPGT will advance the literature to help fill the void in behavioral health research that integrate treatment approaches for chronic pain and opioid misuse with a preventative approach. The following psychosocial interventions targeting chronic pain were included in the development of IPGT: (1) cognitive behavioral therapy, which topics include: pacing and goal setting, negative thinking, coping with stress and anxiety, managing set-backs, treatment adherence, and quality of life; (2) acceptance and commitment therapy which utilizes principles from stages of change and motivational interviewing to help target behavioral change; (3) mindfulness based cognitive therapy and mindfulness-based stress reduction, which included various mindfulness exercises in addition to exercise that incorporate a mindfulness approach to stress reduction; and (4) principles pertinent to chronic pain self-management programs which

include concepts based on peer support, SMART goals, and learning skills that are fundamental in the self-management of chronic pain. The participants are encouraged to set goals around the material being taught at each session and weekly check-ins will offer peer support in progress of their goals. The following psychosocial interventions targeting risk facts of opioid misuse were included in the development of IPGT: (1) cognitive behavioral therapy, this material primarily focuses on the triggers and cravings associated with misusing opioid medications, including early warning sign of misuse; (2) motivational interviewing and stages of change content which helps the participants identify which stage of change they are in if any potential for opioid misuse is present; 3) contingency management is offered through verbal validation, peer support, and healthy food and snacks which is offered at each group session. IPGT also largely operates from a harm reduction and preventative platform with group psychoeducation which addresses issues pertaining to risk factors of opioid misuse, the teaching of healthy pain management skills, medication adherence, and overdose education and training in naloxone administration. This is an innovative approach as historically treatment models have addressed pain and addictions in isolation, overlooking the need to adapt a more holistic framework. As opioid misuse and corresponding rates of addiction and overdose fatalities exceed epidemic proportions, there is a critical urgency for research on best opioid practices while optimizing pain care, which this dissertation will help to address.

Chapter III: Methods

The content in this chapter provides an overview of the procedures and outcomes of the pilot study, discuss the study design, context and intervention, recruitment, and analysis plan for the dissertation: *A Randomized Pilot Trial of a Harm Reduction and Preventative Approach for Patients with Chronic Pain at Risk for Opioid Misuse.*

Overview of the Study

A pilot RCT was conducted to examine an IPGT model in chronic pain patients who were at risk for opioid misuse. The author and colleagues developed the IPGT treatment protocol, which is a new program, targeting psychosocial treatment for patients with chronic pain who are at risk for opioid misuse. IPGT is a comprehensive approach that blends evidenced based psychosocial treatments for CNCP and risk factors associated with opioid misuse. The objective of this pilot study was to examine: (1) feasibility; (2) acceptability; and (3) preliminary efficacy of IPGT for patients with chronic pain who were at risk for opioid misuse. This study has provided foundational data on the feasibility, acceptability, and preliminary efficacy on the integration of treatment and delivery of behavioral health care models for chronic pain patients who are at risk for opioid misuse.

Research Questions

The study research questions included:

1. Does IPGT demonstrate feasibility when applied to patients with chronic pain who are at risk for opioid misuse.
    - Is it possible to recruit the target population?
    - Is it possible to randomize the participants?
    - Will the participants stay engaged for the full six sessions of the intervention?
    - Can the intervention be delivered as per the study protocol?
    - Are the data collection forms and questionnaires appropriate?

2. Does IPGT demonstrate acceptability when applied to patients with chronic pain who are at risk for opioid misuse?
    - What is the recruitment rate and attrition?
    - What are the completion rates to the pre and post treatment assessments?
    - Are the assessments too burdensome?
    - Does this intervention appeal to the patients?

3. Does IPGT demonstrate preliminary efficacy when applied to patients with chronic pain who are at risk for opioid misuse?
    - Is there a reduction in opioid medication misuse behaviors?
    - Is there decreased ratings of pain severity, interference, and catastrophic thoughts related to pain.
    - Is there an improvement in knowledge and attitudes of overdose and training in naloxone administration.

The pilot project was a necessary first step in examining this novel intervention in which study results inform feasibility and acceptability, which is instructive in that it points to modifications needed in the planning and design of a larger efficacy trial.

Study Design and Participant Identification

This dissertation is a small-scale single-blinded 2 group RCT, in which the research assistant who conducted the assessments was blinded to the intervention condition and the principal investigator assigned the patients to the treatment condition, and also conducted the intervention. A RCT design as a pilot study seemed appropriate for the dissertation study with the purpose of determining feasibility of a full trial where participants will be randomly assigned to IPGT or the control arm.

Setting: The study was conducted with patients at an interdisciplinary outpatient pain clinic, the UPMC Pain Medicine Program, which provides comprehensive research, clinical, and educational components committed to the evaluation and treatment of the entire range of pain, disability, and rehabilitation concerns. The UPMC Pain Medicine Program was an exceptional site as it serves the target population for this study and there is a group room in the clinic which was an accommodating setting for the intervention to occur.

Sample Size: Power analyses are often used to determine the sample size needed to offer statistical power to detect a clinically meaningful difference with the specified inferential statistical test. However, given that this was a pilot RCT, a pilot sample size was instead based on the pragmatics of recruitment and the necessities for testing feasibility (Leon, Davis, & Kraemer, 2010). However, extant literature proposes that a pilot study sample should be 10% of the sample projected for the larger fully powered study (Lackey & Wingate, 1986). The sample size for this dissertation was limited by available resources, with 30 patients in total was considered to be a realistic, achievable enrollment. Power analysis for a linear multiple regression with three predictors was conducted in G*Power which determined a power of 0.71 with a sample size of 30 and using an alpha of 0.05, and a large effect size ($f^2 = 0.35$).

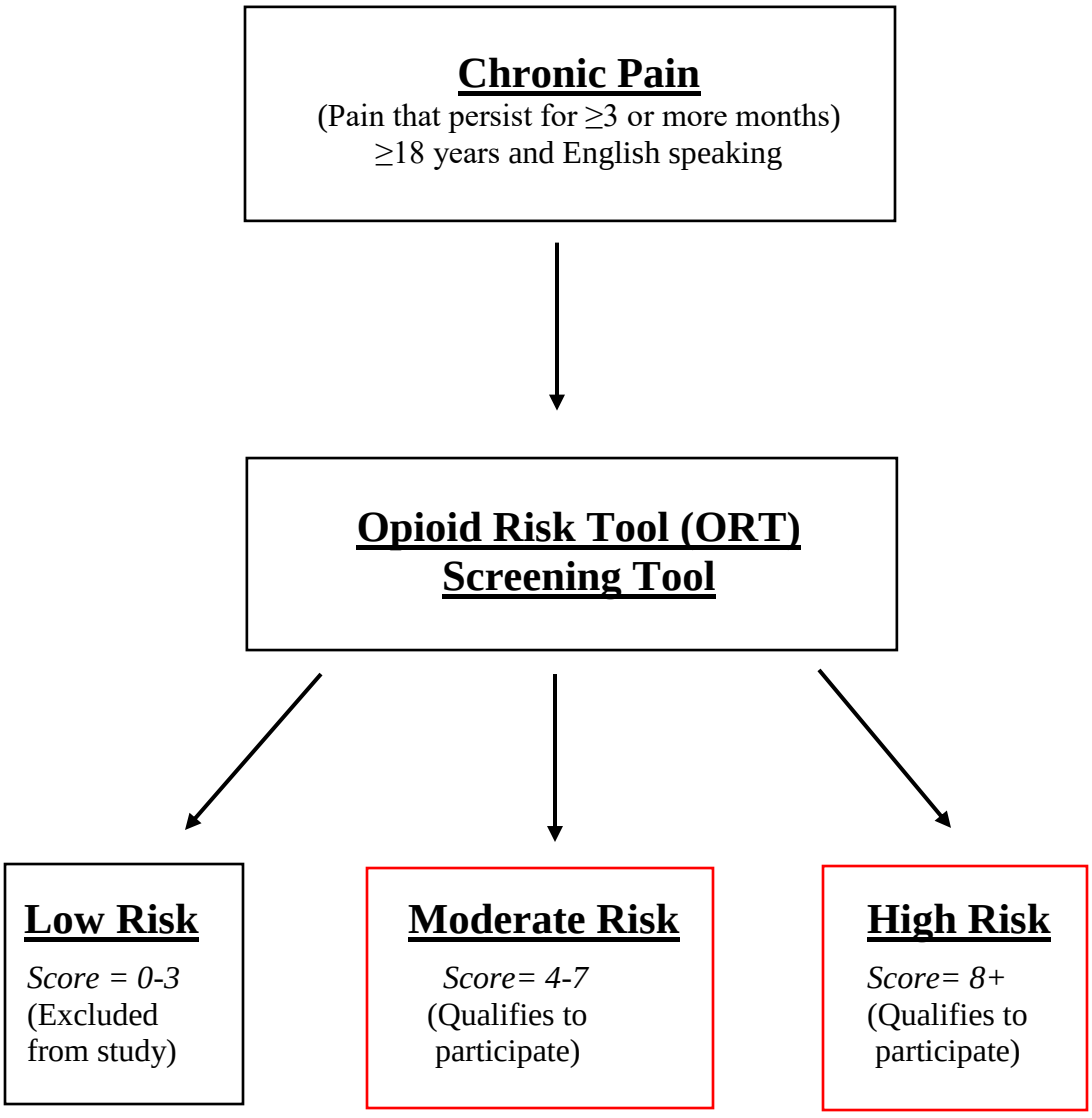
Recruitment and Enrollment

The study was registered with Pitt + Me, which is a voluntary database through the University of Pittsburgh of individuals who have consented to be contacted to participate in research studies. The Registry's software matches participants, based on their demographics, ICD-9/10 codes, in addition to health preferences, with studies for which they may be eligible (CTSI, 2018). Study flyers (see Appendix A for study flyer) were posted at the UPMC Pain Medicine Program, although the primary means of recruitment was through the patient registry. The principal investigator approached patients who wanted to learn more about the study and they were invited to complete a brief screen on a tablet using a Qualtrics survey. The patients were informed that if they were eligible to enroll in the study that they would be compensated up to $165 for full participation.

Inclusion/Exclusion Criteria. Patients were asked in the screening to confirm through self-reported measures if they had chronic pain, were at risk of opioid misuse, were English speaking, and ≥18 years. Patients were excluded if they: (1) were receiving cancer or end of life treatment, which was determined by self-report; (2) were pregnant (due to potential opioid use complications among pregnant women and their offspring); pregnancy was also established by self-report (3) had a psychotic and/or manic episode in the last 30 days; as assessed by the psychosis subscale from the Behavior and Symptom Identification Scale which has demonstrated both reliability and validity (Eisen, Normand, Belanger, Spiro, & Esch, 2004); (4) had planned to leave the Pittsburgh area for an extended period of time within the next 4 months, as specified by the patient. Chronic pain was established by pain that persisted for ≥3 or more months which was captured on a self-report scale. Being at risk for opioid misuse was determined by the Opioid Risk Tool (ORT) which is a brief, self-report screening tool. The ORT is a 5-item validated

questionnaire designed to predict the risk of problematic drug-related behaviors. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid use disorder, and a score of 8 or higher indicates a high risk for opioid use disorder (Lynn R Webster & Rebecca M Webster, 2005). Patients who screened moderate or high risk, in addition to pain for ≥3 months, were invited to enroll in the study as depicted in Figure 5.

Figure 5. Inclusion Eligibility Flow Diagram for Integrated Psychosocial Group Treatment



Patients who were excluded from the study were given education and resource information on issues pertaining to chronic pain and substance abuse. If they required additional assistance accessing care, the principal investigator helped to provide this support. Patients who met eligibility criteria and consented to participate were randomly assigned using a random list generator (www.random.org) on a 1:1 ratio to the TAU or the IPGT condition.

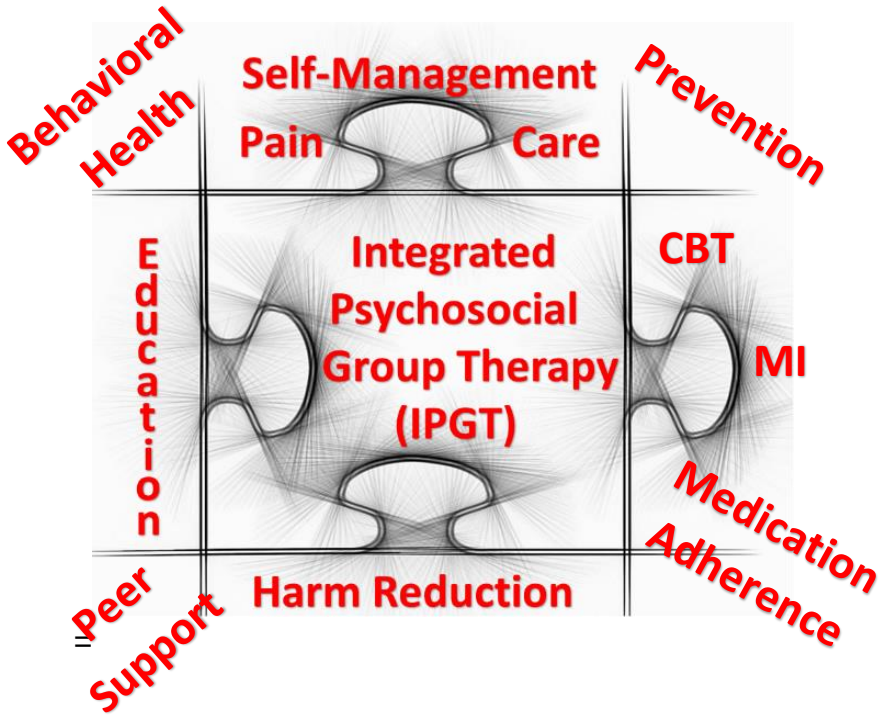
Treatment as Usual and Study Intervention Conditions

Treatment as Usual (TAU) Conditions: The control group received TAU, meaning any other pharmacologic and non-pharmacologic treatments for chronic pain provided by their care provider(s) and not related to the study. The principal investigator systematically documented the participants' receipt of TAU, which included: medications, physical therapy, and other clinic visits that would potentially help address pain, for example a pain specialist or psychologist visit. A TAU control permitted the estimate of retention rates of controls not receiving active treatment, which will help to inform the development of an improved TAU control in the fully powered trial of IPGT.

Description of Study Intervention (IPGT): This behavioral intervention is a comprehensive approach that blends evidenced based psychosocial treatments for chronic pain and issues pertaining to opioid misuse (Figure 6.). The intervention addresses each issue individually, but also the interconnections between the overlapping problems. The development of the study intervention was informed by a literature review of psychosocial interventions for chronic pain and opioid misuse (Hruschak et al., 2018). IPGT consists of 6 weekly group sessions of motivational interviewing and behavioral change, self-management, and pain education focused on adherence to treatment and resisting urges to misuse prescription medications. The intervention also entails an education session on overdose education and

training in naloxone administration. Naloxone is an important factor for overdose prevention in patients receiving opioid prescriptions, and particularly those who are at risk for opioid misuse (Bowman et al., 2013; Weinrib et al., 2017) and thus is an integral component in IPGT. The full treatment manual of IPGT can be found in Appendix B.

Figure 6. Psychosocial Components of Integrated Psychosocial Group Treatment



Format of Group: The closed group met once a week for six weeks, with sessions 90 minutes in duration; Table 3 provides a detailed overview of each individual session. The first session was educational, while the remainder of the group utilized cognitive behavioral therapy, mindfulness-based strategies and relaxation techniques while also allowing for emotional and peer support. Topics covered in the remaining five sessions included: Pacing and goal setting, negative thinking, coping with stress and anxiety, managing setbacks, treatment adherence, and quality of life.

Table 3. Psychosocial Components of Integrated Psychosocial Group Treatment

Integrated Psychosocial Group Treatment (IPGT) Session Content	
Treatment Strategies	IPGT uses principles encompassing motivational interviewing, behavioral change, self-management and patient empowerment. The treatment model also employs: • Cognitive behavioral therapy, mindfulness-based strategies, stress reduction and relaxation techniques while also allowing for emotional and peer support • Patient education on chronic pain, mental health, and issues surrounding substance misuse, addiction and treatment adherence
Session 1	➢ The study facilitator welcomes participants, provides an overview of the study, and works on developing group dynamics and therapeutic alliance ➢ The first session is primarily educational and will cover the following topics: • What is pain (acute vs. chronic) • How pain affects the quality of life • Overview of tolerance, physical dependence, and addiction • The continuum of pain, addiction, and pseudoaddiction • Overview of mental health and comorbid chronic pain • The four A's of pain treatment outcomes • Treatment approaches discussed will include: • Adjunctive Therapies (non-drug approaches and drug-based approaches) o Drug Therapy Approaches including: the benefits and risks, evidence-based vs theory and the analgesic step ladder ➢ The session is closed with a group debrief/check-out and goal setting for the upcoming week
Session 2	➢ The session is started with group check-in and goal setting ➢ The study facilitator introduces the concept of relaxation techniques and leads the group through a visualization exercise ➢ The remainder of the group is spent on medication adherence, education on overdose and training in naloxone administration; participants are afforded the opportunity to engage in a question and answer period ➢ The session is closed with a group debrief/check-out and goal setting for the upcoming week

Session 3	➢ The session is started with group check-in and goal setting ➢ The study facilitator introduces the concept of mindfulness and leads the group through a mindfulness exercise ➢ The remainder of the group addresses the topic of "Stages of Change and Pacing Techniques" with a cognitive behavioral approach addressing both issues of chronic pain in addition to issues around medication adherence ➢ The session is closed with a group debrief/check-out and goal setting for the upcoming week
Session 4	➢ The session is started with group check-in and goal setting ➢ The study facilitator revisits the concept of relaxation techniques and leads the group through a breathing exercise ➢ The remainder of the group addresses the topic of "Negative Thinking, Fear Avoidance, and Pain Catastrophizing" with a cognitive behavioral approach ➢ The session is closed with a group debrief/check-out and goal setting for the upcoming week
Session 5	➢ The session is started with group check-in and goal setting ➢ The study facilitator re-visits the concept of relaxation techniques and leads the group through an imagery exercise ➢ The remainder of the group addresses the topic of "Coping with Stress and Anxiety" with a cognitive behavioral approach ➢ The session is closed with a group debrief/check-out and goal setting for the upcoming week
Session 6	➢ The session is started with group check-in and goal setting ➢ The study facilitator revisits the concept mindfulness techniques and leads the group through a mindfulness exercise ➢ The remainder of the group addresses the topic of "Managing Set-Backs, Treatment Adherence, and Quality of Life" with a cognitive behavioral approach ➢ The session is closed with a group debrief/check-out and address ways to continue progress post study participation

Study Interventionist: The principal investigator was the interventionist for the study and is a Social Work Clinician-Investigator. She has a Post-Graduate Certification in Pain Management from the University of Alberta and has over 10 years of experience conducting behavioral interventions with individuals with chronic pain, substance abuse, and mental health.

Fidelity: To assess treatment fidelity, a masters level research assistant and master's level licensed social worker specialized in chronic pain reviewed all the audiotaped sessions to assess the adherence to the IPGT treatment protocols. We created fidelity assessment sheets that were based on the contents of each manualized session, which were then used to indicate whether the components of the session as described in the manual were included in the session being reviewed. A fidelity score was then computed for each session that represented the percent of essential components of that session that were successfully completed by the interventionist. See Appendix C for completed fidelity assessments.

Assessment, Follow-Up, and Retention

Participants were assessed at baseline, and again following the completion of the study intervention at UPMC Pain Medicine Program or Webster Hall at the University of Pittsburgh. Participants were compensated $40 upon assessment, $50 at mid-intervention, and $75 upon 3 weeks post study completion. To control for the effects of expectations, this study was single-blinded and thus a research assistant conducted all of the assessments. This helped to make groups comparable so that specific and non-specific treatment effects could be determined with less potential for bias (Feys, Bekkering, Singh, & Devroey, 2014). The research assistant helped participants complete the self-administered questionnaires to ensure accuracy of assessments. Participants also underwent a urine analysis to confirm self-reports of substance use. Study efforts to support regular contact with participants included: collecting at least two collateral

contacts, reminder phone calls, cards with appointment times, in addition to sending letters, holiday greeting cards, and electronic messages.

Study Assessment Measures

All study measures used within this dissertation can be located in Appendix D.

Measures of Feasibility and Acceptability

Feasibility. One of the objectives of this study was to demonstrate feasibility of IPGT for chronic pain patients at risk of opioid misuse. Feasibility of recruitment efforts were determined by the proportion of patients contacted for screening versus those who consented. Feasibility of randomization was determined by whether the principal investigator was able to enroll and randomize 30 participants into TAU and IPGT. Feasibility of retention was demonstrated by the mean number of study intervention sessions attended by participants. Feasibility of data collection was determined by retention at the different time points for both groups.

Acceptability. Another objective of this study was to demonstrate acceptability of IPGT in patients with chronic pain who are at risk for opioid misuse. This was achieved through the administration of a Patient Satisfaction Survey, see Appendix B.

Preliminary Efficacy Measures

Preliminary efficacy. Another objective of this study was to examine preliminary efficacy of IPGT in patients with chronic pain who were at risk for opioid misuse through: (1) decreased opioid medication behaviors (2) improved pain severity, interference, and catastrophizing; and (3) enhanced knowledge and attitudes of overdose education and training in naloxone administration.

Substance/Opioid Use and Aberrant Drug Taking Measures

The Prescription Opioid Misuse Index (POMI) was used to evaluate if the participant was engaging in aberrant drug taking behavior (doctor shopping, taking medication at higher doses or more frequently than prescribed, and coping with personal issues) (Knisely et al., 2008) and it has demonstrated both validity and reliability (Knisely et al., 2008). The Drug Abuse Screening Test-10 (DAST-10) was used for assessing severity of any drug use and has demonstrated clinical validity (Bohn, Babor, & Kranzler, 1991; Villalobos-Gallegos, Pérez-López, Mendoza-Hassey, Graue-Moreno, & Marín-Navarrete, 2015; Yudko, Lozhkina, & Fouts, 2007).

Pain Measures

The Brief Pain Inventory Short Form (BPI) was used to assess pain severity and interference. The BPI is one of the most commonly used questionnaire to examine severity of pain and the impact of pain on daily functions. The BPI has excellent test-retest reliability, construct validity, and criterion validity (Erdemoglu & Koc, 2013; Keller et al., 2004; Tan, Jensen, Thornby, & Shanti, 2004). The Pain Catastrophizing Scale (PCS) assessed three components of catastrophizing: rumination, magnification, and helplessness. The PCS is a 13-item instrument that has demonstrated both validity and reliability (M. J. Sullivan, S. R. Bishop, & J. Pivik, 1995; Tan et al., 2004). The Pain Stages of Change Coping Questionnaire (PSOCQ) was used to examine patients' readiness to adopt a self-management approach to chronic pain. The PSOCQ has 4 dimensions each representing the stages of change: pre-contemplation, contemplation, action, and maintenance. The questionnaire is based on a 5-point likert type scale from 'strongly disagree' (1) to 'strongly agree' (5) and classifies patients into a distinct stage. The PSOCQ has demonstrated validity (Carr, Moffett, Sharp, & Haines, 2006).

Knowledge of Overdose Education and Naloxone Administration Measure

The Brief Opioid Overdose Knowledge (BOOK) Questionnaire was used to assess knowledge on overdose and naloxone administration. The BOOK is a 3-factor scale, representing opioid knowledge (4 items), opioid overdose knowledge (4 items), and opioid overdose response knowledge (4 items). The questionnaire has demonstrated both internal and face validity (Kelly E Dunn et al., 2016).

Mental Health Measures

Depression and anxiety was measured with the Hospital Anxiety and Depression Screen (HADS). The questionnaire is comprised of seven questions which assess anxiety and seven questions which examine depression. HADS has demonstrated both reliability and validity (Bjelland, Dahl, Haug, & Neckelmann, 2002). Post-Traumatic Stress Disorder (PTSD) was captured with the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5). The PC-PTSD-5 is a five-item measure that reflects the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) PTSD diagnostic criteria and has demonstrated validity (van Dam, Ehring, Vedel, & Emmelkamp, 2010).

Data Analysis Plan

All data was entered into in Stata 14.2 (StataCorp, 2015). Descriptive statistics including: frequencies, means and standard deviations were computed on variables for all data collection points. Frequency and proportions were conducted on all categorical data and tests of means were conducted on all continuous data depending on its distribution. Continuous data was assessed in order to determine the presence of skewed data, outliers and missing data. For interval/ratio data, means and standard deviations were conducted. Cronbach's alpha for internal consistency reliability coefficients were run on all study instruments and all potential

confounders were determined. All independent variables were assessed for a relationship with the dependent variable and if there was a significant relationship, the independent variable was entered as a covariate. Shapiro-Wilk's test was conducted to assess the assumption of normality and Levene's test was also conducted to evaluate the baseline homogeneity of patients.

Research Question 1: Feasibility

RQ1: Is there a difference in the frequency of attrition across groups (IPGT vs. TAU)?

HO: There is no difference in the frequency of attrition across groups (IPGT vs. TAU).

HA: There is a difference in the frequency of attrition across groups (IPGT vs. TAU).

To examine RQ1, successful delivery of all intervention components to 75% of IPGT recipients were analyzed by conducting a chi-square; the frequency of withdrawal was compared between groups (IPGT vs. TAU). Treatment retention of 75% of IPGT recipients at the completion of the study was analyzed by calculating number of recipients retained at 6 weeks divided by number of consented recipients.

Research Question 2: Acceptability

RQ2: Did the IPGT recipients demonstrate high levels of intervention satisfaction, and retention (75%) at study completion?

H0: IPGT did not demonstrate high levels of intervention satisfaction and retention (75%) at study completion.

HA: IPGT demonstrated high levels of intervention satisfaction and retention (75%) at study completion.

To evaluate RQ2, acceptability was examined with a Patient Satisfaction Questionnaire, which included a 16 item 5-point Likert scale. Means and standard deviations were calculated for each of the questions and delivery of all intervention components to 75% of IPGT recipients was

analyzed by calculating number of recipients retained at 6 weeks divided by number of consented recipients.

Research Question 3a: Preliminary Efficacy

Improved Knowledge on Opioids, Opioid Overdose, and Overdose Response

> **RQ3a**: Do chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate a significant improvement in knowledge on opioid medication, opioid overdose, and opioid overdose response?
>
> **H0**: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU do not demonstrate significantly greater improvements in knowledge on opioid medication, opioid overdose, and opioid overdose response?
>
> **HA**: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate significantly greater improvements in knowledge on opioid medication, opioid overdose, and opioid overdose response?

To examine RQ3a, the Brief Opioid Overdose Knowledge (BOOK) Questionnaire was used to assess knowledge on opioids, overdose, and overdose response. The BOOK contains true or false questions with 3 subscales representing opioid medication knowledge (4 items), opioid overdose knowledge (4 items), opioid overdose response knowledge (4 items), and total knowledge (12 items). Paired-samples t-test were conducted to assess pre-test and post-test scores (9 weeks) of the IPGT treatment group to determine significance of improved knowledge on opioid medications, opioid overdose, and overdose response.

Research Question 3b: Preliminary Efficacy

Opioid Misuse Behavior

RQ3b: Do chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate a significant reduction in opioid misuse?

H0: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU do not demonstrate significant reduction in opioid misuse.

HA: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate significant reduction in opioid misuse.

To assess RQ3b, generalized linear mixed models were used to test the binary dependent variable opioid misuse. Using a multilevel framework is particularly ideal for clinical trials as it permits flexible treatment of time where change in an outcome could be nonlinear or accelerate at different rates across times (Mallinckrod†, Lane, Schnell, Peng, & Mancuso, 2008). Multilevel models also offer the benefit of using all data, including the use of participants who may not have completed all follow up assessments; this is particularly advantageous for pilot studies (De Stavola, 2004). Within these models, we tested a time by intervention condition interaction on the study outcome and the model adjusted for both depression and race given the significant difference at baseline between IPGT and TAU.

Research Question 3c: Preliminary Efficacy

Pain Severity, Interference, and Catastrophizing

RQ3c: Do chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate a significantly greater improvement in pain severity, interference, and catastrophizing?

H0: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU do not demonstrate significantly greater improvements in pain severity, interference, and catastrophizing.

HA: Chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate significantly greater improvements in pain severity, interference, and catastrophizing.

To evaluate RQ3c, a priori intent-to-treat analysis of the longitudinal data using linear mixed models was conducted. Models of longitudinal change followed the mixed model procedure described by Singer and Willett (Singer, Willett, & Willett, 2003). Within the pain severity, interference, and catastrophizing analyses, time invariant covariates included race, depression, and anxiety covariates. Mixed models were estimated for each outcome and if a time by treatment interaction was obtained, the RQ3c was tested using simple slope comparisons (Bauer & Curran, 2005) to specifically compare TAU and IPGT recipients at 3 weeks post treatment. The possibility of interactions was evaluated to determine whether random slope effects were required. False discovery rate (FDR) were used to address type 1 errors. FDR is typically used as an alternative to the Bonferroni correction and controls for a low proportion of false positives, as opposed to guarding against making any false positive conclusion at all. The result is often increased statistical power and fewer type I errors (M. E. Glickman, Rao, & Schultz, 2014).

Study Timeline

This project required just under 12 months to complete as depicted in Table 4.

Table 4. Study Timeline

Project Timeline	Study Month											
Activity	1	2	3	4	5	6	7	8	9	10	11	12
Proposal defense	X											
Finalize study protocol	X	X										
Intervention design	X	X										
Completion of DSMP	X	X										
IRB approval	X	X										
Recruit 30 patients			X	X	X							
Delivery of intervention						X	X	X				
Interim grant report						X						
Data collection						X	X	X				
Data cleaning & analyses						X	X	X	X	X	X	
Dissertation writing							X	X	X	X	X	X
Submit grant report												X
Defend dissertation												X

Ethical Considerations and Study Limitations

Ethical Approval of all procedures that was performed in this study involving human participants was in accordance with the Ethical Standards of the Institutional and/or National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. IRB approval was obtained from the University of Pittsburgh.

Methodology Summary

This chapter defined the methodology of this dissertation in which a pilot RCT was conducted to examine IPGT as a novel behavioral health treatment model for chronic pain patients at risk for opioid misuse. IPGT is a comprehensive treatment approach that integrates evidenced based psychosocial treatments for chronic pain and risk factors associated with opioid misuse. As defined within this chapter, the primary research questions sought to investigate: (1) feasibility; (2) acceptability; and (3) preliminary efficacy of IPGT. Chapter 4 will proceed to review the study findings of each of these research questions.

Chapter IV: Results

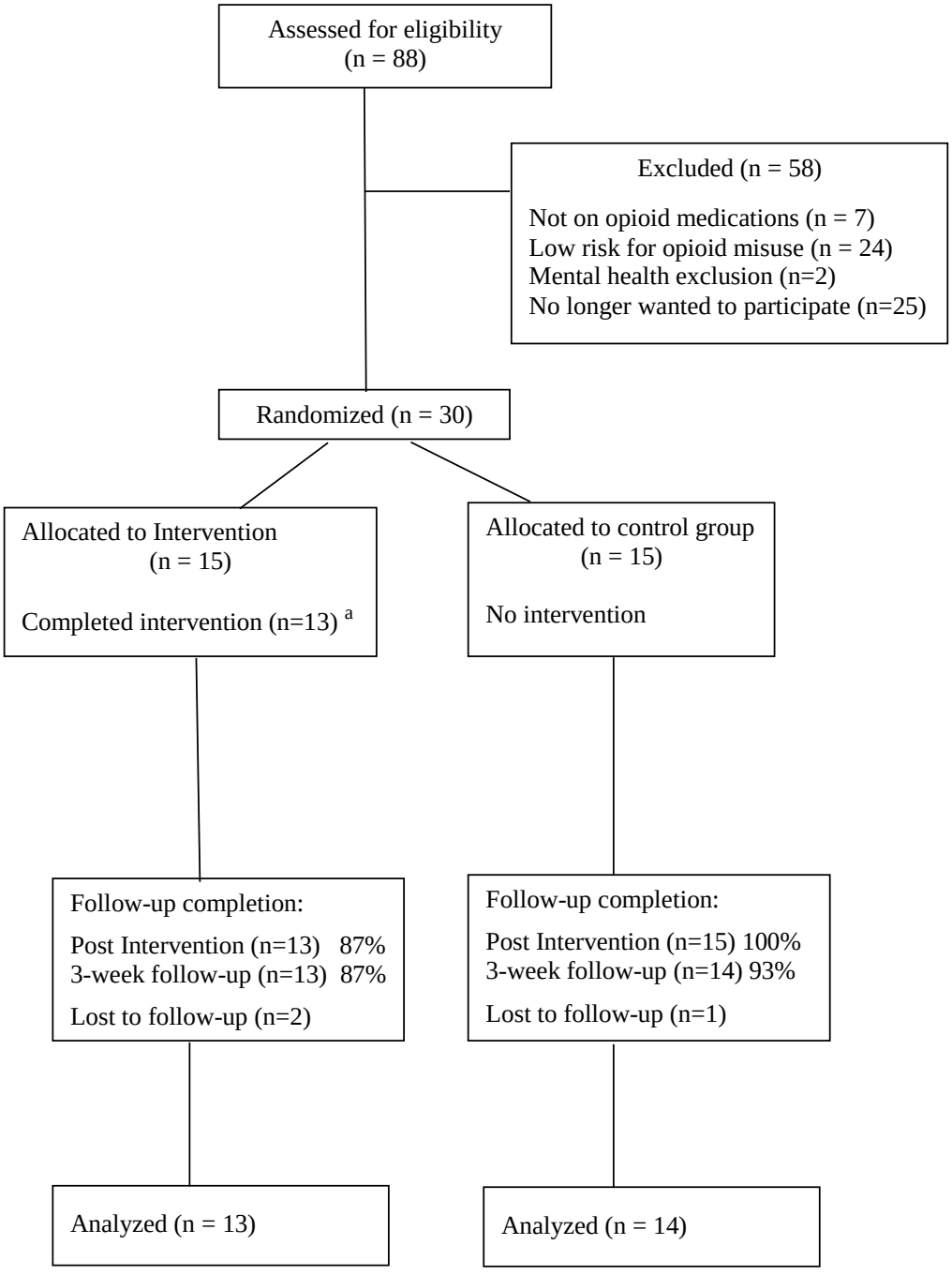
This chapter will provide the results from the dissertation: *A Randomized Pilot Trial of a Harm Reduction and Preventative Approach for Patients with Chronic Pain at Risk for Opioid Misuse.* The primary aim of this study was to examine the feasibility and acceptability of IPGT in a sample of chronic pain patients at risk for opioid misuse who were randomized into either IPGT or TAU. The secondary aim of the study was to investigate preliminary efficacy through changes in pain severity, interference, and catastrophizing in addition to opioid misuse behaviors and increased knowledge of opioid medications, opioid overdose, and overdose response.

Study Recruitment and Retention

Recruitment occurred from June 2018 until November 2018. We approached a total of 88 patients who agreed to participate in screening, of which 58 patients were excluded. Of these excluded patients, 12% (n=7) were not on opioid medication, 41% (n=24) screened 'low risk' for opioid misuse, 3% (n=2) screened positive for either psychosis or mania, and 43% (n=25) no longer wanted to participate; 5% (n=4) of these individuals were eligible but refused to provide consent, contributing to a 88% consent rate. Therefore, a total of 30 patients screened eligible for the study, provided written informed consent, and were assigned to IPGT (n=15) or TAU (n=15) conditions. Two of the participants were randomized to the intervention but did not attend any of the treatment sessions as one participant was hospitalized due to a health condition and the other participant experienced a fall and was confined to bed. Following completion of the intervention, a total of 87% (n=13) of the IPGT recipients and 100% (n=15) of the TAU participants completed the first follow-up, which was 6 weeks after their baseline. A total of 87% (n=13) of the IPGT recipients and 93% (n=14) of the TAU participants completed the second

follow up assessment, which was 9 weeks following completion of baseline. See Figure 7 for study consort details.

Figure 7. Study Consort Diagram



[a] *Two of the patients randomized to IPGT did not attend any sessions as one participant was hospitalized during the time of the intervention and the other participant experienced a fall and had mobility issues*

Baseline Demographics

Participants were on average 52.3 years old (SD=10.54), 66.6% female (n=20), 33.3% employed (n=10), 33.3% receiving disabilities (n=10), and 73.3% (n=22) of the participants had obtained more than high school for their education. To examine the presence of any significant differences between randomized groups, we performed independent sample t-tests and chi squared tests. It was found that there were racial differences in the sample: with 13.3% (n=2) Black participants in the TAU group compared to 66.6% (n=10, p=0.003) of the Black participants in the IPGT group. Results are provided in Table 5.

Table 5. Participant Demographics; (N=30, TAU=15, IPGT=15)

	Treatment Arm				
	Total % (n)	TAU %(n)	IPGT %(n)	X^2 (df)	P
Female	66.6(20)	53.3(8)	80(12)	2.4(1)	0.12
Age [a]	52.3(10.54)	50.7(12.78)	53.9(9.25)	0.83(28)	0.42
Race					
White	60(18)	86.6(13)	33.3(5)	8.90(1)	0.03
Black [b]	40(12)	13.3(2)	66.6(10)		
Education					
More than high school	73.3(22)	66.6(10)	80(12)	4.08(1)	0.42
Employment Status					
Employed	33.3(10)	46.6(7)	20(3)	6.40(1)	0.17
Not employed [b]	33.3(10)	26.6(4)	40(6)		
Receiving disability [b]	33.3(10)	26.6(4)	40(6)		

[a]Mean (SD), t, df; [b]Fisher's exact test

Health Characteristics

For general health, on a 5-point Likert scale with higher scores indicating worse condition, the mean score for the sample was 3.3 (SD=1.01). There were no significant differences in types of chronic pain; 53.3% (n=16) of the participants reported having low back pain, 20% (n=6) participants reported to have chronic post-surgical pain, and 26.7% (n=8) participants had miscellaneous chronic pain not specified. For pain related measures, the mean sample for pain severity (pain at its worst) on a scale of 0-10 was 6.5 (SD=1.94) and the mean

sample for pain interference on a scale of 0-70 was 42.8 (SD=13.83). For pain catastrophizing the mean score of the sample was 28.1 (SD=14.14) on a scale of 0-52, where 0-20 is considered low pain catastrophizing, 21-30 is moderate pain catastrophizing and 31-52 is high pain catastrophizing. There were no significant differences in general health, pain severity, pain interference, and pain catastrophizing. With regards to mental health, 13.3% (n=13) participants screened positive for anxiety, and 30% (n=9) screened positive for PTSD. There were no significant differences in mental health between IPGT and TAU, with the exception of depression where there was a significant differences in the sample: with 40% (n=6) of the participants in the TAU group having a positive screen of depression compared to 66.6% (n=10, p=0.001) participants in the IPGT group.

Table 6. Health Characteristics; (N=30, TAU=15, IPGT=15)

		Treatment Arm			
	Total % (n)	TAU %(n)	IPGT %(n)	X^2 (df)	P
General health [ab]	3.3(1.01)	3.4(1.01)	3.13(1.19)	1.59(32)	0.11
Types of Chronic Pain					
Low Back Pain	53.3(16)	46.7(7)	60(9)	0.54(1)	0.46
Chronic Post Surgical Pain	20(6)	20(3)	20(3)	0.00(1)	1.00
Miscellaneous	26.7(8)	33.3(5)	20(3)	0.68(1)	0.41
Pain Measures					
Pain Severity [ac]	6.5(1.94)	6(1.69)	6.9(2.12)	1.25(28)	0.23
Pain Interference [ad]	42.8(13.83)	40.7(14.43)	44.9(13.35)	0.83(28)	0.42
Pain Catastrophizing [ae]	28.1(14.14)	24.5(15.30)	31.7(12.36)	1.40(28)	0.17
Mental Health					
Depression	53.3(16)	66.6(10)	40(6)	24.29(1)	.001
Anxiety	43.3(13)	46.6(7)	40(6)	0.13(1)	0.71
PTSD	30(9)	33.3(5)	26.6(4)	0.021(1)	0.89
Substance Use					
Opioid misuse [f]	26.6(8)	20(3)	33.3(5)	0.68(1)	0.68
Illicit drug use [f]	23.3(7)	20(3)	26.6(4)	0.17(1)	0.68
Hazard alcohol use [f]	13.3(4)	0(0)	26.6(4)	0.99(1)	0.32

[a]Mean (SD), t, df; [b]5-point Likert scale with higher scores indicating worse condition; [c]Scores range 0-10 with higher scores suggesting increased severity; [d] Scores range 0-70 with higher scores suggesting more interference; [e] Scores range 0-52 with higher scores indicating worse condition; [f]Fisher's exact test

For substance use, 13.3% (n=4) participants screened positive for hazardous drinking, 23.3% (n=7) for current drug use, and 26.6% (n=8) for opioid medication misuse. There were no significant differences between IPGT and TAU for substance use as depicted in Table 6.

Research Question 1: Feasibility

- *Is there a difference in the frequency of attrition across groups (IPGT vs. TAU)?*

The IPGT intervention protocol included six weekly sessions which were 90 minutes in duration. All intervention components were delivered to 87% (n=13) of the participants, successfully achieving the goal of 75% or higher. Despite the modest attrition rate, two of the participants (13.3%) did not attend any of the 6 sessions after they completed their baseline assessment. As mentioned in the recruitment and retention section, one of the participants reported to have been hospitalized due to a health condition, and the other participant reported that she experienced a fall and mobility was a barrier for her to attend the intervention sessions. A chi-square was conducted for incomplete assessments to examine if there was a statistically significant difference between participants (control vs. experimental). The results of the chi-squares were not significant, for baseline $x^2(1) = 0.00$, $p = 1.00$, follow-up at 6 weeks $x^2(1) = 2.14$, $p = 0.48$, or follow-up at 9 weeks $x^2(1) = 0.37$, $p = 0.54$ suggesting no proportional differences of completed assessments by treatment group (Table 7).

Table 7. Chi-Square on Participants that Completed Assessments by Treatment Group

	TAU		IPGT			
Assessment	Incomplete	Complete	Incomplete	Complete	x^2	p
Baseline [a]	0	15	0	15	0.00	1.00
Follow-up 6 weeks [a]	0	15	2	13	2.14	0.48
Follow-up 9 weeks [a]	1	14	2	13	0.37	0.54

[a] Fisher's Exact

Research Question 2: Acceptability

- *Did the IPGT recipients demonstrate high levels of intervention satisfaction, and retention (75%) at study completion?*

IPGT recipients reported a high level of satisfaction with the intervention (Table 8). Specifically, all participants who completed the satisfaction survey (n=13) agreed or strongly agreed to each question, apart from the question "the length and number of sessions were appropriate (6 weeks)." Participants who completed the patient satisfaction survey (N=13), on a 5-point scale (1=strongly disagree, 2=disagree, 3= neither agree or disagree, 4= agree, and 5= strongly agree), gave nearly perfect ratings for the questions: "this group has been helpful to me" (Mean [M]=4.9, SD=0.28), "I have increased my knowledge on how to manage my pain" (M=4.8, SD=0.44), "the facilitator demonstrated expertise in the subject matter" (M=4.9, SD=0.28), "the group handouts were helpful" (M=4.8, SD=0.44), and "I would

Table 8. Mean Scores of Acceptability Survey (N=13)

Patient Satisfaction Questions	M	SD
This group has been helpful to me.	4.9	0.28
I am satisfied that I attended the group.	4.9	0.28
The group handouts were helpful.	4.8	0.44
The exercises enhanced my ability to learn the subject.	4.7	0.48
The group discussions were supportive and informative.	4.8	0.38
The facilitator demonstrated expertise in the subject matter.	4.9	0.28
The facilitator created a comfortable learning environment.	4.9	0.28
The facilitator was sensitive to my cultural background (race, religion, etc.)	5.0	0.00
The length and number of sessions were appropriate (6 weeks)	2.8	1.17
Length (90 minutes) and frequency of sessions was appropriate	4.5	0.52
I have increased my knowledge on how to manage my pain.	4.8	0.44
I have increased my knowledge on the risks for opioid misuse	4.6	0.87
I have increased my knowledge on overdose and naloxone	4.5	0.88
I would recommend this group to others.	4.8	0.38
I am satisfied with my overall experience attending group.	4.8	0.38
Overall, I would rate the group as good.	4.9	0.28

recommend this group to others", (M=4.8, SD=0.38). All participants stated that they strongly agreed to the question "the facilitator was sensitive to my cultural background (race, religion, etc.)." Overall participants seemed to have high levels of satisfaction which is suggested by the fact that all intervention components were delivered to 87% (n=13) of the participants.

Research Question 3: Preliminary Efficacy

Knowledge of Opioids, Overdose, and Naloxone Administration

- *Do chronic pain patients who are at risk for opioid misuse who receive IPGT demonstrate a greater improvement in knowledge of opioids, overdose, and overdose response when compared with those who receive TAU?*

Unadjusted Outcomes Across Time. The Brief Opioid Overdose Knowledge (BOOK) Questionnaire was used to assess knowledge on opioids, overdose, and naloxone administration. The BOOK contains true or false questions with 3 subscales representing opioid medication knowledge (4 items), opioid overdose knowledge (4 items), opioid overdose response knowledge (4 items), and total knowledge (12 items). When examining the pre-test and post-test scores (at 9 weeks) of the IPGT treatment group for the BOOK Questionnaire, results of the paired-samples t-test (Table 9.) demonstrated there was not a significant difference in general opioid knowledge with a mean pre-test score of 2.45(SD=1.36) and a post-test score of 2.93 (SD= 1.10), t(26)= -1.04, p= 0.30. There was a significant difference in opioid overdose knowledge with a mean score of 2.27 (SD= 1.28) and post-test mean score of 3.15(SD= 0.90), t(26)= -2.09, p= 0.05, in addition there was a significant difference in overdose response knowledge with a mean score of 2.27(SD= 1.28) for the pre-test and 3.15(SD=0.90), t(26)=-2.09, p= 0.02 for the post test. Lastly the total score had a significant difference with a mean pre-test score of 7.20 (SD=3.54) and a post-test score of 9.54 (SD=1.85), t(26), p=0.04. Post-tests scores were taken during the participants' second follow-up assessment at 9 weeks.

Table 9. Pre and Post Test (9 weeks) Knowledge Scores for IPGT Treatment Group

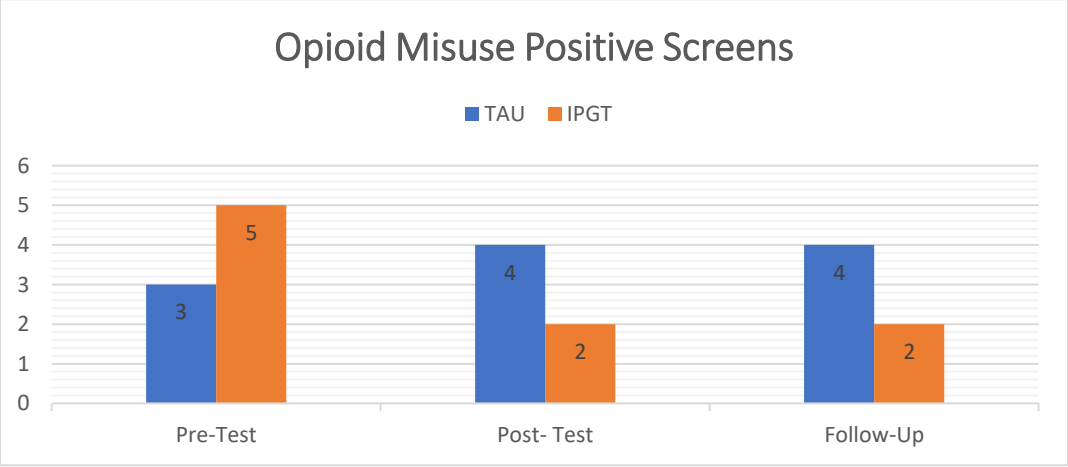
Subscales for Knowledge	Pre-Test M(SD)	Post-Test M(SD)	t	p-value	Cohen's D
Opioid Knowledge [a]	2.45(1.36)	2.93(1.10)	-1.04	0.30	-0.38
Overdose Knowledge [a]	2.27(1.28)	3.15(0.90)	-2.09	0.05	0.32
Overdose Response Knowledge [a]	2.47(1.36)	3.50(0.66)	-2.59	0.02	-0.98
Total Knowledge [b]	7.20(3.54)	9.54(1.85)	-2.13	0.04	-0.81

[a] Subscale Knowledge Score Range 0-4, [b] Total Knowledge Score Range 0-12

Opioid Misuse Behaviors

We examined specific opioid misuse behaviors of the participants at baseline to better understand their risk profile. The majority of participants reported using more of their opioid medication than was prescribed (IPGT=20%, TAU=20%), using the medication more often than prescribed (IPGT=33.3%, TAU=26.6%), needing early refills (IPGT=13.3%, TAU=13.3%), getting high or feeling a buzz from their opioids (IPGT=26.6%, TAU=13.3%), and using the medication to cope with emotional problems (IPGT=6.6%, TAU=6.6%). None of the IPGT or TAU participants reported doctor shopping. The IPGT recipients had 5 positive screens for opioid misuse at baseline and following the completion of the intervention, the group decreased to 2 positive screens. Whereas the TAU group had 3 positive opioid misuse screens at baseline and at the end of the study increased to 4 positive screens as depicted in Figure 8.

Figure 8. Opioid Misuse Behaviors Pre and Post Test



In terms of our multivariate analysis (Table 10), generalized linear mixed models were used to test the binary dependent variable opioid misuse. Within these models, we tested a time by intervention condition interaction on the study outcome and the model adjusted for both depression and race given the significant difference at baseline between IPGT and TAU. We detected no significant differences in opioid misuse between participants who received the IPGT intervention and those patients in the control group (AOR= 069, 95% CI=-0.26, 1.64, *p*=0.16).

Table 10. Opioid Misuse with Treatment By Time Interaction

	AOR	SE	95% CI	*p*
Depression	0.60	0.72	-081, 2.01	0.99
Race	0.01	1.01	-2.11, 2.11	<0.001
Time	-1.90	1.39	-4.63, 0.82	0.17
Treatment	-1.13	0.92	-2.93, 0.67	0.17
Treatment X Time	0.69	0.48	-0.26, 1.64	0.16

Pain Severity, Pain Interference, and Pain Catastrophizing

- *Do chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate a significantly greater improvement in pain severity, interference, and catastrophizing?*

Unadjusted Outcomes Across Time

All scores for the unadjusted outcomes across time for pain severity, pain interference, and pain catastrophizing for both TAU and IPGT can be found in Table 11.

Pain Severity. For pain severity at its worst, on a scale of 0 to 10, the IPGT recipients had a mean score of 8.13 (SD=1.46) at baseline while TAU had a mean score of 7.53 (SD=1.25). IPGT participants had a mean score of 6.54 (SD=2.50) for the first follow-up (6 weeks), and the TAU recipients had 6.29 (SD=1.73). For the second follow-up (9 weeks) IPGT participants had a mean of 7.15 (SD=2.38) and the TAU group had 7.36 (SD=1.55).

Pain Interference. The IPGT recipients on the pain interference measure, which ranged from 0 to 70, had a mean score of 44.93 (SD=13.35) at baseline and TAU participants scored 40.70 (SD=14.44). The IPGT group at the first follow-up (6 weeks) scored a mean of 41.80 (SD=13.76), while the TAU scored 32.60 (SD=18.55). At the second follow-up (9 weeks), the IPGT group had a mean score of 32.80 (SD=17.94) and the TAU had 42 (SD=10.71).

Pain Catastrophizing. The pain catastrophizing measure had a range of 0 to 52, in which the IPGT recipients had a mean score of 31.70 (SD=12.36) at baseline, while the TAU group had 24.52 (SD=15.30). At the first follow-up (6 weeks), IPGT recipients had a mean score of 30.42 (SD=11.84), while the TAU participants had a mean score of 22.90 (SD=14.95). At the second follow-up (9 weeks) IPGT had a mean score of 22.71 (SD=11.14) and the TAU group had 25.93 (SD=11.95).

Table 11. Unadjusted Pain Outcomes (N=30, TAU=15, IPGT=15)

		Treatment Arm	
Pain Measures	Total M(SD)	TAU M(SD)	IPGT M(SD)
Baseline			
Pain Severity	7.81(1.37)	7.53(1.25)	8.13(1.46)
Pain Interference	42.84(11.46)	40.7314.44)	44.93(13.35)
Pain Catastrophizing	28.12(14.14)	24.52(15.30)	31.70(12.36)
Follow-up 1 (6 Weeks)			
Pain Severity	6.41(2.10)	6.29(1.73)	6.54(2.50)
Pain Interference	36.93(16.86)	32.60(18.55)	39.5413.76)
Pain Catastrophizing	26.42(14.95)	22.90(14.95)	30.42(11.84)
Follow-up 2 (9 Weeks)			
Pain Severity	7.32(1.95)	7.36(1.55)	7.15(2.38)
Pain Interference	37.62(15.10)	42(10.71)	32.8(17.94)
Pain Catastrophizing	24.35(11.46)	25.93(11.95)	22.71(11.14)

The results for the effect size for the IPGT treatment group is demonstrated in Table 12. Pain severity from baseline to the second follow-up at 9 weeks was d=0.69, (95% CI= -0.78, 1.45), pain interference was d=0.74, (95% CI= -.024, 1.52), and pain catastrophizing d= 076, (95% CI= -.018, 1.52).

Table 12. Effect Size for IPGT Treatment Group (N=15) from Baseline to Follow-up 2

Pain Outcomes	Effect Size Cohen's D	95% CI
Pain Severity	0.69	(-.078, 1.45)
Pain Interference	0.75	(-.024, 1.52)
Pain Catastrophizing	0.76	(-.018, 1.52)

Multivariate Analyses

To examine the preliminary effectiveness of the IPGT intervention, we used linear mixed modeling to examine the differences between IPGT and TAU, as a function of treatment, time, and treatment X time interaction, on the outcome variables of pain severity, pain interference, and pain catastrophizing. We used an Intention-to-Treat approach as all participants who were randomized were included in the final analyses. Following methods suggested by Singer and Willett (Singer et al., 2003), we sequentially constructed different models to help assess if the increasing polynomial complexity enhanced model fit, according to the Akaike information criterion (AIC), Bayesian information criterion (BIC) and Log-linear likelihood ratio (−2LLR); where non-significant values indicate that the number of variables contained in the model does not improve the fit from the preceding model with less variables.

An unconditional means model (Model A) and an unconditional growth model (Model B) were used to assess whether there was systematic variation in the outcome and whether that variation resided within or between people. We then constructed mixed effects that modelled time as a random effect. The estimates of variation from these two unconditional models were used for subsequent conditional models (Model C and Model D) to assess any reduction in variance and improved model fit by the adding of Level 2 variables.

We built 3 separate models for each dependent variable (pain severity, pain interference, and pain catastrophizing), the results for the model selection is depicted in Table 13. In order to attempt to reduce the effect of confounding variables we controlled for depression and race given the significant difference at baseline between IPGT and TAU. We also controlled for anxiety due to recommendations within the literature (de Heer et al., 2014) as depression and anxiety is often prevalent of patients with chronic pain. Further, depression, anxiety, and chronic pain share underlying cognitive and behavioral processes, such as increased attention towards threat and anxious avoidance of physical exertion which can influence pain catastrophizing and pain-related fear which in turn can potentially lead to greater disability and increased severity of pain (Arnow et al., 2011; de Heer et al., 2014). In the final models, anxiety was significant within the pain interference model and pain catastrophizing outcome model and race was significant in pain interference and pain catastrophizing (Table 13).

Table 13. Results of Fitting Multilevel Models for Pain Outcomes

Pain Severity		**Model A**	**Model B**	**Model C**	**Model D**
Fixed Effects	**Intercept**	7.22 (0.24)	7.78 (0.47)	8.84 (1.05)	8.77 (1.06)
p-value	**(Initial**	<.001	<.001	<.001	<.001
Time	**Status)**		-0.29 (0.22)	-0.72(0.52)	-0.64 (0.53)
p-value			0.20	0.17	0.22
Treatment				-0.53(0.47)	-0.91 (0.69)
p-value				0.26	0.19
Treatment X Time				0.22 (0.23)	0.19 (0.23)
p-value				0.36	0.41
Race					1.02 (0.55)
p-value					0.06
Depression					0.15 (0.44)
p-value					0.73
Anxiety					0.10
p-value					0.84
Variance Components					
Level 1	**Within Person**	2.80 (0.54)	2.66 (0.51)	2.64 (0.51)	2.65 (0.52)
Level 2	**In Intercept**	0.74 (0.50)	0.17 (0.46)	0.16 (0.89)	0.09 (0.87)
In Rate of Change			0.06 (0.12)	0.14 (0.20)	0.14 (0.20)
Goodness of Fit					
−2LLR		-170.69	-169.42	-169.00	-168.86
AIC		347.38	350.84	352.01	355.69
BIC		354.67	365.42	369.02	377.07
ICC		0.21			
Pain Interference		**Model A**	**Model B**	**Model C**	**Model D**
Fixed Effects	**Intercept**	39.13 (1.96)	44.69 (3.87)	58.99 (3.77)	46.85 (8.62)
p-value	**(Initial**	<.001	<.001	<.001	<.001
Time	**Status)**		-2.85 (1.79)	-9.29 (3.95)	-8.85 (3.82)
p-value			0.11	0.02	0.02
Treatment				-7.10 (3.76)	-6.00 (3.60)
p-value				0.06	0.02
Treatment X Time				3.18 (1.75)	3.32 (1.69)
p-value				0.07	0.05
Race					8.07 (3.97)
p-value					0.04
Depression					5.94 (3.26)
p-value					0.07
Anxiety					6.49 (3.30)
p-value					0.05
Variance Components					
Level 1	**Within Person**	183.82(34.72)	171.36 (0.51)	161.7 (31.5)	144.62(27.43)
Level 2	**In Intercept**	48.63(31.38)	37.39 (46.63)	37.28 (46.8)	13.07(40.70)
In Rate of Change			4.15 (9.95)	4.52 (9.99)	5.65 (8.95)
Goodness of Fit Statistics					
−2LLR		-350.54	-349.19	-347.38	-339.72
AIC		707.08	708.38	708.75	699.43
BIC		714.40	720.59	725.85	723.86
ICC		0.21			

Pain Catastrophizing		Model A	Model B	Model C	Model D
Fixed Effects	**Intercept**	26.36 (1.84)	44.69 (3.87)	44.08 (7.42)	30.11 (6.57)
p-value	**(Initial**	<.001	<.001	<.001	<.001
Time	**Status)**		-2.85 (1.79)	-7.08 (3.22)	-6.85 (2.59)
p-value			0.11	0.03	0.008
Treatment				-7.00 (3.31)	-5.32(2.73)
p-value				0.04	0.05
Treatment X Time				2.57 (1.42)	2.74 (1.14)
p-value				0.07	0.02
Race					9.19 (3.13)
p-value					0.003
Depression					-1.15 (2.39)
p-value					0.63
Anxiety					16.03 (2.43)
p-value					<.001
Variance Components					
Level 1	**Within Person**	123.64(23.23)	171.36(0.51)	113.35(21.31)	83.91(16.45)
Level 2	**In Intercept**	57.01(26.62)	37.39(46.63)	56.69(25.52)	18.23(14.77)
In Rate of Change			4.15 (9.95)		5.65 (8.95)
Goodness of Fit Statistics					
−2LLR		-337.78	-336.95	-334.78	-312.75
AIC		681.56	683.90	683.56	645.50
BIC		688.89	696.11	700.66	669.92
ICC		0.32			

Model A: Unconditional Means Model; Model B: Unconditional Growth Model;
Model C: Conditional Growth Model; Model D: Conditional Growth Model

Changes in Pain Across Time

Linear Mixed Models were used to examine the group differences in patterns of change over time for pain severity, pain interference, and pain catastrophizing (Table 14). Results of the Linear Mixed Models analyses showed that the IPGT intervention group made nonsignificant improvements in pain severity compared to the TAU control group (β =0.22, 95% CI= -0.24, 0.66, $p = 0.35$). However, we observed significant treatment X time interactions on the outcome of pain interference (β =3.32, 95% CI= 0.01, 6.65, $p = 0.05$) and pain catastrophizing (β =2.74, 95% CI= 0.49, 4.99, $p = 0.02$).

Table 14. Results from Linear Mixed Models for Pain Outcomes

Pain Severity	B	p-values	95% CI
Anxiety	0.05	0.11	(-0.86, 0.97)
Depression	0.21	0.44	(-0.70, 1.11)
Race	0.81	0.14	(-0.26, 1.87)
Time	-0.70	0.17	(-1.74, 0.30)
Treatment	-0.34	0.49	(-1.30, 0.62)
Treatment X Time	0.22	0.35	(-0.24, 0.66)
Pain Interference	**B**	**p-values**	**95% CI**
Anxiety	6.49	0.05	(0.02, 12.96)
Depression	5.94	0.07	(-0.44, 12.33)
Race	8.07	0.04	(0.29, 15.85)
Time	-8.85	0.02	(-16.34, -1.35)
Treatment	-6.00	0.09	(-13.05, 1.05)
Treatment X Time	3.32	0.05	(0.01, 6.65)
Pain Catastrophizing	**B**	**p-values**	**95% CI**
Anxiety	16.03	<.001	(11.27, 20.79)
Depression	-1.15	0.63	(-5.78, 3.49)
Race	9.19	0.003	(3.06, 15.32)
Time	-6.85	0.008	(-11.93, -1.77)
Treatment	-5.32	0.05	(-10.68, 0.34)
Treatment X Time	2.74	0.02	(0.49, 4.99)

Summary of the Results

A pilot RCT was conducted to examine an IPGT model in chronic pain patients who were at risk for opioid misuse. This study has provided foundational data on the feasibility, acceptability, and preliminary efficacy of improved knowledge, opioid misuse, and pain severity, interference, and catastrophizing. In this chapter, findings of the pilot study were presented and used to answer the research questions and Chapter 5 of this dissertation will further discuss these results in detail.

Chapter V: Discussion

The purpose of this chapter is to provide an overview of the research findings from *Integrated Psychosocial Group Treatment (IPGT): A Randomized Pilot Trial of a Harm Reduction and Preventative Approach for Patients with Chronic Pain at Risk for Opioid Misuse*, while additionally offering a detailed interpretation and a discussion of the study results. This dissertation addressed two research questions which included feasibility and acceptability of IPGT for patients with chronic pain at risk for opioid misuse, and a third research question which was to examine the preliminary efficacy of the intervention including: (a) improved knowledge on opioid medication, overdose, and overdose response; (b) decreased opioid medication misuse; and (c) reductions in pain severity, pain interference, and pain catastrophizing. Following the review of the findings, further discussion of how the study results compare with the current literature will ensue. Lastly, implications for future research and social work practice will occur followed by limitations and conclusions of the study.

Summary of Main Findings

Research Question 1: Feasibility of IPGT

A primary aim of this dissertation was to evaluate IPGT as a feasible intervention for chronic pain patients who are at risk for opioid misuse. The number of patients that withdrew from the control group was (n = 1) and (n=2) from the experiment group. These data suggest that patients are not more likely to withdraw from the study when randomized to receive the IPGT intervention. Additionally, we had an 88% consent rate and all intervention components were successfully delivered to 87% of the participants, thus suggesting that the IPGT intervention is feasible to administer to chronic pain patients at risk for opioid misuse. This data is similar to other cognitive behavioral studies with chronic pain patients that found attrition rates to be less

than 15% in both the treatment and control groups (Glombiewski, Hartwich-Tersek, & Rief, 2010). A low attrition rate and a high compliance often suggest that patients consider treatment valuable, meets their expectations, and is not too intensive. As such, attrition rates and compliance generally are a good reflection of feasibility (Moore, Carter, Nietert, & Stewart, 2011). Both our attrition and compliance rates help demonstrate the feasibility of the IPGT intervention when applied to patients with chronic pain who are at risk for opioid misuse.

The original proposal for this dissertation included recruiting from both the UPMC Pain Medicine Program in addition to the University's research patient registry. Although, once our study was included in the patient registry there was such a substantial amount of interest that there was no longer a need to recruit at the pain clinic. The goal of our study was to recruit 30 eligible participants which occurred in approximately 2 months duration. We approached a total of 88 patients from the patient registry who all agreed to participate in screening, and of the 88 patients, 58 were excluded, allowing us to meet our target goal of 30 participants. The two primary reasons for exclusion was that patients (n=24) were at low risk for opioid misuse and that patients (n=25) were no longer interested in participating as indicated in the consort diagram in Figure 7. Initially, patients with low risk for opioid misuse were excluded from the study given that the conceptual foundation of the intervention was to target knowledge and behaviors that were closely associated with moderate and high-risk for opioid misuse. However, given that there was a such a large proportion of low risk patients (n=25) who expressed interest in this research, it may be worth speculating in future studies if interventions such as IPGT would be appropriate for this low-risk population. It is likely that it would not be suitable for these patients to participate in the same intervention group as the moderate to high risk patients given that their treatment needs would be significantly different. However, prevention can encompass a

continuum of activities as the low risk population would still potentially benefit from increased knowledge on opioids and overdose in addition to enhancing their self-management of chronic pain. For instance, if this patient population were to experience increased stressors, anxiety, or elevated levels of depression, their risk for maladaptive coping such as opioid misuse could increase and thus access to an intervention such as IPGT could serve as a protective factor. Thus, future studies may want to examine feasibility and acceptability of IPGT and patients with chronic pain who are at low risk for opioid misuse and if this intervention would be efficacious in improving clinical outcomes for pain.

The location of the intervention was at the UPMC Pain Medicine Program, which is situated in a central area in Pittsburgh and on a major bus route. All participants were compensated for bus fare, mileage, and parking. The research team had some concerns about attendance given that the intervention was during the holiday season in which sessions fell on both Christmas Eve and New Year's Eve. While there was some apprehension with the participants having other obligations during the holiday season that may affect their ability to participate, the holidays can be a stressful time for patients with chronic pain in which social supports and other psychosocial resources are especially important to help combat exacerbation of pain (Lampe et al., 1998). The study interventionist surveyed the IPGT participants during their first session and asked the group if they would like to attend on holidays or if they preferred to take the day off and add an additional week to the intervention. The majority of participants voted to attend on holiday sessions and at completion of the intervention expressed that they appreciated the support of the group during the stress of the holidays and were grateful to have been asked what their preference was. All intervention components were successfully delivered

to 87% (n=13) of the participants, despite the concern that the holiday season may pose as a potential barrier for participant attendance at the IPGT intervention sessions.

The time of the intervention was deliberately scheduled for the afternoon as some patients reported during the study screening that morning appointments were challenging to attend. While it was not systematically reported, the patients had stated that often their pain was escalated first thing in the morning, or they experienced sleep disturbances due to their pain and prefer to sleep in. This information was taken into account when planning the logistical details of the study. It may be speculated that this patient-centered approach helped contribute to the success of the study feasibility. The research team considered having an evening option for patients who were randomized into the intervention as there were a considerable number of patients who declined study participation as they had either full time or part time employment and could not attend daytime sessions. Unfortunately, the pain clinic was not available during evening hours and the PI was not successful in attempting to secure an alternative venue. Future studies should consider having both daytime and evening session options available for patients as it will not restrict patient recruitment and will capture a more representative sample by including patients with varying levels of function and vocation.

Another important factor to note was that the research team experienced a steady flow of patient recruitment, with patients expressing interest in the study even after recruitment was completed. When we closed out the patient registry in December, 2018 there was a total of an additional 55 patients who were not contacted for screening, which included 143 patients in total who had requested to be contacted for the study in just two months. Additionally, 2 patients found the study on ClinicalTrials.gov and contacted the PI inquiring about the research and particularly with intent of wanting to participate in the intervention arm of the study. While they

were not included in this dissertation, this assertive patient inquiry along with the surplus of participants in the patient registry, may suggest that there is a both a need and desirability amongst this patient population to be involved, which is promising for future research.

Research Question 2: IPGT Acceptability

Another primary aim of this dissertation was to evaluate the acceptability of the IPGT intervention for chronic pain patients who are at risk for opioid misuse. IPGT participants demonstrated high levels of satisfaction as reported in Chapter 4 (Table 8). The majority of questions on the patient satisfaction survey suggested that participants tended to agree or strongly agree on nearly all questions on the 5-point Likert scale regarding the perceived benefit of the intervention. The participants seemed to have found the group to be helpful (M= 4.9, SD= 0.28), the treatment manual and handouts to be beneficial (M= 4.8, SD= 0.44), and overall were satisfied with the group (M= 4.8, SD= 0.38). Upon closure of each session, IPGT participants were invited to ask questions or share any thoughts that they might have regarding their experience of the group. Group members were given the option to provide feedback or make suggestions for improvement both verbally or anonymously by writing comments on a blank piece of paper and submitting their feedback to the facilitator. Studies investigating effective strategies to improve intervention acceptability have found that listening to patients and offering them choices as to their treatment delivery was one of the single most effective strategies (Oldham, Kellett, Miles, & Sheeran, 2012), to empower patients which can improve attendance rates, engagement, and overall patient satisfaction (Dilgul, McNamee, Orfanos, Carr, & Priebe, 2018). Some examples of requests that participants made throughout the intervention included: rules regarding cell phones, options around dietary restrictions, times and dates of IPGT sessions especially around the holiday season, and expectations regarding sharing and group participation.

Several IPGT recipients expressed that having a platform to express themselves made them feel validated and empowered, potentially contributing to increased acceptability.

A critical role of behavioral and psychoeducational interventions is not only to offer treatment specific information but also information about coping and emotional issues to patients who have inadequate levels of knowledge on such pertinent topics (Ong, de Haes, Hoos, & Lammes, 1995). There has been literature to suggest that providing patients with appropriate information on their physical and/or mental health condition, can potentially increase their satisfaction of treatment (Okamura, Fukui, Nagasaka, Koike, & Uchitomi, 2003). There was deliberate intention built into the IPGT intervention design which included a comprehensive literature review (Hruschak & Cochran, 2018) to ensure that all psychoeducation material was based on the needs of the patient population. The IPGT recipients reported increased knowledge on several topics which included: how to manage their pain (M=4.8, SD=0.44), risk factors for opioid misuse (M= 4.6, SD= 0.87), and information pertaining to opioid overdose and naloxone administration (M=4.5, SD= 0.88). It may be speculated that patients demonstrated not only increased knowledge on certain subjects but also that their increased knowledge contributed to their overall satisfaction with the intervention.

The therapeutic relationship or alliance refers to the relationship between a healthcare professional and a patient and is often considered the means by which a therapist and a client hope to engage with each other, and effect advantageous change (Corso et al., 2012). There has been recent literature indicating that the therapeutic alliance is a strong predictor of adherence to psychosocial treatments for chronic pain patients (Corso et al., 2012). Additionally, the therapeutic relationship has been studied extensively across a range of behavioral treatment modalities and more recently, findings have demonstrated a correlation with patient satisfaction

and overall acceptability (Corso et al., 2012). The IPGT recipients reported to have been highly satisfied with the study facilitator, reporting that they believed the facilitator demonstrated expertise in the subject (M= 0.49, SD= 0.28), created a comfortable learning environment (M=4.9, SD= 0.28), and was sensitive to participant's cultural background (M= 5.0, SD= 0.00). It may also be considered that the positive scores regarding the study interventionist, also promoted increased acceptability in the IPGT recipients.

Most participants agreed or strongly agreed that they would recommend the IPGT intervention to others (M= 4.8, SD= 0.38) and overall rated the group as good (M= 4.9, SD= 0.28). The only question on the patient satisfaction survey that the participants either disagreed or strongly disagreed was that the length and number of sessions (6 weeks) were appropriate (M= 2.8, SD= 1.17). However, the participants reported that the length (90 minutes) and frequency of sessions were adequate (M= 4.5, 0.52). There were some comments made by participants indicating that they felt a strong level of rapport from the other group members and looked forward to the intervention session each week. They expressed that they were upset that the group was ending and wished the intervention was longer or that there was some option perhaps to have future booster sessions, peer support, or a slower tapering of sessions before termination. It may be informative to conduct a qualitative study to assess what exactly is important for each of the participants, tailoring the intervention to individual need. Future research may want to consider having a larger continuum of care model where the 6 sessions of IPGT are part of a larger multidisciplinary pain program where patients could continue to progress on advancements made in treatment.

There are several fundamental reasons to evaluate treatment acceptability data as they relate to intervention research. It has been suggested that high levels of acceptability may

improve treatment integrity and ultimately may influence efficacy (Sterling-Turner & Watson, 2002). Treatment acceptability data can provide logistical and insightful information regarding implementation, resources required to implement the intervention, and other characteristics of the intervention and context that have the potential to influence feasibility (Nastasi et al., 2007). Information regarding the acceptability of an intervention may influence participants' decision to complete treatment and can potentially mitigate perceived treatment barriers. Given the influence on treatment selection, implementation, and adherence, it is essential to include an evaluation of treatment acceptability when conducting behavioral health interventions. IPGT recipients demonstrated overall high levels of acceptability with the exception of the number of intervention sessions which may want to be considered in future research in the development of a fully powered study.

Research Question 3: IPGT Preliminary Efficacy

While this study was not powered to test efficacy, we were still interested in exploring the preliminary efficacy of the intervention but emphasize that their results should be interpreted accordingly. Specifically, we wanted to examine do chronic pain patients who are at risk for opioid misuse who receive IPGT when compared with those who receive TAU demonstrate: (a) improved knowledge on opioid medication, overdose, and overdose response; (b) decreased opioid medication misuse; and (c) reductions in pain severity, pain interference, and pain catastrophizing. In summary, while IPGT recipients did not have significantly lower opioid misuse behaviors post intervention, they did demonstrate statistically significant differences in pre and posttest knowledge on opioid overdose, opioid overdose response, and naloxone administration. Regarding pain outcomes, results of the Linear Mixed Models analyses

demonstrated significant treatment X time interactions on the outcome of pain interference and pain catastrophizing. However, there were no significant effects on pain severity.

Opioid Misuse Behaviors and Increased Knowledge

Opioid misuse continues to be a major concern for public health, including the field of pain. A fundamental challenge for healthcare is to achieve a balance between decreasing the misuse of opioids and associated harms while optimizing pain care. This dissertation examined a novel behavioral health intervention for patients with chronic pain who are at risk for opioid misuse. With regard to targeting prevention of opioid misuse in this high-risk population, IPGT encouraged appropriate medication adherence, while also attempting to enhance participants' knowledge on opioid medication, opioid overdose, overdose response, and training on how to obtain and appropriately administer naloxone. There was a significant increase in knowledge acquired from the IPGT recipients across all subjects except for opioid medications which was measured by the BOOK Questionnaire and can be found in Appendix D. Both TAU and IPGT recipients had both high pre and post test scores on opioid medication knowledge with TAU having a mean pre-test score of 2.80(SD=0.77) and a post-test score of 3.21(SD=0.80) and IPGT having a mean pre-test score 2.45(SD=1.36) and a post-test score of 2.93(SD=1.10). It may be reasonable to assume that a considerable amount of chronic pain patients have lived with their condition for a substantial amount of time and as a result, are already familiar with opioid medications. However, our study findings suggest that there is room for improvement in how chronic pain patients are educated about opioid overdose, overdose response, and naloxone administration.

It is critical that patients exposed to opioids, whether through prescriptions or illicit means, have fundamental knowledge of opioid use, opioid overdose, overdose response, and

naloxone administration in order to help prevent fatal overdoses (Huhn, Garcia-Romeu, & Dunn, 2018). Chronic pain patients who are being prescribed an opioid for analgesic purposes have been identified as a high-risk population given their continued access to opioid medications and lower relative knowledge of overdose risks compared with illicit opioid users (Dunn, Barrett, Fingerhood, & Bigelow, 2017; Kelly E. Dunn et al., 2016). The findings from this dissertation suggest that IPGT may be an effective vehicle to increase the knowledge of opioid overdose, overdose response, and naloxone administration in chronic pain patients. These pilot data support a larger-scale evaluation of IPGT as an intervention that may be an effective and scalable method for providing chronic pain patients who are exposed to opioid medications valuable information pertaining to overdose prevention. Further research concerning long-term knowledge retention and demonstration of behavioral skill building following opioid exposure is warranted.

CDC Guidelines recommend nonpharmacologic therapy and nonopioid pharmacologic therapy as a preferred treatment for chronic pain patients (Dowell et al., 2016a). However, despite these non-pharmacological recommendations in addition to strategies for improving patient access to quality, multidisciplinary care, the empirical base supporting such psychosocial interventions are limited (American Society of Anesthesiologists Task Force on Chronic Pain, American Society of Regional, & Pain, 2010; Chou et al., 2009). This dissertation serves as pilot data to help fill this research gap and contribute to the literature on non-pharmacological and behavioral approaches for chronic pain patients who are at risk for opioid misuse. IPGT serves as a holistic approach that teaches various pain coping strategies, encourages medication adherence, and lifestyle changes such as: stretching, walking, pacing activity, nutrition changes, improving sleep hygiene and addressing relationship problems. It may be speculated that providing high-risk chronic pain patients with assertive resources such as the IPGT intervention which

encourages healthy responses to pain, may potentially decrease or eliminate maladaptive coping including pain catastrophizing, pain interference and other distressing behaviors. It should be emphasized that while we saw a reduction in the IPGT participants' opioid misuse following completion of the intervention, the control group exhibited elevated opioid misuse at both the first and second follow up. Thus, further testing is needed to support this intervention in specifically targeting opioid misuse.

Pain Interference and Pain Catastrophizing

Best practice guidelines for chronic pain recommend pain measures and treatment that go beyond pain severity and reflect an effort to improve the physical, mental, and social health of individuals in pain (American Society of Anesthesiologists Task Force on Chronic Pain et al., 2010). The National Institute of Health Patient-Reported Outcomes Measurement Information System (PROMIS) defines pain interference as a measure of the extent to which pain impedes engagement with physical, cognitive, emotional, and recreational activities, including sleep and enjoyment in life (Amtmann et al., 2010). The pain interference subscale of the Brief Pain Inventory, captures these domains with 7 items that measures how much pain interferes with various daily activities and includes two subdimensions: an affective subdimension (relationships with others, enjoyment of life, and mood disturbances) and an activity subdimension (walking ability, general activity, and vocation) (Stanhope, 2016). Whereas pain catastrophizing can be viewed as an appraisal process defined as painful stimuli which are appraised in a primary (magnification, rumination) and secondary (helplessness) manner. These appraisals act in a transactional way to influence an individual's cognitive and behavioral pain coping strategies and often predicts treatment outcomes (Burns, Glenn, Bruehl, Harden, & Lofland, 2003; Khan et al., 2012; Quartana, Campbell, & Edwards, 2009). There have been some studies which suggest

pain catastrophizing can predict pain severity (Arnow et al., 2011; Edwards, Dworkin, Sullivan, Turk, & Wasan, 2016; Quartana et al., 2009); however, we acknowledge that while there were significant treatment X time interactions on pain interference and pain catastrophizing, that there were no significant effects on pain severity. While this was a pilot study, further research that is fully powered and with longer longitudinal follow-ups is needed to better determine the relationship that psychosocial interventions have on opioid misuse and pain outcomes.

IPGT is a behavioral health intervention that specifically targets psychosocial elements of chronic pain patients who are at risk for opioid misuse. It is interesting to note within the study results that pain severity which is more of a physical measure of pain was not significant, while pain interference and pain catastrophizing which are both more of a psychosocial measure of pain were significant. The nature of the psychosocial factors considered in the development of the IPGT intervention appear to support the study findings which concluded that both pain catastrophizing and pain interference significantly improved in participants that were randomized into IPGT. The following psychosocial domains were included in the IPGT intervention design: (1) cognitive behavioral therapy, which topics include: pacing and goal setting, negative thinking, coping with stress and anxiety, managing set-backs, treatment adherence, and quality of life; (2) acceptance and commitment therapy which utilizes principles from stages of change and motivational interviewing to help target behavioral change; (3) mindfulness based cognitive therapy and mindfulness-based stress reduction; and (4) principles relevant to chronic pain self-management programs which include concepts based on peer support, SMART goals, and skills that are fundamental in the self-management of pain. It may be speculated that these behavioral approaches align and support improvement in pain interference and pain catastrophizing.

There has been some debate in the field whether pain interference correlates with physical functioning which is important to understand in the delivery of pain care and the overall scope of the IPGT intervention. As opposed to pain interference, physical functioning can be understood as the ability to execute activities that involve physical action, ranging from self-care to more demanding actions that entail a combination of skills, and often within a social context (Lynch, Dodds, Yu, Pilkonis, & Irrgang, 2016). There is a recent study that demonstrates that there is a moderate correlation in a cross-sectional population between pain interference and physical function, however that change over time does not have a strong correlation (Karayannis, Sturgeon, Chih-Kao, Cooley, & Mackey, 2017). These study findings align with this dissertation which highlights the common misconception that if pain interference improves, that physical function will concomitantly improve. The authors' conclusions about the lack of correlation between pain interference and physical function suggest that the field should consider more than just physical activities to determine the deficit that pain produces in an individual's quality of life. Further, that improvements in quality of life do not depend exclusively on producing a large improvement in physical function (Hølen, Lydersen, Klepstad, Loge, & Kaasa, 2008). This is particularly important when reflecting on the results of this dissertation, as where there were decreases in pain interference this will not necessarily impact a patient's pain severity or physical function. Thus, if a patient has specific goals to improve their functionality, it may be best to refer them on to another member of the multidisciplinary team and that IPGT in isolation may not be the best approach.

Implications for Future Research

It has been suggested that patients may vary in the degree to which they are ready to adopt a self-management or behavioral based approach to chronic pain as an alternative to

traditional medical or surgical interventions (Kerns, Rosenberg, Jamison, Caudill, & Haythornthwaite, 1997). Further, this readiness to adopt a behavioral based treatment may influence the engagement process, and potentially dropout and relapse rates (Kerns et al., 1997). While the IPGT intervention seemed to be appropriate for the participants who were enrolled in the research study, there are potentially other patient populations that may benefit from IPGT, despite that their readiness to attend treatment may be poor. When attempting to recruit for this study, there were a number of patients who expressed interest in participating, although they demonstrated a crisis like presentation that could be perceived as precontemplative with regards to the stages of behavioral change model (Norcross, Krebs, & Prochaska, 2011). Future research may want to consider applying specific strategies or interventions that explicitly target patients who are precontemplative or contemplative and work towards increasing their readiness to attend interventions such as IPGT. For example, there is currently a novel behavioral intervention being tested on patients with opioid misuse that incorporates a patient navigation treatment model. The intervention engages with patients in a community pharmacy setting and primarily is conducted by telephone which is low barriers for patients who experience difficulties in physically attending treatment (Cochran et al., 2018). The intervention works towards linking patients with appropriate services which essentially could aim to increase the patient's stability and their readiness to attend behavioral interventions such as IPGT. Given that this marginalized population is at an increased risk, interventions such as the patient navigation model would be an excellent adjunct to help assist precontemplative and contemplative patients attend IPGT. With this addition, it may be suggested to consider developing a larger continuum of care and expansion of treatment and that intervention readiness should be assessed at intake. As mentioned in the results section regarding intervention acceptability, participants feedback

implied that they felt the intervention was not long enough. Future studies may want to consider increasing the length of the intervention, or develop booster sessions, peer support, or a slower tapering of sessions before intervention completion.

IPGT shows promise as an intervention for chronic pain patients at risk for opioid misuse, and particularly for achieving enhanced knowledge on opioid overdose, overdose response, and naloxone administration and reductions in, pain interference, and pain catastrophizing. Study findings suggest that both feasibility and acceptability was achieved. Dropout rates were modest and typically due to extenuating personal circumstances such as health conditions or mobility issues. We were encouraged by the study participants' positive reactions to the intervention and their responses to the patient satisfaction survey. Given that feasibility, acceptability, and preliminary efficacy was achieved, the next logical steps would be to conduct a fully powered, multisite clinical trial to provide efficacy data on IPGT as an evidenced based behavioral treatment for chronic pain patients at risk for opioid misuse.

Implications for Social Work

The social work profession has a tremendous opportunity to make significant contribution to the field of pain and opioid misuse research. Social workers are an integral component of the multidisciplinary team in various settings across the continuum of pain care and substance abuse. The profession provides services to individuals and families throughout the lifespan, addressing the full range of biopsychosocial issues that impact well-being. This dissertation has provided valuable data which can be used to inform the social work profession and other members of the multidisciplinary team about psychosocial factors in order to help guide robust treatment protocols for chronic pain patients.

Historically within pain care, social work has had an insignificant voice within both research and practice as typically the psychosocial factors of patient care have been predominately treated and examined by the psychology field (Hagelberg, 2010). This has been a substantial loss to the field as social work is an exceptional profession which has the ability to meet the psychosocial demands of chronic pain patients. Social work practitioners' receive training in the biopsychosocial paradigm and can potentially assess psychosocial features associated with pain which is viewed as a critical component of establishing behavioral change goals, or help in guiding treatment interventions (Burns, Dannecker, & Austin, 2019). This is particularly relevant for clinicians working in pain or substance abuse fields as problematic symptoms can be targeted through non-pharmacological approaches rooted in treatments such as IPGT. There are a large number of social workers who receive specialized training in psychosocial interventions that would be necessary to deliver treatment models such as IPGT (Emami, Woodcock, Swanson, Kapphahn, & Pulvers, 2016). As one of the largest health providers in substance use and mental health services, social workers are uniquely positioned to advance psychosocial treatments for chronic pain and opioid misuse and advocate for marginalized population including the promotion of social determinants of health (Morris & Mir, 2015). Given these reasons, social workers are a great candidate to improve the individualization of patient care and the early detection of pain-related psychosocial factors and issues pertaining to opioid misuse (Hruschak & Cochran, 2017; Mendenhall, 2003). The social work profession is an appropriate vehicle to deliver IPGT given that the intervention is rooted in the biopsychosocial model, is patient centered and acknowledges the subjective nature of an individual's pain. Additionally, the profession is well suited to target outcomes such as pain catastrophizing and pain interference given that the profession has a holistic focus, including

cognitive, behavioral and emotional components of treatment across all populations. This study is an essential building block to help fill the gaps in the field while providing additional support of the importance of psychosocial factors and the value of the social work profession in pain care

While the risk for developing chronicity is universal, there are particular populations who are disproportionately susceptible to chronic pain and often are composed of vulnerable individuals including both racial and ethnic minorities (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, & Riley, 2009; Meghani et al., 2012). Demographics captured within this dissertation included 40% (n=12) Black participants in total, however given how the randomization occurred 66% (n=10) of the IPGT recipient were Black. Given that there were two separate IPGT groups being conducted, one of the IPGT groups had 75% (n=6) Black participants and the second IPGT group had 57% (n=4) Black participants. Therefore, despite the report from the 2012 United States Census Bureau, which approximated that the population of Pittsburgh consisted of 64.8% White and 25.8% Black or African Americans ("U.S. Census Bureau," 2012), there seemed to be a significant amount of diversity amongst IPGT participants.

It is interesting to note, that despite the diversity within the IPGT recipients, the only question that all participants scored as strongly agreed was: *"the facilitator was sensitive to my cultural background (race, religion, etc.)."* Social work has been established as a discipline dedicated to serving the needs of all individuals and communities with a focus on marginalized populations and the social determinants of health . Cultural competence is acknowledged as a vital principle of social work education and practice and as the population in the United States continues to quickly diversify, and particularly in pain care, the need for culturally competence is imperative (Hagelberg, 2010). Over the past decade, a cultural competence mandate was established by the Council on Social Work Education (CSWE) Education Policy and

Accreditation Standards (EPAS) and the National Association of Social Work (NASW) Code of Ethics. This provides a level of reassurance that the social work profession is highly proficient in working with diverse populations (Parrott, 2016). IPGT provided culturally responsive care that integrated patient's cultural values and beliefs into treatment and created a platform were participants were able to effectively communicate despite differences in values, beliefs, perceptions, and expectations about pain care. The facilitator who was a trained social worker, treated all participants with respect, continuously engaged in rapport building, and used culturally sensitive communication and culturally valid assessments. Given the high level of acceptability demonstrated within the cultural competency question of the patient satisfaction questionnaire, IPGT may serve as an effective treatment model within the field of pain in how to provide culturally sensitive and responsive care to diverse populations.

Limitations

There are many promising aspects of this study, including its randomized design, the integrated model of care for chronic pain and opioid misuse, the high levels of feasibility and acceptability, and the intervention's preliminary efficacy. However, this study possesses limitations that must be considered when interpreting its findings. As mentioned in the implications for research section, given the scope of this pilot study and limited resources, the sample size was relatively small and not powered to detect efficacy. Future research must seek to expand the number of patients recruited and randomized. Participants of this study were recruited by convenience from Pittsburgh, thus our findings are limited in that they may not be generalizable to the broader population of individuals within the US or other countries. Additionally, our second follow-up assessment was at 3-weeks post intervention, which is a relatively short time period. Future studies should consider longer follow-up periods to examine

long-term sustainable change produced by the IPGT intervention. It may also be of benefit to attempt to transfer the IPGT treatment modality to alternative treatment populations such as pediatrics, or patients with HIV, chronic pain, and who are also at risk for opioid misuse.

An additional limitation was the use of self-report measures to assess the various behavioral health and pain outcomes, including opioid misuse. The use of self-reported measures may increase the risk of social desirability, recall bias, or errors in self-observation. Often patients experience stigmatization with issues such as mental health and substance use. While the participants were thoroughly informed about confidentiality, there remains a potential threat of inaccuracy of self-reports and thus should be considered. While the pain catastrophizing measure is commonly endorsed in the field, there are various shortcomings associated with the state pain catastrophizing literature that are in need of empirical attention. There are many variables that fall into a negative pain schema, including pain anxiety, fear of pain and pain helplessness in which pain catastrophizing shares significant variance with broader negative affect constructs, such as depression, anxiety, anxiety sensitivity, and worry (Hirsh, George, Riley, & Robinson, 2006; Sullivan & D'Eon, 1990). Thus, it is a common standard to statistically control for both depression and anxiety when investigating relations between pain catastrophizing and pain-related outcomes. While this study did control for both depression and anxiety, it is vital that future research may consider the need to more rigorously explore the distinctiveness of the pain catastrophizing construct apart from related constructs, such as negative affect, depression, and anxiety. Additionally, novel assessments are needed to move beyond self-report, so that the process of catastrophizing can be more readily characterized (Quartana et al., 2009).

It should also be noted that when examining the preliminary efficacy for pain outcomes that while building the models for the multivariate analyses for the pain severity outcome, we experienced some conflicting results with the goodness of fit statistics. While constructing different models to help assess if the increasing polynomial complexity enhanced model fit, while the -2LLR decreased, the AIC and BIC increased in the conditional models when compared with the unconditional models. While pain severity was not a significant outcome, this discrepancy should still be considered with interpreting the results. Fortunately for both significant pain outcomes, pain interference and pain catastrophizing, there were no discrepancies in the goodness of fit statistics. Despite these limitations, these pilot data will help to support further testing of a new treatment model (IPGT) for chronic pain patients at risk for opioid misuse while providing greater insight into strategies to address this public health crisis in the management of chronic pain and the opioid epidemic.

Conclusion

The United States is experiencing a public health crisis, involving the management of chronic pain and the risks associated with opioid misuse which requires a response of both prevention in addition to improved pain care. From a biopsychosocial, systems theory and ecological perspective, chronic pain is seen as a multifaceted experience emerging from the dynamic interplay of a patient's physiological state, thoughts, emotions, behaviors, and sociocultural influences. The field has made progress in the realm of chronic pain management through the applications of biopsychosocial treatments. However, with the disturbing outcomes from the opioid epidemic, there has been less advances in preventative approaches that incorporate harm reduction strategies. This dissertation conducted an RCT to investigate an IPGT model for chronic pain patients who are at risk for opioid misuse. This is an innovative

approach as typically treatment models have addressed pain and addictions in isolation, overlooking the need to adapt a more holistic framework.

This dissertation provides initial support for the IPGT intervention being acceptable and feasible for delivery in chronic pain patients at risk for opioid misuse in which efficacy was demonstrated in both pain interference and pain catastrophizing. In order to better establish these findings, future studies should expand on these preliminary data by further investigating this intervention within a fully powered clinical trial framework. The social work profession is well positioned to pursue this work due to their biopsychosocial approach and their ability to understand a patient's multifaceted experience of pain including social determinants of health. The findings of this dissertation support the next steps of the development of a novel treatment model (IPGT) to address chronic pain patients at risk for opioid misuse while providing greater insight into strategies to address this public health crisis.

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APPENDIX A

Study Recruitment Flyer

University of Pittsburgh

UPMC LIFE CHANGING MEDICINE

DO YOU HAVE CHRONIC PAIN?

Are you 18 years or older?
Has your pain lasted longer than 3 months?

WOULD YOU LIKE TO PARTICIPATE IN A RESEARCH STUDY?

If yes, researchers from the University of Pittsburgh and UPMC would like to invite you to participate in a pain management program.

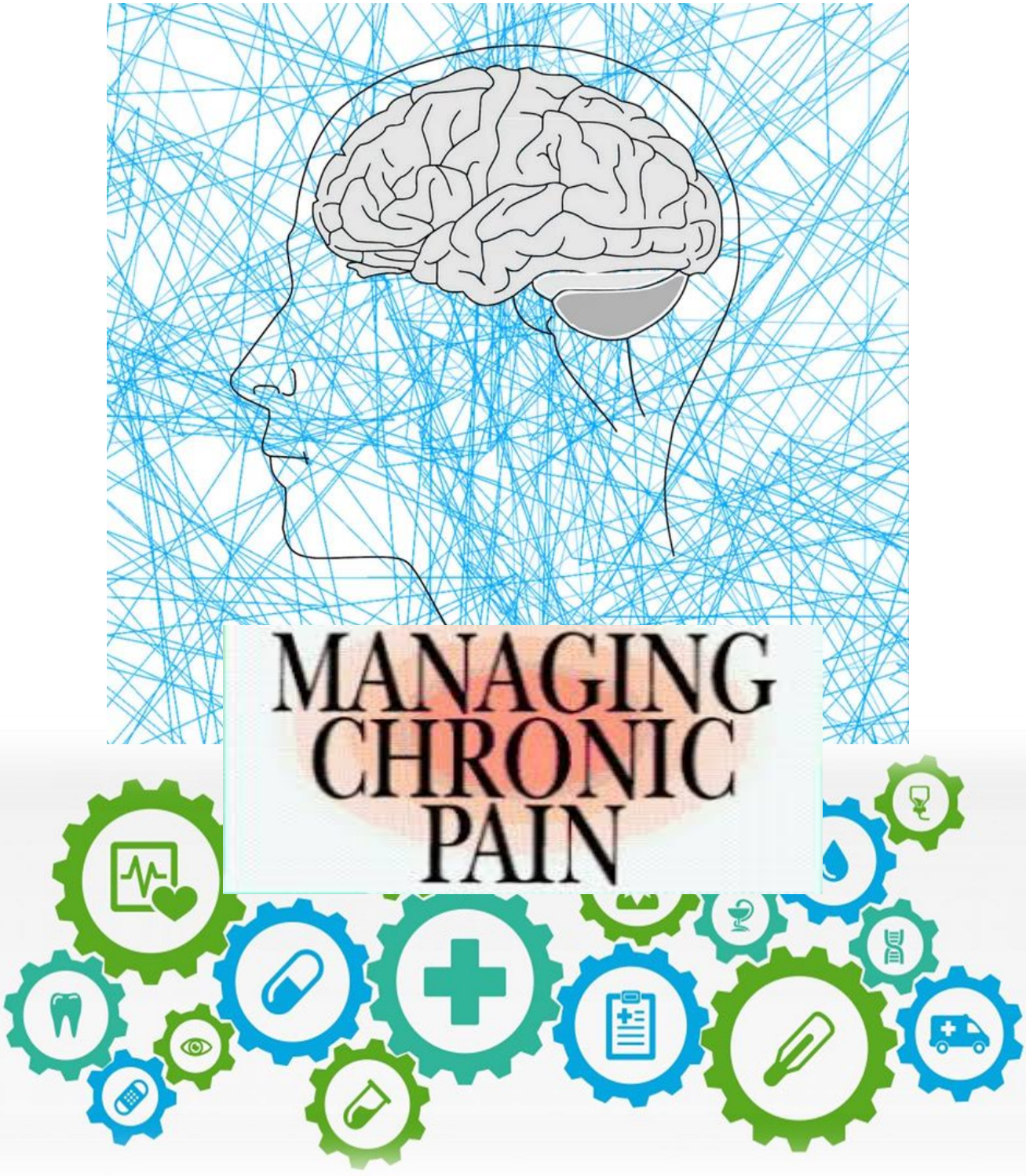
Receive up to $125 in gift cards for full participation

Please let the attendant at the front desk know you are interested or contact the Principal Investigator of the study for more information at: 412-609-0791 or VJH6@pitt.edu.

APPENDIX B

IPGT Study Manual Session Topics

Integrated Psychosocial Group Treatment

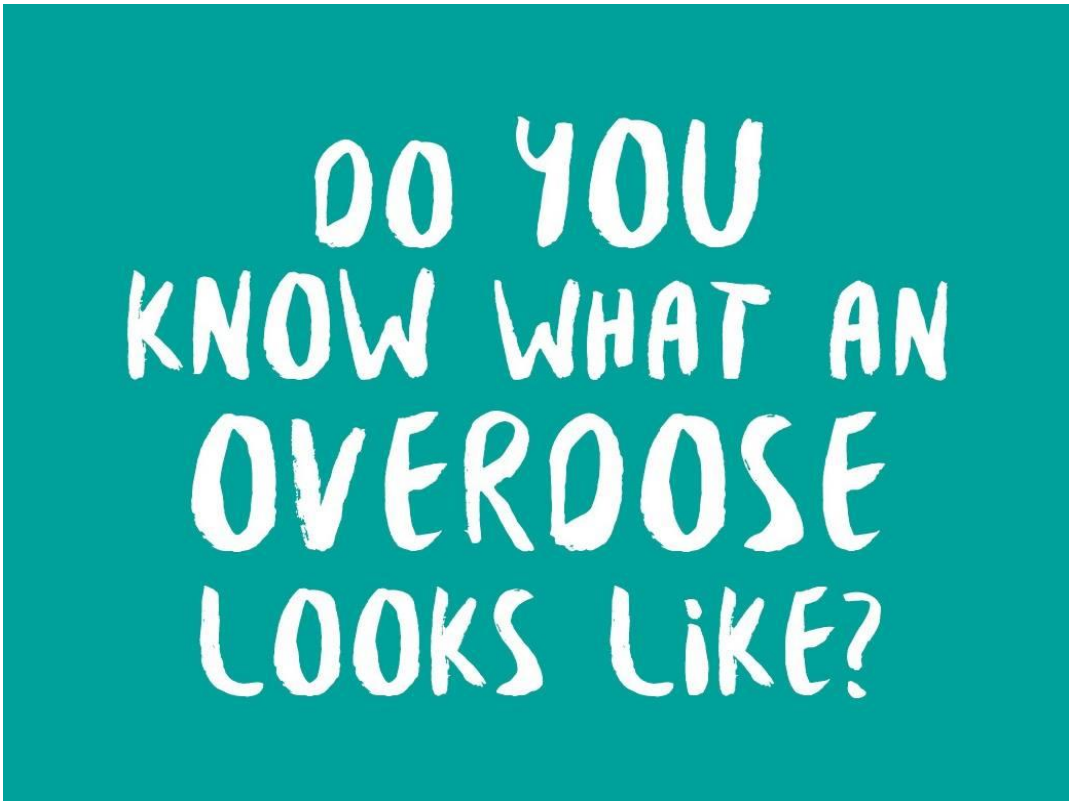


Integrated Psychosocial Group Treatment

CHRONIC PAIN

Session One: Learning the Foundations for People Living with Chronic Pain

Integrated Psychosocial Group Treatment



Session Two: Overdose Education and Naloxone Distribution

Integrated Psychosocial Group Treatment

Session Three: Stages of Change and Pacing Techniques

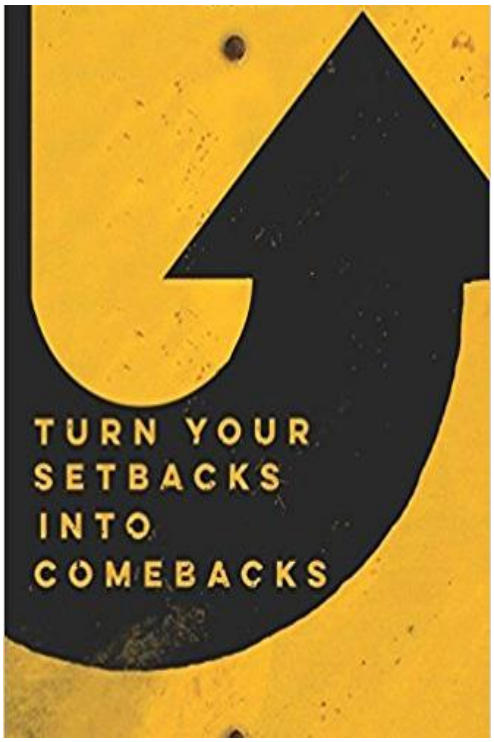
Integrated Psychosocial Group Treatment

Session Four: Negative Thinking, Fear Avoidance, and Pain Catastrophizing

Integrated Psychosocial Group Treatment

Session Five: Coping with Stress & Anxiety

Integrated Psychosocial Group Treatment



Session Six: Managing Setbacks, Treatment Adherence, and Quality of Life

APPENDIX C

Fidelity Checklist

IPGT Fidelity Checklist, Session One:

Name of person completing fidelity: *Megan, MSW*

Group : *One*
Session: *One*
Date: *January 16, 2019*

Check-in and Introduction	**Yes**	**No**	**NA**	**Comments**
Did the facilitator introduce herself, background, and the context of the group and format of the research study?	X			
Did the facilitator adequately give each participant the opportunity to check-in with their ice breaker questions?	X			Everyone was given the amount of time they desired in a reasonable manner for check-in
Were the group rules reviewed (confidentiality, attendance respect, etc.) and were participants invited to create their own group rules?	X			Facilitator checked in with group in case they were in need of a break at the appropriate time.
Was the concept of SMART goals discussed and how it fits into the context of the group?	X			Goals were discussed in detail with examples given for participants to learn from.
Psychoeducational Material	**Yes**	**No**	**NA**	**Comments**
Was pain defined (acute vs. chronic) and the continuum from acute to chronic pain and the risk factors?	X			The idea of pain being subjective and complex was a great introduction into this topic.
Was the Four A's of Pain Outcomes discussed with the group (analgesia, activities of daily living, adverse effects, and aberrant drug taking behaviors)?	X			
Was the WHO analgesia step ladder defined and explained? Was adjunctive therapies vs. drug therapy approaches reviewed?	X			
Were opioid medications reviewed? Were issues pertaining to opioid misuse and opioid use disorder and addiction discussed? Was tolerance and dependence reviewed?	X			
Were evidence-based treatments for chronic pain reviewed (multidisciplinary care, self-management models, CBT,	X			

mindfulness, relaxation, behavioral change, goal setting etc.)?				
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out?	X			
Were group members invite to ask any questions and share feedback either in person or by completing the autonomous feedback form?	X			Group members shared a lot of positive feedback about how the first group went.
Did the facilitator explain that the group will start goal setting on a regular basis starting next week?	X			
Were group members thanked for their participation and praised for their efforts and any progress made?	X			

IPGT Fidelity Checklist, Session Two:

Name of person completing fidelity: *Megan Tierney*

Group : *One and Two*
Session: *Two (Guest Speaker: JoEllen Marsh, Opioid Community Response Manager at Allegheny County Health Department)*
Date: January 24, 2019

Check-in and Introduction	**Yes**	**No**	**NA**	**Comments**
Did the facilitator re-introduce herself, to the new group members and talk about the purpose of the session/guest speaker?	X			
Did the facilitator adequately give each participant the opportunity to check-in and become familiar with the different group members (given this session combine group 1 and 2)?	X			Introductions were given by each participant that allowed the group to become comfortable with each other.
Was the guest speaker adequately introduced (background and purpose for coming to speak with the group)?	X			Speaker was introduced with details about her work and experience in a way that was relevant to the group.
Was group 1 given the opportunity to check in about their goals (group 2 was one week behind and hadn't started yet)?	X			All group members were able to check in and discuss goals.
Guest Speaker: Opioid Medications, Overdose Education, and Naloxone Distribution	**Yes**	**No**	**NA**	**Comments**
Were opioid medications defined and reviewed with the participants?	X			
Were the overdose rates, patterns and trends in the US and specifically in the Allegheny County discussed?	X			Great conversation and participation from group members
Was overdose explained, including the signs and symptoms? Were the risks of overdose reviewed?	X			
Was harm reduction, overdose, addiction, and stigma reviewed?	X			Group members had thoughtful questions throughout the presentation
Were the steps in responding to overdose reviewed with the participants?	X			

Did the facilitator explain how and where participants can obtain a naloxone kit?	X			Group members had a lot of conversation surrounding naloxone with great input.
Were initiatives targeting chronic pain and issues of opioids in the Allegheny County reviewed with participants?	X			Guest speaker spoke about her work and what the county is doing to eliminate/improve problems surrounding opioids. Resources were also given to group members.
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out?			X	There was not much time for each individual to do a check-out because of the guest speaker but participants were still able to speak with the facilitator with questions. Participants also gave positive feedback about the guest speaker.
Were participants given the opportunity to ask the guest speaker any questions?	X			
Were group members invited to ask any questions in general and/or share feedback in person or by completing the autonomous feedback form?	X			
Did the facilitator explain that the group will start goal setting on a regular basis once they start back in their regular groups?	X			Touched on more in the beginning when explaining the guest speaker purpose and how each session will normally go.
Were group members thanked for their participation and praised for their efforts and any progress made?	X			13 of 15 group members were present for the session and positive feedback/praise was given.

IPGT Study Fidelity Checklist, Session Three

Name of person completing fidelity: *Shaddy Saba, MSW*

Group: *One*
Session: *Three*
Date: *January 21, 2018*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?	x			
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?	x			
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?				Recording does not start at beginning of session – not sure Also appears they did not do goals last week – NA?
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?				Recording does not start at beginning of session – not sure Also appears they did not do goals last week – NA?
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?	x			Suggested online shopping, leaning on shopping cart
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	x			
Did the facilitator invite the participants to try the technique?	x			
Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	x			
Did the facilitator debrief the experience with the participants?	x			
Did the facilitator offer suggestions to participants that may have had troubles with the activity?	x			

CBT Session Content: Stages of Change and Pacing Strategies	Yes	No	NA	Comments
Did the facilitator describe each of the stages of change? Was the relevance of the model and chronic pain reviewed?	**x**			
Were the participants given the opportunity to complete the planning for change worksheet?	**x**			
Were the participants invited to share the content from their action plan?	**x**			
Did the facilitator adequate review the concept of pacing strategies with the group members?	**x**			
Were the participants given the opportunity to create a pacing plan and share this with the group?				I believe this was given as a home suggestion for sharing later?
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	**x**			
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	**x**			
In instances that goals did not meet the SMART goal criteria, did the facilitator help to highlight potential issues and offer suggestions to overcome the issues?	**x**			
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?	**x**			
Were group members thanked for their participation and praised for their efforts and any progress made?	**x**			

IPGT Study Fidelity Checklist, Session Three

Name of person completing fidelity: *Qi Chen, MSW*

Group: *Two*
Session: *Three*
Date: *February 6, 2018*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?			√	The part I am not sure in this section is the goal for the week. It seems like the group progress was interrupted by the guest speaker so the last session didn't really talk about their goals?
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?	√			One thing I particularly like in this part is you connected one participant's coping strategies to the topic today – the pacing strategies to open the conversation
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?			√	More general barriers like holiday stress.
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?	√			Group members got to this part by themselves.
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?			√	Not related to the goal but help the participants address the holiday stress
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	√			Encourage the participant to define and think about how their experiences can be related to the technique. Keep exploring the pros of the technique and keep them engaged.
Did the facilitator invite the participants to try the technique?	√			

Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	√			
Did the facilitator debrief the experience with the participants?	√			
Did the facilitator offer suggestions to participants that may have had troubles with the activity?	√			
CBT Session Content: Stages of Change and Pacing Strategies	**Yes**	**No**	**NA**	**Comments**
Did the facilitator describe each of the stages of change? Was the relevance of the model and chronic pain reviewed?	√			
Were the participants given the opportunity to complete the planning for change worksheet?	√			Participants were given the opportunities to define themselves using the technique. The facilitator also asked about the potential barriers and check with skills they can use to overcome.
Were the participants invited to share the content from their action plan?	√			
Did the facilitator adequate review the concept of pacing strategies with the group members?	√			The facilitator also reviewed how it is relevant with pain. Ex. How it relates with participant's holiday shopping experiences.
Were the participants given the opportunity to create a pacing plan and share this with the group?			√	The facilitator invited the group member to share their prior pacing strategies and use it as an example. It was not like creating a new plan but it worked well to meet the same purpose of helping participants understand and practice.

Goal Setting and Check-Out	Yes	No	NA	Comments
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	√			Everyone shared their goals.
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	√			
In instances that goals did not meet the SMART goal criteria, did the facilitator help to highlight potential issues and offer suggestions to overcome the issues?	√			Encouraged the group member 1) to be more specific: ex. "more"→"once a day"; 2) to focus on one thing; 3) make the goal measurable: ex. "I want to reduce stress" → "I will see the therapist once a month for relaxation treatment"
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?		√		The facilitator didn't check about their confidence level. Running out of time.
Were group members thanked for their participation and praised for their efforts and any progress made?	√			The facilitator praised more about the attendant and openness, maybe can talk more about their actual progress.

IPGT Study Fidelity Checklist, Session Four

Name of person completing fidelity: *Qi Chen, MSW*

Group: *One*
Session: *Four*
Date: *January 16, 2018*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?	√			
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?			√	Group members all shared how they couldn't reach their goal last week. The facilitator can acknowledge their efforts to try the technique even though it didn't work well and encourage them to continue practice in the future.
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?	√			
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?			√	
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?	√			1. The facilitator revisited the pacing strategies to address the holiday overwhelming. 2. The facilitator proposed one participant to try meditate with her stressful husband to meet their unique circumstance. 3. The facilitator encouraged the participant to reevaluate the situation and adjust to a much easier goal.
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	√			The facilitator provided very detailed education and addressed one participant's concern about "processing" vs "avoiding"

Did the facilitator invite the participants to try the technique?	√			
Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	√			The facilitator encouraged the participants over the week at the beginning of the conversation.
Did the facilitator debrief the experience with the participants?	√			The facilitator received positive feedback from group member and provided appropriate self-confrontation and good reflections of participants' feedback.
Did the facilitator offer suggestions to participants that may have had troubles with the activity?	√			When participants said they couldn't concentrate when they are in too much pain, the facilitator suggested them to practice he technique at a time they feel comfortable and using the 10-point pain scale to help them define "good time"
CBT Session Content: Negative Thinking, Fear Avoidance, and Pain Catastrophizing	**Yes**	**No**	**NA**	**Comments**
Was the concept of pain catastrophizing reviewed and how this can influence the pain experience? Were the participants invited to complete the measure?	√			
Was negative thinking and depression reviewed and how it is relevant to chronic pain (the pain cycle)?	√			
Was the treatment for depression reviewed (pharmacological, psychosocial, nutrition, exercise, CBT)?	√			The facilitator mentioned DSM to help the participant understand clinical level depression. Maybe can talk more about different treatments option? Not just focus on evidence-based behavioral treatment.
Was healthy thinking and cognitive appraisals reviewed (ie focusing on the negatives, shoulds, overgeneralizing, all or nothing thinking, and fear avoidance)?	√			

Were the participants encouraged to complete the cognitive reconstructing worksheet?	√			
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	√			
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	√			
In instances that goals did not meet the SMART goal criteria, did the facilitator help to highlight potential issues and offer suggestions to overcome the issues?	√			When one participant formulated an umbrella goal, the facilitator encouraged her to focus on one goal and smaller criteria.
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?	√			
Were group members thanked for their participation and praised for their efforts and any progress made?	√			

IPGT Study Fidelity Checklist, Session Five

Name of person completing fidelity: *Shaddy Saba, MSW*

Group: *Two*
Session: Five
Date: *January 21, 2018*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?	x			
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?	x			
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?	x			
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?	x			
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?	x			Facilitated dialogue between participants
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	x			
Did the facilitator invite the participants to try the technique?	x			
Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	x			
Did the facilitator debrief the experience with the participants?	x			
Did the facilitator offer suggestions to participants that may have had troubles with the activity?	X			

CBT Session Content: Coping with Stress and Anxiety	Yes	No	NA	Comments
Did the facilitator invite the participants to take the stress quiz? Were the group members invited to share an discuss their scores and how it relates to their pain?	**X**			
Was the term stress defined? Was the difference between acute and chronic stress defined?	**X**			
Were the physical, emotional, cognitive and behavioral symptoms of stress defined?	**X**			
Was the relationship between stress and chronic pain explored?	**X**			
Was anxiety defined? Was it discussed in the context of chronic pain. Was treatment for anxiety discussed?	**X**			
Where the 4 A's of stress management reviewed with opportunities for the participants to apply to their situation?	**X**			
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	**X**			
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	**X**			
In instances that goals did not meet the SMART goal criteria, did the facilitator help to highlight potential issues and offer suggestions to overcome the issues?	**X**			
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?		**X**		
Were group members thanked for their participation and praised for their efforts and any progress made?	**X**			

IPGT Study Fidelity Checklist, Session Five

Name of person completing fidelity: *Qi Chen, MSW*

Group: *One*
Session: Five
Date: *February 11, 2018*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?	√			
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?	√			The facilitator praised patients on coming to all the appointments.
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?	√			
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?	√			One participant used the technique the facilitator suggested in the last session and she succeeded. Great job.
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?	√			The facilitator encouraged the participants to always adjust their goal and track their steps.
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	√			
Did the facilitator invite the participants to try the technique?	√			
Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	√			The facilitator can use a more positive tone: ex. “Don’t do if it is not helpful” →”practice it at a time you feel that would be helpful”
Did the facilitator debrief the experience with the participants?	√			

Did the facilitator offer suggestions to participants that may have had troubles with the activity?	√			The facilitator tried to ease the participant's frustration when they failed to achieve their goals and offer to record the visualization if it is helpful.
CBT Session Content: Coping with Stress and Anxiety	**Yes**	**No**	**NA**	**Comments**
Did the facilitator invite the participants to take the stress quiz? Were the group members invited to share and discuss their scores and how it relates to their pain?	√			
Was the term stress defined? Was the difference between acute and chronic stress defined?	√			
Were the physical, emotional, cognitive and behavioral symptoms of stress defined?	√			
Was the relationship between stress and chronic pain explored?	√			
Was anxiety defined? Was it discussed in the context of chronic pain. Was treatment for anxiety discussed?	√ ?			Not really talk about the anxiety in the context of chronic pain but I checked the manual, it also didn't include any relative content. It is more like some general definition of anxiety.
Where the 4 A's of stress management reviewed with opportunities for the participants to apply to their situation?	√			
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	√			
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	√			
In instances that goals did not meet the SMART goal criteria, did the facilitator	√			The facilitator consistently try to coach one participant to come out with a SMART goal

help to highlight potential issues and offer suggestions to overcome the issues?				by reminding her purpose of the goal when she brought out a not measurable goal. The facilitator also suggested one participant to engage her partner with goal formulation and supervision.
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?		√		The facilitator didn't assess the confidence level.
Were group members thanked for their participation and praised for their efforts and any progress made?	√			

IPGT Study Fidelity Checklist, Session Six

Name of person completing fidelity: *Megan Tierney, MSW*

Group: *One*
Session: Six
Date: *February 1, 2019*

Check-in	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately give each participant the opportunity to check-in and review their goal for the week?	X			
Did the facilitator praise participants for achieving their action goals or for other success that they have experienced throughout their week?	X			
Did the facilitator ask the participants if they experienced any barriers while attempting to achieve their goals?	X			
Did the facilitator ask the participant what skills they used throughout the week in order to achieve their goals?	X			
If the participant stated that they did not achieve their action plan, did the facilitator problem solve with the participant(s)? How did the facilitator help the participant(s)?	X			
Relaxation/Mindfulness Techniques	**Yes**	**No**	**NA**	**Comments**
Did the facilitator adequately take the time to explain the technique?	X			
Did the facilitator invite the participants to try the technique?	X			
Did the facilitator encourage the participants to attempt to use and practice this technique throughout the week?	X			
Did the facilitator debrief the experience with the participants?	X			
Did the facilitator offer suggestions to participants that may have had troubles with the activity?	X			

CBT Session Content: Managing Set-Backs, Treatment Adherence, and Quality of Life	Yes	No	NA	Comments
Was the concept of chronic pain setbacks defined? Were the group members given the opportunity to share examples of times when they experienced setbacks?	X			
Were opioids defined and discussed in the context of medication adhere an risk factors associated with misuse or abuse?	X			
Were participants invited to complete the self-assessment worksheet?	X			
Did the facilitator review the importance of self-care and within the context of people with chronic pain?	X			
Were the participants given various examples of self-care? Were the participants given the opportunity to provide their own examples?	X			
Was the concept of the Self-Care Wheel reviewed? Were participants invite to complete their own self-care wheel?	X			
Goal Setting and Check-Out	**Yes**	**No**	**NA**	**Comments**
Did the facilitator give each participant the opportunity to check-out and review their new goal for the week?	X			
Did the facilitator remind the participants of the SMART goal acronym and help to assess if goals were: specific, measurable, attainable, realistic, and timely?	X			
In instances that goals did not meet the SMART goal criteria, did the facilitator help to highlight potential issues and offer suggestions to overcome the issues?	X			
Was confidence level assessed? In instances where the participants scored their confidence under 6, were they encouraged to choose a different goal?	X			

APPENDIX D

Study Measures

Patient Satisfaction Survey

Please read each of the following statements carefully. Then indicate the extent to which you **agree** or **disagree** by checking the box that best represents your response to the question.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. This group has been helpful to me.					
2. I am satisfied that I attended the group.					
3. The group handouts were helpful.					
4. The activities and exercises enhanced my ability to learn the subject matter.					
5. The group discussions were supportive and informative.					
6. The facilitator demonstrated expertise in the subject matter.					
7. The facilitator created a comfortable learning environment.					
8. The facilitator was sensitive to my cultural background (race, religion, language, etc.)					
9. The length number of sessions were Appropriate (6 weeks)					
10. The length of sessions (90 minutes) and the frequency of sessions (once a week) was appropriate.					
11. I have increased my knowledge on how to manage my chronic pain.					
12. I have increased my knowledge on the risks for opioid misuse					
13. I have increased my knowledge on overdose and naloxone distribution					
14. I would recommend this group to others.					
15. I am satisfied with my overall experience attending group.					
16. Overall, I would rate the group as good.					

Please share your thoughts and opinions on the following questions:

17. What did you like most about the group?

_____

_____

_____

_____

18. What did you like least about the group?

_____

_____

_____

_____

19. Do you have any suggestions of how to make the group better?

_____

_____

_____

_____

20. Is there any other information that you would like to share or feedback to provide us with that you have not yet mention?

_____

_____

_____

Thank-you for participating and for sharing your feedback!

Demographic Questionnaire

Instructions: Fill in the blank or check the appropriate response that best describes your situation

1. What is your age? _____

2. What is your gender?
____ Male
____ Female

3. What is your race?
____ White
____ Black
____ American Indian or Alaska Native
____ Native Hawaiian or Pacific Islander
____ Other
____ Prefer not to answer

4. What is your ethnicity?
____ Hispanic or Latino
____ Not Hispanic or Latino
____ Prefer not to answer

5. What is your marital status?
____ Single, never married
____ Married or in a domestic partnership
____ Separated or divorced
____ Widowed

6. Who are the other members in your household?
____ Spouse/partner
____ Parents
____ Children
____ Friend(s) or roommate(s)
____ Lives alone

7. What best describes your education level?

____ Less than high school
____ High school
____ Trade school
____ Technical/associate degree
____ Bachelor's degree
____ Graduate/professional degree

8. Current employment

____ Spouse/partner
____ Parents
____ Children
____ Friend(s)/roommate(s)
____ Lives alone

9. What is your approximate yearly household income?

____ Less than $25,000
____ $25,000 to $34,999
____ $35,000 to $49,999
____ $50,000 to $74,999
____ $75,000 to $99,999
____ $100,000 to $149,999
____ $150,000 or more
____ Prefer not to answer

10. Do you have health insurance?

___ Yes
___ No

Brief Pain Inventory

1. Please rate your pain by circling the number that best describes your pain at its **worst** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate your pain by circling the number that best describes your pain at its **least** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

3. Please rate your pain by circling the number that best describes your pain on the **average**.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the number that tells how much pain you have **right now**.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. What treatments or medications are you receiving for your pain?

_____

6. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the percentage that most shows how much relief you have received.

0 % 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

No relief Complete relief

7. Circle the number that describes how, during the past 24 hours, pain has interfered with your:

a. General Activity

1 2 3 4 5 6 7 8 9 10

Does not Interfere Completely interferes

b. Mood

1 2 3 4 5 6 7 8 9 10

Does not Interfere Completely interferes

c. Walking ability

1 2 3 4 5 6 7 8 9 10

Does not Interfere Completely interferes

d. Normal Work (includes both work outside the home and housework)

1 2 3 4 5 6 7 8 9 10

Does not Interfere Completely interferes

e. Relations with other people

1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely interferes

f. Sleep

1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely interferes

g. Enjoyment of life

1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely interferes

Pain Catastrophizing Scale

Everyone experiences painful situations at some point in their lives. We are interested in the types of thoughts and feeling that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

	Not at all	To a slight degree	To a moderate degree	To a great deal	All the time
I worry all the time about whether the pain will end	0	1	2	3	4
I feel I can't go on	0	1	2	3	4
It's terrible and I think it's never going to get any better	0	1	2	3	4
It's awful and I feel that it overwhelms me	0	1	2	3	4
I feel I can't stand it anymore	0	1	2	3	4
I become afraid that the pain will get worse	0	1	2	3	4
I keep thinking of other painful events	0	1	2	3	4
I anxiously want the pain to go away	0	1	2	3	4
I can't seem to keep it out of my mind	0	1	2	3	4
I keep thinking about how much it hurts	0	1	2	3	4
I keep thinking about how badly I want the pain to stop	0	1	2	3	4
There's nothing I can do to reduce the intensity of the pain	0	1	2	3	4
I wonder whether something serious may happen	0	1	2	3	4

Pain Stages of Change Questionnaire (PSCQ)

Part I

1. I have tried everything that people have recommended to manage my pain and nothing helps.

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. My pain is a medical problem and I should be dealing with physicians about it.

Strongly Disagree Disagree Neutral Agree Strongly Agree

3. Everybody I speak with tells me that I have to learn to live with my pain, but I don't see why I should have to.

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. I still think despite what doctors tell me, there must be some surgical procedure or medication that would get rid of my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

5. The best thing I can do is find a doctor who can figure out how to get rid of my pain once and for all.

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. Why can't someone just do something to take away my pain?

Strongly Disagree Disagree Neutral Agree Strongly Agree

7. All of this talk about how to cope better is a waste of my time.

Part II

1. I have been thinking that the way I cope with my pain could improve.

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. I have recently realized that there is no medical cure for my pain condition, so I want to learn some ways to cope with it.

Strongly Disagree Disagree Neutral Agree Strongly Agree

3. Even if my pain doesn't go away, I am ready to start changing how I deal with it.

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. I realize now that it's time for me to come up with a better plan to cope with my pain problem.

Strongly Disagree Disagree Neutral Agree Strongly Agree

5. I am beginning to wonder if I need to get some help to cope with my pain problem.

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. I have recently figured out that it's up to me to deal better with my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

7. I have recently come to the conclusion that it's time for me to change how I cope with my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

8. I'm starting to wonder whether it's up to me to manage my pain rather than relying on physicians.

Strongly Disagree Disagree Neutral Agree Strongly Agree

9. I have been thinking that doctors can only help so much in managing my pain and that the rest is up to me.

Strongly Disagree Disagree Neutral Agree Strongly Agree

10. I have been wondering if there is something I could do to manage my pain better.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Part III

1. I am developing new ways to cope with my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. I have started to come up with strategies to help myself control my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

3. I'm getting help learning some strategies for coping better with my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. I am learning to help myself control my pain without doctors.

Strongly Disagree Disagree Neutral Agree Strongly Agree

5. I am testing out some coping skills to manage my pain better.

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. I am learning ways to control my pain other than with medications or surgery.

Part IV

1. I have learned some good ways to keep my pain problem from interfering with my life.

Strongly Disagree Disagree Neutral Agree Strongly Agree

2. When my pain flares up, I find myself automatically using coping strategies that have worked in the past, such as relaxation exercise or mental distraction.

Strongly Disagree Disagree Neutral Agree Strongly Agree

3. I am using some strategies that help me better deal with my pain problem on a day-to-day basis.

Strongly Disagree Disagree Neutral Agree Strongly Agree

4. I use what I have learned to help keep my pain under control.

Strongly Disagree Disagree Neutral Agree Strongly Agree

5. I am currently using some suggestions people have made about how to live with my pain problem.

Strongly Disagree Disagree Neutral Agree Strongly Agree

6. I have incorporated strategies for dealing with my pain into my everyday life.

Strongly Disagree Disagree Neutral Agree Strongly Agree

7. I have made a lot of progress in coping with my pain.

Strongly Disagree Disagree Neutral Agree Strongly Agree

Brief Opioid Overdose Knowledge (BOOK) Questionnaire

Instructions: For each of the following items, please □ whether you believe the answer is true or false. If you are not certain, please □ "I don't know".

	True	False	Don't Know
1. Long-acting opioids are used to treat chronic "round the clock" pain.	□	□	□
2. Methadone is a long-acting opioid.....	□	□	□
3. Restlessness, muscle and bone pain, and insomnia are symptoms of opioid withdrawal.....	□	□	□
4. Heroin, OxyContin, and fentanyl are all examples of Opioids.....	□	□	□
5. Trouble breathing is NOT related to opioid overdose. ..	□	□	□
6. Clammy and cool skin is NOT a sign of an opioid overdose.	□	□	□
7. All overdoses are fatal (deadly).	□	□	□
8. Using a short-acting opioid and a long-acting opioid at the same time does NOT increase your risk of an opioid overdose.....	□	□	□

	True	False	Don't Know
9. If you see a person overdosing on opioids, you can begin rescue breathing until a health worker arrives	☐	☐	☐
10. A sternal rub helps you evaluate whether someone is unconscious.....	☐	☐	☐
11. Once you confirm an individual is breathing, you can place him/her into the recovery position.....	☐	☐	☐
12. Narcan (naloxone) will reverse the effect of an opioid overdose	☐	☐	☐

Attitudes on Naloxone Distribution Survey

Please read each of the following statements carefully. Then indicate the extent to which you **agree** or **disagree** by checking the box that best represents your response to the question.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Providing naloxone to first responders would save lives.					
2. Providing naloxone to friends and family members would save lives					
3. Distributing naloxone will encourage people to use even more opioid analgesics					
4. Preventing overdoses is ineffective because people will overdose again.					
5. Naloxone should only be given by medical professionals.					

The Prescription Opioid Misuse Index (POMI)

The POMI initially was an eight item interview which was reduced to six items after further testing and analysis. It includes a question about pain relief to confirm that any increase in prescription use was not due to inadequate pain control.

1. Do you ever use MORE of your medication, that is, take a higher dosage, than is prescribed for you? Yes/ No
2. Do you ever use your medication MORE OFTEN, that is, shorten the time between dosages, than is prescribed for you? Yes/ No
3. Do you ever need early refills for your pain medication? Yes/ No
4. Do you ever feel high or get a buzz after using your pain medication? Yes /No
5. Do you ever take your pain medication because you are upset, using the medication to relieve or cope with problems other than pain? Yes/ No
6. Have you ever gone to multiple physicians including emergency room doctors, seeking more of your pain medication? Yes/ No

An affirmative answer to more than one question correctly classified an individual as an opioid misuser, with high sensitivity and specificity. The strengths of POMI include ease of administration by a non-physician, clear criteria and brevity. This screen should be considered by all medical practices that prescribe medications for pain relief

Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	**Female**	**Male**
Family history of substance abuse		
Alcohol		
Illegal drugs		
Rx drugs		
Personal history of substance abuse		
Alcohol		
Illegal drugs		
Rx drugs		
Age between 16-45		
Mental health		
ADHD, Bipolar, Schizophrenia, Anxiety		
Depression		
Scoring Totals		

Drug Abuse Screening Test, DAST-10

The following questions concern information about your possible involvement with drugs not including alcoholic beverages during the past 12 months. "Drug abuse" refers to (1) the use of prescribed or over - the - counter drugs in excess of the directions, and (2) any nonmedical use of drugs. The various classes of drugs may include cannabis (marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD) or narcotics (e.g., heroin). Remember that the questions do not include alcoholic beverages. Please answer every question. If you have difficulty with a statement, then choose the response that is mostly right.

In the past 12 months…. (Circle)

1. Have you used drugs other than those required for medical reasons? Yes No

2. Do you abuse more than one drug at a time? Yes No

3. Are you unable to stop abusing drugs when you want to? Yes No

4. Have you ever had blackouts or flashbacks as a result of drug use? Yes No

5. Do you ever feel bad or guilty about your drug use? Yes No

6. Does your spouse (or parents) ever complain about your involvement with drugs? Yes No

7. Have you neglected your family because of your use of drugs? Yes NO

8. Have you engaged in illegal activities in order to obtain drugs? Yes No

9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs? Yes No

10. Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)? Yes No

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time		3	Nearly all the time
	2	A lot of the time		2	Very often
	1	From time to time, occasionally		1	Sometimes
	0	Not at all		0	Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite as much		1	Occasionally
2		Only a little		2	Quite often
3		Hardly at all		3	Very often
		I get frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I do
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful			**I can enjoy a good book, radio, or TV program**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not over often
0		Most of the time		0	Not at al
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not often	2		Not often
	3	Not at all	3		Very seldom

Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)

Sometimes things happen to people that are unusually or especially frightening, horrible, or traumatic. For example:

- A serious accident or fire
- A physical or sexual assault or abuse
- An earthquake or flood
- A war
- Seeing someone be killed or seriously injured
- Having a loved one die through homicide or suicide.

Have you ever experienced this kind of event? YES NO

- If no, screen total = 0. Please stop here.
- If yes, please answer the questions below.

In the past month, have you…

1. had nightmares about the event(s) or thought about the event(s) when you did not want to? **YES NO**

2. tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)? **YES NO**

3. been constantly on guard, watchful, or easily startled? **YES NO**

4. felt numb or detached from people, activities, or your surroundings? **YES NO**

5. felt guilty or unable to stop blaming yourself or others for the event(s) or any problems the event(s) may have caused? **YES NO**