2018

Medication-Assisted Therapy Interventions and Prescription Opioid Misuse

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Abstract

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MS, Catholic University of America, 2008

BS, University of Maryland, 2003

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

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November 2018

Abstract

Opioid drug misuse and dependence are a social and public health problem in the United States. Prescription opioid abuse and misuse have been associated with substantial morbidity and mortality rates as well as social and economic costs. The purpose of this project was to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions in addressing the problem of prescription opioid misuse in health care settings. The systematic review was completed through a literature search conducted across five electronic databases. The review was guided by the health belief model and eligible studies were rated using Johns Hopkins hierarchy of evidence. Fifteen peer-reviewed journal articles published from 2011 met the inclusion criteria and were reviewed in full. Of these, 14 were randomized controlled trials and 1 was a quasi-experimental study. The most commonly explored interventions were psychosocial interventions in conjunction with medications for opioid addiction. Review findings provided moderate evidence to support the effectiveness of psychosocial interventions in conjunction with medications in the treatment of opioid dependence, although the strength of the efficacy varied depending on the intervention provided. This project may advance nursing field by promoting provision of care to opioid dependent patients based on the best available evidence. Evidence-based care to patients with prescription opioid dependence will positively impact social change by improving the quality of life of patients, relieving caregivers of the burden of monitoring the addicted patients and saving millions of dollars spent in the criminal justice and health care systems.

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Dedication

Thanks to my supportive husband Mr. Tommy Jefferies, and my wonderful daughter and son, Tomella and Joseph Jefferies who has been the best family ever during my joy and pain while studying. Thanks guys for all the sacrifices you've made when I had to stay indoor studying and missing out on family outing. Tommy, you are my Rock and my number one supporter, and I love you dearly.

Mom and Dad, Nelly and Stephen Kiah, thank you for bringing me to America from Liberia, West Africa to get a better education and a great future. I am forever grateful.

Thanks to my Lord and Savior Jesus Christ for giving me the wisdom, knowledge and understanding that I needed during this DNP program.

Acknowledgments

I would like to acknowledge Dr. Barbara Niedz my chair at Walden university who has been very supportive and encouraging. Thank you for helping me to be re-registered when Walden accidentally dropped me during the last semester of my DNP program. I would like to say thanks to Dr. Margaret F. Harvey committee member who give me great insight during my oral presentation.

I am forever grateful and would like to say thanks to Dr. Nikki Ezeani, CRNP, DNP who has been an inspirational, professional coach and my clinical instructor. You encouraged me to pursue my doctoral of nursing practice degree, you also guided me during the process and made yourself available whenever I felt stuck. I appreciate all you have done for me.

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Section I: Overview of the Evidence-Based Project

Introduction

Opioid drug misuse and dependence is a major social and public health problem in the United States (U.S) that has reached epidemic levels in the past few decades (Rudd et al., 2016). Indeed, about 2 million U.S. adults abused or were addicted to prescription opioids in the year 2014 (Hedden, 2015). Researchers have found that at least one in four people who have received prescription opioids for pain not related to cancer become addicted at some point (Boscarino et al., 2010). According to Crane (2013), at least 1,000 people are received daily in emergency departments as a result of abusing prescription opioids. Addiction to opioid has been associated with substantial health risks including the transmission of viral infections such as hepatitis B and C as well as Human Immunodeficiency Virus (HIV) (Suryaprasad et al., 2014). Prospective studies have shown that the risk of adverse health outcomes continues for many years after a diagnosis suggesting that opioid dependence may be considered a chronic health condition (Edlund et al., 2014; Hser, Evans, Grella, Ling, & Anglin, 2015).

Besides the adverse health effects associated with this form of substance misuse, the use of opioids (including heroin and prescription opioids) led to the death of around 33,000 people in 2015, the highest mortality rate that has ever been reported (Center for Disease Control and Prevention [CDC], 2017), suggesting that the mortality rate has been increasing. Likewise, the National Institute on Drug Abuse (2017) reported that overdose deaths related to prescription opioids increased three times between 2001 and 2015. Almost 50% of all deaths related to opioid misuse involve a prescription opioid (Kolodny

et al., 2015), highlighting the role of health care providers in promoting the health of people misusing opioids.

Beyond the high mortality and morbidity rates, dependence on opioid inflicts huge social and economic costs as a result of lost productivity, breakdown in relationships, health care costs, and expenses related to law enforcement. It is estimated that prescription opioid misuse and dependence carries a high economic burden for the U.S, with the aggregate economic burden projected at $78.5 billion (Florence, Zhou, Luo, & Xu, 2016). About 25% of this cost is borne by the public health care sector, substance use therapy, and the costs incurred in the criminal justice system (Florence et al., 2016). The findings shed light on the economic effect of opioid abuse and dependence; hence highlighting the need to develop strategies aimed at reducing the social, economic, and public health burden.

This project has implications for positive social change. In this project I have provided a systematic and a critical review of the existing evidence on the effectiveness of medication-assisted therapy interventions in reducing the problem of opioid misuse and dependence in primary care setting. As a result, the study will ensure that nurse practitioners stay at par with the best evidence on treatment of opioid dependence and abuse. This will ascertain that they are able to provide evidence-based care to opioid dependence patients leading to optimal patient outcomes, reduced health care costs, and reduced mortality rate attributable to substance misuse.

Problem Statement

Statistics on the prevalence of substance abuse indicate that substance use disorder is a severe public health issue that requires evidence-based interventions. Public health officials among other policymakers seem to have reached a consensus that the opioid epidemic cannot be adequately resolved through the current punitive drug policies (Substance Abuse and Mental Health Services Administration (SAMHSA) 2013; Volkow, 2014). As a result, training programs aimed at impacting nurse practitioners with the knowledge and appropriate skills to provide effective medication-assisted therapies for patients on opioids are being offered in the U.S.

Nurse practitioners are ideally suited to carry out substance abuse interventions because of their knowledge in the setting of health promotion (Nyamathi et al., 2011). According to Lock et al. (2006), nurse-led interventions are effective in addressing behavioral problems related to chronic alcohol intake among patients seeking care in the primary care setting. However, information is lacking about the effectiveness of a nurse-led intervention designed to reduce opioid abuse among adults receiving medication-assisted therapy in primary care settings. Therefore, the purpose of the capstone project was to provide a systematic review of the literature on the effectiveness of medication-assisted therapy interventions in reducing the problem of opioid misuse and dependence by adults seen in primary care settings.

Purpose Statement

The purpose of this capstone DNP project was to synthesize the best available evidence on the effectiveness of medication-assisted therapy interventions in reducing the

problem of opioid misuse and dependence by adults seen in primary care settings. A gap exists in practice when nurse practitioners or other health care providers administer interventions that are not supported by the best available evidence (Solomon, 2016), and it was the purpose of this project to address such a gap. Thus, a systematic review is in accord with the American Nurse Practitioner Association (ANA) position that as providers offering care on the front lines of the opioid epidemic, registered nurse practitioners are qualified and have a responsibility to play a leading role in monitoring and managing patients struggling with this form of addiction (ANA, 2015). The identified gap was addressed by conducting a systematic review of the existing empirical research on the effectiveness of medication assisted therapy in dealing with the problem of prescription opioid misuse and abuse by patients.

The population, intervention, comparison, and outcomes (PICO) question for this project was: Does medication-assisted therapy interventions reduce the problem of opioid dependence and misuse by adults seen in primary care settings? The population of interest includes adult patients who are opiate addicts receiving care in primary settings, the interventions and comparison include both pharmacotherapeutic and psychological management of opioid addiction while the outcome measures of interest include abstinent at follow up, withdrawal of signs and symptoms, adverse effects of treatment, and completion of treatment.

The project has the potential to address the identified practice gap. It provided scholarly information on best practices for the provision of medication-assisted therapies by nurse practitioners to manage the problem of opioid misuse among patients seeking

care at the practicum site. The evidence on best practices will empower practice nurse practitioners in the mental health setting to make best decisions regarding patient care based on EBP rather than rituals, traditions, and opinions by colleagues. The evidence can also be used to develop educational programs aimed at raising nurse practitioner knowledge and skills to offer effective medication-assisted therapies to opioid dependent patients.

Nature of the Doctoral Project

There is a broad range of treatment options including psychosocial and pharmacotherapeutic interventions that have been approved to treat opioid dependence. There are currently three types of medications that have been approved for treatment of opioid dependence, including naltrexone, buprenorphine, and methadone (Volkow et al., 2014). Each of these drugs is to be used within a framework of social, medical, and cognitive support which is part of the inclusive opioid dependence treatment approach (Volkow et al., 2014). Nevertheless, there is a scarcity of reviews assessing the effectiveness of medication-assisted therapy interventions by nurse practitioners in reducing the problem of opioid misuse by adults seen in primary care (Brady, McCauley, & Back, 2015). As a result, the purpose of the capstone project was to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions by nurse practitioners in reducing the problem of prescription opioid misuse by adults seen in primary care settings.

To accomplish the purpose of the review, a literature search was carried out to identify appropriate sources of evidence. Articles on the effectiveness of medication-

assisted therapies were collected. Procedures followed in this review included defining the research question, developing a literature search strategy, searching and identifying relevant sources, extracting and analyzing data, and presenting and disseminating the findings (Higgins & Green, 2011). The search for the literature focused on primary studies as the main source of evidence. The search was conducted through five electronic databases including EMBASE, CINAHL, PubMed, Cochrane Library, and PsyINFO. Search terms related to psychosocial treatment, opioid dependence, addiction, medication assisted therapy, and effectiveness were developed. The search was restricted to materials available in full, published within the past decade and available in English language. The title and abstracts of the articles were reviewed before downloading them and determining their relevance. The findings will later be shared with the nurse practitioners at my practicum setting and regional conferences held by mental health nurse practitioners. An elaborate description of the sources of evidence is presented in Section 3.

Significance

Evidence-based practice (EBP) is crucial in the provision of quality care to patients suffering from opioid dependence problems (Volkow et al., 2014). This capstone project has the potential to strengthen EBP in the management of patients presenting with opioid dependence in health care settings. The project was carried out through a systematic review of the existing evidence on the effectiveness of medication assisted interventions in reducing opioid dependence symptoms as well as promoting abstinence in both the short and long-term. As a result, the capstone project provided the best

available evidence on the management of opioid dependent patients thus empowering nurse practitioners and other health care providers to make decisions regarding patient care on the basis of the best available evidence rather than on traditions, rituals, and opinions from colleagues. The literature reviewed has demonstrated the magnitude and the burden posed by prescription opioid dependence on the health care system and society in general (Edlund et al., 2014; Kolodny et al., 2015; Rudd et al., 2016); thus demonstrating the importance of adopting the EBP to tackle the problem.

Implications for Social Change in Practice

As an advanced practice registered nurse (ANRP) who acts as an agent of change for adoption of EBP, quality improvements efforts to promote the provision of care that is consistent with the patient needs and supported by the best available evidence is essential (Sperhac & Clinton, 2008). Nurse practitioners with a doctoral degree have a key responsibility of shaping policies that could have an impact on nursing practice as well as patient outcomes (Zaccagnini & White, 2015). The DNP capstone project was carried out through a systematic review of literature approach, and the best available evidence was synthesized to inform practice on the effectiveness of treatment strategies used to manage opioid dependence. A review of literature highlighted a practice problem where health care providers including nurse practitioners have poor prescription practices for the management of opioid dependence (Solomon, 2016).

Health promotion is an essential role of a nurse with a doctoral degree (Sperhac & Clinton, 2008). Evidence obtained from this capstone project could be used to advance nursing practice by promoting safe and effective treatment methods for opioid

dependence. The findings of the review can also promote practice change by providing evidence-based models for management of patients suffering from opioid dependence. Nurse practitioners ought to advocate for improved access of opioid dependence patients to treatment programs providing evidence-based care. This will ensure that patients benefit from the provision of patient-centered care that meets their short and long-term needs.

The DNP project has the capacity to promote further positive social change in the near future. Provision of care that is consistent with the patient needs and the best available scientific evidence will positively impact social change by improving the quality of life of opioid dependence patients. It will also result in a reduction in social injustices that are as a result of opioid dependence while relieving family members and care givers the burden of monitoring the patient addicted to prescription opioids. Moreover, integration of the best available evidence will lead to a reduction in the economic, social, and criminal justice system burden placed by opioid dependence.

Summary

In this section, prescription opioid dependence has been identified as a substantial social and public health problem in the U.S. There are a broad range of treatment options including psychosocial and pharmacotherapeutic interventions that have been approved to treat opioid dependence. Nevertheless, there is a scarcity of reviews assessing the effectiveness of medication-assisted therapy interventions by nurse practitioner in reducing the problem of opioid misuse by adults seen in primary care. In addition,

existing literature has identified poor prescription practices in the management of patients suffering from opioid dependence.

The purpose of this capstone DNP project was to synthesize the best available evidence on the effectiveness of medication-assisted therapy interventions in reducing the problem of opioid misuse and dependence by adults seen in primary care settings. The project will facilitate social change by promoting provision of evidence-based care leading to improved quality of life for opioid dependence patients as well as reductions in economic burden and contact with the criminal justice system. The next section will provide a review of specific and general literature and a discussion of the theoretical framework for this project.

Section 2: Review of Scholarly Evidence

Introduction

The primary purpose of this scholarly project is to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions in reducing the problem of opioid dependence. Section 2 of the project scrutinizes general and specific literature on the problem of opioid dependence. Specifically, the section discusses the current guidelines for management of opioid dependence, the role of advanced practice nurse practitioners in the management of opioid dependence and provides the theoretical framework to guide the review.

Concepts, Models and Theories

Health Belief Model

The Becker's (1974) health belief model (HBM) provided the theoretical framework for the review. The HBM is a psychological model that was developed to explain and predict health behaviors, especially regarding uptake of treatment and health promotion services (Maiman & Becker, 1974). The model attempts to demystify and predict human health related behaviors with a particular focus on their attitudes and beliefs. It was initially developed in the 1950s by Hochbaum, Kegels and Rosenstock in to explain why free screening programs provided by the U.S Public Health Services, particularly for tuberculosis, were not effective. Since then, the model has been used to examine a variety of short and long-lasting health behaviors such as sexual health risks and substance misuse and dependence.

The HBM is based on the premise that an individual will take a health related action if he or she: feels that it is possible to avoid the negative health condition, perceive themselves to be susceptible, believe that there would be serious repercussions, and believe that there would be some benefits as a result of change (DiClemente, Salazar, & Crosby, 2013). The model is composed of four major constructs including perceived susceptibility, perceived severity, perceived benefits, and perceived barriers. These concepts account individual's readiness to change (Janz & Becker, 1984).

Additional concepts include cues to action which refers to readiness and stimulate overt behavior and self-efficacy, which can be described as the confidence of an individual in his or her capability to perform a certain action (Franckowiak & Glick, 2015). Having the confidence to taking action and integrating health behavior into the daily life of the patient are essential in the management of chronic health conditions. The efficacy of medical interventions is mostly dependent on the involvement of the patient in self-care activities. Opioid addiction is by definition, a chronic health condition, and the HBM has been used to study a variety of chronic health illnesses (Franckowiak & Glick, 2015).

Johns Hopkins Hierarchy of Evidence

The Johns Hopkins Nursing EBP model will be used to rate the strength of the included evidence which may be judged by the type of the research design and quality of methods. The model has five levels and has been selected because it is designed to meet the needs of practicing nurse practitioners. Level I evidence refers to systematic reviews or meta-analysis of experimental studies, experimental studies or randomized controlled

trials (RCTs). Level II studies include quasiexperimental studies or systematic reviews of quasi-experimental studies. Level III refers to nonexperimental studies as well as systematic reviews with or without meta-analysis. The nonexperimental studies can be quantitative surveys or qualitative studies or their systematic reviews with or without meta-analysis. Level IV includes opinions of nationally recognised expert committees or consensus panels reviewing scientific evidence. Lastly, Level V is based on experiential evidence such as literature reviews, case reports, and quality improvement programs (Dearholt & Dang, 2012).

Relevance to Nursing Practice

This DNP project is of relevance to nursing practice because it provided an update on the effectiveness of medication-assisted interventions in improving outcomes in patients living with opioid dependence. Nursing practice has a reputation for promoting and enhancing the population health in the American society (Camicia et al., 2013). Unsafe prescription practices for opioid addicts lead to medication errors and undermine the reputation of nursing practice and, ultimately, the overall health care system (Ladd, Sweeney, Guarino, & Hoyt, 2017). Reviewing evidence on medication-assisted therapies can help registered nurse practitioners safely treat opioid addiction contributing to high quality and safe care (Boscarino et al., 2010; Kolodny et al., 2015; Volkow et al., 2014). A synthesis of best available practices can help address poor prescribing practices which are not evidence-based leading to improved outcomes of patients with opioid dependence problems.

The scope of practice for an APN allows for health assessment, diagnosis, treatment, health education, prescriptive authority, and preventative health care among more other responsibilities (Committee on the Robert Wood Johnson Foundation Initiative on the Future of Nursing, at the Institute of Medicine., Robert Wood Johnson Foundation., & Institute of Medicine, 2011). APNs have played a critical role in addressing shortage of health providers in rural and marginalized areas (Tierney et al., 2015). A 2010 report by the Institute of Medicine (IOM) emphasized that nurse practitioners should be allowed to practice to the full extent of their training (IOM, 2011). Nevertheless, states have depicted disparities in granting legal autonomy of doctorally prepared nurse practitioners to practice and administer medications. Currently, 28 states do not allow APNs to prescribe buprenorphine unless they are working in collaboration with a physician who have a federal license to practice it (Pew Charitable Trusts, 2017). Therefore, most APNs are prohibited from practicing to their full potential in the provision of care to patients addicted to opioids despite evidence indicating that APNs provide safe and effective quality care (Newhouse et al., 2011).

Advanced practice registered nurse's narcotic prescriptive authority varies from one state to another with some states granting nurse practitioners broader prescriptive choice in comparison to others. For instance, Alabama and Florida have allowed APNs to administer only a limited selection of controlled medications while 19 other states have granted APNs permission to offer schedule II to IV drugs (Pew Charitable Trusts, 2017). The variation in prescription authority is questionable considering that the level of educational preparation and qualification for APNs is comparable across states and there

are national accreditation programs to ensure quality and consistency. The DNP candidate is a certified buprenorphine provider and has been approved for medication assisted therapy for patients addicted to prescription opioids.

Existing Scholarship and Current State of Practice

The prevalence of prescription abuse and misuse has greatly increased in the past two decades in the U.S. Currently, prescription opioids are the most frequently misused drugs, second only to cannabis, with about 1.9 million people trying them on an annual basis (Alderks, 2013). Data from the 2012 National Survey on Drug Use and Health point out that there are around 12.5 million Americans who misused prescription opioids, a substantial surge from 4.9 million reported in 1992 (Abuse, 2013). Cases of unintentional prescription opioid overdose increased by four times and cases of emergency department visits due to prescription opioid misuse increased by more than five times between 2000 and 2010 (CDC, 2017).

Some years before the 1990s, doctors were criticized for undertreating pain. However, there was a paradigm shift in the 1990s and pain came to be known as the "fifth vital sign" and general practitioners were encouraged to manage and address pain aggressively (Brady et al., 2015; Calcaterra, Glanz, & Binswanger, 2013). Later in 2012, the number of prescriptions written for opioids (259 million) was equivalent to the adult population of the U.S (Brady et al., 2015). Pain management is now at the center of the U.S. health care system with lawmakers and health practitioners attempting to minimize the adverse effects of the increased access to prescription opioids at the same time ensuring that pain is properly controlled.

Prescription Practices

Opioids include both natural opiates and artificial congeners which are drugs that generate morphine like effects. They act principally on three types of receptor in the nervous system: delta, kappa, and mu (Tarter, Ammerman, & Ott, 2013). The mu receptor is basically responsible for the analgesic and euphoric features of opioids and attempts to generate an agent that produces analgesia without abuse potential have been futile. Most of the opioid analgesics currently in use are full mu agonists (hydrocodone, oxycodone, and morphine).

Buprenorphine is a partial mu agonist and an antagonist at the kappa receptor and was approved by Food and Drug Administration (FDA) in 2002 for office-based management of opioid dependence (Veilleux et al., 2010). The drug can be used during maintenance and detoxification phases of opioid addiction. Considering that it is a partial agonist, there is reduced risk of overdose and its use in the long-term has not been associated with the development of severe withdrawal symptoms. Opioid antagonists such as nalmefene, naltrexone, and naloxone bind to opioid receptors and can be administered to prevent the effects of opioids (Kelly, Daley, & Douaihy, 2012).

Opioid encompass many specific agents available in a broad range of preparations. Short-acting orally administered opioids including oxycodone, immediate-release morphine, codeine, and hydromorphine usually have a quick onset of action (10-60 minutes) and a short duration of action (2-4 hours) and are commonly used to manage acute breakthrough pain (Zacharoff et al., 2010). Long-acting or extended release opioids have a gentler onset of action (30-90 minutes) and a longer duration of action (4-72

hours) and are commonly used in the management of chronic pain (Wilson, 2015). It is recommended that providers should avoid administering more than one short-acting opioid concomitantly unless there are documented medical reasons (Nuckols et al., 2014).

A combination of opioid and non-opioid analgesics is frequently used in the management of patients with moderate pain. Using a combination product when dosage intensification is needed raises the risks of adverse effects from the non-opioid co-analgesic even if increasing the opioid dosage was an appropriate action. In such instances, the use of single agent formulations of opioid may be desirable (Kelly et al., 2012; Nuckols et al., 2014).

As concerns about opioid abuse and misuse have increased, attempts focused on developing abuse-deterrent and tamper-resistant opioid formulations have been made. A 4:1 formulation of buprenorphine and naloxone designed for sublingual administration, marketed under the name Suboxone, is the most commonly used buprenorphine formulation (Brady et al., 2015). Sublingual naloxone will not provoke withdrawal; nevertheless, if Suboxone is administered intravenously, the naloxone will block the euphorigenic effects of buprenorphine and might trigger withdrawal (Tarter et al., 2013). Another deterrent technique is modifying the physical structure of tablets and incorporating compounds that make it difficult to liquefy, concentrate or otherwise transform the tablets. For instance, in 2014, FDA approved a new extended release oxycodone/ naloxone formulation with abuse deterrent properties (Wilson, 2015). Such preparations have been perceived as less vulnerable to abuse or misuse, though there is still potential for misuse.

The Office of National Drug Control Policy has put various strategies into place to deter opioid misuse and abuse. The strategies include educating health care providers as well as patients about the risks that are associated with abuse and misuse, promoting the Prescription Drug Monitoring Program, and supporting proper disposal of prescription drugs to avert diversion (Kuehn, 2014). On the other hand, best practice recommendations by Executive Office of the President of the US (2011) acknowledged the importance of balancing the benefits of opioids in pain management with the potential risks conferred, especially by chronic pain. The guidelines advocate for the universal application of risk mitigation strategies including mental health screening, conducting urine screening tests, treatment agreements, and dosing guidelines.

Screening and Assessment

Considering that it is a challenge to predict who will misuse opioid medications, universal risk assessment has been recommended. This means that all patients, including those not chronically receiving opioid analgesics on a daily basis should be assessed for the possibility of opioid abuse using validated tools prior to the commencement of opioid therapy (Meltzer et al., 2011). Positive results from the assessment should be followed up by a more rigorous assessment to collect further details. It is recommended that all patients on opioid therapy should receive education on safe usage and disposal regardless of their risk level (Barclay, Owens, & Blackhall, 2014).

There are a number of validated tools that can be used by health care providers to weigh the risk of potential opioid misuse. It is essential that all patients undergo screening before commencing opioid therapy. Validated screening measures include the

Screener and Opioid Assessment for Patients with Pain and the Opioid Risk Tool (Passik, Kirsh, & Casper, 2008). The two instruments are suitable for identification of patients at risk of abuse or misuse before commencing opioid therapy. According to Butler et al. (2010), positive screening alone is inadequate to rule out opioid therapy, and positive results should be accompanied by a broader assessment such as clinical assessment and urine drug screening to determine the safety and the risk benefit ratio of the treatment.

Treatment of Prescription Opioid use Disorders

Though disorders due to prescription opioid are around four times more common compared to those of heroin use, therapy outcome research specific to prescription use disorders is scanty, and the scope to which therapeutic interventions developed to address the problem of heroin misuse can be effectively generalized to prescription opioid dependence remains to a large extent ambiguous (Brady et al., 2015; Holmes, 2012). In the absence of clear protocols to prescription opioid use disorders, most providers rely on their clinical knowledge or experience regarding treatment options for opioid use disorders.

Treatment for opioid use disorders typically involve medically supervised withdrawal from the addicting drugs followed by maintenance with opioid substitution therapies (Calcaterra et al., 2013). Opioid substitution or replacement therapy involves administration of a longer acting opioid with less euphoric effects in an attempt to lessen craving and reduce withdrawal symptoms. Opioid substitution therapy mostly involves use of medication in the long-term, and in some cases, lifetime (Holmes, 2012). The two most commonly used substitution therapies are buprenorphine and methadone. Around

25% of patients with opioid use disorders have been administered with methadone maintenance therapy (MMT), making it one of the most frequently administered replacement therapy for opioid abuse and misuse disorders (Brady et al., 2015).

Effectiveness rate for MMT ranges from 20% to 70%, and the outcomes are dose related, with individual variability in the effective dose (Mattick, Kimber, Breen, & Davoli, 2008). Lower dosages (20-40mg/day) have been found to be effective at subduing opioid withdrawal symptoms though they may not adequately reduce craving or block the effects of other opioids. Maintenance dosages are generally in the range of 70-120 mg/day, though some patients require more than 120 mg/day for optimal therapeutic response (Mattick et al., 2008). The drug has been found to be effective in suppressing withdrawal and blocking the effects impact of other opioids. There is evidence that MMT improves treatment retention, reduces illicit opioid use, and is associated with reduced criminal activities related to opioid misuse (Brady et al., 2015).

Buprenorphine was approved by FDA in 2002 as an office-based medication for prescription opioid dependence, and by 2012, 51% of opioid treatment programs was offering the drug (Wilson, 2015). The drug is a partial mu agonist; hence it is associated with less euphoria and sedating effects compared to methadone. It has also been shown to reduce withdrawal, hospital admission, morbidity, and mortality among individuals with opioid use dependence (Bell et al., 2009). Similar to MMT, buprenorphine therapy can be sustained for years (Rosenthal et al., 2016).

Lifetime or long-lasting opioid dependence therapy is not a preferable option for some people with opioid dependence. In such a scenario, a substitution therapy (mostly

Suboxone or buprenorphine) is steadily tapered and ultimately substituted with naltrexone to promote continuous opioid abstinence (Tarter et al., 2013). Naltrexone is an opioid antagonist that blocks the euphorigenic effects of opioids. While the efficacy of naltrexone has been traditionally hampered by low adherence rates, injection and implant options lately permitted by FDA have shown promising results (Kelly et al., 2012). The medication can be administered with ease, is not addictive, and has not been found to induce tolerance (Tarter et al., 2013). Nevertheless, considering that naltrexone minimizes opioid tolerance, it can raise the risk of having an overdose among individuals who return to illicit drug use. Mortality rates as a result of oral naltrexone are three to seven times higher than those associated with MMT (Brady et al., 2015).

Local Background and Context

As providers offering frontline care to patients with opioid dependence, advanced practice registered nurse practitioners are qualified and have a responsibility to play a leading role in monitoring and managing patients. It is essential for nurse practitioners to administer care that is backed by the best available evidence. Nurse practitioners at the practicum site have limited knowledge of administering medication-assisted therapies and are not confident in teaching patients about managing opioid dependence. The practicum site is a mental health facility with a mission of empowering its clients and families to cope with the challenges of various mental illnesses in an attempt to improve the quality of their lives. The vision of the mental health center is to become a center of excellence and a state leader in the field of mental health.

The community mental health center serves adults aged 16 and above with various mental challenges or symptoms of psychiatric illness. The mental health facility also deals with the issue of opioid dependence and has care providers who administer opioid medications. Collecting and analyzing data relating to the effectiveness of interventions aimed at addressing the problem of opioid dependence will assist the nurse practitioners at the practicum site by keeping them abreast of the changes in the field. The evidence can also be used to improve their knowledge and skills in management of opioid dependence thus reducing the impact of this problem on the individuals, families, society, and the health care system.

Definitions of Terms

This subsection defines terms frequently used in this paper.

Advanced practice registered nurse: This is a nurse who has a master's, post-master's certificate or doctoral of nursing educational level in nursing and had passed a national licensure examination for nurse practitioners (ANA, 2010). They are also referred to as advanced practice nurse practitioners (APNs), and both terms will be used in this paper.

Opioid addiction/dependence: This is the inability of an individual to refrain from using opioid drugs regardless of the detrimental problems and no benefits attributable to their use (Edlund et al., 2014).

Evidence-Based practice: Refers to the integration of patient values, clinical research, and best available evidence to make decisions regarding the provision of care to patients (Sackett, 1997).

Role of the DNP Student

I am an advanced practice nurse with background in primary care and mental health and have worked for the current health center for more than a decade. I have taken a course in opioid dependence management and I am certified to administer medications and other interventions to manage this condition in an office-based setting. My motivation for this project was to review evidence on the effectiveness of interventions aimed at managing opioid dependence.

Opioids are commonly administered for management of severe pain and are commonly abused by patients. I have been dealing with opioid dependent patients and my optimism about this topic is that the evidence will improve nurse practitioners' knowledge, skills, and confidence in the management of patients with this problem. Having interacted with opioid dependent patients and administered medications might have introduced bias in the review. To mitigate this bias, I followed the systematic and consistent procedures in the process of searching, retrieving, and reviewing the evidence presented in various studies before reaching a conclusion. I also did not have any competing interest or further information that need to be disclosed prior to conducting this review.

Summary

The prevalence of prescription abuse and misuse has skyrocketed in the past two decades in the US. Currently, prescription opioids are the most frequently misused drugs, second only to cannabis, with around 1.9 million people trying them on an annual basis. Though disorders due to prescription opioid are four times more common compared to

those of heroin use, therapy outcome research specific to prescription use disorders is limited. In the absence of clear protocols to prescription opioid use disorders, most providers rely on their clinical knowledge regarding treatment options for opioid use disorders. Therefore, there was a need to assess evidence from primary studies on the effectiveness of medication assisted therapies in management of prescription opioid dependence.

Section 3: Collection and Analysis of Evidence

Introduction

The purpose of the capstone project was to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions in reducing the problem of prescription opioid misuse by adults seen in primary care settings. It is important to have a clear understanding of the most effective and safe combination of medication assisted therapy to effectively treat opioid dependence. Section 3 offers a thorough description and justification of the methodology that will be used to carry out the proposed systematic review.

Specifically, the section discusses the literature search techniques including the databases, search engines, key words, and inclusion and exclusion criteria. This is followed by a discussion of data analysis and quality assessment of the included journal articles. Although there are other approaches that can be used to carry out a secondary study, a systematic review approach was viewed as the most appropriate for the project of this nature to collect and analyze evidence of effectiveness of medication assisted therapy in treatment of opioid dependence.

Practice-Focused Question

Information is lacking about the effectiveness of nurse-led interventions aimed at reducing the problem of opioid dependence in mental health settings. A gap exists in practice when nurse practitioners or other health care providers administer interventions that are not supported by the best available evidence. Therefore, the purpose of the capstone project was to provide a systematic review of the literature on the effectiveness

of medication-assisted therapy interventions in reducing the problem of opioid misuse and dependence by adults seen in primary care settings. The question designed to guide this project was: Do medication-assisted therapy interventions reduce the problem of opioid dependence and misuse by adults seen in primary care settings? The gap in practice was addressed by carrying out a systematic review of relevant evidence on the effectiveness of interventions aimed at reducing the problem of opioid dependence.

Sources of Evidence

The DNP project was completed using the systematic review of literature method of assessing the existing body of evidence on the effectiveness of medication assisted therapies in the treatment of opioid dependence. The review was carried out based on a revised version of the Cochrane systematic review handbook methodology. Steps identified by the handbook include designing the research questions, developing the literature search strategy, choosing and reviewing appropriate journal articles, gathering and evaluating data, followed by presentation and analysis of the findings (Higgins & Green, 2011). Data on the effectiveness of medication assisted interventions by nurse practitioners in the treatment of opioid dependence was searched and critically assessed while addressing the adequacy of the evidence and evaluating the outcomes.

Godfrey and Harrison (2010) asserted that a systematic review of literature involves the analysis of the existing body of literature to establish the effectiveness of a given practice. Reviewing evidence systematically provides a predetermined plan to ensure consistency and minimize bias (Thomas, Ciliska, Dobbins, & Micucci, 2004), making the findings of a review to be more reliable compared to those of individual

studies. Nevertheless, the strength of the findings of a systematic review are good as that of the included primary studies (White & Waddington, 2012), suggesting that if the included studies contained flawed results; the conclusions reached on the review would not be credible.

Published Outcomes and Research

The systematic review was carried out following a critical review of the existing literature on the effectiveness of medication assisted therapy in treatment of opioid dependence. The literature search was carried through five electronic databases including PubMed, PsycINFO, EMBASE, CINAHL, and Cochrane Library. The electronic databases were selected because they contain peer-reviewed journal articles. According to Sampson et al. (2009), peer review process is an important step in validating the quality of research as a result of through the rigorous steps involved in the process. A supplementary search for grey literature was carried out through Google Scholar and organizational websites that offer services or carry out research involving people living with prescription opioid dependence.

Search terms related to psychosocial treatment, opioid dependence, addiction, medication assisted therapy, and effectiveness were used. The search terms were broadened to identify appropriate journal articles. The searches were restricted to all fields including keywords, abstracts, and titles and will be restricted to studies involving human participants. A computer-assisted search through the various databases was carried out using the same search terms. This process was supplemented by performing a hand search to check the relevance of the included data. This is in line with Armstrong et

al.'s (2005) affirmations that hand searching is suitable tool in the search for evidence because it promotes the inclusive analysis of journal issues which may be in form of conference proceedings or case studies not published in major electronic databases.

Boolean operators (AND, OR or NOT) were used in the literature search to combine search terms in an attempt to build a more focused search. Another advanced literature search technique that was used is truncation (e.g effect* to retrieve articles that included the word effect, effectiveness, and effective) to broaden the search process. Spelling variations and alternative words were also be taken into consideration so as to build a comprehensive search. The use of advanced search techniques has been supported by Ecker and Skelly (2010) who claimed that it makes it allows reviewers to identify appropriate journal articles with ease.

Other major literature search techniques employed to carry out the review included citation searching and footnote chasing. Citation searching is a powerful technique that focuses on identifying articles citing known journal articles published previously (Kear & Colbert-Lewis, 2011). The technique was used to locate all articles that were the original sources on the research topic. A closely related literature search technique is footnote chasing and was used to locate relevant journal articles by carefully searching the bibliography of the identified papers. According to Tubré et al. (2011), footnote chasing tends to have a high precision considering that other researchers had reviewed the content of the materials and found them relevant to the current topic. Citation searching and footnote chasing literature search techniques were used to

supplement the literature search and possibly led to identification of up-to-date articles missed during the electronic database search.

Evidence Generated for the Doctoral Project

The literature search was to journal articles published from January 2011 to 2018. This is in accord with Booth, Sutton, and Papaioannou's (2016) recommendation that reviewers should strive to include a realistic timeframe to act as a benchmark for deciding which studies should be included in a review. The search was restricted to studies available in English language and those involving human beings as participants. The participants should be adult patients receiving treatment of prescription opioid dependence from nurse practitioner or other health care providers. Outcomes of interest include opioid use, changes in symptoms, treatment retention, and attendance to counseling attendance.

Eligible materials include articles evaluating the effectiveness of medication assisted therapy for treatment of prescription opioid dependence. In an event that an article presented a secondary analysis of data from an eligible study, the original report will be tracked and included in the review. Study designs that were considered included quasi-experimental, randomized controlled trials, case control, and cohort studies. Only articles available in full were included.

The exclusion criteria included journal articles published before 2010, those involving participants receiving treatment for opioid dependence not as a result of prescription, and those published in any other language apart from English. The review also excluded non-empirical articles including editorials, literature reviews, and

commentaries. In addition, studies that failed to include sufficient control groups or whose study design did not allow for determination of the effectiveness of medication assisted therapies in combination with psychological treatment will be ineligible.

Procedures

Plonsky and Gass (2011) asserted that clinical trials are crucial resources that have an impact on decisions relating to management of chronic health conditions. Dixon-Woods et al. (2007) added that assessing the quality of the research techniques used to conduct research is an essential strategy in the identification of the most robust evidence in health care. The claim has been reinforced by arguments (Thomas & Harden 2008) that the characteristic of the techniques used in conducting a primary study can indicate the level of validity and reliability of the findings of the study. Moreover, assessing the methods used to conduct research is essential because the differences in the quality of the methodology used can have a profound effect on the conclusions reached about the effectiveness of a particular intervention.

Following a scrutiny of several reviews, Moher et al. (2009) found that randomized controlled trials that failed to offer essential details such as how the blinding of participants was done tended to report biased positive results compared to those that had outlined the procedures clearly. Assessing the quality of primary studies has attracted much debate in the recent past, with a number of tools being developed to assess the credibility of the included studies.

The John Hopkins Evidence-based Practice model was used to evaluate the quality of the included evidence. The model has placed primary research into three levels

including level I (randomized controlled trials), level II (quasiexperimental) and level III which includes observational studies such as cohort studies and case series (Dearholt & Dang, 2012). Evidence from these study designs is rated on a three-point scale of high quality (Grade A), good quality (Grade B), and low quality (Grade C). High quality evidence comes from studies that had involved a representative and sufficient sample size, had adequate control, and produced findings that can be generalized. Good quality evidence comes from studies that had an adequate sample size, some control, and reasonably consistent results. Grade C evidence comes from studies that did not have representative and sufficient sample size for generalizability of the findings (Johns Hopkins Medicine, 2017) (See Appendix A).

Protection of Human Subjects

The review did not involve human participants directly hence it can be considered to be of low risk considering that ethical issues such as confidentiality and informed consent that arises with the collection of primary data will be minimal. As highlighted in the previous sub-section, the DNP candidate collected data regarding the effectiveness of medication-assisted therapies in the management of opioid dependence. Therefore, no human participants were required to take part or a direct medical record will be used to identify participants, hence no need to seek informed consent. Nevertheless, to ensure that the review complies with all ethical principles guiding research and fulfill the University's DNP project, the project leader sought Institutional Review Board at Walden University, following the guidelines in the systematic review manual for approval.

Analysis and Synthesis

The data were extracted by the reviewer together with a colleague. Any differences that emerged as a result of the differences in the extracted information were solved through a discussion. This is in line with Cronin, Ryan, and Coughlan's (2008) recommendation that the data collection process should not be affected by any form of researcher prejudice. To accomplish this, Ramdhani, Ramdhani, and Amin (2014) recommended collecting data with the help of a colleague so as to not only reduce bias, but also save time on the data collection exercise.

The review involved screening of the titles and abstracts of journal articles to determine if an article satisfied the inclusion criteria. The project leader extracted the data while her colleague cross-checked the data extraction forms for consistency, comprehensiveness, and accuracy. Characteristics of the study including authors, study design, participants, intervention, and main findings were collected to provide an overview of the included studies. This was followed by a critical analysis of the included materials to determine if there were confounding factors that may have led to biased results or conclusions.

The evidence from eligible studies was rated using Johns Hopkins hierarchy of evidence. The hierarchy of evidence has three levels including level I for RCTs, level II for quasi-experimental and level III for observational studies (Johns Hopkins Medicine, 2017). Word processing software was used to store the references in a systematic manner. This is a valuable approach in processing and generating a list of reference list of

journals which allows duplicate references to be identified and deleted with ease (Cronin, Ryan, & Coughlan, 2008).

The process for developing a systematic literature review begins with the development of a practice-focused question, acquisition of evidence, appraisal of the evidence, determining applicability, putting into practice, and assessing the outcomes (Godfrey & Harrison, 2010). The collection of the literature was completed through the search conducted through the electronic databases.

Summary

A clear understanding of the most effective interventions in the management of prescription opioid abuse and misuse is critical. As a result, the purpose of the capstone project was to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions in reducing the problem of prescription opioid misuse by adults seen in primary care settings. This section provided a discussion of the methodologies that was used to carry out the study. In summary, an exhaustive search was carried out across five major databases and data was collected, analyzed, and critiqued using the Johns Hopkins hierarchy of evidence model. Section 4 presents an evaluation of the findings of the systematic review.

Section 4: Findings and Recommendations

Prescription opioid abuse and dependence is a major social and public health problem that has been escalating at a high rate in the U.S leading to high rates of overdose deaths and an increased number of patients seeking help for opioid dependence. The current problem of opioid dependence cannot be solved through the current punitive drug policies (Volkow, 2014). Nurse practitioners are ideally suited to carry out substance abuse interventions because of their knowledge to promote health. Therefore, the purpose of the capstone project was to provide a systematic review of the literature on the effectiveness of medication-assisted therapy interventions in reducing the problem of opioid misuse and dependence by adults seen in primary care settings.

The sources of evidence were mostly peer-reviewed journals, both from nursing and other healthcare related disciplines. The review was carried out based on a revised version of the Cochrane Systematic Review Handbook methodology. Steps identified by the handbook include designing the research questions, developing the literature search strategy, choosing and reviewing appropriate journal articles, gathering and evaluating data, followed by presentation and analysis of the findings (Higgins & Green, 2011). Data on the effectiveness of medication-assisted interventions by nurse practitioners in the treatment of opioid dependence was searched and critically assessed while addressing the adequacy of the evidence and evaluating the outcomes.

Literature Search Results

The literature search was carried out across CINAHL, Google Scholar, PubMed, and Cochrane library and it led to the identification of 912 studies, which after removing duplicates, 832 articles were left for the review. The titles and abstracts of the articles were reviewed to establish if they had satisfied the inclusion criteria. In total, 104 articles were reviewed in full, and 15 articles were identified as eligible for inclusion in this review. 14 were randomized controlled trials while only one study could be classified as quasi-experimental (see Figure 1).

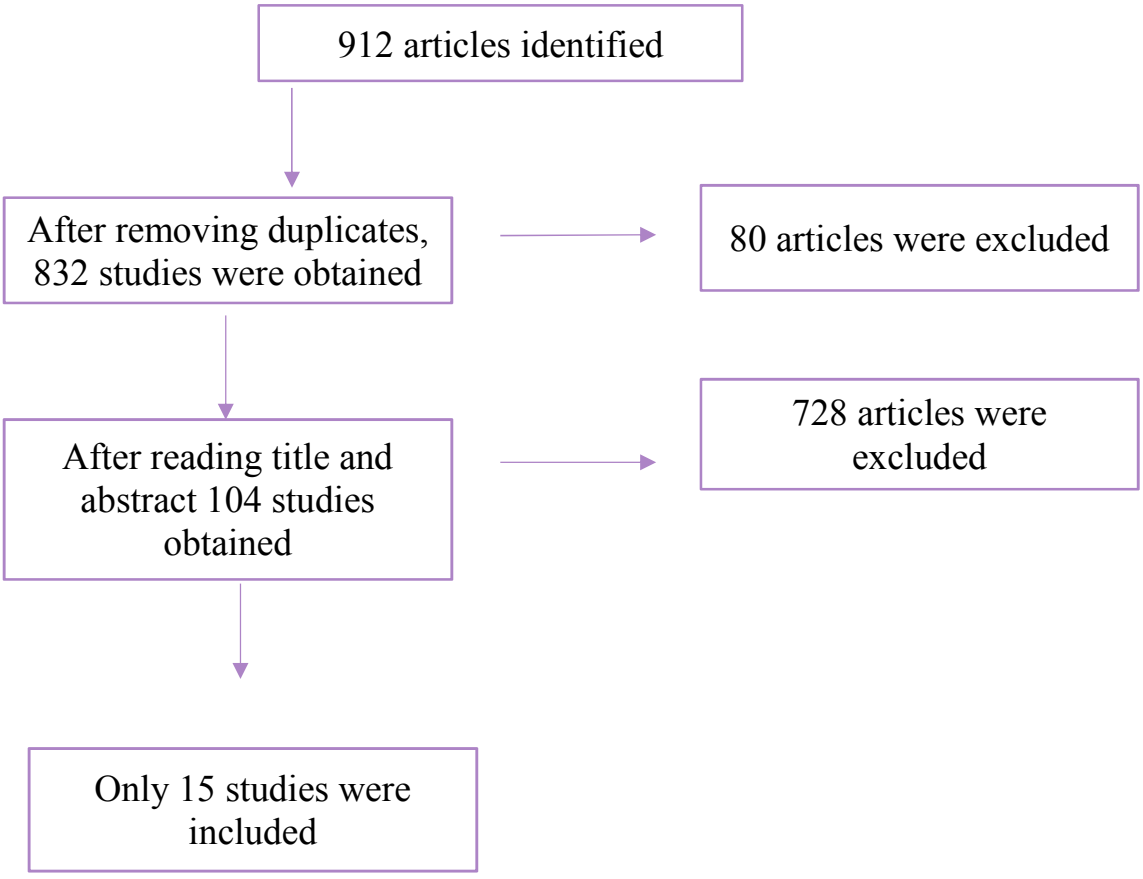

Figure 1. Selection process of the studies.

The Johns Hopkins Nursing EBP model was used to rate the strength of the included evidence based on the type of the research design and quality of methods (Appendix B). The most commonly explored interventions were psychosocial interventions in conjunction with medications for opioid addiction. The most commonly investigated psychosocial intervention was cognitive behavioral therapy while the most frequently administered medication was methadone. The results of this review found moderate evidence to support the effectiveness of psychosocial interventions in conjunction with medications in the treatment of opioid dependence, although the strength of the efficacy varied from one study to another depending on the intervention provided.

Study Outcomes and Limitations of Included Studies

Most of the studies (n=15) indicated improvements in one or more of the outcome measures. Three of the included studies (Chen et al., 2013; Kidorf et al., 2013; Petry, Alessi, & Ledgerwood, 2012), focused on contingency management of opioid addiction, which is a type of treatment that provides rewards to people who demonstrate the desired behaviors such as reduced opioid misuse.

Chen et al. (2013) sought to determine whether contingency management intervention implemented by the methadone maintenance treatment (MMT) clinic staff would improve adherence to treatment and reduce addiction to opioid misuse. A total of 126 patients were randomly assigned to receive prize-based contingency management while 120 were placed in the MMT group which was the usual care. All the participants had to provide urine samples twice a week for a period of 12 weeks, and those in the contingency management group won awards after delivering morphine negative urine

samples and attend MMT. The retention rate and negative urine testing was 14.2% (p = 0.010) and 10.7% ($p < 0.001$) higher in the contingency management group compared to the usual care group, respectively. In comparison to the usual treatment groups, those in the contingency group attended more statistically significant more days of therapy ($p <$ 0.01). The findings indicate that contingency management is an effective approach to reducing opioid misuse and encouraging attendance to treatment sessions for people addicted to opioids.

Consistent findings were reported by Kidorf et al. (2013) randomized controlled trial that found participants in the contingency management group attended more psychiatric sessions each month (M = 5.71 vs. 2.44, $p < .001$) in comparison to the control group. The study involved 125 patients who were involved in the contingency management group and the control group. Participants in the two groups received the same schedule and magnitude of treatment which included daily methadone administration. Those in the contingency group received $25 per week upon attending all the sessions. Although the participants in the contingency group demonstrated greater attendance at psychiatric sessions, no significant differences were noted between the two groups in terms of substance use outcomes. Contrary to the findings of Chen et al. (2013), these researchers failed to find any evidence to support the effectiveness of contingency management in reducing substance use.

Petry, Alessi, and Ledgerwood (2012) assessed the effectiveness of contingency management delivered by clinicians in a randomized controlled trial. There were 16 healthcare providers who provided care to 130 patients placed in the contingency

management or the usual clinic care (MMT). Urine and breath samples were collected biweekly for a period of 12 weeks. Those in the contingency group had an opportunity to win prices of up to $100 for submitting urine samples negative of opioids and alcohol. Similar to Chen et al. (2013), those in the contingency management group remained in the study longer (9.5 weeks versus 6.7 weeks), abstained from opioid misuse for a longer duration (4.7 weeks versus 1.7 weeks), and submitted a higher percentage of negative urine samples (67.7% versus 29.4%) compared to those in methadone maintenance therapy alone. Nevertheless, the findings of the study ought to be interpreted in the context of its limitations. The differential rates of follow-up may have biased the long-term outcome measures (most of the participants followed were in the intervention group). At the same time, the study was carried out by clinicians at methadone clinics and involved methadone dependent patients hence the findings may not be generalizable to other clinician and patient population.

Cognitive-behavioral Therapy (CBT)

Of the 19 studies included in this review, there were seven that assessed the effectiveness of CBT in combination with medication-assisted therapy. Kouimtsidis, Reynolds, Coulton, and Drummond (2012) multicenter randomized controlled trial evaluated the effectiveness of CBT in combination with MMT in the UK context. Participants were randomly assigned to the usual care group (MMT, n=31) or MMT plus CBT group (intervention, n=29). In addition to receiving the usual care, those in the intervention group took part in weekly individual CBT sessions for a period of six months. Although participants in the intervention group demonstrated statistically

significant improvements in positive expectancies of treatment, the findings showed no substantial between group mean differences in terms of abstinence rates, MMT compliance, psychological symptoms, and severity of psychosocial problems.

Likewise, Moore et al. (2013) pilot study assessed the efficacy and feasibility of MMT as usual care (n=18) in combination with Therapeutic Interactive Voice Response (IVR) (n=18) for patients addicted to illegal opioids. IVR is a CBT-based therapeutic approach system that incorporates coping skills, goal setting, and self-monitoring. Consistent with the findings of Kouimtsidis et al. (2012), the trial did not find statistically significant differences between the groups in terms of substance use, study retention, MMT satisfaction, coping skills, or urinalysis-verified opioid abstinence. Those in the intervention group, however, were more likely to report opioid abstinence on the days the used the recovery line ($p=0.01$) in comparison to the days they did not. Participants were not followed-up, thus, making it hard to determine the impact of the intervention in the long-term. Besides, a small sample size was used hence the findings may not be generalizable to other settings.

Pan et al. (2015) sought to determine whether CBT in conjunction with MMT therapy can reduce opiate misuse. The trial involved 240 opiate-dependent patients seeking care in community-based clinics and were randomly placed into the MMT groups (n=120) or the MMT plus CBT group (n=120). Compared to the standard care group, the CBR group had a higher percentage of opiate-negative urine tests at the end of three months (59% vs. 69%, $p<0.05$) and 63% vs. 73%, $p<0.05$) at the end of six months. The findings are contrary to those reported by Kouimtsidis et al. (2012) and Moore et al.

(2013) who did not find statistically significant improvements. Nevertheless, there was no follow-up in Pan et al. (2015) study thus it cannot be determined if the positive aspects persist in the long-term.

Amini-Lari et al. (2017) evaluated the effectiveness of CBT in the treatment of opiate dependence in conjunction with MMT. A total of 118 participants who were regular users of opiates were randomly selected and placed in the usual care group (n = 59) or the CBT plus MMT group (n = 59). CBT significantly reduced opiate use ($p <$ 0.01, d = 0.89) and the severity of opioid dependence ($p < 0.01$, d = 0.64) after one month of treatment. The findings indicate that the addition of the CBT component improves MMT effectiveness in reducing opiate dependence.

Salehi and Alizadeh (2018) assessed the effectiveness of CBT and MMT in preventing opiate dependence based on cognitive-behavioral relapse prevention model. The study involved a total of 50 patients with opiate dependence and was randomly assigned into two groups. At the end of the six-month study period, 84% and 48% of the participants in the intervention and control groups showed abstinence from opioid misuse ($P < 0.001$). CBT was also associated with substantial improvement in self-efficacy of the participants in the intervention group.

There were two included trials which explored the effectiveness of CBT in combination with buprenorphine treatment. The first one was by Fiellin et al. (2013) trial that sought to establish the effect of CBT in combination with naloxone/buprenorphine treatment for opioid dependence. The study involved 141 opioid-dependent patients in a primary care clinic. There were no statistically significant differences between the two

groups in terms of reductions in opioid misuse, although the two groups had a statistically significant pretest-posttest reduction in opioid misuse (p <0.001). It should be noted that the structured physician management usual care was more frequently administered than the standard practice for clinicians managing opioid dependence; thus, the care provided by clinicians could have created treatment outcomes that made it difficult to demonstrate the effectiveness of CBT.

A similar study by Moore et al. (2012) explored the effect of two counseling sessions with two medication dispensing methods in patients receiving buprenorphine in primary care settings. In a three-month duration, opiate-dependent patients were assigned to physician management weekly buprenorphine therapy (n=28) and while 27 participants were placed in the buprenorphine and CBT group (intervention). There were no statistically significant differences between the two groups with regards to opioid abstinence, treatment retention, and participant satisfaction. Among those in the intervention group, CBT session attendance was positively associated with negative opioid urine (p <0.05).

General Supportive Counseling

Gu et al. (2013) sought to determine the effectiveness of adding psychosocial intervention to the usual clinic care in decreasing attrition and addressing non-attendance by the first-time newly admitted MMT users (n=288). Social workers provided counseling sessions based on the behavioral maintenance theory. Family members were involved, and misconceptions about MMT were addressed. In comparison to the control

group, the intervention group had a statistically significant lower risk of attrition and attended more days of MMT treatment (p <0.001) during the study period.

A similar study by Weiss and Rao (2017) evaluated the effectiveness of opioid dependence counseling sessions in conjunction with buprenorphine (n=653). The trial failed to demonstrate any benefits of adding counseling to buprenorphine/naloxone medical management. Only around 7% of the patients achieved successful abstinence or near abstinence from opioids within an eight-week period of follow-up. Long-term follow-up findings were more encouraging with patients on opioid agonist treatment more likely to experience better outcomes. Although the study did not find sufficient evidence to support general counseling, this does not mean that patients should not be counseled. Some may do well with just medical management while others might do better upon receiving additional counseling.

Other Psychosocial Interventions

Brigham et al. (2014) assessed the effectiveness of a community reinforcement approach and family training in the context of buprenorphine treatment (n=104). The 14-week trial involved opioid-dependent adults enrolled in a residential buprenorphine detoxification program and concerned significant others (CSO) to improve treatment and treatment retention. The intervention led to moderate but non-significant improvements in treatment retention compared to the control group. When CSO was a family member, there was a significant impact on treatment retention (p <0.01). Community reinforcement and family training is a promising intervention, but there is a need for further studies to confirm the findings. The study suffered from a series of limitations

such as small sample sizes, lack of power to determine the effectiveness of the intervention, and limited generalizability of the findings.

The use of telephonic support systems to provide counseling in conjunction with buprenorphine care was assessed in Ruetsch, Tkacz, McPherson and Cacciola (2012) trial. A total of 1,426 patients were randomized to standard care (buprenorphine) or buprenorphine in conjunction with general counseling delivered through telephone calls. The study found that participants who accepted at least three intervention calls were more adherent to medication than those in the usual care group after one year (64.4% vs. 56.1%, $p < 0.25$). Patients who were compliant with treatment reported statistically significant lower scores of all the addiction severity index scores suggesting lower severity on addiction-related problems.

Zhang et al. (2016) sought to explore the effects of standard care (MMT) in comparison to MMT in conjunction with psycho-education on opioid use, treatment adherence, and methadone use. The study involved a total of 492 MMT clients who had tested positive for morphine prior to intervention. The educational intervention focused on increasing methadone treatment literacy, promoting adherence to MMT, and goal setting. In the course of the intervention, positive urine morphine rates decreased by 22.3% from 49.3% ($p < 0.001$). In addition, the average daily methadone dosage increased to 72.6 mg from 63.0 ($p < 0.001$) while the average number of days the participants were able to access MMT increased by 4.5% from 69.4% over a period of three months. The findings show that psycho-education in conjunction with MMT has the potential to promote adherence to treatment, reduce opioid misuse, and improve patient outcomes.

Nevertheless, the use of urine morphine test results was the main indicator of effectiveness, and participants could avoid using opioids prior to the urine tests thus generating a spurious intervention effect. The absence of a comparison group makes it hard to confidently determine the effectiveness of the intervention provided.

Recommendations

The primary focus of this review was on providing a systematic review of the literature on the efficacy of medication-assisted therapies in the management of the opioid dependence problems. The incremental benefit of adding psychosocial interventions to medically assisted treatments varied across studies with the psychosocial interventions provided. The findings of this review can be used to improve practice in the management of opioid dependence problem. The importance of developing best practices regarding management of opioid dependence is crucial. With the increasing number of U.S citizens struggling with opioid addiction and with the enactment of the Affordable Care Act, it is likely that the demand for management of opioid dependence will continue increasing.

It is important to ascertain that physicians and advanced nurse practitioners understand the best outcomes that may be achieved once they manage opioid dependence through the various medication-assisted therapies. It is also critical that advanced nurse practitioners with authority to manage opioid dependence problems should be knowledgeable about various pharmacological approaches as well as psychosocial interventions and be able to use them in conjunction. A clear understanding of safety and efficacy is needed for them to manage opioid dependence problems successfully.

Appropriate use of medication and psychosocial interventions will also have implications for social change. It will enable people with opioid addiction problems to seek therapy and reduce the social injustices that are associated with addiction. In the future, the findings of this review can help reduce the criminal justice and health-care burdens incurred due to prescription opioid dependence.

Strengths and Limitations

A strength of this review is that it contributes to the existing body of knowledge by critically reviewing evidence from various primary studies about the effectiveness of medication-assisted therapies in addressing the problem of opioid dependence. In addition, most of the studies included in this review were randomized controlled trials which are considered as gold standard in research; hence the findings are less susceptible to bias due to randomization of the participants into the intervention or control groups.

The review was affected by several limitations. The first one is that the literature search was limited to only those materials published in English language. The second limitation is that the researcher did not carry a formal assessment of the risk of bias as required in systematic reviews and meta-analysis, although risk of bias is likely to be low considering that the researcher collected data together with a colleague. Implications for future research is determining the specific forms of psychosocial interventions that are most effective when used alone or in combination with medications depending on the patient populations and treatment settings.

Section 5: Dissemination Plan

Dissemination of scholarly findings marks the conclusion of doctoral nursing projects; it is essential to share the findings of an EBP project with other practitioners to improve healthcare practice (Zaccagnini & White, 2015). The outcomes of a project should be shared with the academic community, project stakeholders, and other practitioners working in similar settings. Dissemination of the scholarly findings may be of benefit to other practitioners in similar settings. There are several approaches to disseminating project findings that can be used to disseminate the findings of this review.

The first approach that will be used to disseminate the findings of this review is through the publication of the results. The DNP candidate will seek publication of the findings in a nursing journal that is that deals with addiction problems and other mental health issues. An abstract or a summary of the project in a peer-reviewed journal such as the Journal of Addictions Nursing would be an ideal approach. Publication in this journal would allow the results to reach nurse practitioners and other practitioners dealing with patients addicted to opioids.

The second approach that can be employed to disseminate the findings is an oral presentation. This can be in the form of oral presentation or lectures in a given context (Edwards, 2015). I plan to create a professional poster and share the findings of the review with my colleagues in the workplace. I am also considering attending a regional conference on addiction problems, and this would provide an ideal platform to share the information regarding the findings of this project. Annual conference within my state can

provide an ideal opportunity to attract a large group of healthcare professionals providing care to patients who are opioid dependent.

The crucial audience for the output of this project includes the project team at my workplace with whom I discussed the ideas within this project. Individuals that I discussed this project with included the nursing manager, site mentors, and nurse practitioners working at the hospital. Implementation of any practice change was beyond the scope of this review, but the findings could promote a reevaluation of the current practice to ensure that patients addicted to opioids benefit from the medication provided as well as appropriate cognitive and behavioral interventions.

Analysis of Self

The complexity of the contemporary healthcare environment requires nurse practitioners to be up to date with information and be in a position to address the gap between research evidence and practice. Based on the knowledge and skills that I have developed in the course of carrying out this review and my DNP course, I feel adequately prepared to perform my roles as an advanced nurse practitioner. In this subsection, I will provide an analysis of self as a practitioner, scholar, and project manager while drawing a connection between my experience in this project and long-term professional goals.

As a Nurse Practitioner

Translation of research findings into practice in the increasingly complex healthcare environment is the hallmark of scholarly nursing practice (Zaccagnini & White, 2015). Even though I was aware of the importance of evidence-based practice when commencing my DNP project, carrying out this review made me reflect on my

practice as an advanced nurse practitioner certified to manage patients with opioid addiction problems. I have been able to appreciate the role of behavioral and cognitive therapies in the management of opioid dependence problems and I will now be able to make the best clinical decisions based on the best available evidence.

I have developed expertise throughout the DNP course and project that will help me function as a nurse leader. I aspire to become a nurse leader and promote adoption of best practices in the field of mental health. According to American Association of Colleges of Nursing (AACN) (2006), doctorally prepared nurse practitioners are expected to provide leadership for the adoption and implementation of evidence-based practices for the management of the various conditions. Throughout the DNP course and project, I have developed in various aspects of an advanced nurse practitioner; I have become equipped with knowledge and skills to review, appraise, and make use of research evidence to improve nursing practice.

As a Scholar

AACN (2018) defines nursing scholarship as activities that characteristically advance the teaching, research, and practice of nursing through rigorous processes. By carrying out the systematic review of the effectiveness of the various medication-assisted therapies in the management of opioid dependence, I have been able to contribute to scholarship in the field of addiction and substance misuse. I intend to further contribute to nursing scholarship through the distribution of the findings of this DNP project as outlined in the dissemination plan.

Carrying out this research has also improved my writing skills which are critical for an advanced nurse practitioner. I encountered several revisions, and this contributed to improvements in my writing skills. My writing skills have improved, and I have been able to acquire the status of a scholarly doctoral writer. I have also developed my critical analysis skills which I could have described as basic at the beginning of my doctoral project. The research involved reading research materials from different sources, critically appraising the information, and synthesizing the findings to reach meaningful conclusions.

As a Project Developer

A doctorally prepared nurse is expected to be in a position to identify and address a healthcare problem in their setting. As a nurse practitioner, I have encountered numerous patients addicted to opioids initially prescribed to manage non-cancer pain. Thousands of people are dying due to opioid dependence highlighting the need for effective interventions to reduce the addiction and mortality associated with opioid dependence. As a result, I carried out this literature review with an intention of identifying best practices in the management of opioid dependence.

The process of completing this doctoral project was challenging but provided me with an opportunity to learn through experience. Carrying out a literature search and synthesizing the information took more time than I anticipated. In essence, time management was an issue, and I found myself lagging behind the project schedule. Upon reflecting on this challenge, I realized that I had allocated inadequate time to the various phases of this review. I had to revise my schedule to allow more time for various

activities such as literature search and analysis. I also had to work towards improving my personal discipline in following a set schedule by avoiding unnecessary interruptions and having specific, measurable, and realistic goals. The knowledge and the time management skills that I developed by carrying out this project have improved my confidence as a manager, and I will now be able to take part in identifying and developing evidence-based solutions to the current problems facing nursing practice.

Summary

Prescription opioid misuse and dependence has risen to epidemic proportions in the U.S. The problem has been associated with substantial morbidity and mortality rates besides inflicting huge social and economic costs as a result of lost productivity, health care costs, and expenses related to criminal justice. The purpose of this project was to provide a systematic review of literature on the effectiveness of medication-assisted therapy interventions in addressing the problem of prescription opioid misuse in health care settings. The most commonly explored interventions in the included studies were psychosocial interventions in conjunction with medications for opioid addiction. The most commonly investigated psychosocial intervention was cognitive behavioral therapy while the most frequently administered medication was methadone. The results of this review found moderate evidence to support the effectiveness of psychosocial interventions in conjunction with medications in the treatment of opioid dependence.

It is important that advanced nurse practitioners with authority to manage opioid dependence problems are knowledgeable about various pharmacological approaches as well as psychosocial interventions and be able to use them in conjunction. A clear

understanding of safety and efficacy is needed for them to manage opioid dependence problems successfully. Appropriate use of medication and psychosocial interventions will also have implications for social change. It will enable people with opioid addiction problems to seek therapy and reduce the social injustices that are associated with addiction. In the future, the findings of this review can help reduce the criminal justice and health-care burdens incurred due to prescription opioid dependence.

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Appendix A: Systematic Review Matrix

Citation	Country	Objective	Research Design (include tools) and Sample Size	Key Findings	Strengths and limitations	Level of Evidence
Amini-Lari et al. (2017)	Iran	To evaluate the effectiveness of CBT in the treatment of regular opiate use on a stable methadone dose	Multicenter RCT Valid and reliable tool (Severity of Dependence Scale) 118 patients who were regular opiate users were selected Control 59, Intervention 59	CBT significantly reduced opiate use ($z = 3.73$, $P = 0.01$, $d = 0.89$) and the severity of opiate dependence ($z = 7.36$, $P = 0.01$, $d = 0.64$) after four weeks of treatment	Strengths No participant attrition Limitation Only one follow-up 95% of the participants were men, hence findings largely applies to men Participants not blinded	Level 1, Quality B
Brigham et al. (2014)	USA	To test the efficacy of a new psychosocial intervention (CRAFT-T) in comparison to usual treatment	RCT 52 adult participants with prescription opioid dependence	CRAFT-T led to moderate effect on treatment retention ($p = 0.058$,). There were large and statistically significant effects on treatment retention when family members were involved ($p < 0.01$).	Strengths Randomization reduces bias in the selection process No missing data on the primary outcome measure Limitations Small sample size: lack of generalizability, lack of power to evaluate therapist effects and to fully evaluate the effects of CSO relationship type, and possibly distorted estimates of effect sizes	Level 1, Quality B
Chen et al. (2013)	China	To assess the impact of contingency management intervention implemented by MMT clinic on treatment attendance and drug abstinence.	RCT, 126 participants received contingency management (CM), while 120 received usual treatment (UT), Zung Self-rating Depression Scale was used	The retention rate and negative urine testing rate were 14.2% ($P=0.010$) and 10.7% ($P<0.001$) higher in the CM group compared to usual care group, respectively. In comparison to UT, CM group missed an average of 7.3 fewer ($p=0.008$) and were 1.91 (95% CI: 1.53-2.39) times more likely to submit a negative urine sample.	Strengths Randomization eliminates bias in the selection process Sample selected from different part of the city hence findings are representative Limitations Lower frequency of urine monitoring (twice a week while past studies monitored more than 3 times a week)	Level 1, Quality A

Fiellin et al. (2013)	USA	To assess the effects of CBT on outcomes in primary care, office-based buprenorphine/naloxone treatment of opioid dependence	24-week randomized clinical trial 141 opioid-dependent patients Patients were randomized to UT or UT + CBT	The 2 treatments had similar effectiveness in reduction of self-reported frequency of opioid use, from 5.3 days per week (95% confidence interval, 5.1–5.5) at baseline to 0.4 (95% confidence interval, 0.1–0.6) for the second half of maintenance (P<.001 for the comparisons of induction and maintenance with baseline), with no differences between the 2 groups (P=.96) or between the treatments over time (P=.44).	No selection bias due to randomization An appropriate sample size hence findings generalizability Limitations Eligibility criteria could have excluded people who were less likely to experience significant improvements	Level 1, Quality B
Gu et al. (2013)	China	To investigate the relative efficacy of adding a psycho-social intervention to the usual care in decreasing attrition and non-attendance among first-time newly admitted MMT users	RCT, 142 participants in intervention group, 146 in the usual care group	Compared to the usual care group, those in the intervention group showed significantly lower risk of attrition (HR =0.55, 95 % CI 0.39-0.80), lower estimated probability of attrition after one year (0.35 vs. 0.55)	Strengths A relatively large sample used Randomization reduces selection bias Limitations Study only carried out in one city No blinding of participants or healthcare providers	Level 1, Quality B
Kidorf et al. (2013)	USA	To assess the effectiveness of contingency management to enhance the use of psychiatric services located and integrated within a community-based MMT program.	RCT, 125 Opioid-dependent outpatients took part Participants met DSM-IV-R criteria for psychiatric diagnosis Self-Report Measure of Medication Adherence was used	Participants in the intervention group attended more overall psychiatric sessions at the first month ((M = 7.53 vs. 3.97, p < .001, month 2 (M = 6.31 vs. 2.81, p < .001, and month 3 (M = 5.71 vs. 2.44, p < .001). Similar rates of drug-positive urine samples. No differences in study	Project was associated with significant improvements in attendance of the treatment sessions Limitation Concerns regarding feasibility due to high cost of attendance incentives ($165) Study did not control for prescription practices, which may have	Level 1, B

				retention were observed.	introduced unknown error variance	
Kouimtsidis et al. (2012)	UK	To investigate the effectiveness and cost-effectiveness of CBT in MMT for opioid dependent patients	RCT, 60 patients	No substantial between groups mean differences in terms of abstinence rates, MMT compliance, psychological symptoms, and severity of psychosocial problems.	Strength Randomization Limitations Small sample size	Level 1, C
Moore et al. (2012)	USA	To investigate the impact of two counseling intensities in patients receiving buprenorphine in primary care	RCT Intervention group, 28 UT + CBT Control, 27 UT Self-reported opioid abstinence questionnaire used	Analyses adjusting for baseline characteristics showed no significant differences between groups on retention or drug use based on self-report or urines.	Strength Randomization reducing selection bias Limitation Small sample size lacking statistical power Lack of follow-up after intervention	Level I, B
Moore et al. (2013)	USA	To assess the feasibility, acceptability, and efficacy of interactive voice response for patients receiving MMT	RCT, 36 patients, UT or recovery line + UT	Patients were more likely to report abstinence for opioids and cocaine on days they used the Recovery Line ($p = .01$) than those they did not.	Randomization of participants Limitations Small sample size There were marginally significant differences on baseline variables such as gender	Level I, C
Pan et al., 2015	China	To test whether CBT in conjunction with MMT improves treatment retention and decreases opiate use	RCT, 240 opiate dependent patients, CBT=120 patients, standard 120 Addiction Severity Index (ASI) scale used	Compared to control group, intervention group had a higher proportion of opiate-negative urine tests At both 12 and 26 weeks, CBT group exhibited more	Strengths Random selection of participants Large sample size Limitations Frequency of urine collection may not have	Level I, B

				decreases in ASI employment scores at week 26 and more decrease in the PSS total score at week 12 and week 26.	been sufficient to detect drug use	
Petry, Alessi, & Ledger wood (2012)	USA	To assess the effectiveness of contingency management (CM) in treating opioid dependence	RCT, 130 patients randomized to CM or standard care	CM group remained longer in the study (9.5 ± 3.6 versus 6.7 ± 5.0 weeks), and submitted a higher proportion of negative samples (57.7% ± 40.0% versus 29.4% ± 33.3%) than those assigned to standard care	Strengths Randomization Limitation Differential rates of follow-up completion likely biased long-term outcome Provision of cash gift prices raises costs hence concerns regarding sustainability	Level I, B
Ruetsch et al. (2012)	USA	To assess the impact of telephonic patient support program on opioid dependent patients	RCT, 1426 opioid dependent patients completed the Addiction Severity Index (ASI) pre and post-intervention	Compared to patients who were non-compliant with BUP, compliant patients reported significantly lower scores on all 7 of the ASI composite scores, indicating lower severity on addiction-related problems.	Strength Huge sample size Generalizability Limitations Missing follow-up data	Level I, B
Salehi & Alizadeh (2018)	Iran	To assess the effectiveness of CBT on relapse prevention in opioid dependent people	RCT, 50 opioid users Placed into UT (control) or UT+ CBT (intervention)	At the end of 6 months, 84% and 48% of the subjects from the intervention and control groups showed abstinence from drug use, respectively. The findings indicated a significant difference regarding self-efficacy between the groups ($P < 0.001$).	Randomization Limitations Small sample size 92% of participants were males, limited diversity	Level I, B

Weiss & Rao (2017)	USA	To determine the impact of adding opioid drug counseling to buprenorphine-naloxone plus medical management on opioid use outcomes	Two-phase RCT, 653 participants age >18. Composite International Diagnostic Interview to assess substance misuse	Vast majority of prescription opioid users failed to achieve success after tapering off bup-nx, whereas about half of the patients achieved successful outcomes while maintained on bup-nx.	Strength Long follow-up period, 42 months National, multi-site study sample Limitation Trial failed to demonstrate any benefits of adding counseling to UT	Level I, B
Zhang et al (2017)	China	To investigation effects of psychoeducation on treatment compliance, methadone dose, and heroin use among MMT clients	Quasi experimental, 492 MMT clients who tested positive for urine morphine	During the intervention, urine morphine positive rates reduced to 27 % from 49.3 % previously; $p < 0.001$	Huge sample size Limitation No comparison group Spurious intervention effect	Level II, B

Appendix B: Evidence Level and Quality Guide

Evidence Levels	Quality Guides
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	**A High quality:** Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence **B Good quality:** Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence **C Low quality or major flaws:** Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi-experimental, or quasi-experimental studies only, with or without meta-analysis	
Level III Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis Qualitative study or systematic review with or without a meta-synthesis	

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