FINAL APPROVED DNP Project:

Off Label Use of Semaglutide in Combination with Intermittent Fasting for Treatment of Obesity and Overweight

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South University – DNP Program

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Abstract

This DNP Capstone Project (DNP CP) addresses the pressing issue of obesity, which remains a global health crisis, with a particular emphasis on its impact in the United States. Obesity has multifaceted implications including physical health challenges and complex psychological and societal consequences. The primary objective of this study is to rigorously evaluate the effectiveness of combining semaglutide, an antihyperglycemic medication, with Intermittent Fasting (IF) as a novel approach to weight management in non-diabetic adults who have not responded to traditional weight loss methods. The DNP study's findings indicate that semaglutide, both individually and in combination with IF, is effective for short-term weight loss in this population. While the combination approach did not yield significantly superior results within the study's timeframe, further research is recommended to explore long-term effects and lifestyle integration post-medication. This study offers a potential avenue to optimize obesity management practices and contribute to combating the ongoing obesity epidemic.

DNP Project:

Off Label Use of Semaglutide in Combination with Intermittent Fasting for Treatment of Obesity and Overweight

Introduction

The escalating global health problem of obesity, particularly in developed countries like the United States (US), necessitates comprehensive approaches to address both its physiological aspects and the psychological and societal barriers that individuals with obesity face (CDC, 2020; Tiwari & Balasundaram, 2023). Obesity is associated with mental health strains, discrimination, and stigma, affecting overall quality of life (Brown et al., 2022; Tiwari & Balasundaram, 2023). This Doctor of Nursing Practice Capstone Project (DNP CP) aims to evaluate the effectiveness of combining the off-label use of semaglutide with Intermittent Fasting (IF) as a novel strategy for weight management in non-diabetic adults who have not responded to traditional methods, using the PICOT model as a foundational framework for scientific inquiry.

Conventional weight management strategies, primarily focusing on diet and exercise, have only sometimes provided sustainable outcomes, with many adults needing help to maintain weight loss, leading to health complications and increased fiscal expenses (Hall & Kahan, 2018; Plotnikoff et al., 2015). Furthermore, adherence to these conventional weight loss methods is often low, resulting from factors like motivation deficit and the perceived rigor of lifestyle changes, resulting in inefficiency in care delivery (Deslippe et al., 2023; Hall & Kahan, 2018). This DNP CP explores a novel approach, combining the pharmacological intervention of semaglutide with the dietary approach of IF. The potential benefits of this combination are supported by studies indicating the efficacy of semaglutide in weight management (Alabduljabbar et al., 2022; Colin & Gérard, 2022). Hence, the primary purpose of this DNP

project is to investigate an evidence-based alternative to traditional weight management strategies for non-diabetic adults.

Given the magnitude of the obesity epidemic in the US (CDC, 2020) and the limitations of prevalent methods, it is imperative to explore innovative approaches that can yield sustainable outcomes. Current literature has underscored the potential of pharmacological strategies such as semaglutide, particularly when combined with dietary modifications like IF (Alabduljabbar et al., 2022; Colin & Gérard, 2022; Singh et al., 2022; Welton et al., 2020). If proven effective, this DNP CP can influence a paradigm shift in weight management practices, promoting better health outcomes, fiscal responsibility, efficiency in care delivery, and optimizing healthcare quality.

Clinical Problem

Obesity is an escalating global health concern, particularly in developed countries like the US (World Health Organization, 2021). Recent statistics underscore the gravity of this epidemic, revealing that approximately one-third of the U.S. adult population is now classified as obese (CDC, 2020). While obesity is often linked to numerous physiological complications, its implications span beyond the physical realm. Individuals with obesity face multifaceted challenges, including psychological strains (Brown et al., 2022) and societal hurdles (Tiwari & Balasundaram, 2023). Historically, dietary modifications and physical exercise have been the primary countermeasures against obesity. However, their long-term effectiveness has been questioned, especially among specific demographics. This limitation has paved the way for innovative solutions like the medication semaglutide (Alabduljabbar et al., 2022; Colin & Gérard, 2022) and dietary strategies such as IF (Vasim et al., 2022). Such a novel intervention combo is the topic of this paper to address the clinical problem associated with the US obesity epidemic.

Specifically, the US obesity epidemic affects approximately one-third of American adults who are categorized as overweight or obese according to their Body Mass Index (BMI) (Centers for Disease Control and Prevention [CDC], 2022). Consequently, the domino effects of obesity and being overweight cascade into a myriad of other health issues, from cardiovascular and metabolic diseases to mental health challenges. And while the cardiovascular and physiological consequences of obesity, such as hypertension, are well-documented, its implications extend to socioeconomic, psychological, and even sociological domains (Powell-Wiley et al., 2021).

Finding themselves grappling with the health ramifications and societal pressures of being categorized as overweight or obese, some of these affected individuals seek help. Over the years, the modalities of weight management primarily focus on lifestyle modifications encompassing diet and exercise. However, the heterogeneity in the responses of individuals to these traditional interventions suggests the need for a paradigm shift. Notably, non-diabetic adults, whose weight management concerns are often less complicated by metabolic conditions, still struggle to achieve desired weight loss outcomes through these conventional means (Hall & Kahan, 2018). This unpalatable scenario prompts the imperative for novel, multifaceted interventions catering to this demography's unique needs.

Until recently and magnified by social media posting of celebrities, the pharmacological landscape has seen the emergence of semaglutide, a Glucagon-Like Peptide Receptor Agonist 1 (GLP-1) drug that has transcended its initial role in diabetes mellitus type 2 (DM2) management to offer off-label promise in the realm of weight control (Alabduljabbar et al., 2022; Singh et al., 2022). Colin and Gérard (2022) delineate semaglutide’s potential, especially in its once-weekly 2.4 mg dosage, highlighting its transformative capabilities. Concurrently, dietary practices have

evolved, with IF emerging as a method that tempers the temporal dimensions of eating, offering potential benefits in weight management (Welton et al., 2020).

As such, this DNP CP revolves around a comprehensive exploration of the confluence of these two promising strategies. Specifically, this DNP study aims to discern the comparative efficacy of semaglutide, in tandem with IF, versus the medication's isolated application, in catalyzing weight loss among non-diabetic adults. These adults, characterized by a BMI ranging from 25 to 39, represent a cohort that has remained resistant to the conventional dyad of diet and exercise. By juxtaposing the effects of semaglutide, both as a singular intervention and in synergy with IF, this study aspires to illuminate pathways that could redefine obesity management protocols for this demographic (Alabduljabbar et al., 2022; Colin & Gérard, 2022; Singh et al., 2022; Welton et al., 2020).

Significance

The significance and repercussions of the obesity epidemic go far beyond personal health, impacting the broader dynamics of community healthcare. Given the centrality of nursing and healthcare professionals in this scenario, they are not merely care providers but essential advocates for public health education and outreach (CDC, 2020). The CDC's report indicating a persistent rise in adult obesity rates highlights the undeniable role that healthcare professionals, especially nurses, have in both prevention and intervention. Their responsibilities range from prescribing medical treatments such as semaglutide (Alabduljabbar et al., 2022; Colin & Gérard, 2022) to advocating for and guiding patients on lifestyle interventions like IF (Vasim et al., 2022). The distinct variations in obesity prevalence across states (Centers for Disease Control and Prevention, 2022) further underscore the need for adaptive and community-specific

healthcare strategies. These discrepancies require community health workers, including nurses, to be informed and flexible.

Furthermore, as Deslippe et al. (2023) point out, there are inherent challenges in adherence to weight management strategies. Nurses and healthcare professionals serve as a bridge in such scenarios, helping patients traverse both personal and socio-cultural barriers. Beyond the clinical scope, their roles extend to counseling and offering support, especially considering the pervasive weight stigma many confront (Brown et al., 2022). Such a stigma, which frequently leads to prejudice, accentuates the necessity for a compassionate approach in healthcare. In this light, the obesity epidemic underscores the urgency for the nursing and healthcare community to realign their services, ensuring they resonate with the broader vision of comprehensive community well-being.

Benefits of the DNP Project to Practice, Individuals, and Society

This DNP project on understanding and intervening in the obesity epidemic has multifarious benefits to healthcare practice. First, by providing a comprehensive insight into the current state of the obesity epidemic, healthcare professionals can tailor interventions to serve better the needs of different populations, particularly in regions with higher obesity prevalence. Introducing evidence-based pharmacological interventions, such as semaglutide, into routine practice can transform how obesity is managed, leading to more effective patient outcomes (Alabduljabbar et al., 2022). Besides, by promoting lifestyle interventions like IF, healthcare providers can empower patients to take proactive steps towards their health, leading to sustainable weight management outcomes in alignment with evidence-based guidelines (Vasim et al., 2022).

Furthermore, understanding the barriers to adherence and the socio-cultural impediments, such as weight stigma, enhances the practice in two crucial ways. Firstly, it allows for individualized patient counseling and strategy formulation, ensuring patients have the tools and support they need to overcome personal and societal challenges (Brown et al., 2022; Deslippe et al., 2023). Secondly, by actively addressing and mitigating weight stigma in healthcare settings, this project can create an environment of inclusivity and empathy, thus enhancing patient trust and cooperation. These evidence-informed strategies and interventions benefit the specific Southern California population of interest in focus. They can be extrapolated to other demographics or settings nationwide, thereby driving a ripple effect of improved health outcomes across broader communities.

Definition of Terms

In the context of a DNP CP focusing on the off-label use of semaglutide in combination with IF, it is essential to define the terms and identify the variables clearly. Semaglutide, a medication approved for the treatment of DM2 (Type 2 Diabetes Mellitus), is being investigated for its potential benefits in weight management among non-diabetic adults (Alabduljabbar et al., 2022; Colin & Gérard, 2022). Intermittent fasting (IF) refers to an eating pattern that cycles between periods of fasting and eating, which has been suggested to support weight loss and metabolic health (Vasim et al., 2022).

In this study, the independent variable is the intervention, which is the administration of semaglutide whether alone or in combination with the patient's adherence to an IF regimen. The dependent variables are the outcomes measured to assess the effectiveness of the two interventions (i.e., semaglutide alone or semaglutide in combo with IF), which include changes in body weight and Body Mass Index (BMI). The hypothesis is that semaglutide, when used

alongside IF, will lead to greater weight loss and improved metabolic health indicators compared to the group receiving the semaglutide intervention alone (Tiwari & Balasundaram, 2023).

PICOT

The central PICOT question (a mnemonic for P or Patient Population, I or Intervention, C or Comparison, O or Outcome, and T or Timeframe) that drives this DNP project is as follows: "*In non-diabetic adult patients aged 18-64 with a BMI of 25 to 39 who have not responded to conventional diet and exercise regimens (P), how does the off-label use of semaglutide for weight management in combination with Intermittent Fasting or IF (I) compared to the off-label use of semaglutide alone (C) impact weight loss in terms of percentage weight loss and BMI improvement (O) over a 2-month period (T)?*" (Melnyk & Fineout-Overholt, 2018).

In the structure of a PICOT question for this DNP project, each of the five (5) elements — i.e., Population, Intervention, Comparison, Outcome, and Timeframe—serves a distinct purpose in outlining the study strategy and focus. This format ensures that the clinical question is specific and measurable, which is essential for evidence-based practice. The following sections details each of these five (5) PICOT elements (Melnyk & Fineout-Overholt, 2018).

The first element is P for Population. The population in this DNP project includes non-diabetic adult patients aged 18-64 with a BMI (Body Mass Index) of 25 to 39 who have not achieved desired outcomes with conventional diet and exercise regimens. This demographic is significant as it represents a substantial portion of the adult population struggling with overweight and obesity issues, which are major risk factors for a range of chronic diseases (CDC, 2020).

The second element is I for Intervention. The intervention considered here is the off-label use of semaglutide for weight management in combination with IF. Semaglutide is a GLP-1

receptor agonist originally approved for the treatment of DM2, which has recently garnered attention for its potential in weight management (Alabduljabbar et al., 2022; Colin & Gérard, 2022).

The third element is C for Comparison. The comparison involves the off-label use of semaglutide alone, without the addition of Intermittent Fasting. This allows for a clear distinction to be made regarding the efficacy of the combined intervention versus semaglutide as a standalone treatment (Melnyk & Fineout-Overholt, 2018).

The fourth element is O for Outcome. The outcomes to be measured are the percentage of weight loss and the improvement in BMI over the course of the intervention. These outcomes are tangible and quantifiable, providing clear metrics for evaluating the success of the treatment (Melnyk & Fineout-Overholt, 2018).

The fifth and final element is T for Timeframe. The timeframe for assessing the intervention's impact is set at two months. This duration allows for the observation of initial treatment effectiveness while being practical for maintaining participant adherence and follow-up (Melnyk & Fineout-Overholt, 2018).

Overall, the overarching PICOT question seeks to establish the effectiveness of a combined semaglutide and IF regimen for weight loss in a specific Southern California patient population over a set time of two months. It is hypothesized that the combination of semaglutide with IF will yield superior results in weight reduction compared to semaglutide alone.

In the subsequent sections, a detailed breakdown of literature reviews from scientific and peer-reviewed articles gleaned from searches of the South University Online Library (SUOL) will be presented. The scientific literature search involved a methodical process centered around the PICOT framework established earlier (Melnyk & Fineout-Overholt, 2018).

Review of Literature

Search Process

The PICOT question drives the literature search for relevant studies that examine the off-label use of semaglutide for weight management in Non-Diabetic Adults with Obesity or Overweight (NDAWOOO). Inclusion criteria for the literature search include original research studies from peer-reviewed journals, published within the past ten years (unless deemed a "classic" study), and conducted in the United States. Exclusion criteria include non-original research (e.g., review articles or editorials), non-peer-reviewed sources, and studies not focused on the target population or intervention of interest. This approach will ensure a rigorous and up-to-date analysis of the available evidence (Melnyk & Fineout-Overholt, 2018).

The primary outcomes of interest include weight loss and safety outcomes, which will provide a comprehensive understanding of the benefits and potential risks associated with off-label semaglutide use for weight management. As this inquiry progresses, it is crucial to consider the implications of the findings for clinical practice and healthcare policy. If the off-label use of semaglutide is found to be safe and effective for weight management in NDAWOOO, it could represent a valuable addition to the current therapeutic arsenal. Furthermore, the potential benefits of semaglutide use could extend beyond weight loss alone, as previous research has suggested that GLP-1 receptor agonists may also improve cardiovascular outcomes (Marso et al., 2016). Additionally, it is important to acknowledge the potential limitations of the available evidence and the need for further research. For instance, the generalizability of study findings may be limited by factors such as the study population's demographics, the duration of the intervention, and the specific methods employed to measure weight loss and safety outcomes. Moreover, while the 2-month time frame specified in the PICOT question is a reasonable starting

point for assessing the short-term effects of semaglutide use, it is essential to investigate the long-term safety and sustainability of this intervention as well.

Evaluation of Credibility

To evaluate the credibility of the selected articles, the following four (4) criteria were considered: (1) the publication source, (2) the authors' qualifications and expertise, (3) the rigor of the research methodology, and (4) the consistency of the findings with the existing literature (Polit & Beck, 2017). The articles selected for full-text review were published in reputable, peer-reviewed journals, authored by researchers with recognized expertise in the field, and employed rigorous study designs, such as Randomized Controlled Trials (RCTs) or Systematic Reviews (SRs). This suggests that the evidence presented in these articles is reliable and can be used to inform clinical practice (Melnyk & Fineout-Overholt, 2018).

The review of the literature revealed consistent evidence supporting the efficacy of semaglutide for weight management in non-diabetic adult patients between the ages of 18 to 64 years old, with BMI between 25 to 39, and with obesity or overweight who have not responded to conventional interventions (Blundell et al., 2017; Davies et al., 2021; O'Neil et al., 2018). In addition, the safety profile of semaglutide was generally favorable, with most adverse events being mild to moderate and transient in nature (Marso et al., 2016). However, some concerns were raised regarding the long-term safety of semaglutide, particularly in relation to its potential effects on cardiovascular outcomes (Bhatt et al., 2021). Therefore, further research is warranted to evaluate the long-term safety and effectiveness of semaglutide for weight management in this population.

A Literature Review (LR) is a comprehensive analysis of published research on a specific topic, which aims to identify, evaluate, and synthesize the available evidence (Galvan & Galvan,

2021). The primary purpose of an LR is to provide an overview of current knowledge on a particular subject and identify gaps in the existing research that warrant further investigation. In the context of nursing practice, LRs are essential for identifying evidence-based interventions that have the potential to improve patient outcomes and inform clinical decision-making (Polit & Beck, 2020). For this DNP project's LR, a search was conducted using the South University Online (SUO) Library, utilizing two databases: CINAHL and PubMed. The keywords and Boolean operators used in the search were "semaglutide," "weight management," "obesity," "overweight," "non-diabetic," and "off-label use." The search was limited to articles published in peer-reviewed journals within the last ten years to ensure the currency and relevance of the evidence. A total of 243 articles were retrieved, of which 108 were from CINAHL and 135 articles were identified in PubMed. After reviewing the abstracts, 36 articles were selected for full-text review based on their relevance to the PICOT question.

Summary of Results

This DNP project is anchored and guided by the integration of thematic findings. These findings are crucial in understanding the underlying principles that guide our approach to weight and obesity management. By logically sequencing each of the LRs (shown in the Evaluation Tables or ETs in Appendix A) alongside the Theoretical Frameworks used in this project (which will be discussed in much detail in a subsequent section), a comprehensive and robust understanding of the research topic will be formed. This process will inform the research methodology and aid in the interpretation of the results, ultimately contributing to the field's knowledge and the improvement of clinical practice in weight management and obesity control (Melnyk & Fineout-Overholt, 2018). The detailed and methodological literature search centering on semaglutide and IF provide the backbone to this DNP CP.

Analysis of Evidence

Analyzing the gathered evidence in the LR's, Appendix A outlines a descriptive and detailed analysis of the DNP study. Evidence appraisal in nursing is a critical step in evidence-based practice. It involves a descriptive and detailed research analysis, assessing the study's design, quality, potential bias, and clinical relevance (Melnyk & Fineout-Overholt, 2018). The descriptive analysis identifies the study's aim, research question, design, population, intervention, comparison group, and outcomes. The detailed analysis delves deeper, evaluating the study's methodology, results, potential for bias, and generalizability (Polit & Beck, 2017). For example, Singh and associates (2022) reviewed Wegovy (a brand name for semaglutide), a new weight loss drug for chronic weight management, discussing its pharmacology, clinical efficacy, safety profile, and potential applications in obesity management. This LR is a Level Five (V) evidence that informs on the selected PICOT question (Melnyk & Fineout-Overholt, 2018).

In contrast, using another LR example, Davies et al. (2021) evaluated the efficacy of liraglutide, another Glucagon-Like Peptide 1 Receptor Agonist (GLP-1 RA), for weight loss in patients with type 2 diabetes mellitus (DM2), using Randomized Controlled Trial (RCT) which is a Level II Evidence. Davies et al. (2021) found that liraglutide, a chemical compound similar to semaglutide, which is the intervention for this student's DNP CP, in addition to a reasonable diet and exercise program such as IF, resulted in significant weight loss compared to placebo among the tested population.

This student goes through the entire process of appraising the peer-reviewed scientific literature searched during the previous DNP courses, providing descriptive and detailed analysis of the research conducted that are relevant to the DNP study related to weight loss employing the interventions of an off-label use of the GLP-1 medication semaglutide alone, IF alone, or

semaglutide in combination with IF using a methodological and exhaustive SUOL search process (Melnyk & Fineout-Overholt, 2018).

Key LR Examples that Inform the DNP CP

Appendix A details key LR examples that ultimately led to the conceptualization, formation, and implementation of this DNP scholarly project (Melnyk & Fineout-Overholt, 2018). The following sections will detail eight (8) of such LR examples.

First, the LR of Harris and associates (2018) is a systematic review and meta-analysis scrutinizing IF's effectiveness in treating adult obesity. The gathered data from forty studies revealed that individuals undergoing periodic calorie restriction regimens, the central premise and fundamental principle behind IF, experienced more significant weight reduction than those with constant caloric limits or no intervention altogether. This research confirms that adopting an approach incorporating intermittent caloric restrictions may be beneficial for overweight and obese adult individuals seeking to manage their body weights effectively (Harris et al., 2018).

Second, the LR of Jensen et al. (2014) informs how the American Heart Association (AHA), the American College of Cardiology (ACC), and The Obesity Society (TOS) have joined forces to tackle the issue of adult obesity. This joint initiative aims to provide evidence-based guidelines for managing obesity, which combines lifestyle interventions with pharmacotherapy or surgical procedures, including bariatric surgery. The comprehensive approach has been proven to be effective in addressing this issue. Moreover, it is highly recommended that physicians extend their support to clients struggling with obesity and follow these guidelines during weight management efforts. Although this LR appears outdated (now ten years old), Jensen et al. (2014) remain the latest multi-agency collaboration report on obesity management.

Third, the LR of Johns et al. (2016) explains how to help people lose weight effectively, whereby the researchers conducted trials assigning study participants to a minimalistic intervention group while others received active dietary and exercise interventions. Results showed that those placed into low intervention groups gained an average of 0.4 kg annually, according to a detailed analysis across forty different studies by authors researching this subject matter. Therefore, it is evident there is still much work needed towards designing efficient interventions aimed at reducing obesity rates globally among populations who struggle with this health concern regularly since low levels of control seem ineffective in preventing unhealthy changes in Body Mass Index (BMI) (Johns et al., 2016).

Fourth, the LR of Patterson and Sears (2017) extensively covers the metabolic effects of IF in this informative review article. Readers can discover the potential advantages, such as better insulin sensitivity, decreased inflammation levels, and effective weight loss strategies while understanding their mechanisms vividly explained by the authors' detailed analysis. Maximizing sustained health benefits related to IF from this process-driven method requires further research to address optimal protocols for achieving the required results and disease prevention measures (Patterson & Sears, 2017).

Fifth, the LR of Silva et al. (2010) is a Level II (2) scientific evidence utilizing a Randomized Controlled Trial (RCT) in women using Self-Determination Theory (SDT) to promote physical activity and weight control. The importance of maintaining healthy habits cannot be overstated enough - mainly when staying active and keeping weight under control. To explore ways to enhance these efforts among women specifically, researchers focused on SDT. Through conducting an RCT, one group of participants was provided with a year-long SDT-based program while the other group received General Health Education (GHE). As a result,

improvements in physical activity levels, weight loss, and intrinsic motivation were observed among the intervention group with SDT compared to those who only received GHE. These findings, although a bit dated, stand out because it suggests that SDT interventions promote better physical activity levels and weight control in women (Silva et al., 2010). This study is outdated but this author cannot find a similar most recent study that employs SDT exclusively for the female gender.

Sixth, the LR of Teixeira et al. (2012) is a Level IV (four) evidence comprising a Cohort Study (CS). In this CS, overweight and obese adults' long-term weight control was examined regarding motivation and self-determination. The findings demonstrated a positive correlation between autonomous motivation, perceived competence, and maintaining weight loss at the 3-year follow-up. For effective long-term weight control, the study emphasizes the value of fostering autonomous motivation and perceived competence (Teixeira et al., 2012). Once again, this study appears dated, but this student cannot find a similar recent one, especially employing a cohort study methodology applying principles of SDT for weight loss.

Seventh, the LR of Wang et al. (2011) is another Level 4 (i.e., Modeling Study) that, although outdated by 12 years, remains relevant and unique as it cuts across two countries on two continents. In the United States and the United Kingdom, this modeling study forecasts the economic and health costs of obesity. The study is a classic as it predicted quite accurately that obesity is to rise by 33% in the U.S. and 11% in the U.K. by 2030, leading to millions more cases of diseases associated with obesity and billions more in healthcare costs. The study highlights the critical need for efficient public health initiatives to prevent and treat obesity (Wang et al., 2011). Although the LR data used is outdated, the evidence-based process is relevant for extrapolating the latest data available in each country, with this DNP CP particularly interested in the US data

(CDC, 2020). One can argue about the classical nature of this LR because of its methodology and its uncanny accuracy on hindsight.

Finally, the eighth example, LR of Wilding et al. (2021), is another Level 2 evidence comprised of another RCT. In this peer-reviewed study, researchers sought to examine whether administering once-weekly injections of semaglutide could help individuals with overweight problems or obesity manage their weight safely and effectively. Participants were randomly assigned to take either semaglutide or a placebo alongside lifestyle modifications for several months. The study determined that individuals taking semaglutide had achieved much more significant average weight loss than those taking the placebo (14.9% versus 2.4%). This RCT study suggests that using this medication, semaglutide, may be worthwhile as part of treatment plans for individuals dealing with overweight and obesity (Wilding et al., 2021). As such, this LR by Wilding and associates (2021) is foundational to this DNP CP.

Synthesis of the Evidence

The final LR synthesis evaluates this DNP study's relevance to clinical practice, considering potential benefits, harms, feasibility, and patient preferences (Melnyk & Fineout-Overholt, 2018). Thus, the appraisal of evidence is vital in ensuring high-quality, patient-centered care, as will be demonstrated in the upcoming sections. In the LR, studies should be organized systematically and subsequently logically sequenced, presenting the evolution of the research topic, revealing gaps in knowledge, and demonstrating the need for the DNP project (Polit & Beck, 2017).

This progression from broad to specific, with inclusion and exclusion criteria defined during the scientific literature search process utilizing South University’s Online Library (SUOL), provides the basis for the research question and objectives as represented by the

PICOT-formatted question referenced and explained in the earlier section (Melnyk & Fineout-Overholt, 2018). An apt analogy is that the PICOT question and the Theoretical Frameworks (TFs) provide the scaffold for the DNP study, giving structure to the literature interpretation and the project's design (McEwen & Wills, 2017). It presents a system of ideas about how phenomena are related, offering a lens through which to view the DNP project study problem, formulate the study questions, and interpret results. For instance, since this DNP project is on patient self-management of obesity and being overweight, Self-Determination Theory (SDT) and Chronic Weight and Obesity Management Model (CWOMM) could underpin the Literature Review (LR) and project design, guiding the identification and understanding of critical factors that influence self-management and autonomous motivation (Teixeira et al., 2012; Xie et al., 2022). Therefore, one logical sequencing of this student's DNP project, based on the pieces of evidence amalgamated in his previous DNP course of studies, is as follows: semaglutide can be a valid and safe off-label pharmacological intervention for obesity and overweight management in non-diabetic adults, and when combined with IF can lead to better results based on SDT, CWOMM, and addressing the issue on weight stigma (Xie et al., 2022). Various permutations of these TFs and LRs can lead to specific logical scenarios. Eventually, this DNP student chooses the initial PICOT-formatted question following that important session with this student's DNP CP faculty advisors and clinical mentors.

The bottom line is that this student's chosen PICOT question remains a viable and logical sequence based on the gathered evidence from the literature searches of scientific papers from credible publications from SUOL. The credibility of this PICOT search is even bolstered following the positive peer reviews from this student's classmates during their online classes as part of the DNP course curriculum (Melnyk & Fineout-Overholt, 2018).

Strengths and Limitations of the Evidence

A comprehensive analysis of the current research, including its strengths, limitations or weaknesses, and gaps, is essential for the DNP project. Strengths of a study might include a rigorous methodology, large sample size, or innovative approaches that contribute valuable insights to the field of study involved (Polit & Beck, 2017). For instance, an RCT with a large sample size and strict control of confounding variables could provide strong evidence for the effectiveness of a nursing intervention (Ali et al., 2018).

Limitations (aka, weaknesses), on the other hand, may involve methodological flaws, small sample sizes, or limitations in generalizability. For example, a qualitative study might provide in-depth insights but have limitations in generalizability due to a small, specific sample (Polit & Beck, 2017; Stevenson et al., 2012).

Identifying gaps in the literature is crucial for establishing the need for further study or research. These gaps could be unexplored areas or inconsistent findings that require clarification (Melnyk & Fineout-Overholt, 2018). Hence, a detailed appraisal of the strengths, weaknesses, and gaps in current study is vital in informing the direction of a DNP project and contributing to evidence-based practice. Appendix A details the various Strengths, Weaknesses, and Gaps in the current study leading to the current PICOT-question. Specifically, this DNP project ultimately aims on evaluating whether the combination of an off-label use of semaglutide and IF will lead to better obesity and overweight management for non-diabetic adults.

Application to DNP Capstone Project

The synthesis of literature is key to the application and integration of this DNP CP, providing a comprehensive understanding of the current and latest state of study and demonstrating how the DNP project fits into this landscape. Based on the appraisal of the

individual evidence, studies, Literature Reviews (LRs), and Evaluation Tables (ETs) as captured in Appendix A, the scientific literature synthesis offers a broader perspective of the research area. It identifies common themes, conflicting evidence, and gaps in the existing research (Polit & Beck, 2017). This literature synthesis is instrumental in revealing the need for the DNP project and informing its design. For example, the literature synthesis reveals consistent findings on the effectiveness and safety of semaglutide use as a particular nursing intervention for managing obesity in non-diabetic patients (Singh et al., 2022). Also, IF has been shown to be an effective and safe nursing intervention to obesity and overweight management (Patterson & Sears, 2017). Consequently, what is a research gap and a big unknown, as gleaned from the training and review session with this DNP student's faculty advisors, is the effect of semaglutide use in combination with IF. In this case, this student's DNP project could be designed to address this research gap or inconsistency, perhaps by conducting a more rigorous study or exploring the factors that may explain the differing results. Ultimately, the synthesis of the literature helps to justify this DNP project's significance and potential contribution to nursing practice and the wider body of research (Melnyk & Fineout-Overholt, 2018).

Theoretical Framework

The Theoretical Framework (TF) illuminating this DNP CP can be summed into two (2) relevant Theoretical or Conceptual Model (TOCM): (1) the Self-Determination Theory (SDT), and (2) the Chronic Weight and Obesity Management Model (CWOMM). SDT (Ryan & Deci, 2000) emphasizes the role of autonomy, competence, and relatedness in fostering self-determined motivation and psychological well-being. The components of SDT are autonomy (feeling self-directed), competence (feeling capable), and relatedness (feeling connected with others). These elements promote intrinsic motivation and psychological well-being, essential for

sustainable health behaviors (Ryan & Deci, 2000). This scientific paper on SDT, developed by Ryan and Deci in the year 2000, appears outdated at this time but is nevertheless considered a classic peer-reviewed article because SDT still plays a pivotal role in the understanding of motivation and psychological well-being. SDT highlights three critical components that together foster self-determined motivation and are essential for psychological well-being. Why is this outdated article important? Because the three (3) factors discussed in the article are key to intrinsic motivation. Also, there is a more recent article by Xie and associates in 2022 which builds on the old 2000 article by Ryan and Deci and both articles can link sustainable health behaviors to personal goals like weight loss (Ryan & Deci, 2000; Xie et al., 2022).

The CWOMM, on the other hand, encapsulates comprehensive strategies and interventions for managing weight and obesity over time (Colin & Gérard, 2022; Singh et al., 2022). Moreover, the CWOMM is centered around structured, personalized approaches to diet, physical activity, behavior changes, and pharmacotherapy, all aiming to achieve and maintain weight loss over time (Colin & Gérard, 2022; Singh et al., 2022).

In relation to the clinical problem of obesity and the proposed intervention of semaglutide with IF, the two theory and model (i.e., SDT and CWOMM) highlight the importance of patient autonomy, competence, and personalization of care. SDT underscores that fostering a sense of self-efficacy and personal control could enhance the adherence to and efficacy of the proposed weight management strategy. Similarly, the CWOMM suggests that an individualized, multifaceted approach, such as combining semaglutide with IF, may yield more sustainable weight loss results.

As such, anchoring this DNP project in the two above-mentioned TOCMs (i.e., SDT and CWOMM) provides a structured, coherent approach to understanding the phenomenon of

interest of this DNP project. In other words, both SDT and CWOMM offer different, yet complementary perspectives. While SDT helps understand the psychological factors influencing behavior change, the CWOMM provides a practical, comprehensive approach to addressing obesity. Together, these two (2) TOCMs form an overarching framework to guide this student's DNP project from research questions formulation to interpretation of findings (Melnyk & Fineout-Overholt, 2018).

Methodology

Study Design

The following DNP study design addresses the pervasive issue of obesity and being overweight, particularly in non-diabetic adults who have not favorably responded to conventional diet and exercise regimens, which necessitates innovative interventions and a rigorous examination of their efficacy. This DNP study employs the PICOT model as a foundational framework for scientific inquiry, focusing on the off-label use of semaglutide combined with IF and comparing it to the use of semaglutide alone for weight management (Eriksen & Frandsen, 2018). More specifically, as was stressed previously, this DNP Capstone study is a Quality Improvement Project (QIP) structured within the PICOT framework (Melnyk & Fineout-Overholt, 2018).

Overview of the Approach/Design

Involving four elements, this DNP CP follows a meticulously planned approach, design, and timeframes guided by the PICOT structure (Melnyk & Fineout-Overholt, 2018). Recruitment is the first element that started since the South University Institutional Review Board (SU IRB) approved this DNP CP on August 23, 2023.

The pre-test, the second element, follows and involves data collection (weight and height) for patients taking semaglutide for at least two months. The third element, post-test, entails a similar weight and height data collection and commences once the initial two months of semaglutide only and the subsequent two months of combined IF and semaglutide are complete (Melnyk & Fineout-Overholt, 2018).

Finally, data analysis involving descriptive and inferential statistics is the fourth and final element and entails at least a one-week timeframe (Vetter, 2017). The overall timeframe is not linear, with overlaps between the three elements (i.e., recruitment, pre-, and post-test) depending on how far along the volunteer is on the semaglutide treatment (Melnyk & Fineout-Overholt, 2018).

Sample Population

The study population consists of non-diabetic adults aged 18-64 with a BMI of 25 to 39 who have not responded to conventional diet and exercise. It involves the use of semaglutide for weight management in combination with IF, compared to the use of semaglutide alone. The primary outcomes are percentage weight loss and BMI improvement over a 2-month period. The following sections discuss the sample population for this DNP project treatment (Melnyk & Fineout-Overholt, 2018).

Sample population comprised of volunteer participants are selected from patients attending the weight management programs in the private practice clinics of Dr. Heidi Regenass, MD. The study includes non-diabetic adults aged 18 to 64 with BMI values ranging between 25 to 39. This target group was intentionally chosen to assess the impact of semaglutide in tandem with IF (Restore Med Clinic, 2023; Serenite Wellness Medicine, 2023). The Medical Screening & Recruitment Survey Form (MS&RSF) shown in Appendix B implements a comprehensive

medical screening process. Only candidates deemed medically suitable will proceed to subsequent phases of the study. Ethical considerations are upheld throughout, with participants provided with detailed information about the study (Alabduljabbar et al., 2022; Colin & Gérard, 2022; Singh et al., 2022; Welton et al., 2020). Limitations on the sample population primarily involve a more affluent patient demographics which may not translate on a statewide or nationwide perspective nor generalizability.

Setting

The setting for this DNP study will be undertaken within two reputable clinics serving a well-defined demographic group, such as Restore Med Clinic (2023) and Serenite Wellness Medicine (2023) clinic. The selection of non-diabetic adult participants who have not responded to conventional weight management strategies will provide valuable insights into potential alternatives for weight management in this population. As such, this DNP CP represents a thorough and methodical approach to understanding the potential benefits of using semaglutide in combination with IF for weight management in non-diabetic adults in a relatively affluent Southern California sample population setting. The methodology facilitates a deep dive into the existing records at Restore Med Clinic and Serenite Wellness Medicine clinic, both bustling private practice clinics in Newport Beach and Ontario, respectively, located approximately forty miles apart in Southern California (Restore Med Clinic, 2023; Serenite Wellness Medicine, 2023). The defined population of non-diabetic adults aged 18 to 64 with a BMI of 25 to 39, who have not seen improvements with traditional diet and exercise regimes, presents a clear target for exploring the potential of semaglutide and IF as innovative weight management strategies. Correspondingly, the rigorous methodology employed in this project, including explicit inclusion and exclusion criteria, ensures the reliability and validity of the data collected. Furthermore, the

comprehensive data analysis plan involving descriptive and inferential statistics ensures that the collected data will be carefully examined to draw meaningful and impactful conclusions.

In essence, the execution of this DNP Capstone Project (CP) underscores the commitment to advancing nursing knowledge and practice and exploring novel strategies to improve patient outcomes in the ongoing fight against obesity and being overweight. This DNP CP is also poised to stimulate further studies and broaden the scope of weight management strategies in clinical practice. The implications of this DNP project could extend beyond the confines of the study's demographic, potentially benefitting a more comprehensive range of individuals struggling with weight management. Hence, this DNP CP aims to contribute significantly to nursing knowledge and practices by offering robust evidence on the potential effectiveness of semaglutide, coupled with IF, for weight management in non-diabetic adults across demographics. It underlines the importance of innovative, evidence-based approaches in addressing health challenges and underscores the pivotal role that nurses, particularly DNPs, play in advancing healthcare (Melnyk & Fineout-Overholt, 2018).

So, in a nutshell, the DNP study setting was selected out of convenience due to easy patient accessibility since the volunteer participants are already existing patients that may fit the mold of the projected sampling population (Restore Med Clinic, 2023; Serenite Wellness Medicine, 2023).

Interventions

The specific DNP interventions expand on the QIP approach discussed earlier. The DNP CP interventions are meticulously structured to address a pressing public health issue prevalent among adults in the US: obesity and a novel solution to tackle it. Aligned perfectly with the procedures of a Quality Improvement Project (QIP), which features a Pre-Test and Post-Test

design, the interventions also aim to provide an educational segment to bolster the understanding of participants regarding the interventions (Melnyk & Fineout-Overholt, 2018). Given that this DNP study is built on the foundations of a QIP combined with a Pre-Test and Post-Test design, the DNP methodology is instrumental in gauging the impact of interventions by analyzing the differences observed between the pre-test and post-test phases. Furthermore, a dedicated educational segment seeks to acquaint participants with the semaglutide treatment and its potential for weight management, ensuring participants are well-informed and not merely passive recipients (Melnyk & Fineout-Overholt, 2018).

This DNP QIP interventions comprises of three phases: (1) Recruitment and Informed Consent acquisition, (2) Pre-test evaluation, and (3) Post-test analysis. Consequently, the primary intervention revolves around using and educating the use of semaglutide subcutaneous injections alone for weight loss. Expected outcomes target observing changes in weight and BMI metrics before and after the intervention, which will be subjected to in-depth statistical analysis (Alabduljabbar et al., 2022; Colin & Gérard, 2022; Singh et al., 2022; South University, 2023; Welton et al., 2020). The second specific intervention involves the combination of both an off label semaglutide subcutaneous injection along with IF. And the educational component interspersed between these two interventions rounds up the third intervention. In summation, this DNP CP involves a total of three interventions, two of which (i.e., semaglutide injection alone, or in combo with IF) will be measured, compared, and analyzed in future sections (Melnyk & Fineout-Overholt, 2018).

Explanation of Methods and Interventions Including Timeframe and Other Details

The DNP QIP methodology is further deconstructed into four (4) actionable tasks or stages in various delineated timeframe to ensure clarity and feasibility of the DNP CP. The first

stage is the Recruitment and Consent (R&C) phase, where potential participants for the QIP include patients undergoing weekly semaglutide subcutaneous injections at the clinic. These individuals will be shown the QIP Recruitment Flyer (shown in Appendix C) and receive comprehensive answers to their queries. If they express interest, the QIP Informed Consent Form (shown in Appendix D) will be used to elaborate on the study's details, risks, and benefits. Following verbal consent, participants will be medically screened using the Medical Screening & Recruitment Survey Form (MS&RSF) as shown in Appendix B. Successful candidates will then formally consent using the QIP Informed Consent Form and move to the next stage (Melnyk & Fineout-Overholt, 2018).

The second stage is the Pre-Test and Education. Before the inaugural weekly subcutaneous dose of semaglutide, participants' initial weight, height, and BMI will be recorded at the clinic (Serenite Wellness Medicine, 2023). Detailed information on semaglutide will be based on the recommended clinical guidelines (Melnyk & Fineout-Overholt, 2018). Additionally, each participant will attend an educational session to be apprised of the treatment protocol, mechanism, and potential advantages in weight management. This interactive educational session allows participants to ask questions and clarify any doubts they might have. Volunteer participants will also be provided with informational brochures and material detailing the potential benefits and side effects of semaglutide, as well as general tips on maintaining a healthy lifestyle and diet during the intervention period. All these materials have been designed considering evidence-based guidelines and recommendations (Singh et al., 2022).

The third stage is the Post-Test and Evaluation. Following the intervention period of eight (8) weeks, during which the participants would have received weekly subcutaneous (SQ) injections of semaglutide, a post-test assessment will be conducted. This stage would involve

measuring and recording the participant's weight and BMI again to ascertain any changes that might have occurred during the intervention. Alongside these quantitative metrics, qualitative feedback will also be sought from the participants regarding their experience with the treatment, any side effects they might have encountered, and their overall satisfaction with the intervention. Furthermore, the data collated from the pre-test and post-test stages will be analyzed using appropriate statistical tests. This analysis aims to determine whether there is a statistically significant difference in weight and BMI metrics pre- and post-intervention, thus providing a robust assessment of the intervention's effectiveness (Alabduljabbar et al., 2022; Melnyk & Fineout-Overholt, 2018; Welton et al., 2020).

The fourth stage includes Confidentiality and Ethical Considerations. Utmost care will be taken to ensure that all participants' data remains confidential. All forms, measurements, and feedback will be anonymized using unique identification codes, ensuring that personal identities are not revealed during the data analysis or dissemination phases (Melnyk & Fineout-Overholt, 2018). The research has been structured to abide by the highest standards of ethical considerations. As mentioned previously, participants will be fully informed about the nature of the study, its objectives, potential risks, and benefits, ensuring they provide informed consent before participation (Colin & Gérard, 2022).

Circling back on the methodology and interventions, this DNP CP employs a holistic QIP approach to evaluate the effectiveness of semaglutide in weight management among a specific demographic. It aims to provide comprehensive insights into the intervention's potential benefits and implications using a pre-test and post-test design combined with a rigorous educational component. This DNP CP methodology facilitates easy replication by healthcare professionals

interested in verifying the findings or exploring similar interventions in their settings, ensuring clarity, transparency, and adherence to ethical guidelines (Melnyk & Fineout-Overholt, 2018).

Data Collection

In advanced nursing education, a DNP CP serves as a fundamental component, underpinning the integration of Evidence-Based Practice (EBP). A cornerstone of this DNP CP is meticulous data collection, which necessitates a forward-thinking approach to lay a sturdy foundation rooted in pertinent data, subsequently setting the stage for analysis and interpretations (Graves et al., 2021). In the progression of this DNP CP, important strides have been made concerning the meticulous data collection process without sacrificing patient privacy and confidentiality. Consistent with the earlier outlined methodology, this student has methodically utilized Data Collection Forms (DCFs) as the primary tool for capturing relevant data from the participants at Serenite Wellness Medicine clinic (Eriksen & Frandsen, 2018). These DCFs have been indispensable in maintaining data accuracy and relevance, mitigating potential biases and errors while ensuring privacy and confidentiality (Graves et al., 2021).

Moreover, this DNP student has conducted pivotal meetings with his Clinical Preceptor and her staff to ensure alignment in data collection timelines and processes. These interactions, which emphasize the criticality of timely data collection, have granted this student the required confidential database access, facilitating ongoing data collection (Bemker & Schreiner, 2016).

Furthermore, data such as weight and height at designated timelines have been diligently recorded, aligning with the DNP CP phase (Matheson, 2019). An essential addition to this process has been the Intermittent Fasting Compliance Tracking Form (IF CTF) shown in Appendix E, ensuring adherence to the IF intervention over the two-month study period approved by the SU IRB. During the initial but critical phase of this DNP study, the resultant

delay in data collection is due to the timing differences in the start and completion dates for implementing IF in combo with semaglutide.

The recruitment phase of patient volunteers for this DNP CP uses a flyer approved by the SU IRB (Eriksen & Frandsen, 2018). This stage leads to the MS&RSF, which filters potential participants inducting them as qualified volunteers. Upon acquainting themselves with the SU IRB-sanctioned DNP CP teachings, including insights on semaglutide and a PowerPoint elaboration on IF, the patient volunteers are free to raise queries before signing an informed consent (Bemker & Schreiner, 2016). The data collection then proceeds to the pre-test stage, noting initial metrics such as weight and BMI. This step is followed by a two-month intervention phase where participants undergo dual interventions of semaglutide and IF. Concluding this, the post-test phase mirrors the pre-test metrics, facilitating a Comprehensive Statistical Data Analysis (CSDA), which leverages descriptive and analytical statistics. The interpretation includes vital statistics like means, frequencies, and standard deviations, potentially utilizing a paired sample t-test to gauge the intervention's impact (Vetter, 2017). The following explains each DCF used in this DNP CP.

DCF 1 is a consolidation of attestations confirming adherence to all DNP CP phases, from the SU IRB-approved recruitment flyer to the follow-ups on education components for both pre-and post-test phases. This phase ensures that the collected data is robust and maintains its integrity (Graves et al., 2021). Conversely, DCF 2 determines the participants and pinpoints the exact data collection completion date, emphasizing the urgency due to the limited timeframe until DNP program completion (Bemker & Schreiner, 2016).

While the data collection is in progress, additional data requisites and discernible data voids are clearly indicated. For example, timely and precise weight and height data collection is

imperative within the DNP CP phase (Matheson, 2019). A crucial meeting was convened between this DNP student, his Clinical Preceptor, and her team to discuss the intricacies of the data collection trajectory. This discourse reiterated the significance of the two DCFs and the timeliness of data collection. A crucial resolution from this meeting was granting database access to this DNP student. However, as will be addressed in a separate section, concerns were raised once again over the "protection of the human subjects" primarily for privacy and confidentiality, which accounted for the unsuccessful initial patient data collection at Restore Med Clinic (2023).

Another pivotal data is the Intermittent Fasting Compliance Tracking Form (IF CTF). This form's primary objective is to meticulously track each volunteer's adherence to the IF intervention across the SU IRB-approved two months study period. Hence, the data collection phase is essential to this DNP CP, ensuring that every piece of information is meticulously gathered, analyzed, and interpreted to provide conclusive results and insights (Melnyk & Fineout-Overholt, 2018). Table 1 details the data collected.

Data Analysis

A rigorous data analysis plan will be employed upon completion of the data collection described in much detail in the previous section. The Comprehensive Statistical Data Analysis (CSDA) will incorporate descriptive statistics, including measures of central tendencies, frequencies, and standard deviations. These statistics will offer insights into the variations and commonalities within the collected data (Vetter, 2017).

Descriptive statistics, which pertain to measures such as means, modes, frequencies, and standard deviations, will concisely summarize the collected data's main aspects. The mean will offer an average value, thereby demonstrating a central tendency of the dataset. The mode will represent the middle numerical value and is typically used if non-normal data distribution is

obtained. Frequencies will display the number of times a particular value or a range of values occur within the dataset, which can be crucial for identifying patterns or commonalities (Cooksey, 2020). The standard deviation will indicate the variation or dispersion of a set of values, which is integral to understanding the spread and reliability of the data (Vetter, 2017). These statistics will collectively offer insights into the collected data's variations, patterns, and commonalities, laying a foundation for further inferential analysis. Using descriptive statistics as a starting point is a recognized method in various research disciplines, enabling this student to summarize and visualize large volumes of data efficiently (Cooksey, 2020). By doing so, this student can make preliminary observations and generate hypotheses for subsequent testing (Batko & Ślęzak, 2022).

In addition to descriptive statistics, further statistical tests may be explored depending on the nature of the data and the research questions. These tests could include inferential statistics to make predictions or inferences about the population based on the sample data (Cohen, 2021; Guetterman, 2019). For example, a potential paired sample t-test is initially under consideration as a methodological approach to assess the significance of semaglutide and IF interventions on weight and BMI improvement. The paired sample t-test is particularly advantageous in this context as it is designed to compare the means of two related groups. The groups are ‘paired’ because they are somehow related or matched, which is the case for before and after measurements on the same patient subjects (Cohen, 2021). However, this line of analysis will only apply if the data collected exhibit normal distribution.

This analytical approach aligns seamlessly with the initial plan, ensuring a systematic and rigorous evaluation of the intervention’s impact on the non-diabetic adult population under study (Khanna et al., 2022). In the context of interventions such as semaglutide and IF, employing a

paired sample t-test is beneficial for detecting any significant differences in weight and BMI before and after the application of interventions (Xu et al., 2017). Once again, it is crucial to mention and important to reiterate that while the paired sample t-test is a robust analytical tool, assumptions such as normality and homogeneity of variances must be checked to ensure the validity of the test results (Field, 2018). Therefore, a thorough examination of these assumptions will be performed as part of the data analysis process, allowing for any necessary adjustments or adaptations in the approach (Noyes et al., 2019). In which case, the mode, instead of the mean, is the appropriate measure that must be employed in the overall analysis. Table 1 details the raw and coded data used in the statistical analysis.

Human Subjects Protection

Several measures were undertaken to protect the human participants in this DNP CP. First, this student and his faculty advisor completed the Association of Clinical Research Professionals (ACRP) certification course on "Ethics and Human Subject Protection: A Comprehensive Introduction" and are both certified to work with Human Subjects in a DNP study such as this DNP QIP. Also, each clinical staff involved in the data collation and analysis signed a confidentiality agreement, once again to protect the privacy of each volunteer participants. Furthermore, each Data Collection Form (DCF) is coded to protect patient privacy and confidentiality (Eriksen & Frandsen, 2018).

Confidentiality and continuity in data collection concepts remains paramount. One primary approach in this DNP CP is using the PICOT strategy in literature searches, employing a structured data collection method (Eriksen & Frandsen, 2018). Correspondingly, during the data collection stage, this same and parallel approach entails the development of specific Data Collection Forms (DCF)s to streamline and standardize the information. Such DCFs act as

pivotal tools ensuring data relevancy and precision, thus offsetting potential biases or errors, and playing a critical role in consolidating the data gathered and summarizing it and identifying additional data requirements (Eriksen & Frandsen, 2018).

It is important to stress that, in accordance with the ethical standards of the South University (SU) Institutional Review Board (IRB), which was used in this DNP CP because both Restore Med and Serenite Wellness Medicine clinics do not have an inhouse IRB, stringent measures were undertaken to protect the wellbeing and privacy of all DNP study participants throughout. Prior to commencement, this DNP Capstone study received IRB approval on August 23, 2023. Subsequently, all volunteer participants were briefed on the nature of the study, its objectives, potential risks, and benefits, as well as the volunteer participant's right to withdraw from the study at any time without penalty. Informed consent was obtained from all participants after ensuring they understood the study's procedures, which followed the Declaration of Helsinki and local legislation. Participants' anonymity was safeguarded by assigning unique identification codes, and personal information was stored in a secure, encrypted database with limited access (Eriksen & Frandsen, 2018).

The importance of the IRB preapproval process is very evident. It provides the foundation for ethical research, ensuring that all activities involving human subjects are conducted responsibly. The IRB is a committee established to review and approve research involving human subjects. The primary role of the IRB is to ensure that the rights, welfare, and privacy of human subjects are protected. The principles of the IRB process draw from classic documents such as the Belmont Report and the Office for Human Research Protections (OHRP) Regulations. Consequently, the Belmont Report, published in 1979, outlines the fundamental

ethical principles that must be upheld when conducting research involving human subjects (Nagai et al., 2022).

It is important to reiterate the main essence of Human Subjects Protection by elaborating on the three (3) fundamental ethical principles once again as briefly explained previously. First is “Respect for Persons”. This principle acknowledges the dignity and autonomy of individuals. It requires obtaining informed consent from potential research subjects, ensuring they are provided with sufficient information about the research and its potential risks and benefits. Second is “Beneficence” which warrants that people conducting studies and research must maximize potential benefits and minimize potential harms to the human subjects. It involves a thorough risk-benefit analysis to ensure the well-being of the subjects. And the third is “Justice”. This principle ensures that the selection of study or research subjects is equitable. Vulnerable populations should not be targeted simply because of their availability, nor should they be systematically excluded without a valid scientific reason. Especial protections are accorded to the very young (less than 18 years old), the old (over 64 years old), the pregnant women, the war veterans, and the mentally challenged (Nagai et al., 2022).

Furthermore, the Code of Federal Regulations for the Department of Health and Human Services Part 46, often referred to as the "Common Rule", provides detailed guidelines and regulations for the protection of human subjects in research and studies (White, 2020). Key points of these code include: (1) “Institutional Assurance”: institutions conducting human subject research or study must provide written assurance to the Office for Human Research Protections (OHRP) that it will comply with the requirements set forth in the regulations; (2) “Review Process”: research or study proposals must undergo a thorough review by the IRB where there are provisions for expedited review in certain cases where the research or study involves minimal

risk; (3) “Informed Consent”: informed consent from participants is central to ethical research and study such that the regulations outline the essential elements of the informed consent process and the criteria for its documentation; and (4) “Protection of Vulnerable Populations”: additional protections are stipulated for research and studies involving pregnant women, fetuses, neonates, prisoners, and children (White, 2020).

As such and having completed the IRB approval process for this DNP CP on the synergistic use of GLP-1 semaglutide with Intermittent Fasting (IF) to address the current obesity epidemic, this student was both curious and intrigued to read the article by Szanton et al. (2013) that discusses the IRB approval process tailored specifically for a DNP student. Szanton et al. (2013), underscored the unique challenges that a DNP student often face, given that the projects typically focus on Quality Improvement Projects (QIP) and implementation of Evidence-Based Practices (DBP), thereby distinguishing this DNP CP (QIP) from traditional research projects (Szanton et al., 2013).

Furthermore, the Szanton and the other authors detailed a preapproval process that streamlines the review and decreases waiting times. This is invaluable for a busy DNP student, given the time constraints and the practice-focused nature of his DNP CP. Comparatively, there were intricate nuances to navigate. For example, the combinatory nature of GLP-1 semaglutide with IF meant diving deep into each element's side effects, potential risks, and benefits to the participants. While Szanton et al.'s proposed process emphasizes a streamlined review, this student often felt the need for a more specialized and tailored review that understands the specific intricacies of his DNP CP. Ultimately, the common denominator is semaglutide treatment, and the intervention focuses on the addition of IF to evaluate impact on the overall improvement in weight loss and BMI reduction. And one of the most insightful takeaways from

the article was the collaborative approach between the DNP faculty and the IRB, enabling clear communication channels and ensuring that all involved parties had a shared understanding of the project's intent and scope (Szanton et al., 2013).

Ultimately, the student and the faculty advisors settled on a QIP methodology, with a Pre-Test and a Post-Test design and an educational component revolving around semaglutide with or without IF. The DNP CP volunteer participants will comprise of recruited non-diabetic adult patients between the ages of 18 to 64 and a BMI between 25 to 39 who (1) have been medically screened and found eligible for semaglutide and IF treatment; (2) signed an informed consent; (3) completed the pre-test and post-test surveys; and (4) completed the required education components during each stage of the study. Moreover, there will be three stages to this DNP CP: (1) recruitment and consent, (2) pre-test, and (3) post-test. The intervention involves the education and addition of IF into the usual semaglutide treatment for weight loss. The two measured expected outcomes are changes in weight and BMI pre- and post- intervention in both groups. The outcomes will be statistically analyzed. Instead of recruitment at Restore Med Clinic (which is prohibited by that Clinic's management due to strict Privacy and Confidentiality policy in that clinic), patient recruitment will be conducted at an off-site in a similar private practice of Dr. Heidi Regenass – i.e., at Regenass Healthcare Group dba Serenite Wellness Medicine clinic in Ontario, about an hour (or an hour and a half drive depending on prevailing traffic) from the original Newport Beach Clinic. In short, reflecting on the entire IRB application process, much of the back and forth were centered around the QIP methodology, the site of recruitment, and revisions to the required forms. It greatly helped that the South University (SU) DNP Director and the Faculty advisor conducted training on this matter. Consistent with what Szanton et al (2013) elucidated in their article, the SU DNP Program Director also emphasized in her online

recorded training / webinar that “it is particularly important that faculty and students recognize which DNP students’ projects should be considered as “human subjects research” or “quality improvement.” The former require IRB review, whereas the latter may be eligible for expedited review” (Szanton et al., 2013). From that webinar, this student also learned an important information: how the QIP methodology works and how it can be leveraged for this DNP CP.

Navigating the IRB process has been an invaluable learning opportunity for this DNP student. Submitting a research or study proposal requires rigorous planning to address all ethical concerns and to ensure that the DNP study’s design upholds the principles of respect, beneficence, and justice. The SU IRB's feedback often prompted deeper consideration of potential risks and ways to mitigate them. While the SU IRB review process can be seen as lengthy and bureaucratic, its importance becomes clear when reflecting on the ethical foundations it upholds. The process serves as a safeguard against potential oversights and biases that may inadvertently harm participants or produce misleading results (Szanton et al., 2013).

In the end, the IRB process is pivotal in upholding the ethical standards of research and studies involving human subjects. By adhering to principles laid out in foundational documents like the Belmont Report and OHRP Regulations, the IRB ensures that the rights, welfare, and privacy of study and research participants are prioritized (Nagai et al., 2022; White, 2020). It is the DNP Capstone study team’s responsibility to respect these principles, ensuring that the DNP study contributes positively to the body of knowledge without causing undue harm to the human subjects of the study.

Circling back, the IRB approval process is crucial for ensuring the ethical integrity of projects, especially in the health and nursing domain as it applies to the DNP CP. Tailoring the process for DNP students, given the unique nature of their projects, is essential. While the

journey has been enlightening, there's always room for improvement, particularly in fostering collaboration and mutual understanding, as this DNP student personally experienced (Nagai et al., 2022; White, 2020).

The Institutional Review Board (IRB) Process

The IRB review process was initiated by submitting a detailed DNP CP protocol outlining the study design, participant recruitment strategy, methods of data collection, and procedures for ensuring participant confidentiality and risk minimization, among other SU IRB requirements. Accordingly, and subsequently, the SU IRB conducted a thorough review to ascertain that the study met ethical research standards and mandated modifications to the protocol to enhance human patient participant safety. Following the implementation of suggested changes, the IRB granted approval, signifying that the study adhered to ethical guidelines for human subject's research (Eriksen & Frandsen, 2018; Nagai et al., 2022; White, 2020).

Informed Consent or Waiver

Written informed consent was obtained from all participants. The informed consent form detailed the study's purpose, procedures, potential risks, and benefits, as well as the confidentiality measures in place. A waiver of consent was not sought as the study involved direct interaction with the participants and potential risks that needed to be communicated (Eriksen & Frandsen, 2018). Appendix D shows a copy of the QIP Informed Consent.

Coding and De-identifying the Data

Preparing the data is critical in this DNP study, especially when working with medical data, where strict ethical guidelines must be followed. Moreover, before any analysis is performed, the collected data must be cleaned, organized, and validated (Greiner & Knebel,

2023). Confidentiality and privacy are paramount for patient data study, and specific procedures are established to achieve this goal. The specific goal is to ensure that the data collection follows the Health Insurance Portability and Accountability Act (HIPAA). De-identifying personally identifiable information is essential to accomplish this goal (Theodos & Sittig, 2020). This process involves removing or replacing individual details like names, addresses, and social security numbers, ensuring that the data cannot be traced back to a specific individual. This DNP study chose coding for this particular purpose.

Coding is one approach that aids in data anonymization. Researchers assign each participant a unique code instead of directly using patient names or other identifiable data. These codes have no meaningful connection to the individual, thereby protecting their identity. The key linking the code to the identifiable information should be stored securely and separately from the coded data to prevent unintentional breaches of privacy (Rodriguez et al., 2022). In short, coding ensures that even if anecdotes or specific details are mentioned, they cannot be linked to the actual individual patient volunteer.

Approach to Protecting the Rights of Subjects in this DNP CP

The absolute sanctity of human rights for individuals who participate in modern scientific investigation is of paramount importance, whether the investigation involves a research project or a Quality Improvement Project (QIP) study such as this student's DNP CP. Consequently, ethical standards evolved over time, shaped by earlier wrongdoings (Artal & Rubenfeld, 2017). History is replete with examples of these past transgressions, such as the medical experiments conducted by German physicians on thousands of Nazi concentration camp prisoners without the prisoners' consent. These sins against humanity happened during the Holocaust and resulted in

the creation of the Nuremberg Code – regarded as the first international document advocating voluntary participation and informed consent (Annas, 2018). Another most recent example of an ethical scandal involves the Tuskegee Syphilis Study in the United States (US), brought to light by the Belmont Report and resulting in the formation of the US National Research Act (Adashi et al., 2018).

Given this historical lesson as a backdrop, this paper emphasizes the approach taken to ensure the protection of individuals who voluntarily participate in a DNP CP on the off-label use of the Glucagon-Like Peptide 1 (GLP-1) receptor agonist semaglutide in a novel combination with Intermittent Fasting (IF) to address the currently raging obesity epidemic. This DNP CP employs the PICOT model to structure an organized scientific inquiry and enable a systematic search for relevant peer-reviewed scientific articles (Eriksen & Frandsen, 2018).

Ethical considerations are of prime importance when conducting any clinical investigation, especially with interventions like the off-label use of medications (Rusz et al., 2021). Specifically, this DNP CP that focuses on the off-label use of semaglutide combined with IF to address obesity at Restore Med Clinic and Serenite Wellness Medicine Clinic, is a QIP that must adhere to strict ethical guidelines. Overly simplified as the "unapproved use of approved drugs," Rusz et al. (2021) explain the need to ensure safe practice in dispensing these off-label medications. As such, and as discussed briefly earlier, four (4) detailed measures protect the rights and well-being of the patients who volunteer to participate in this DNP CP.

The first measure involves the use of Informed Consent (IC). Central to the ethics of research on human subjects is the principle of IC (Manti & Licari, 2018). Before initiating the DNP CP, every potential patient participant is given a comprehensive IC form, as Appendix D shows. This form is not merely a procedural hurdle. However, it serves as an ethical instrument

protecting the rights of the human subjects that elucidates the nature of the DNP study, the potential risks and benefits, detailed procedures, and, crucially, emphasizes the voluntary nature of participation in the DNP CP. By transparently providing this depth of information, human participants are empowered to make a genuinely informed decision about their involvement in the study or research (American Psychological Association, 2020).

On the other hand, the second measure entails the protection of the volunteer patient's Privacy and Confidentiality (P&C). Protecting the identities of participants is a fundamental ethical obligation (Turcotte-Tremblay & McSween-Cadieux, 2018). In this DNP CP, meticulous measures were put in place to protect the privacy of all subjects. Volunteer participant's personal data was coded and stored distinctly from the primary study data, ensuring that published results or internal evaluations could never be linked to any individual participant. Moreover, strict access protocols ensured that only the core DNP Capstone study team could access this sensitive information.

Meanwhile, a third measure involves the minimization of risk. While some degree of risk is inherent in most clinical investigations, the obligation of the DNP study team is to minimize and manage these risks (Council for International Organizations of Medical Sciences, 2016). Given the off-label use of semaglutide and the potential physiological effects of Intermittent Fasting (IF), the DNP study team thoroughly studied and outlined the potential side effects. This preparation ensured that participants were informed and continuously monitored for any adverse effects. At any juncture, participants were free to withdraw from the study if they felt uncomfortable or at risk. Appendix B shows the Medical Screening & Recruitment Survey Form (MS&RSF), which sets the tone for minimizing risk. The purpose of this MS&RSF is to assess for the presence of any contraindications for both semaglutide and IF. These contraindications

serve as the exclusion criteria, which minimizes the risk to the patient volunteer by simply disqualifying any patients who fall into these exclusion criteria.

Lastly, a fourth measure entails continuous monitoring of all volunteer participants to the DNP CP. Complementing the minimization of risks is a robust system of continuous monitoring. A dedicated Serenite Wellness Medicine Clinic DNP Capstone study team is on standby for participants to report any side effects or other concerns they might encounter during the DNP CP. Such a proactive approach underscores the study's commitment to participants' well-being and ensures rapid interventions are available if deemed necessary (Council for International Organizations of Medical Sciences, 2016).

Ethical Principles Applied in the DNP CP

The off-label use of semaglutide combined with IF as a potential treatment strategy for obesity, as explored in the DNP CP at Restore Med Clinic and Serenite Wellness Medicine Clinic, stands on four (4) fundamental ethical principles. These principles, as briefly mentioned in an earlier section, ensured the research's integrity, and prioritized the well-being and rights of the participants involved (Varkey, 2021).

The first ethical principle is "Autonomy". The principle of autonomy is rooted deeply in bioethical considerations, emphasizing individuals' inherent right to make decisions concerning their own lives and bodies (Varkey, 2021). Within the context of this DNP CP, respect for the autonomy of persons is paramount. Every participant's independent choice, be it the decision to join the study or to withdraw from it at any point, is honored unequivocally. There will be no repercussions, implicit or explicit, for any decisions made by the participants regarding their involvement, thus upholding their rights to self-determination.

The second ethical principle is “Beneficence”. Beneficence encompasses actions that promote the well-being of others (Varkey, 2021). In line with this, the DNP CP is not a mere academic exercise but is designed to benefit the participants. The combined approach of semaglutide and IF is a novel and potentially transformative treatment strategy for weight loss. Throughout the research, meticulous efforts were dedicated to ensuring that the potential benefits of the treatment strategy were maximized while any associated risks were minimized. For example, Appendix B, which shows the Medical Screening & Recruitment Survey Form (MS&RSF), immediately assesses for the presence of any contraindications for both semaglutide and IF, thereby minimizing patient risk.

The third ethical principle is “Justice”. Justice in research refers to the fair distribution of the burdens and benefits of participation (Varkey, 2021). In the DNP CP, this principle was applied rigorously during participant selection. The inclusion and exclusion criteria were based purely on factors relevant to the study's objectives, ensuring that no potential participant was discriminated against based on unrelated attributes. This approach ascertained that the benefits and burdens of the research were equitably distributed among participants, preventing any group from being disproportionately burdened or unjustly denied potential advantages.

Finally, the fourth ethical principle is "non-maleficence." Perhaps most foundational in healthcare ethics is the principle of non-maleficence, encapsulated by the adage "First, do no harm" (Quick, 2022). It serves as a reminder that the health and well-being of patients and participants should always be a primary concern, superseding other interests (Varkey, 2021). With these principles at the forefront, this DNP CP (QIP) was executed with rigorous oversight and protocols to prevent any form of harm, be it physical, emotional, or psychological, to the volunteer patient participants.

Organizational Factors

The organizational factors impacting this DNP CP revolves around the organizational dynamics and communication culture among the staff of the two (2) Southern California clinical premises. The first is at the Restore Med Clinic (2023), a highly respected medical and surgical private practice in Newport Beach, a Southern California location renowned for its affluent population (Restore Med Clinic, 2023). The Restore Med Clinic, known for its diverse range of health services and emphasis on an integrated approach to health and wellness, serves as an appropriate site for this study. The clinic's clientele predominantly comprises individuals from the upper economic stratum, reflecting the socio-economic characteristics of Newport Beach. Hence, the participants for this study will be carefully selected from the patient records of the Restore Med Clinic, in alignment with the PICOT question. The same applies for the second clinical site at the Serenite Wellness Medicine clinic located in Ontario, California (Restore Med Clinic, 2023; Serenite Wellness Medicine, 2023).

However, due to privacy restrictions at the Restore Med Clinic's Newport Beach location, the DNP CP venue is changed to the second and additional off-site location located several miles away in Ontario known locally as Serenite Wellness Medicine, which is another private practice clinic owned by the preceptor of this DNP graduate student with prior approval from the faculty (Serenite Wellness Medicine, 2023). Specifically, to address any communication errors, inclusion and exclusion criteria for data collection were clearly established at the onset. The inclusion criteria focus on non-diabetic adults aged between 18 and 64 with a Body Mass Index (BMI) ranging from 25 to 39 (Melnyk & Fineout-Overholt, 2018). These parameters were chosen to represent a population that may struggle with weight management but does not have diabetes

mellitus, thus allowing the study to focus on the efficacy of semaglutide and IF in weight management outside of a diabetic context.

On the one hand, another inclusion criterion also specifies individuals who lack improvement with traditional weight management strategies. This criterion is paramount as it signifies a need for alternative or supplementary weight management strategies, thereby emphasizing the relevance and potential value of investigating semaglutide and IF as weight management strategies (Melnyk & Fineout-Overholt, 2018). Similarly, the exclusion criterion identifies incomplete patient charts or co-existing medical conditions that could affect weight or BMI independently of the interventions being studied. Such criteria help ensure that the study findings accurately represent the effects of the interventions being examined and are not confounded by unrelated health issues (Melnyk & Fineout-Overholt, 2018). These two criteria will apply and will be clearly communicated during the data collection stage to address the existing organizational factors and dynamics at the selected DNP-CP sites: Restore Med Clinic and Serenite Wellness Medicine Clinic (Restore Med Clinic, 2023; Serenite Wellness Medicine).

DNP Study Instruments: Reliability and Validity

This section discusses the study instruments, their reliability, validity, and the data measurements for this graduate student's DNP CP. In the context of this DNP project that addresses the obesity epidemic through a combination of off-label semaglutide use and IF, several Data Measurement Instruments (DMI) will be utilized. These data measurements include weight, height, and BMI. The validity of these DMIs is ensured through their widespread acceptance and usage in obesity-related studies and clinical practice. Furthermore, the DMI's reliability has been confirmed through numerous scientific studies and the DMI's ability to provide consistent results over time (Bemker & Schreiner, 2016).

For this DNP CP, weight is defined as the participant's body mass measured in pounds and converted to kilograms to calculate Body Mass Index (BMI). At the same time, BMI is calculated as weight (in unit kilogram abbreviated as kg) divided by the square of the height (in unit square meter abbreviated as m2). It is important to note that these DMIs used for weight, height, and BMI, while commonly used, do not directly assess body fat, and can be influenced by factors like muscle mass. To be more specific, for the DMI for weight, height, and BMI, a digital weighing scale and a stadiometer will be used respectively. The digital weighing scale offers precise weight measurements and has been calibrated to ensure reliability and accuracy. The stadiometer, used for measuring height, is a highly reliable and valid instrument in clinics and hospitals (Warrier et al., 2020). It is vital to ensure that the DMIs are periodically calibrated, and the measurement procedures standardized to maintain reliability and validity. Reliability pertains to the consistency of a measure, i.e., whether the data measurements can be reproduced under similar conditions. In contrast, validity relates to the accuracy of a standard, i.e., whether the data measurements represent what they are supposed to measure (Matheson, 2019).

On the other hand, BMI is calculated by dividing weight (in kilograms) by the square of the height (in meters squared), as discussed earlier. This data measurement for BMI is widely accepted due to its ease of use and proven utility in assessing overweight and obesity (Zierle-Ghosh & Jan 2018). While BMI does not directly measure body fat, research indicates a strong correlation between BMI values and body fat percentage, making it a valid instrument to measure degree of obesity (Zierle-Ghosh & Jan 2018).

The data needed above, definitions, and measurement strategies were established based on a review of the literature and following established clinical guidelines. Ensuring the reliability and validity of measurements is crucial in producing credible and dependable data (Polit & Beck,

2017). Furthermore, the target population for this DNP QIP study consists of overweight or obese adults aged 18-65 who can and are willing to commit to a structured IF program and a regimen of semaglutide and IF. Regarding generalizability, the findings from this DNP CP can be extended to a larger population of overweight and obese adults, considering the use of IF and semaglutide. However, caution will be necessary due to nonprobability sampling from the small sample size, which may not fully represent the larger population. This concept will be discussed in detail in the following section.

Results

Participants

Initially, there were a total of 31 volunteer participants: 8 are naturally born male and the rest (i.e., 23) are naturally born female. Percentage-and-gender-wise, the participants comprise of 26% male and 74% female. The initial plan at the start of this DNP CP is to recruit at least 30 participants to meet the minimum sample required to approximate standard normal distribution and meet the Central Limit Theorem that should make for a simpler and more straight-forward statistical analysis (Kwak & Kim, 2017).

In the end, only 13 participants successfully followed-through and completed the DNP Capstone program. Majority were not able to make it to the cut-off period due to the end time nearing the DNP course completion date. Time is a constraint given that the DNP CP must be completed within an allotted timeframe and ideally before the DNP course completion date (Melnyk & Fineout-Overholt, 2018).

It is also important to mention, and as will be explained in a subsequent section, that one participant is an outlier which failed to satisfy the PICOT framework and ended up being rejected and being excluded to the final pool of study participants (Melnyk & Fineout-Overholt,

2018). In the end, there were only 12 patient volunteers who made it into the final pool of study participants.

Descriptive Measures

The following section details the statistical analysis and descriptive measures. Based on the data collected comprised of filled-out and coded DCF-1, DCF-2, and DCF-3, some of the DCFs were incomplete because the milestone dates of these volunteer patient participants fall outside this DNP course completion date. As such, the data collection had to be terminated resulting to only 13 final sample. It is also evident that specific data gaps exist in the form of partially filled Data Collection Forms (DCFs). These partially filled-out DCFs come in two variances. The first variance comprises the raw data because it contains patient-identifiable information and the required signature attesting to the integrity and veracity of each data collected. The second variance is an extract from the first data, which means that all patient-identifiable information will be removed and adequately coded to protect and safeguard the privacy and confidentiality of each patient participant (Graves et al., 2021).

Descriptive statistics, encompassing metrics like means, modes, frequencies, and standard deviations, succinctly summarize the primary elements of the gathered data. Table 1 details these data collected. The mean offers an average value, signifying the data's central tendency. The mode represents the middle value. The frequency represents a specific value or set of values within the data, which is crucial for pinpointing patterns or similarities (Cooksey, 2020). Meanwhile, the standard deviation indicates the variability or spread of a dataset, which is fundamental for gauging data reliability (Vetter, 2017). Table 1 also shows the coded data collected.

Collectively, these descriptive statistics provide insights into the data's variations, patterns, and similarities, establishing a groundwork for further inferential evaluations. Leveraging descriptive statistics as an initial step is acknowledged in numerous research and study domains, allowing scholars to succinctly depict and visualize vast datasets (Cooksey, 2020). This step facilitates preliminary insights and the development of hypotheses for subsequent examination (Batko & Ślęzak, 2022).

Beyond descriptive metrics, additional statistical evaluations might be pursued based on the data's character and the study inquiries. Such evaluations could incorporate inferential statistics, facilitating predictions or deductions about a broader population from the sample data (Guetterman, 2019). Moreover, at the earlier data collection stage, the paired sample t-test is thoughtfully considered to measure the significance of interventions such as semaglutide and IF on weight and BMI enhancement. In this setting, the paired sample t-test is particularly apt since it compares the means of two interrelated groups, which, in this scenario, pertains to before-and-after measurements on identical subjects (Cohen, 2021). This strategy aligns with the initial blueprint, ensuring a thorough and stringent evaluation of the intervention's effects on the studied non-diabetic adult demographic (Khanna et al., 2022). In the realm of interventions like semaglutide and IF, using a paired sample t-test is valuable for discerning notable differences in weight and BMI before and after administering the interventions (Xu et al., 2017).

It is worth noting that while the paired sample t-test is a potent analytical instrument, assumptions related to normality and homogeneity of variances must be examined to guarantee the authenticity of the test outcomes (Field, 2018). Therefore, a meticulous review of these assumptions will be integral to the data evaluation process, accommodating any essential modifications or refinements in methodology (Noyes et al., 2019). However, and as will be

demonstrated in the following sections, with a small sample size (n) of only 12, which is so far from the desirable n=30 to demonstrate CLT and approximate a standard normal data distribution, this student ended up not using the paired t-test for inferential statistical analysis of the resulting descriptive measures (Kwak & Kim, 2017).

Outcomes

Tables 1, 2, and 3 summarizes this DNP study outcomes, consistent with the overarching purpose of this DNP CP which is to provide a comprehensive examination of weight management strategies and treatments targeting non-diabetic adults using either semaglutide alone or in combination with IF. The DNP study outcomes show successful weight loss achieved using both interventions – whether using semaglutide alone or in combination with IF (Melnyk & Fineout-Overholt, 2018). The following section discusses the process leading to this DNP CP's outcomes.

The research methodology is meticulously aligned with the protocols characteristic of a Quality Improvement Project (QIP) to achieve this objective. This alignment was essential to maintain the integrity and robustness of the DNP CP process (Melnyk & Fineout-Overholt, 2018). The QIP protocol was specifically chosen because it emphasizes continual assessment and refinement. Incorporating both a Pre-Test and Post-Test design, the study integrated an educational component, ensuring participants had a foundational understanding of the study's purpose and their role within it (Melnyk & Fineout-Overholt, 2018). This educational facet was pivotal, not just for ethical reasons but also to ensure participants remained engaged and informed throughout the program. Targeting non-diabetic adults aged between 18 to 64 years was a deliberate decision. This demographic, with BMI values ranging between 25 and 39, represents a significant portion of the population at risk of obesity-related complications (Restore Med

Clinic, 2023; Serenite Wellness Medicine, 2023). By focusing on this group, the study aimed to yield results that would be both pertinent and actionable for a considerable segment of the population. The multi-stage nature of the study, encompassing recruitment, informed consent, pre-test assessments, interventions, and post-test assessments, was structured to ensure a comprehensive evaluation. This systematic approach aimed to clarify the intervention's efficacy by quantifying changes in weight and BMI both before and after the study's core intervention phase (Melnyk & Fineout-Overholt, 2019). Ensuring the reliability and validity of the measurements was also paramount. Using digital weighing scales and stadiometers was a conscious choice to guarantee precise and consistent measurements across all participants. The calculation of BMI, a widely accepted metric for assessing overweight and obesity statuses, was performed by dividing an individual's weight (in kilograms) by their height squared (in meters squared) (Warrier et al., 2020). This method offers a scientifically rigorous and universally recognized means to evaluate weight relative to height, and to medically diagnose obesity and being overweight.

The increasing prevalence of obesity and overweight conditions among non-diabetic adults demands novel approaches for management, especially when traditional strategies prove ineffective. The DNP study, first conducted at Restore Med Clinic and then at Serenite Wellness Medicine (2023) clinic, strives to fill this gap. Guided by the PICOT model, the project investigates the combined efficacy of semaglutide and IF versus semaglutide alone in weight management (Eriksen & Frandsen, 2018). This PICOT question encapsulates the project's primary goal of introducing innovative solutions to the obesity problem and validates the need for rigorous data collection and analysis. By bridging this inquiry with evidence-based practices, the project emphasizes the indispensable role of data in the nursing domain (Graves et al., 2021).

To arrive at the above-mentioned DNP study outcomes, meticulous attention is paid to the data collection process to ensure that the project's objectives align with its goals as outlined earlier. Leveraging DCFs has been instrumental in obtaining accurate and relevant data from participants at the Serenite Wellness Medicine (2023) clinic, ensuring the study's validity and reliability (Eriksen & Frandsen, 2018). Regular consultations with the Clinical preceptor affirm the importance of precise and timely data collection. Tools like the Intermittent Fasting Compliance Tracking Form (IFCTF) also validate participants' adherence to the IF intervention throughout the study, reinforcing the study's comprehensiveness and rigor.

However, delays in data collection have been noted due to varying start and end dates for the IF intervention. To uphold the highest ethical standards without sacrificing data integrity, each DCF is coded, ensuring patient privacy and confidentiality remain uncompromised. A systematic data analysis plan, as initially described earlier, were then executed upon completion of the data collection process. The CSDA deployed descriptive statistics such as means, modes, frequencies, and standard deviations, granting an in-depth understanding of the dataset's inherent patterns and variations (Vetter, 2017; Cooksey, 2020). This approach aligns with accepted research practices, facilitating efficient data visualization and hypothesis generation for subsequent validation (Batko & Ślęzak, 2022). Depending on the data's nature and research objectives, advanced statistical tests, such as inferential statistics, are then conducted to draw insights about larger populations from the sample data (Guetterman, 2019). In this case, because of the non-normal data set distribution, a paired t-test inferential analysis is discounted, and a new technique will be adopted as will be subsequently discussed in another section.

In summary, this DNP project's outcomes underscore the essential linkage between diligent data collection, rigorous analysis, and the broader objectives of introducing novel

strategies in the fight against obesity. By doing so, it strives to revolutionize nursing practices, offering a template for future endeavors. In wrapping up, the DNP Capstone Project delved deeply into the challenges and solutions associated with the obesity epidemic, particularly among non-diabetic adults (Melnyk & Fineout-Overholt, 2018). The findings and insights gleaned from this DNP study are poised to make substantial contributions to developing and refining future weight management strategies and treatments as will be explained in the following sections.

Discussion of Findings

The findings of this DNP CP suggest that semaglutide, both individually and in combination with IF, is effective for short-term weight loss in non-diabetic adults. However, the combination approach did not yield significantly superior results within the study's 2-month timeframe. This outcome challenges the presupposition that a combination approach would yield superior results and may suggest potential limitations in study duration or sample size (Melnyk & Fineout-Overholt, 2018).

Furthermore, the null hypothesis that “there is no statistically significant difference in weight and BMI of non-diabetic adults before and after using semaglutide alone AND in combination with IF" is rejected and the alternative hypothesis that "there is a statistically significant difference in weight and BMI of non-diabetic adults before and after using semaglutide alone AND in combination with IF” is accepted (Guetterman, 2019; Melnyk & Fineout-Overholt, 2018).

Correspondingly, this section details the discussion of this DNP CP’s findings and the process leading up to them. After data collection, the data was analyzed. Data analysis means cleaning, organizing, and subjecting the data to both descriptive and inferential statistical analysis (Guetterman, 2019). Descriptive Statistics (DS), shown in Table 2, clearly summarizes

the sample's central tendency, distribution, and spread (Cooksey, 2020). The next step is to delve into data analysis, ensuring that the correct statistical tests are applied to derive meaningful insights and build on the foundation of the data preparation process (Guetterman, 2019).

Inferential Statistics (IS), outlined in Table 3, followed the DS and gave inferences for the before-and-after nature of the study. This DNP CP's primary aim was to compare pre- and post-intervention data. Various inferential tests were considered. A paired sample t-test may be an appropriate inferential tool to determine if there is a statistically significant difference in weight loss and BMI improvement after applying interventions but was later discounted as will be discussed in the following section (Trafimow & MacDonald, 2017).

As was discussed earlier, a paired t-test is an ideal choice for dependent data, where the same subjects (i.e., the same patient volunteers) are being measured at two different times or under two conditions (Mishra et al., 2019), which initially appears to be the case in this DNP CP study. This method allows us to identify if any observed differences are statistically significant, thereby providing empirical support for the intervention's efficacy.

However, it is crucial to ensure that the data meets the assumptions of the paired t-test. One of the key assumptions is that the differences between the paired observations should be approximately normally distributed (Mishra et al., 2019). The Central Limit Theorem (CLT) posits that the data can be considered customarily distributed if the sample size is more significant than when the sample size is equal to or more than thirty (n=/>30) (Kwak & Kim, 2017; Sawada, 2021). If the sample size is below this n=30 threshold, it is advisable to conduct normality tests. Standard tests to verify this assumption include the Kolmogorov–Smirnov test and the Shapiro–Wilk test (Kwak & Kim, 2017; Sawada, 2021). In the case of this DNP CP, the Shapiro-Wilk test is used to verify normality and conformance to CLT.

If the data does not meet the normality assumption, it is imperative to consider non-parametric tests. For instance, the Wilcoxon sum rank test is a suitable option for paired data, and the Mann-Whitney U-test can be considered when comparing two independent groups (Kwak & Kim, 2017; Sawada, 2021). These non-parametric tests do not operate under the assumption of normality and can provide valid insights even when the data deviates from a normal distribution. In this DNP CP, the Wilcoxon sum rank test is the inferential statistical tool employed because of the non-parametric nature of the test.

Due to these considerations, this DNP study recognizes that reviewing the nature of the collected data, its distribution, and sample size before finalizing the analysis approach is essential. Ensuring the proper statistical methods are employed will enhance the validity of the findings and contribute to the broader scientific discourse on obesity treatment (Kwak & Kim, 2017; Sawada, 2021). In conclusion, adequate data preparation and analysis are paramount for the integrity and utility of any DNP study or research project. By employing a structured approach, standardized measurement tools, and rigorous analytical methods, this DNP CP promises to deliver insightful findings that can contribute to the Evidence-based process (EBP).

Statistical Data Analysis Using SPSS

To analyze the effects of semaglutide and IF on weight loss and BMI in non-diabetic adults, the DNP data guided by the PICOT model was entered into the Statistical Package for the Social Sciences (SPSS) software (Kent State University, 2018; Pallant, 2020).

Preliminary Data Testing

The initial data analysis revealed that the total sample size was comprised of 13 patients which was then finally trimmed down to 12. Box plots, shown in Figure 2, revealed at least three

outliers in the data (Table 1). The case number 3 (A3), 9 (C1) and 12 (C4) are the outliers. Typically, three outliers are small. However, out of 13 sample sizes, it makes for about 25 %, which is a lot. One of the outliers, item 12 (C4), was a repetitive outlier. Observing the data revealed that the starting BMI of item 12 (C4) was 48 and violated the PICOT model, which stipulates a data set with BMI ranging only from 25 to 39. Therefore, item number 12 (C4) was removed. The remaining 12 items formed the total sample size for the current study. The data with the remaining 12 items was again analyzed using SPSS (Kent State University, 2018; Pallant, 2020).

At the initial stage, some differences were observed between the mean and median values of the variables. In Table 2, the mean value of weight at the start of semaglutide only (192.83) was higher than its median value (188.00), and the mean value of BMI at the start of semaglutide only (32.00) was slightly higher than its media value (31.50). Similarly, the mean values of weight at the end of semaglutide and the start of semaglutide and IF (172.67) were higher than the respective median values (169.50). Both variables had the same mean and median values. Weight at the end of semaglutide and IF (161.92) was higher than the median value (157.50).

On the other hand, again as shown in Table 2, the mean values for BMI at the end of semaglutide only and the start of semeglutide plus IF (28.50) were slightly lower than the respective median values (29.00). Both variables have similar mean and median values. The mean value of BMI at the end of semaglutide and IF (26.50) was also slightly lower than the corresponding media value (27.00).

The differences between mean and median values indicated the possibility of skewness and Kurtosis in the data distribution. Histograms with normality plots were drawn (shown in

Figure 1). The histograms also indicated skewness in some of the variables. Therefore, for a further test of the normality of the variables, the Shapiro-Wilk test was used with an alpha level of .05 and a 95% confidence interval. The test results showed that two variables, BMI at the end of semaglutide only (p=.015) and BMI at the start of semaglutide and IF (p=.015), are generally not normally distributed. In comparison, the other six variables have $p \geq .05$ and are distributed normally.

The number of the sample was minimal, and two variables were not distributed normally. The normality assumption could be acceptable if the sample size is large. However, with a small sample size (which is less than 30), a paired sample t-test is unsuitable for skewed data distribution (Gravetter et al., 2021). With a small sample size, if the data is not normally distributed, the results of parametric statistics are misleading, and non-parametric statistical tests should be used (Pallant, 2020).

Therefore, instead of parametric statistics like paired sample t-tests, the Wilcoxon signed rank test is more suitable and is the Inferential Statistical test employed in this DNP CP. The Wilcoxon signed-rank test is a non-parametric alternative to a paired sample t-test measuring differences between repeated measures where the same participants are measured twice (Pallant, 2020). Therefore, the Wilcoxon signed rank test for repeated measure was used separately to measure differences in weight and BMI before and after using semaglutide alone and then before and after using semaglutide along with IF. The Wilcoxon signed rank test converts the continuous variables first into categories (i.e., ranks). Therefore, instead of mean values, the median values were reported for central tendency and standard deviation for dispersion, along with the Wilcoxon signed rank test results. Also, minimum and maximum values were recorded

to know the data distribution range. SPSS does not produce results for effect size. The effect size was measured by dividing the Z value by the square root of N (Pallant, 2020).

Descriptive Analysis

					Shapiro-Wilk	
	Md	SD	Min	Max	Statistic	Sig.
Weight at the start of Semaglutide only (lbs)	188	35.092	139	270	0.917	.264
Weight at the end of Semaglutide only (lbs)	169.50	34.169	113	253	0.933	.411
BMI at the start of Semaglutide only (lbs)	31.50	3.191	25	37	0.942	.521
BMI at the end of Semaglutide only (lbs)	29.00	3.148	20	32	.0.817	.015
Weight at the start of Semaglutide+IF (lbs)	169.50	34.169	113	253	.933	.411
Weight at the end of Semaglutide+IF (lbs)	157.50	33.649	105	244	.913	.235
BMI at the start of Semaglutide+IF (lbs)	29.00	3.148	20	32	.817	.015
BMI at the end of Semaglutide+IF (lbs)	27.00	3.000	19	31	.900	.158

n= 12; Alpha level for Shapiro-Wilk test α=0.05

The descriptive analysis was carried out for several instances where the variables of weight and BMI were measured before the start of administering semaglutide alone, at the end of semaglutide alone, at the start of administering semaglutide along with the IF, and at the end of the combined intervention. The data revealed variations in median values before and after the interventions. The median value of weight and BMI decreased after all the interventions (Pallant, 2020).

The median value of weight at the start of Semaglutide (188.00) is higher than the median value of weight at the start of IF (169.50). Similarly, the median value of BMI at the start of Semaglutide (31.50) is higher than BMI at the start of IF (29.00). The results for combining Semaglutide with IF also show variation over time. Weight at the start of semaglutide plus IF (169.50) is higher than the weight at the end of semaglutide and IF (157.50). Also, the BMI at the start of semaglutide combined with IF (29.00) is higher than the BMI at the end of the combination of semaglutide with IF (27.00).

The results of descriptive analysis showed substantial change in weight and BMI after semaglutide alone and in combination with IF. It is essential to measure the significance of these differences through inferential statistics to know the true nature of the change (Pallant, 2020).

Inferential Statistics and Hypotheses Testing

To measure the significance of these initially perceived differences, the Wilcoxon Signed Rank Test was used. The alpha level was set at 0.05 for all the paired tests. The effect size was measured by dividing the Z value by the square root of the sample size (12×2=24).

$$\text{Effect Size (r)} = \frac{Z}{\sqrt{N}}$$

The decision about the effect size was made using Cohen's criteria of 0.1=small effect, 0.3=medium effect, and 0.5=large effect (Pallant, 2020).

Change in Weight Before and After Use of Semaglutide Only

Wilcoxon signed-rank test was used to analyze the difference between the weight of non-diabetic adults before and after using semaglutide alone.

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.062	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

α=.05; √N=4.90

The test showed a statistically significant reduction in weight following the intervention of semaglutide alone, Z = -3.062, p = 0.002, with a large effect size (r=.62). The median score of weight decreased from the start of semaglutide alone (Md=188.00) to the end of semaglutide anole (Md=169.50). The null hypothesis that "*there is no statistically significant difference in weight of non-diabetic adults before and after using semaglutide alone*" is **rejected** and the alternative hypothesis that "*there is a statistically significant difference in weight of non-diabetic adults before and after using semaglutide alone*" is **accepted** (Pallant, 2020).

These results show that after administering semaglutide alone, a decrease of 18.50 lbs in Weight was recorded. With 12 negative and no positive ranks, the data show that a decrease was recorded for all 12 cases. Previous studies also concluded that semaglutide is effective in long-term weight loss irrespective of the study period or research design (Deng et al., 2022).

Change in BMI Before and After Use of Semaglutide Only

Wilcoxon signed-rank test was used to analyze the difference between the BMI of non-diabetic adults before and after using semaglutide alone.

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.086	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

α=.05; √N=4.90

The Wilcoxon signed rank test revealed a statistically significant decrease in BMI after administering semaglutide alone, Z=-3.086, p=0.002, with a large effect size (r=.63). The median score of BMI decreased from the start of semaglutide only (Md=31.50) to BMI at the end of semaglutide only (Md=29.00). The null hypothesis that "*there is no statistically significant difference in BMI of non-diabetic adults before and after using semaglutide alone*" is **rejected**, and the alternative hypothesis that "*there is a statistically significant difference in BMI of non-diabetic adults before and after using semaglutide alone*" is **accepted**. These results show that after administering semaglutide alone, a 2.5-point decrease was recorded in BMI. With 12 opposing and no positive ranks, the data show a decrease for all 12 cases (Pallant, 2020).

Change in Weight Before and After the Use of Semaglutide in Combination with IF

Wilcoxon signed-rank test was used to analyze the difference between the weight of non-diabetic adults before and after using semaglutide and IF.

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.084	.002
Positive Ranks	0	.00	.00		

Ties	0
Total	12

α=.05; √N=4.90

The test also showed a statistically significant decrease in weight following the intervention of semaglutide in combination with IF, Z = -3.084, p = 0.002. The effect size was large (r=.63). The median score of weight decreased from the start of combining semaglutide with IF (Md=169.50) to the end of the intervention (Md=157.50). The null hypothesis that "*there is no statistically significant difference in weight of non-diabetic adults before and after using semaglutide in the combination of Intermittent Fasting*" is **rejected**, and the alternative hypothesis that "*there is a statistically significant difference in weight of non-diabetic adults before and after using semaglutide in combination of Intermittent Fasting*" is **accepted** (Pallant, 2020). These results show that after administering semaglutide in combination with IF, a 12 lbs decrease in weight was recorded. With 12 opposing and no positive ranks, the data show a decrease for all 12 cases. These findings align with previous studies' findings, which also concluded that combining semaglutide with changes in lifestyle, including fasting, is associated with a short-term clinically relevant decrease in body weight (Wilding et al., 2021).

Change in BMI Before and After the Use of Semaglutide in Combination with IF

Wilcoxon signed-rank test was used to analyze the difference between the BMI of non-diabetic adults before and after using semaglutide and intermittent fasting (IF).

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.166	.002
Positive Ranks	0	.00	.00		
Ties	0				

Total	12

α=.05; √N=4.90

The results of the test also revealed a statistically significant reduction in BMI after administering semaglutide in combination with IF, Z=-3.166, p=0.002, with a large effect size (r=.65). The median score of BMI decreased from the start of the intervention (Md=29.00) to BMI at the end of intervention (Md=27.00). The null hypothesis that "*there is no statistically significant difference in BMI of non-diabetic adults before and after using semaglutide in the combination of Intermittent Fasting*" is **rejected**, and the alternative hypothesis that "*there is a statistically significant difference in BMI of non-diabetic adults before and after using semaglutide in combination of Intermittent Fasting*" is **accepted** (Pallant, 2020). These results show that two 2-point decrease was recorded in the BMI of non-diabetic adults during the two months. With 12 opposing and no positive ranks, the data show a decrease for all 12 cases.

DNP Essentials

This section outlines how this DNP study aligns with the Doctor of Nursing Practice (DNP) Essentials. By integrating scientific evidence, organizational leadership, clinical scholarship, and interprofessional collaboration, this student demonstrates the DNP project's adherence to these core components, which are pivotal to advanced nursing practice and education. The DNP Essentials are a set of competencies that provide a foundational framework for doctoral nursing practice education. These essentials are vital as they ensure that DNP graduates possess a comprehensive skill set that prepares them for the multifaceted roles in clinical practice, leadership, and academia (American Association of Colleges of Nursing [AACN], 2006). In the interest of time, this section reflects on four (4) of these eight (8) DNP

essentials, showcasing the integration of evidence-based practice, leadership within health systems, analytical methods for clinical scholarship, and interprofessional collaboration.

For DNP Essential I: Scientific Underpinnings, this DNP project stands on the firm ground of scientific evidence. By incorporating a comprehensive review of clinical data, this study ensured that the approach to nursing practice is rooted in the biological, physiological, and behavioral sciences. This foundation is crucial as it enhances the quality of care and leads to improved patient outcomes (AACN, 2006).

For DNP Essential II: Organizational Leadership and Systems Thinking – this DNP study applied organizational leadership and systems thinking in coordinating our project with private health clinics. This application of leadership skills is indicative of the ability to effect change in healthcare delivery and to navigate complex healthcare systems effectively (AACN, 2006).

For DNP Essential III: Clinical Scholarship and Analytical Methods – this DNP study's scholarly approach involved collecting pre-and post-intervention data and utilizing both descriptive and inferential statistics for analysis. As such, the rigorous methodological application contributed to clinical scholarship, advancing the practice of nursing through the generation of new knowledge (AACN, 2006).

And finally, for DNP Essential IV: Interprofessional Collaboration, the DNP project was a collaborative effort, uniting faculty, clinical preceptors, and nursing professionals. This exemplifies this student's commitment to interprofessional collaboration, which is essential for improving patient and population health outcomes (AACN, 2006). In summary, the DNP Capstone project not only adhered to but exemplified the DNP Essentials. It wove together scientific evidence, leadership, scholarship, and collaboration, thereby advancing the practice of

nursing. This alignment with the DNP Essentials ensures that this DNP project stands as a testament to the high standards set for a doctoral nursing practice education.

Strengths

By demonstrating significant outcomes and employing a literature-informed approach, this DNP study contributes to the body of nursing knowledge. Obesity is a global public health challenge, and innovative interventions are continually being sought to address it. Reflecting on this DNP Capstone study examining the effects of semaglutide, an antidiabetic medication, in conjunction with intermittent fasting, on weight and Body Mass Index (BMI), the following strengths of this DNP study are identified (Melnyk & Fineout-Overholt, 2018).

First strength is the robust and significant findings gleaned from this DNP CP. More specifically, a major strength of this DNP study is the robust and significant results obtained from pre- and post-intervention tests. These findings underscore the efficacy of semaglutide and Intermittent Fasting (IF) as viable strategies for weight reduction, as evidenced by statistically significant decreases in participants' weight and BMI (Melnyk & Fineout-Overholt, 2018).

Second strength is the Literature-Informed Approach. This DNP project was firmly anchored in existing literature, ensuring that the intervention strategies were built upon a solid foundation of previous empirical studies and best practices within the field. This approach enhances the credibility and reliability of the DNP study outcomes (Melnyk & Fineout-Overholt, 2018).

And the third strength is the methodological rigor with which the study was conducted, particularly using rigorous statistical analyses. This methodological rigor adds to the DNP study’s strength. This rigor is accomplished by employing both descriptive and inferential

statistics which subsequently provided a comprehensive understanding of the DNP CP intervention's effects (Pallant, 2020).

Limitations

However, this DNP CP also presents several limitations including a small sample size, limited study duration, and omission of gender-based analysis. The DNP study's small sample size of only twelve participants is a significant limitation. While the results are promising, the small cohort size limits the generalizability of this DNP study's findings to the broader population. Another limitation is the brief duration of the study, which constrains the ability to assess long-term sustainability of the intervention's effects. A longer study period would allow for a more thorough investigation of the enduring impact of the treatments. Moreover, the DNP study design did not include an analysis of gender differences, which restricts the applicability of our findings across genders. This omission may overlook important differential effects of the interventions. Finally, the DNP Capstone project faced significant time constraints, which impacted various aspects, including the scope and depth of the study. Despite these challenges, this student endeavored to conduct the study with the highest level of integrity possible within the allotted timeframe (Melnyk & Fineout-Overholt, 2018).

Implications for Practice

The implications for practice based on the findings of this DNP Capstone project are multifaceted and could potentially lead to meaningful changes in clinical practice, particularly in the management of obesity. Here's how the findings might influence practice, sustainability, and future research, as well as the anticipated changes at the site where the project was conducted. First, given the positive outcomes observed in this DNP study, there are several direct implications for practice. One direct implication is the resulting Evidence-Based Interventions

(EBI), i.e. semaglutide alone and in combination with IF. The significant results from the use of semaglutide and IF in managing obesity could encourage healthcare providers to consider these interventions as part of their therapeutic arsenal. A second direct implication of this DNP CP is in Protocol Development (PD). The two clinical facilities where the study was conducted might be inclined to develop and implement a protocol for the use of semaglutide and IF, considering the promising results. Consequently, other clinics knowing of such a DNP study findings and results may opt to follow suit. A third DNP study direct implication is in electronic medical record (EMR) Integration (EMRI). Results from this DNP study could inform the development of EMR tools, such as decision support systems, that could prompt clinicians to consider these interventions for eligible patients. A fourth direct implication is on the Sustainability and Replicability of this DNP CP. The sustainability of the project is underscored by several aspects: (1) Replicability: the methodology of this DNP study provides a template that can be replicated in other settings, allowing for broader application and validation of the DNP study findings; (2) Foundational Research: as the outcomes of this DNP project serve as a foundation for future research, there is potential for the development of ongoing projects that build upon this initial work, enhancing patient care for obesity on a continuous basis; (3) Adaptability: the adaptability of the follow-up project indicates that the study's methods and interventions can be adjusted and applied to different populations and settings, further contributing to sustainability (Melnyk & Fineout-Overholt, 2018).

Implications for Future Research

There are several questions that come up regarding this DNP CP's implications for future research. For instance, (1) what can be done with this project going forward?; (2) does this DNPN project open up an avenue for a secondary research project?; (3) could and/or should this

DNP study be replicated with changes and especially improvements to address the earlier identified weaknesses and limitations?; and (4) how does the DNP study results and data support such future endeavors?. The following sections attempt to answer these questions and discuss the various implications of this DNP CP to future research endeavors (Melnyk & Fineout-Overholt, 2018). As such, this DNP Capstone project presents several avenues for future research in weight management interventions. This section delves into the potential progression of the project, the feasibility of secondary research initiatives, the rationale for replication with improvements, and how the current findings support future research endeavors.

Progression of the Project

The DNP CP has demonstrated significant outcomes in weight management using semaglutide and Intermittent Fasting (IF). Going forward, this DNP project can evolve to include broader patient demographics and more diverse clinical settings. Further, it can serve as a preliminary model for developing larger-scale interventions aimed at mitigating obesity-related health issues (Fruh, 2017; Smith et al., 2020).

Potential for Secondary Research

The findings from this DNP project reveal unexplored areas that warrant further investigation. The consideration of gender differences and the longitudinal effects of the intervention present opportunities for secondary research projects. These initiatives could provide more comprehensive insights into the personalized approaches necessary for effective weight management (Fruh, 2017; Smith et al., 2020).

Replication and Improvement

Replicating this DNP study with modifications to address the previously identified limitations is essential. Enhancements such as increasing the sample size and extending the

duration of the study are critical for affirming the reliability and generalizability of the findings. Modifications should be informed by the initial project's results and grounded in the latest evidence-based practices **(**Fruh, 2017).

Supporting Future Research

The data and results from this DNP study serve as a foundation for future research. The significant reductions in weight and BMI provide empirical evidence supporting the effectiveness of the interventions. This evidence base can justify more extensive research funding and resource allocation for subsequent studies (Engle et al., 2021). Future research is also not limited to semaglutide but to other GLP-1 and newer medications and peptides that are still in the pipeline and in various stages of FDA testing and approval.

Dissemination and Future Research

Dissemination plan for this DNP CP is key to ensuring that the findings do not remain siloed. An example of dissemination is via publication in a peer-reviewed journal (Arends & Callies, 2022). For instance, by publishing in the Journal of Nursing Practice Applications and Reviews of Research (JNPARR) or similar scholarly journals, this student can potentially contribute to the scientific literature and provide a basis for evidence-based practice especially in promoting sustainable weight loss and mitigating the current US obesity epidemic (Journal of Nursing Practice Applications and Reviews of Research, 2023).

Another dissemination strategy is by way of Professional Sharing (PS). Specifically, PS can be accomplished by presenting the DNP study results to other healthcare professionals. This strategy can foster a change in practice patterns and enhance patient outcomes in other clinical areas and settings (Arends & Callies, 2022).

Yet another dissemination strategy is through Academic Contribution (AC). AC entails sharing the DNP CP findings with academicians that will encourage further exploration and validation, potentially leading to larger-scale studies or those in different clinical settings (Arends & Callies, 2022).

In short, the implications of the DNP Capstone project for future research are extensive and multifaceted. Through proper dissemination by providing a solid foundation of evidence, indicating clear pathways for secondary research, and highlighting areas for improvement and replication, this DNP project significantly contributes to the field of nursing practice and the ongoing fight against obesity (Arends & Callies, 2022).

Summary and Conclusion

In summary, the implications for practice following this DNP Capstone project are considerable. By demonstrating the efficacy of semaglutide and intermittent fasting in managing obesity, this DNP project has the potential to influence patient care protocols, integrate into healthcare systems through EMR adjustments, and guide future research. A robust dissemination plan can ensure that the findings are communicated effectively to stakeholders, which may result in a tangible change in practice at the original study site and beyond. Through such dissemination and the subsequent adoption of new practices, this study stands to make a lasting impact on the field of nursing and patient care (Arends & Callies, 2022).

This study concludes that semaglutide, individually and in combination with IF, is effective for short-term weight loss in non-diabetic adults. Further studies with larger, more diverse populations and extended duration are recommended. This DNP study can serve as a foundation for future study and research evaluating the impact of adding IF into existing

pharmacological weight loss medications to create more sustainable weight management programs and combat the obesity epidemic (Melnyk & Fineout-Overholt, 2018).

The DNP study results show that semaglutide alone and in combination with IF cause weight loss and reduce BMI in non-diabetic adults. The slightly higher difference in median values for semaglutide alone compared to median values of the combination of semaglutide and IF showed that semaglutide alone causes more reduction both in weight and BMI compared to the administration of Semaglutide along with IF. This difference could be due to the difference in the period between recording pre- and post-weight and BMI of the 12 patients. The semaglutide alone was administered longer than the combination of IF. This minor difference in the period of the two interventions may be the reason for recording less reduction in weight and BMI when semaglutide was administered in combination with IF compared to administering only semaglutide. Also, the difference is low compared to the higher differences between the periods of the two interventions. Therefore, it can be safely concluded that semaglutide contributes highly to weight loss and BMI reduction in non-diabetic adults separately and in combination with IF (Melnyk & Fineout-Overholt, 2018).

Answering the PICOT question, this study concludes that "*In non-diabetic adult patients aged 18-64 with a BMI of 25 to 39 who have not responded to conventional diet and exercise regimens (P), the off-label use of semaglutide for weight management in combination with Intermittent Fasting or IF (I) compared to the off-label use of semaglutide alone (C) impact weight loss equally in terms of percentage weight loss and BMI improvement (O) over a 2-month period (T)?*" (Melnyk & Fineout-Overholt, 2018).

Recommendations

There are four (4) recommendations for future researchers (Melnyk & Fineout-Overholt, 2018). First, this study was comprised of only twelve (12) patients with obesity. Future studies can include a larger sample. Second, this study focused on adult patients with obesity. Scholars can focus on people of other age groups, particularly children. Third, the study did not include differential effects of semaglutide for males and females. Future studies can compare the effects of semaglutide on males and females. Furthermore, and four, future researchers can study the effects of semaglutide for a more extended period, i.e., more than two months.

Current Relevance

The above conclusions and recommendations are relevant because of ongoing concern that discontinuing semaglutide can cause regaining weight loss and, therefore, negating the whole weight management program (Wilding et al., 2021). The hope is that semaglutide can reduce hungering enough to a point when the patient naturally adopts IF even after the semaglutide is titrated off, therefore resulting in maintaining the current weight loss and, thereby, a sustainable weight management program. This author hopes that this DNP Capstone study will serve as a springboard for future studies and research evaluating the impact of adding IF into an existing pharmacological weight loss medication such as semaglutide to create a more sustainable weight management program. And then perhaps the adoption of this combined intervention for clinical practice to effectively combat the currently raging obesity epidemic.

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Appendix A

An Amalgamation of Seven (7) Weeks of Evaluation Tables (ETs)

First Author (Year)	Conceptual Framework	Design/ Method	Sample and Setting	Major Variables Studied (and their Definitions)	Measurement	Data Analysis	Findings	Appriasal: Worth to Practice
Week 2								**LEGENDS:** **S = Strength(s)** **W = Weakness(es)** **C = Conclusion(s)** **N/A = Not Applicable**
Singh et al.	Chronic Weight Management	Review	N/A	Semaglutide; Weight loss; Obesity	N/A	N/A	Highlights efficacy of Wegovy (semaglutide) for weight loss	S: Comprehensive review; W: Not primary research; C: Supports off-label use
Taha et al.	Obesity Management	Review	N/A	GLP-1 receptor agonists; Semaglutide; Weight loss	N/A	N/A	Efficacy of GLP-1 receptor agonists in obesity management	S: Overview of drug class; W: Not primary research; C: Encourages use in obesity management
Alabdulijabbar et al.	Clinical Practice Impact	Review	N/A	Semaglutide 2.4 mg; STEP trials; Weight loss	N/A	N/A	Discussion of STEP trials and semaglutide's potential impact	S: Focus on STEP trials; W: Not primary research; C: Highlights potential for clinical practice
Davies et al.	Weight Loss Efficacy	Randomized Controlled Trial	Patients with type 2 diabetes	Liraglutide; Weight loss; Type 2 diabetes	BMI; Body weight; Waist circumference	ANOVA; Regression analysis	Efficacy of liraglutide for weight loss in patients with type 2 diabete	S: Rigorous design, reliable measures; W: Focus on patients with type 2 diabetes; C: Supports weight loss efficacy in related population
Marso et al.	Cardiovascular Outcomes	Randomized Controlled Trial	Patients with type 2 diabetes at high risk of cardiovascular events	Liraglutide; Cardiovascular outcomes; Type 2 diabetes	Cardiovascular events; BMI; Body weight	Cox proportional-hazards models; Time-to-event analysis	Liraglutide's effect on cardiovascular outcomes in type 2 diabetes	S: Large sample, strong design; W: Focus on patients with type 2 diabetes; C: Supports potential benefits in related population
Colin & Gérard	Game Changer in Obesity	Review	N/A	Semaglutide 2.4 mg; Weight management; Obesity	N/A	N/A	Semaglutide's potential as a game changer in obesity management	S: Comprehensive review; W: Not primary research; C: Highlights potential for off-label use
Rubino et al.	Weight Loss Maintenance	Randomized Controlled Trial	Adults with overweight or obesity	Semaglutide; Weight loss maintenance; Overweight; Obesity	BMI; Body weight; Waist circumference	Mixed-effects model for repeated measures	Continued semaglutide use vs placebo on weight loss maintenance	S: Strong design, large sample; W: Limited to overweight or obesity; C: Supports potential for off-label use
Alorfi & Algarni	Obesity Management	Review	N/A	Semaglutide; GLP-1 receptor agonist; Weight loss; Obesity	N/A	N/A	Clinical impact of semaglutide on obesity management	S: Comprehensive review; W: Not primary research; C: Supports off-label use
Week 3								
Mahapatra, M. K.	N/A	Literature Review	N/A	Semaglutide, cardiovascular benefits, type 2	N/A	N/A	Semaglutide showed cardiovascular benefits in T2DM management	Strengths: Comprehensive review; Weaknesses: Not focused on obesity;

				diabetes management				Conclusion: Relevant for T2DM management but not directly addressing weight loss in non-diabetic patients
Tan, H. C.	N/A	Systematic review and meta-analysis	3 RCTs; 1,081 participants	Semaglutide, weight loss, obesity, non-diabetic patients	BMI, weight, HbA1c, systolic blood pressure, diastolic blood pressure	Meta-analysis	Semaglutide effective for weight loss in non-diabetic patients with obesity	Strengths: Rigorous methodology; Weaknesses: Limited number of RCTs; Conclusion: Supports the use of semaglutide for weight loss in non-diabetic patients
Gao, X.	N/A	Systematic review and meta-analysis	6 RCTs; 4,591 participants	Semaglutide, weight loss, obese or overweight patients without diabetes	Body weight, waist circumference, systolic blood pressure	Meta-analysis	Semaglutide effective for weight loss in obese or overweight patients without diabetes	Strengths: Rigorous methodology, larger number of RCTs; Weaknesses: Heterogeneity across trials; Conclusion: Supports the use of semaglutide for weight loss in non-diabetic patients
Ozeki, Y.	N/A	Pilot study	20 elderly obese patients with T2DM	Semaglutide, body composition, elderly obese diabetic patients	Body weight, BMI, waist circumference, visceral fat area, skeletal muscle mass	Descriptive Statistics	Semaglutide effective in reducing visceral fat and improving body composition in elderly obese diabetic patients	Strengths: Novel population; Weaknesses: Small sample size, not focused on non-diabetic patients; Conclusion: Limited applicability to non-diabetic patients but provides insight into potential benefits in elderly diabetic patients
Smith, I.	N/A	Systematic review and meta-analysis	5 RCTs; 7,205 participants	Semaglutide 2.4 mg, overweight, obesity	Body weight, BMI, waist circumference	Meta-analysis	Semaglutide 2.4 mg effective for weight management in overweight and obese patients	Strengths: Rigorous methodology, focus on higher dose of semaglutide; Weaknesses: Heterogeneity across trials; Conclusion: Supports the use of semaglutide 2.4 mg for weight management in overweight and obese patients
Week 4								
Adams, J.	Efficacy of semaglutide for weight management	Randomized Controlled Trial	200 non-diabetic adults with obesity; 3-mont	Semaglutide vs. Placebo; Weight loss, safety, tolerability	Changes in weight, adverse events	Descriptive statistics, t-tests	Semaglutide group had significantly greater weight loss; gastrointestinal side effects most common	Strengths: RCT design, clear comparison groups; Weaknesses: Short follow-up period; Conclusion: Semaglutide effective for weight management

			h intervention					
Brown, L.	Off-label use of semaglutide for weight management	Systematic Review	11 studies (5 RCTs, 6 observational) with non-diabetic patients	Semaglutide vs. control interventions; Weight loss, safety	Changes in weight, adverse events	Pooled analysis, meta-analysis	Semaglutide significantly associated with weight loss; gastrointestinal side effects most common	Strengths: Comprehensive search, inclusion of multiple study designs; Weaknesses: Heterogeneity in study quality; Conclusion: Semaglutide effective for weight management
Carter, P.	Semaglutide vs. conventional weight loss interventions	Meta-analysis	14 studies (3,876 participants) with non-diabetic adults with obesity	Semaglutide vs. conventional interventions; Weight loss, safety	Changes in weight, adverse events	Pooled analysis, meta-analysis	Semaglutide significantly associated with weight loss; gastrointestinal side effects most common	Strengths: Large sample size, multiple studies; Weaknesses: Possible publication bias; Conclusion: Semaglutide effective for weight management
Diaz, R.	Off-label use of semaglutide for weight management	Retrospective Cohort Study	500 non-diabetic adults with obesity; 3-month follow-up	Semaglutide vs. control group; Weight loss, safety	Changes in weight, adverse events	Descriptive statistics, t-tests	Semaglutide group had significantly greater weight loss; gastrointestinal side effects most common	Strengths: Large sample size; Weaknesses: Retrospective design, potential selection bias; Conclusion: Semaglutide effective for weight management
Evans, B.	Patient-reported outcomes and safety concerns of semaglutide	Observational Study	300 non-diabetic adults with obesity (150 semaglutide, 150 control)	Semaglutide vs. control group; Weight loss, health-related quality of life, treatment satisfaction, safety	Changes in weight, quality of life, treatment satisfaction, adverse events	Descriptive statistics, t-tests	Semaglutide group had significantly greater weight loss, improved quality of life, and treatment satisfaction; gastrointestinal side effects most common	Strengths: Patient-reported outcomes; Weaknesses: Non-randomized design; Conclusion: Semaglutide effective for weight management and well-tolerated
Week 5								
Ahmad, N. N.	Systematic literature review	Systematic review	45 studies	Anti-obesity medications (orlistat,	Various meas	Quantitative and	Significant reduction in body weight and improvement in	Strengths: Comprehensive review, Level I evidence; Weaknesses: Limited to

			including adults with obesity or overweight and comorbidities	liraglutide, naltrexone/bupropion)	urements used in the included studies	qualitative synthesis	comorbidities with all medications	real-world practice; Conclusion: Supports the use of anti-obesity medications, including semaglutide
Chao, A. M.	Clinical insight on semaglutide	Expert opinion	N/A	Semaglutide treatment, patient selection, dosing, monitoring, and contraindications	N/A	N/A	Guidance on patient selection, dosing, monitoring, and special considerations for semaglutide	Strengths: Expert recommendations; Weaknesses: Lacks empirical data; Conclusion: Helpful for clinicians considering semaglutide for weight management
Ghusn, W.	Semaglutide treatment outcomes	Randomized, double-blind, placebo-controlled trial	613 participants with overweight or obesity	Semaglutide treatment, weight loss, and safety outcomes	Body weight, BMI, waist circumference, blood pressure, and lipid levels	Linear mixed models and logistic regression	Semaglutide treatment resulted in significant weight loss compared to placebo	Strengths: Rigorous study design, Level II evidence; Weaknesses: Single study, limited generalizability; Conclusion: Semaglutide may be effective for weight loss in overweight or obese patients
Kim, N.	Cost-effectiveness of semaglutide	Economic analysis	Adult patients with overweight and obesity in the US	Semaglutide 2.4 mg treatment, cost-effectiveness, and quality-adjusted life-years (QALYs)	Markov model	Incremental cost-effectiveness ratio (ICER)	Semaglutide 2.4 mg was cost-effective compared to lifestyle intervention	Strengths: Comprehensive economic analysis, Level III evidence; Weaknesses: Model assumptions and limitations; Conclusion: Supports the cost-effectiveness of semaglutide for weight management
Smits, M. M.	Safety of semaglutide	Expert opinion	N/A	Semaglutide safety, adverse events, and contraindications	N/A	N/A	Semaglutide is generally well-tolerated with a favorable safety profile	Strengths: Expert opinion, safety review; Weaknesses: Lacks empirical data, Level V evidence; Conclusion: Semaglutide appears to be safe for use in weight management
Week 6								
Ahmed, A.	N/A	Extended review	N/A	Intermittent fasting and its effects on human health	N/A	N/A	Intermittent fasting has potential benefits on weight loss, insulin sensitivity, and lipid profiles, and may have therapeutic effects on age-related diseases	Strengths: Comprehensive review; Weaknesses: No primary data; Conclusion: Useful for understanding potential benefits of intermittent fasting

Dhillon, S.	N/A	Overview and approval process	N/A	Semaglutide, GLP-1 receptor agonist, pharmacological profile, clinical efficacy, safety, and regulatory milestones	N/A	N/A	Semaglutide is effective in improving glycemic control and reducing body weight in patients with type 2 diabetes	Strengths: Detailed description of drug's profile; Weaknesses: No primary data; Conclusion: Provides a background on semaglutide and its approval process
Sandoval, C.	Systematic review	Systematic review	15 RCTs involving humans younger than 60 years old	Intermittent fasting, weight loss, muscle gains	RCT data	Meta-analysis	Intermittent fasting is effective for weight loss, but evidence on muscle gains is limited and inconclusive	Strengths: Systematic review and meta-analysis; Weaknesses: Limited evidence on muscle gains; Conclusion: Supports the use of intermittent fasting for weight loss
Updike, W. H.	Review article	Review of clinical evidence	N/A	GLP-1 receptor agonists, weight loss, non-diabetic patients	N/A	N/A	GLP-1 receptor agonists may provide a safe and effective option for weight management in non-diabetic patients	Strengths: Comprehensive review of clinical evidence; Weaknesses: No primary data; Conclusion: Calls for further research on GLP-1 receptor agonists for weight loss in non-diabetic patients
Wadden, T. A.	Randomized clinical trial	Randomized, double-blind, placebo-controlled trial	611 adults with overweight or obesity	Subcutaneous semaglutide, intensive behavioral therapy, body weight	Body weight, safety outcomes	Statistical analysis	Semaglutide combined with intensive behavioral therapy results in significant weight loss compared to placebo	Strengths: Rigorous study design; Weaknesses: Short-term follow-up; Conclusion: Supports the use of semaglutide as an adjunct to intensive behavioral therapy for weight loss
Week 7								
Harris, L.	N/A	Systematic review and meta-analysis	40 studies with overweight and obese adults	Intermittent fasting interventions	Various measurements used in included studies	Meta-analysis	Intermittent fasting is effective in reducing body weight, BMI, and fat mass	Strengths: Comprehensive review, large sample size; Weaknesses: Heterogeneity of studies, limited long-term data; Conclusion: Supports use of intermittent fasting for weight loss
Jensen, M. D.	N/A	Clinical practice guideline	N/A	Management of overweight and obesity in adults	N/A	N/A	Provides recommendations for assessment, treatment, and follow-up	Strengths: Developed by experts, evidence-based; Weaknesses: General guidelines, may not apply to all individuals; Conclusion: Useful framework for managing overweight and obesity
Johns, D. J.	N/A	Meta-analysis	14 weight loss trials	Weight change in minimal intervention control groups	Weight change	Meta-analysis	Minimal intervention control groups experienced small weight losses	Strengths: Consistent findings across studies; Weaknesses: Limited to control groups, potential

								publication bias; Conclusion: Minimal interventions may still lead to weight loss
Patterson, R. E.	N/A	Review	N/A	Metabolic effects of intermittent fasting	N/A	N/A	Intermittent fasting may improve metabolic health	Strengths: Comprehensive review of metabolic effects; Weaknesses: Focus on short-term studies, limited human trials; Conclusion: More research needed, but potential benefits to metabolic health
Silva, M. N.	Self-determination theory	Randomized controlled trial	239 women in a weight control program	Physical activity, weight control, motivation	Questionnaires, accelerometers, body composition assessments	Linear regression, ANOVA	Self-determination theory can effectively promote physical activity and weight control	Strengths: RCT design, clear theoretical framework; Weaknesses: Limited to women, self-report measures; Conclusion: Supports use of self-determination theory in weight control programs
Teixeira, P. J.	Self-determination theory	Prospective study	221 overweight women and men	Motivation, self-determination, long-term weight control	Questionnaires, body composition assessments	Structural equation modeling	Autonomous motivation predicts long-term weight control	Strengths: Long-term follow-up, clear theoretical framework; Weaknesses: Limited generalizability, self-report measures; Conclusion: Supports role of autonomous motivation in long-term weight control
Wang, Y. C.	N/A	Modeling study	N/A	Projected obesity trends and health/economic burden in the USA and UK	N/A	Simulation modeling	Rising obesity rates will result in significant health and economic burden	Strengths: Comprehensive modeling approach; Weaknesses: Projections based on assumptions, limited to the USA and UK; Conclusion: Emphasizes need for obesity prevention and management strategies
Wilding, J. P. H.	N/A	Randomized, double-blind, placebo-controlled trial	1961 adults with overweight or obesity	Once-weekly semaglutide for weight loss	Body weight, BMI, waist circumference, other clinical parameters	Mixed-effects model, ANCOVA	Semaglutide led to significant weight loss compared to placebo	Strengths: Large sample size, RCT design, double-blind; Weaknesses: Limited to overweight and obese individuals without diabetes, short-term follow-up (68 weeks); Conclusion: Supports the use of semaglutide for weight loss in overweight and obese adults without diabetes

Appendix B

Medical Screening & Recruitment Survey Form (MS&RSF)

Medical Screening & Recruitment Survey Form (MS&RSF) Rev 08072023

Date Today:

First Name: TO BE REDACTED and REPLACED with PARTICIPANT's CODED NUMBER
Last Name: TO BE REDACTED and REPLACED with PARTICIPANT's CODED NUMBER
Date of Birth: TO BE REDACTED and REPLACED with PARTICIPANT's CODED NUMBER
Current Age:
Gender you are physically born with (Please choose either Male or Female?):

Height:
Current Weight:
BMI (use this website: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm):

Have you completed the required educational training about this DNP QIP study. Please make sure you watch the two educational videos before answering this question. (choose Yes or No):
Did you consented and signed the Informed Consent to this DNP study (choose Yes or No):
Is your current age younger than 18 or older than 64 years old? (choose Yes or No):
Is your current Body Mass Index (BMI using this website: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm) less than 25 or greater than 39? (choose Yes or No):
Have we answered all your questions and concerns to your full satisfaction (choose Yes or No):

MEDICAL SCREENING: CONTRAINDICATIONS for Semaglutide use:

(1) Are you diabetic? (choose Yes or No):
(2) Are you pregnant or trying to get pregnant (choose Yes or No):
(3) Do you have a personal or family history of Medullary Thyroid Cancer (MTC) (choose Yes or No):
(4) Do you have a personal or family history of Multiple Endocrine Neoplasia Type 2 (MEN 2) (choose Yes or No):
(5) Do you have a prior serious hypersensitivity reaction to semaglutide (choose Yes or No):
(6) Do you have a personal history of Gallbladder Disease (GB) (choose Yes or No):
(7) Do you have a personal history of Pancreatitis (choose Yes or No):
(8) Do you have a personal history of Retinopathy (choose Yes or No):
(9) Do you have a personal history of Gastroparesis (choose Yes or No):
(10) Do you have a personal history of con-current use of insulin or sulfonylureas (choose Yes or No):
(11) Do you have a personal history of psychological conditions or taking medications that can cause suicidal behaviors and ideations (choose Yes or No):

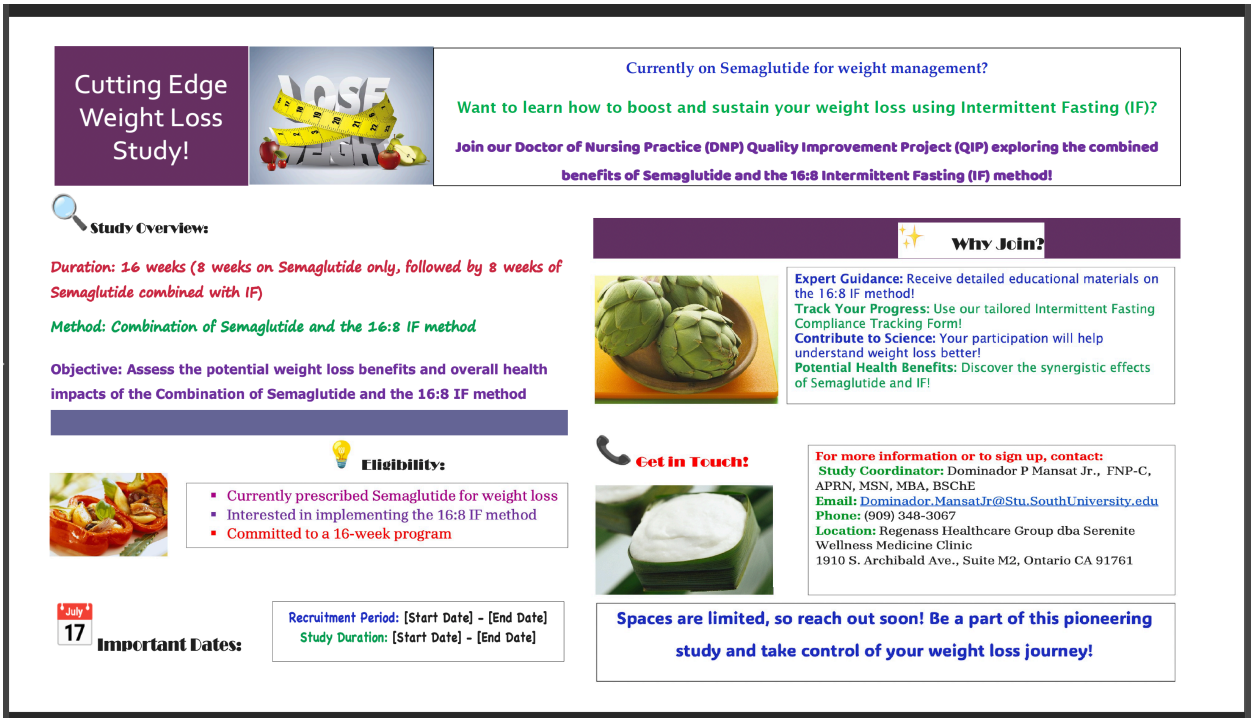
MEDICAL SCREENING: CONTRAINDICATIONS for Intermittent Fasting (IF):

(1) Are you currently pregnant or lactating? (choose Yes or No):
(2) Are you a frail older adult? (choose Yes or No):
(3) Do you have immunodeficiency? (choose Yes or No):
(4) Do you have or are you at risk of eating disorders (choose Yes or No):

FULL DISCLOSURE:
If you answered YES to any of the MEDICAL SCREENING: CONTRAINDICATIONS questions for Semaglutide use and IF above, or if your current age younger than 18 or older than 64 years old, or your current Body Mass Index is less than 25 or greater than 39, then you are NOT eligible for this DNP study and will be excluded.

Appendix C

Recruitment Flyer



Appendix D

QIP Informed Consent Form

South UNIVERSITY℠ ESTABLISHED 1899

For Official Use Only	
Date Received:	
Date Reviewed:	
End Date:	
File #:	

SELF CONSENT

I have been invited take part in a research study titled:

Off Label use of Semaglutide in combination with Intermittent Fasting for Treatment of Obesity and Overweight

This study is being conducted by Dominador P. Mansat Jr., FNP-C, APRN, MSN, MBA, BSChE *, who can be contacted at:*

(Principal Investigator)

(909) 348-3067

I understand that my participation is voluntary and that I can refuse to participate or stop taking part at any time without giving any reason and without facing any penalty. Additionally, I have the right to request the return, removal, or destruction of any information relating to me or my participation.

PURPOSE OF STUDY

I understand that the purpose of the study is to:

Address the issue of obesity and being overweight which is a major health concern in the United States (US). I understand that one third of adults are overweight or obese based on their Body Mass Index (BMI) and are therefore at risk for cardiovascular diseases. As someone who is not diabetic and is looking to lose weight, I believe that it is important to explore viable approaches to weight loss. Based on current evidence, combining medication like semaglutide with dietary strategies such as Intermittent Fasting (IF) appears promising. As such, I understand that this DNP capstone study that I choose to participate in, will be comparing the effectiveness of using semaglutide alongside Intermittent Fasting versus using just semaglutide alone, among non-diabetic adult patients with a BMI between 25 and 39 who have not seen positive results from traditional diet and exercise methods.

PROCEDURES

I understand that if I volunteer to take part in this study, I will be asked to:

Follow these tasks involved in this DNP Quality Improvement Project (QIP):
1)Recruitment and Consent:
Weight loss patients receiving weekly semaglutide subcutaneous (SQ) injections at the clinic are potential candidates for this QIP. Each QIP candidate will be shown the QIP Recruitment Flyer (attached) and their questions and concerns will be answered and addressed. Upon expressing interest to the QIP, the participant will be provided with a detailed explanation of the study and its potential risks and benefits (please refer to attached QIP Informed Consent Form). Once the participant verbally consents to participate, the participant will undergo an eligibility medical screening by filling up the Medical Screening & Recruitment Survey Form (MS&RSF). If the participant is eligible (i.e., if participant passes the MS&RSF) then the participant will sign the QIP Informed Consent Form (QIP ICF) and will proceed to the next step.
2) Pre-Test and Education prior to start of Semaglutide weekly injections: Before receiving the 1st weekly subcutaneous dose of semaglutide, the participant's initial weight, height, and Body Mass Index (BMI) will be measured and recorded at the Clinic. The dose and administration of Semaglutide will follow guidelines specified by the manufacturer and previous studies. The participant will receive the attached education materials on Semaglutide before the 1st weekly injection.
3) If the patient QIP volunteer has already completed the two-months weekly semaglutide injections, the recorded weight and BMI prior to the 1st semaglutide SQ dose will be obtained from the patient's existing medical records.
4) Post Test after two-months of Semaglutide treatment: the participant's weight and BMI will be measured and recorded again at the Clinic during the patient's 9th weekly semaglutide injection visit (which means that the patient has completed a total of 8 weeks or two months semaglutide treatment).
5) Once again, if the patient has already completed the two-months weekly semaglutide injections, the recorded weight and BMI before receiving the 9th semaglutide SQ dose will be obtained from the patient's existing medical records.
6) Pre-Test and Education prior to start of Intermittent Fasting (IF) while continuing with the Semaglutide treatment:
During the participant's 9th weekly semaglutide injection visit at the Clinic, the participant will receive the attached education materials on Intermittent Fasting (IF). The participant's weight and BMI will be measured and recorded again at the Clinic during the patient's 9th weekly semaglutide injection visit. This data will constitute the post- test after the two months semaglutide treatment, as well as the pre-test before the start of IF.
7) If the patient has already completed 2 months of semaglutide injection and opts to try IF and participate in this QIP, the participant will receive the attached education materials on Intermittent Fasting (IF). The participant's weight and BMI will be measured and recorded again at the Clinic and this data will constitute the post- test after the two months semaglutide treatment, as well as the pre-test before the start of IF.
8) Tracking compliance with IF: During the weekly patient visits for semaglutide injections at the clinic and while the patient is on the two-months IF, the patient will complete the IF Compliance Tracking Form (IFCTF) (attached) for the next two months.
9) Post-Test after two-months of IF while continuing with the Semaglutide treatment: After 2 months of concurrent IF and semaglutide treatment, the participant's weight and BMI will be measured and recorded again during the patient's 17th weekly semaglutide injection visit at the Clinic.
10) NOTE: Weight and Height measurement will follow standardized method and will use calibrated weighing scale and stadiometer at the Clinic. Body Mass Index (BMI) will use the latest US Department of Health & Human Services online BMI calculation tool (https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm)

BENEFITS

I understand that the benefits I may gain from participation include:

I may lose weight and BMI, and may correspondingly reduce my risk for cardiovascular disease.

RISKS

I understand that the risks, discomforts, or stressors I may face during participation may include:

the potential risks for gastrointestinal side effects such as nausea, vomiting, diarrhea, heartburn, pancreatitis, and increased heart rate. I may also experience hunger, weakness, and even loss of concentration during my intermittent fasting (IF) periods. I may also experience the potential risk of overeating during my non-fasting periods, leading to inadequate weight loss results.

CONFIDENTIALITY

I understand that the only people who will know that I am a research subject are members of the research team. No individually-identifiable information about me, or provided by me during the study will be shared with others except when necessary to protect the rights and welfare of myself and others (for example, if I am injured and need emergency care, if the provided information concerns suicide, homicide, or child abuse, or if revealing the information is required by law).

FURTHER QUESTIONS

I understand that any further questions that I have, now or during the course of the study, can be directed to Dominador P. Mansat Jr., FNP-C, APRN, MSN, MBA, BSChE

(Principal Investigator)

Additionally, I understand that questions or problems regarding my rights as a research participant can be addressed to the Institutional Review Board Director of Compliance and Training for South University at IRB@southuniversity.edu.

My signature below indicates that the researchers have satisfactorily answered all of my current questions about this study and that I understand the purpose, procedures, benefits, and risks described above. I have also been offered a copy of this form to keep for my own records.

Participant Printed Name

Signature of Participant | Date

Signature of Principal Investigator | Date

Appendix E

Intermittent Fasting Compliance Tracking Form (IFCTF)

Intermittent Fasting Compliance Tracking Form (IF CTF)

Participant CODED Number: _____

Date	Time of First Meal of the Day	Time of Last Meal of the Day	Total Hours Fasted	Eating Window (Hours)	Did you adhere to the 16:8 IF Method (Yes or No)
Week 1					
Week 2					
Week 3					
Week 4					
Week 5					

Table 1:

Coded Raw Data

CODED Data Collection Form : CODED Weight and BMI (Final Data Collection Date = 11/06/2023)

N (Data set)	Assigned DNP CP Code	Age (years)	Height	Start Date of Semaglutide onlyTreatment	Weight at start of Semaglutide only (lbs)	BMIt at start of Semaglutide only Treatment	End Date of Semaglutide only= Start Date of IF+Semagalutide	Weight at end of Semaglutide only (lbs)	BMI at end of Semaglutide only	Weight at start of IF+Semaglutide (lbs)	BMI at start of Semaglutide+IF	End Date of IF+Semaglutide	Weight at end of IF +Semaglutide (lbs)	BMI at end of IF+Semaglutide
1	A1	57	5 ft 6 in	3/13/23	186	30	9/11/23	167	27	167	27	11/6/23	150	24
2	A2	54	5 ft 3 in	3/13/23	181	32	9/11/23	162	29	162	29	11/6/23	154	27
3	A3	58	6 ft 2 in	7/14/23	270	35	9/11/23	253	32	253	32	11/6/23	244	31
4	A4	28	5 ft 3 in	5/31/23	173	31	9/11/23	151	27	151	27	11/6/23	143	25
5	A5	34	5 ft 9 in	7/3/23	244	36	9/11/23	204	30	204	30	11/6/23	191	28
6	A6	60	5 ft 4 in	5/19/23	175	30	9/11/23	161	28	161	28	11/6/23	153	26
7	A7	47	4 ft 11 in	4/3/23	161	33	9/11/23	145	29	145	29	11/6/23	134	27
8	A8	54	5 ft 6 in	4/2/23	190	31	9/11/23	172	28	172	28	11/6/23	164	26
9	C1	59	5 ft 3 in	3/13/23	139	25	9/11/23	113	20	113	20	11/6/23	105	19
10	C2	53	5 ft 2 in	4/12/23	200	37	9/11/23	173	32	173	32	11/6/23	161	29
11	C3	54	5 ft 6.5 in	4/2/23	192	31	9/11/23	186	30	186	30	11/6/23	173	28
12	C4	57	5 ft 3 in	5/27/23	269	48	9/11/23	255	45	255	45	11/6/23	240	42
13	C6	55	5 ft 6 in	4/3/23	203	33	9/11/23	185	30	185	30	11/6/23	171	28

Cleaned, De-identified, and Coded Data Set n (n=12)

Assigned DNP CP Code	Height	Start Date of Semaglutide onlyTreatment	Weight at start of Semaglutide only (lbs)	BMI at start of Semaglutide only Treatment	End Date of Semaglutide only= Start Date of IF+Semagalutide	Weight at end of Semaglutide only (lbs)	BMI at end of Semaglutide only	Weight at start of IF+Semaglutide (lbs)	BMI at start of Semaglutide+IF	End Date of IF+Semaglutide	Weight at end of IF +Semaglutide (lbs)	BMI at end of IF+Semaglutide
A1	5 ft 6 in	03132023	186	30	09112023	167	27	167	27	11062023	150	24
A2	5 ft 3 in	03132023	181	32	09112023	162	29	162	29	11062023	154	27
A3	6 ft 2 in	07142023	270	35	09112023	253	32	253	32	11062023	244	31
A4	5 ft 3 in	05312023	173	31	09112023	151	27	151	27	11062023	143	25
A5	5 ft 9 in	07032023	244	36	09112023	204	30	204	30	11062023	191	28
A6	5 ft 4 in	05192023	175	30	09112023	161	28	161	28	11062023	153	26
A7	4 ft 11 in	04032023	161	33	09112023	145	29	145	29	11062023	134	27
A8	5 ft 6 in	04/02/2023	190	31	09112023	172	28	172	28	11062023	164	26
C1	5 ft 3 in	03132023	139	25	09112023	113	20	113	20	11062023	105	19
C2	5 ft 2 in	04122023	200	37	09112023	173	32	173	32	11062023	161	29
C3	5 ft 6.5 in	04022023	192	31	09112023	186	30	186	30	11062023	173	28
C6	5 ft 6 in	04032023	203	33	09112023	185	30	185	30	11062023	171	28

Table 2:

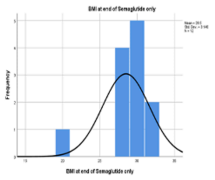
Descriptive Statistics

Descriptive Statistics

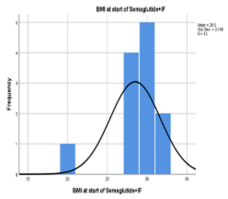
					Shapiro-Wilk	
	Md	SD	Min	Max	Statistic	Sig.
Weight at the start of Semaglutide only (lbs)	188	35.092	139	270	0.917	.264
Weight at the end of Semaglutide only (lbs)	169.50	34.169	113	253	0.933	.411
BMI at the start of Semaglutide only (lbs)	31.50	3.191	25	37	0.942	.521
BMI at the end of Semaglutide only (lbs)	29.00	3.148	20	32	.0.817	.015
Weight at the start of Semaglutide+IF (lbs)	169.50	34.169	113	253	.933	.411
Weight at the end of Semaglutide+IF (lbs)	157.50	33.649	105	244	.913	.235
BMI at the start of Semaglutide+IF (lbs)	29.00	3.148	20	32	.817	.015
BMI at the end of Semaglutide+IF (lbs)	27.00	3.000	19	31	.900	.158

1. Shapiro-Wilk Test results for BMI at the end of Semaglutide only and BMI at the start of Semaglutide + IF are significant, indicating that these two variables are not distributed normally. All other variables have normal distribution.
2. Median values for all the pre-post data have changed (Lower post-test results than pre-test results), indicating possible effectiveness of intervention.

Descriptive Statistics			
Intervention	Weight before Intervention (lbs)	Weight after intervention (lbs)	% Weight Change
Semaglutide only	188	169.5	-11%
Semaglutide with IF	169.5	157.5	-8%
% Weight Change = (Weight after intervention - Weight before Intervention) / Weight after intervention			



Intervention	BMI before Intervention	BMI after intervention	% BMI Change
Semaglutide only	31.5	29	-9%
Semaglutide with IF	29	27	-7%
% BMI Change = (BMI after intervention - BMI before Intervention) / BMI after intervention			



Intervention	% Weight Loss	% BMI Loss
Semaglutide only	**- 11%**	**- 9%**
Semaglutide with IF	**- 8%**	**- 7%**

Table 3:

Inferential Statistics

Change in Weight & BMI Before and After Use of Semaglutide Only

Weight

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.062	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

Wilcoxon Signed Rank Test
95% CI and α= 0.05
Z-value: -3.062, p=.002
H0= Rejected, Ha= Accepted

BMI

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.086	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

Wilcoxon Signed Rank Test
95% CI and α= 0.05
Z-value: -3.086, p=.002
H0= Rejected, Ha= Accepted

Change in Weight & BMI Before and After Use of Semaglutide and IF

Weight

	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.084	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

Wilcoxon Signed Rank Test
95% CI and α= 0.05
Z-value: -3.084, p=.002
H0= Rejected, Ha= Accepted

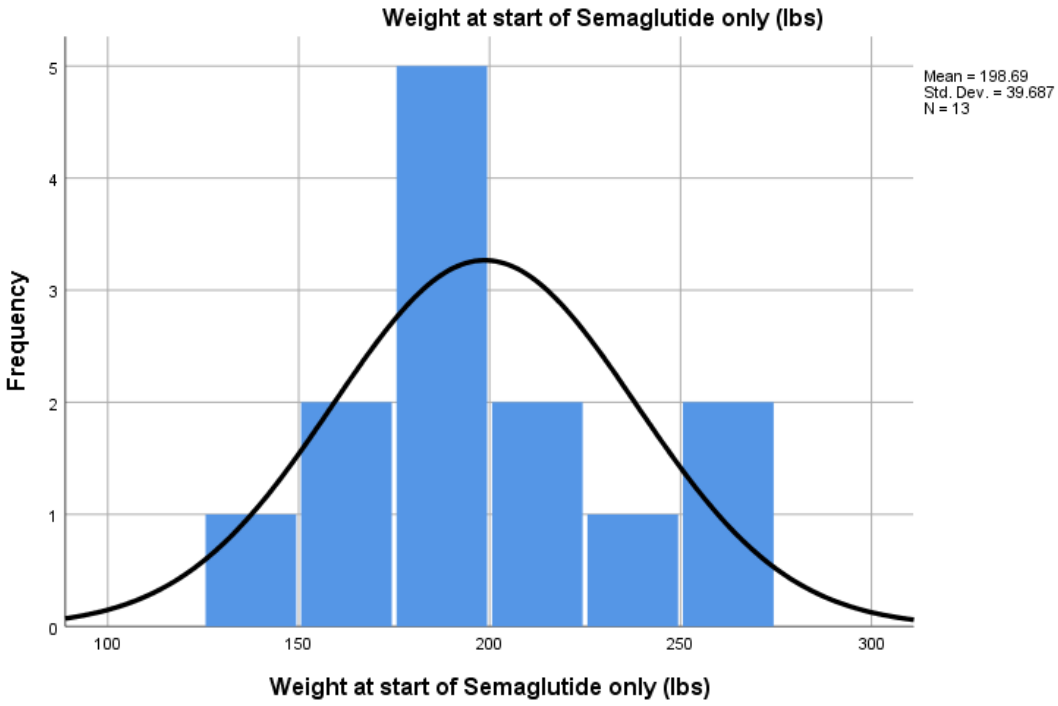
BMI

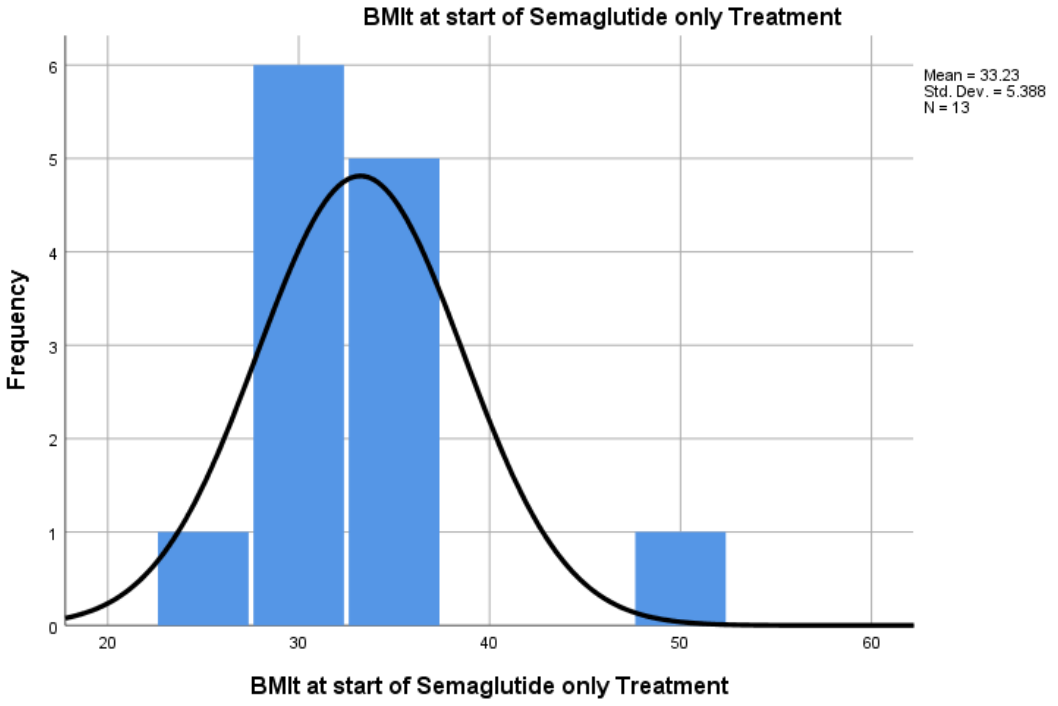
	N	Mean Rank	Sum of Ranks	Z	Sig.
Negative Ranks	12	6.50	78.00	-3.166	.002
Positive Ranks	0	.00	.00		
Ties	0				
Total	12				

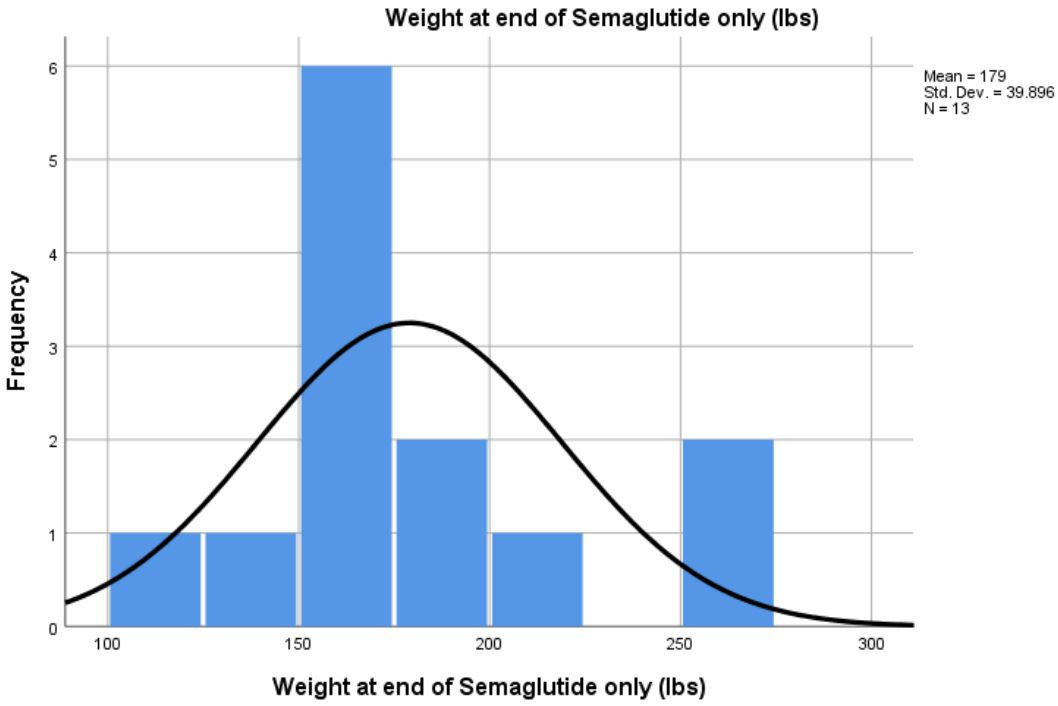
Wilcoxon Signed Rank Test
95% CI and α= 0.05
Z-value: -3.166, p=.002
H0= Rejected, Ha= Accepted

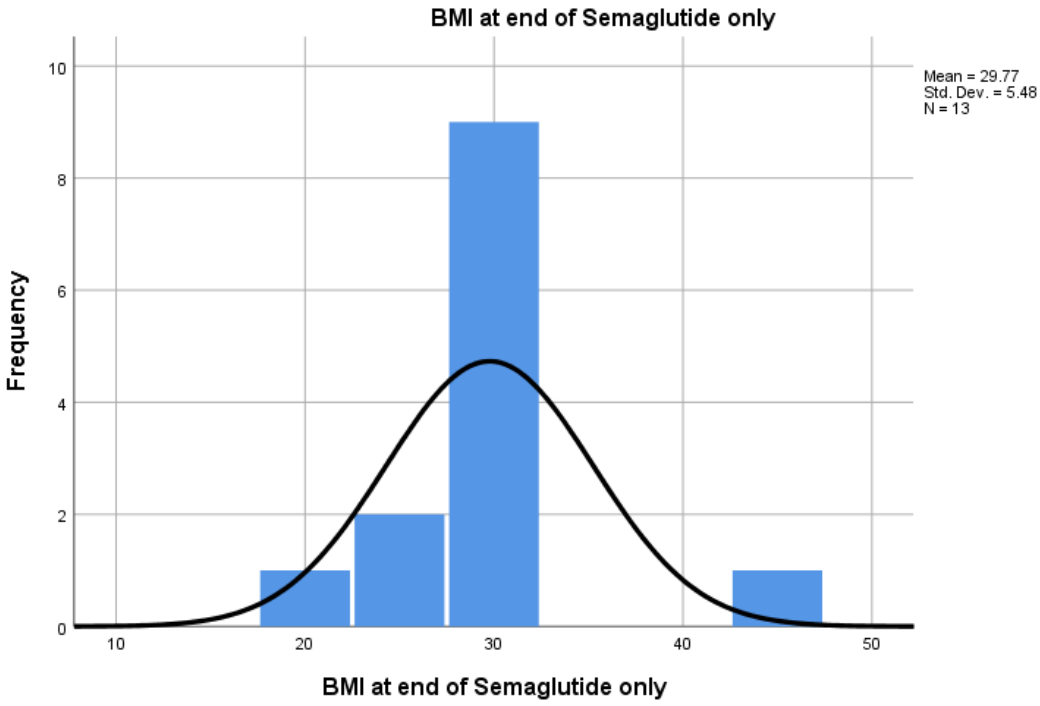
Figure 1:

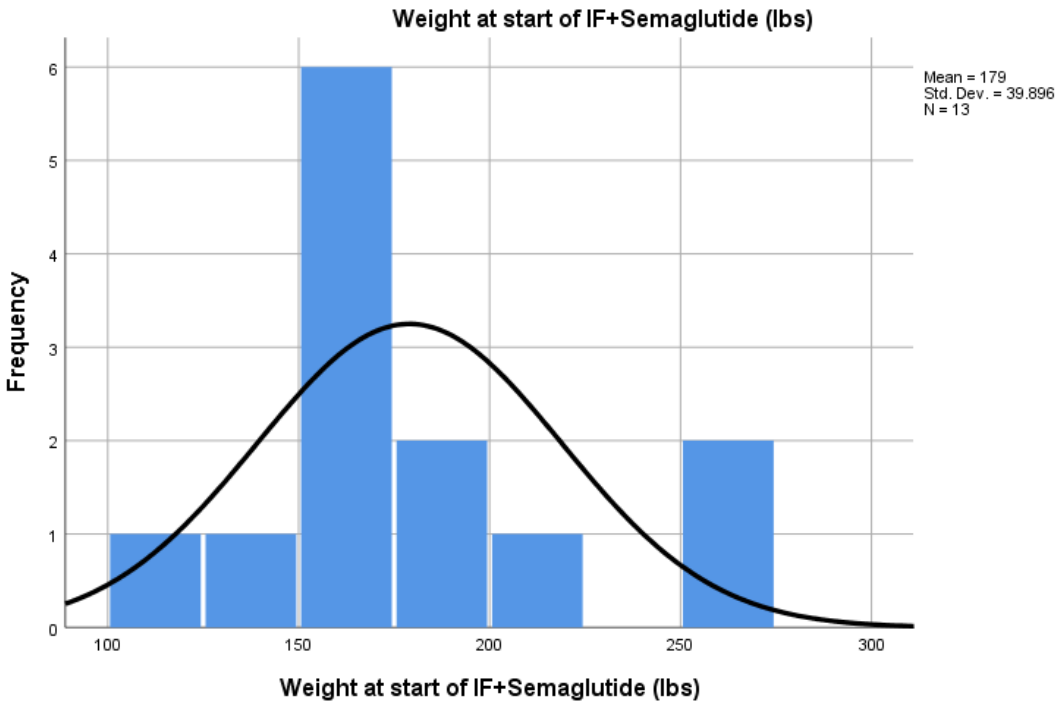
Histograms

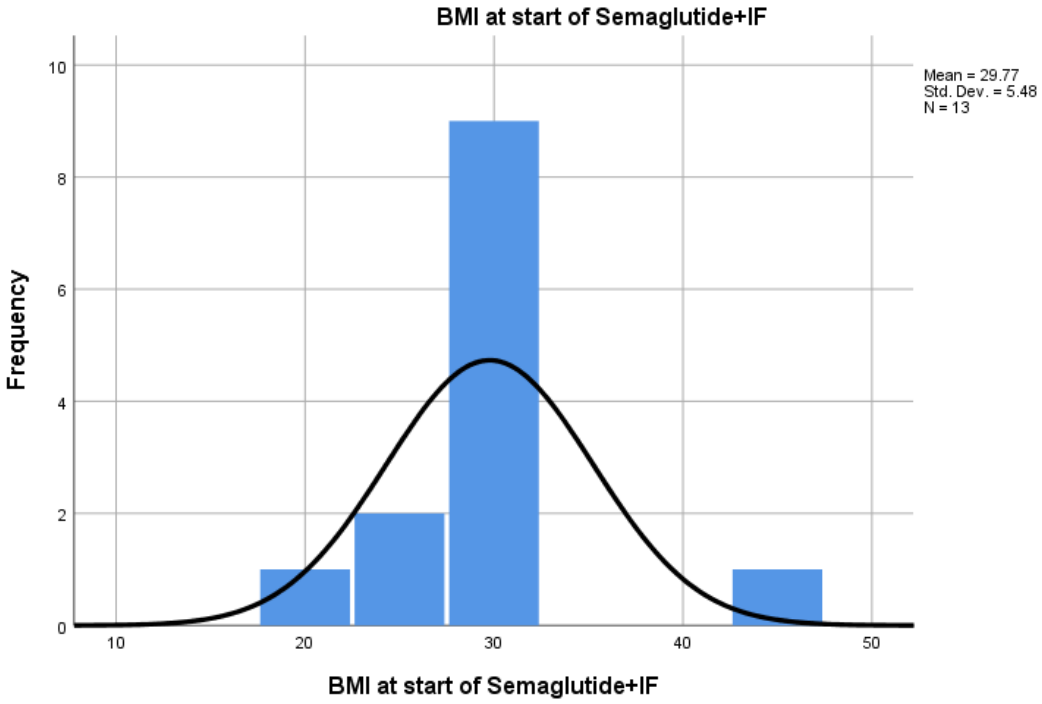


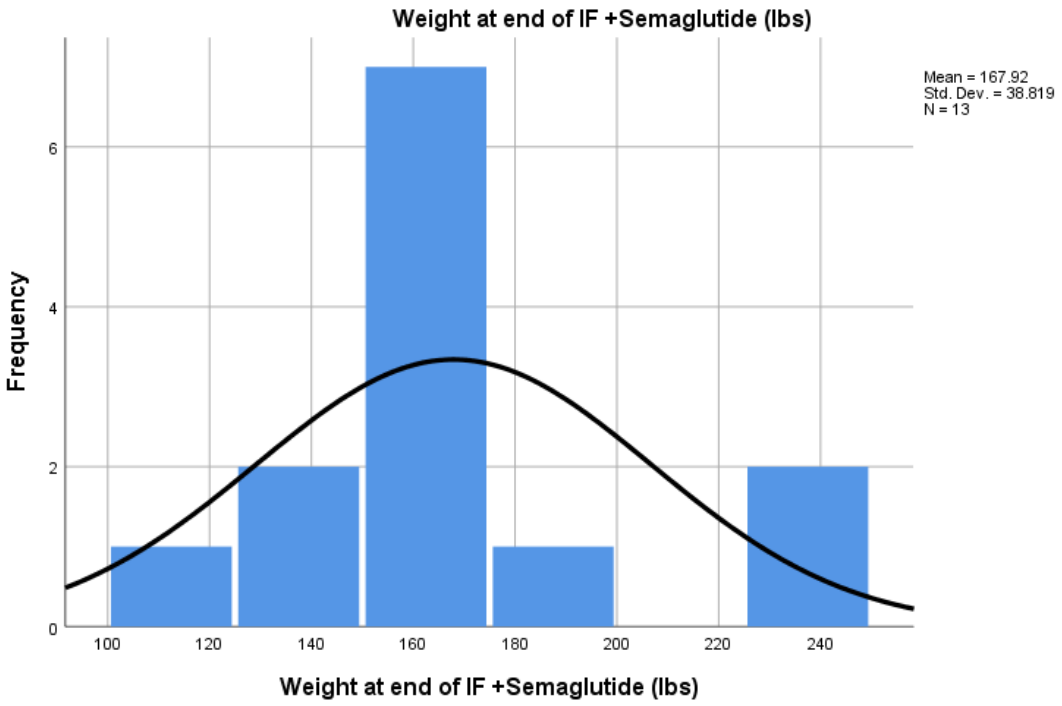



Weight at end of Semaglutide only (lbs)
Mean = 179
Std. Dev. = 39.896
N = 13
Frequency
0
1
2
3
4
5
6
100
150
200
250
300
Weight at end of Semaglutide only (lbs)


BMI at end of Semaglutide only
Mean = 29.77
Std. Dev. = 5.48
N = 13
Frequency
0
2
4
6
8
10
10
20
30
40
50
BMI at end of Semaglutide only


Weight at start of IF+Semaglutide (lbs)
Mean = 179
Std. Dev. = 39.896
N = 13
Frequency
0
1
2
3
4
5
6
100
150
200
250
300
Weight at start of IF+Semaglutide (lbs)


BMI at start of Semaglutide+IF
Mean = 29.77
Std. Dev. = 5.48
N = 13
Frequency
0
2
4
6
8
10
10
20
30
40
50
BMI at start of Semaglutide+IF


Weight at end of IF +Semaglutide (lbs)
Mean = 167.92
Std. Dev. = 38.819
N = 13
Frequency
0
2
4
6
100
120
140
160
180
200
220
240
Weight at end of IF +Semaglutide (lbs)

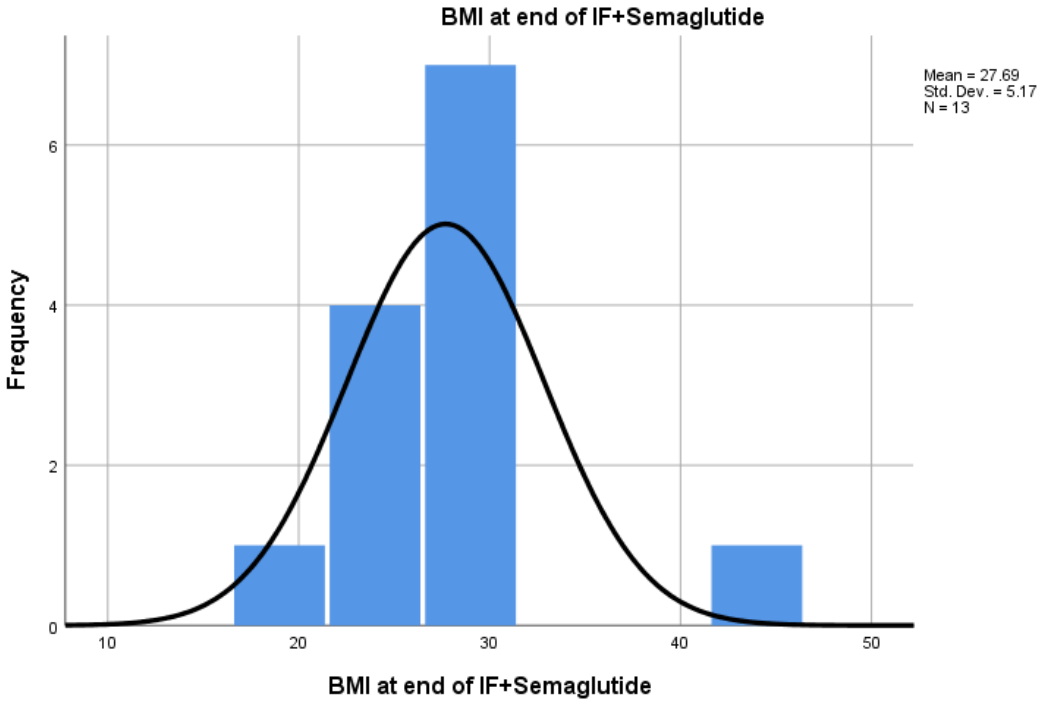
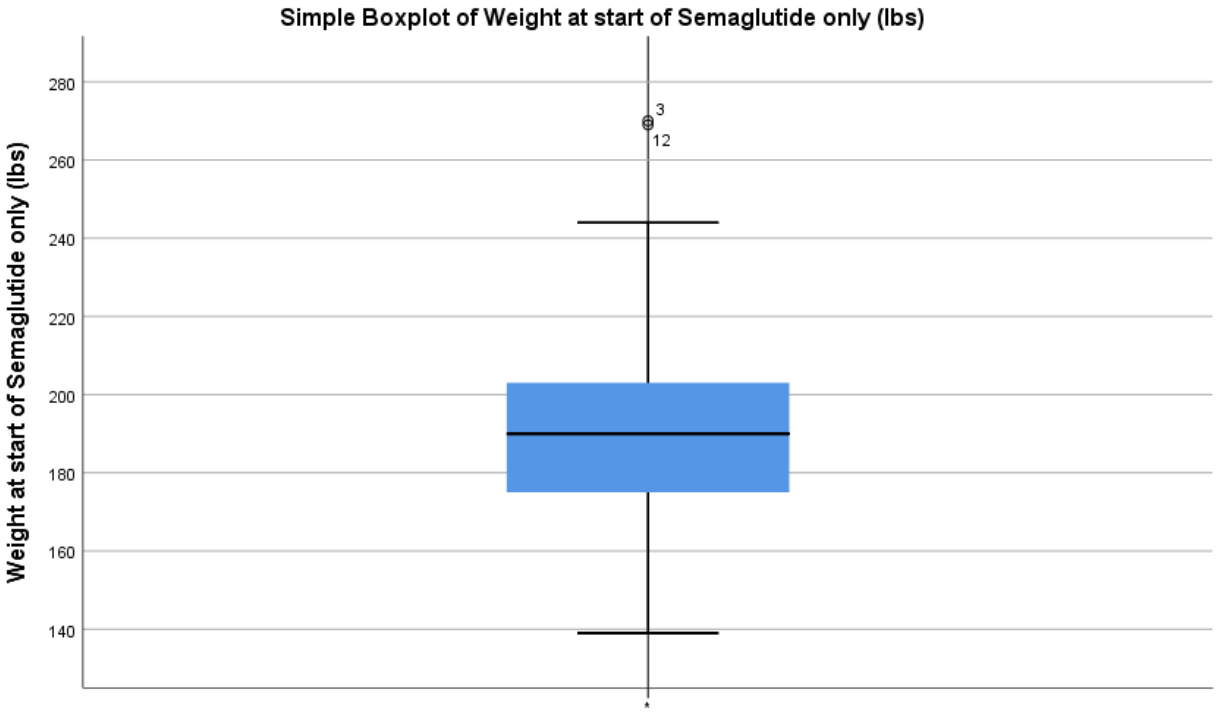
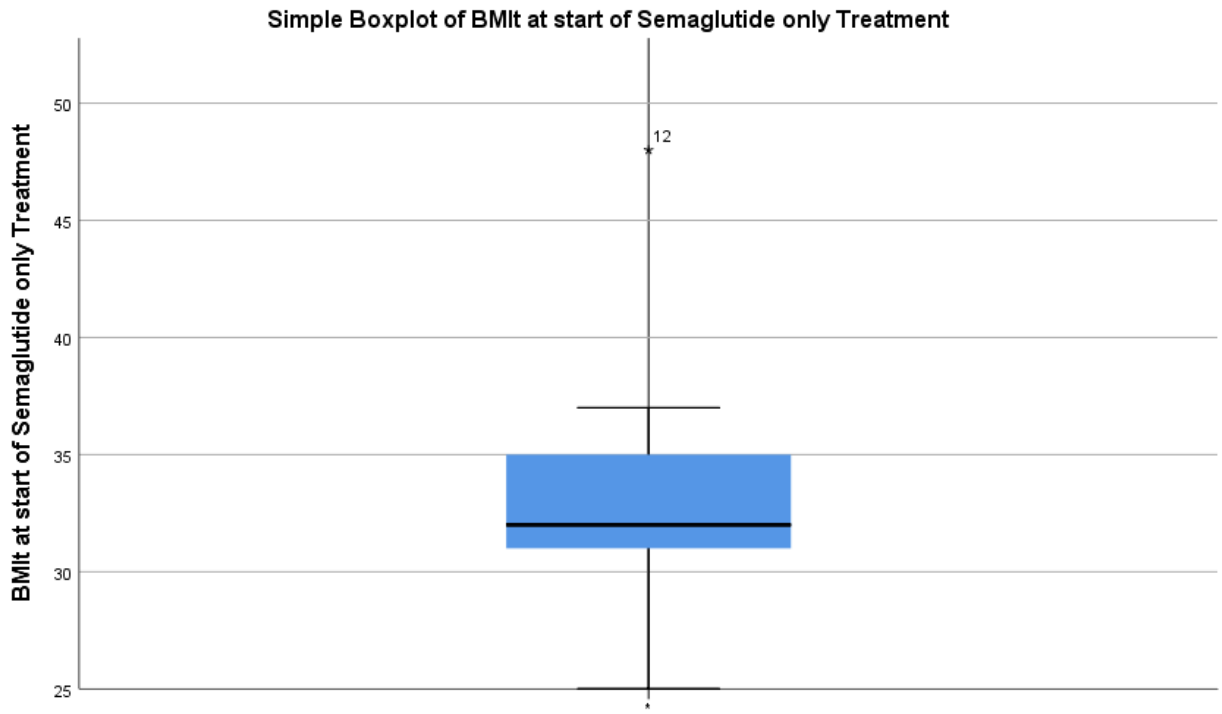
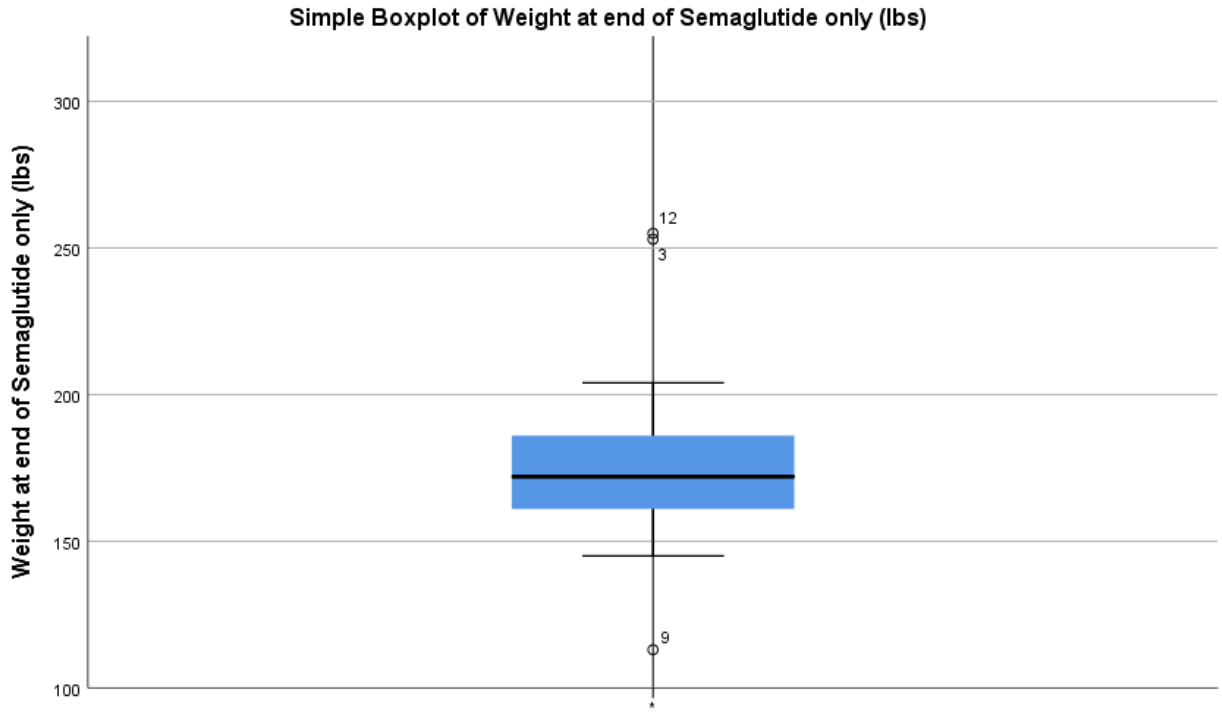

BMI at end of IF+Semaglutide
Mean = 27.69
Std. Dev. = 5.17
N = 13
Frequency
0
2
4
6
10
20
30
40
50
BMI at end of IF+Semaglutide

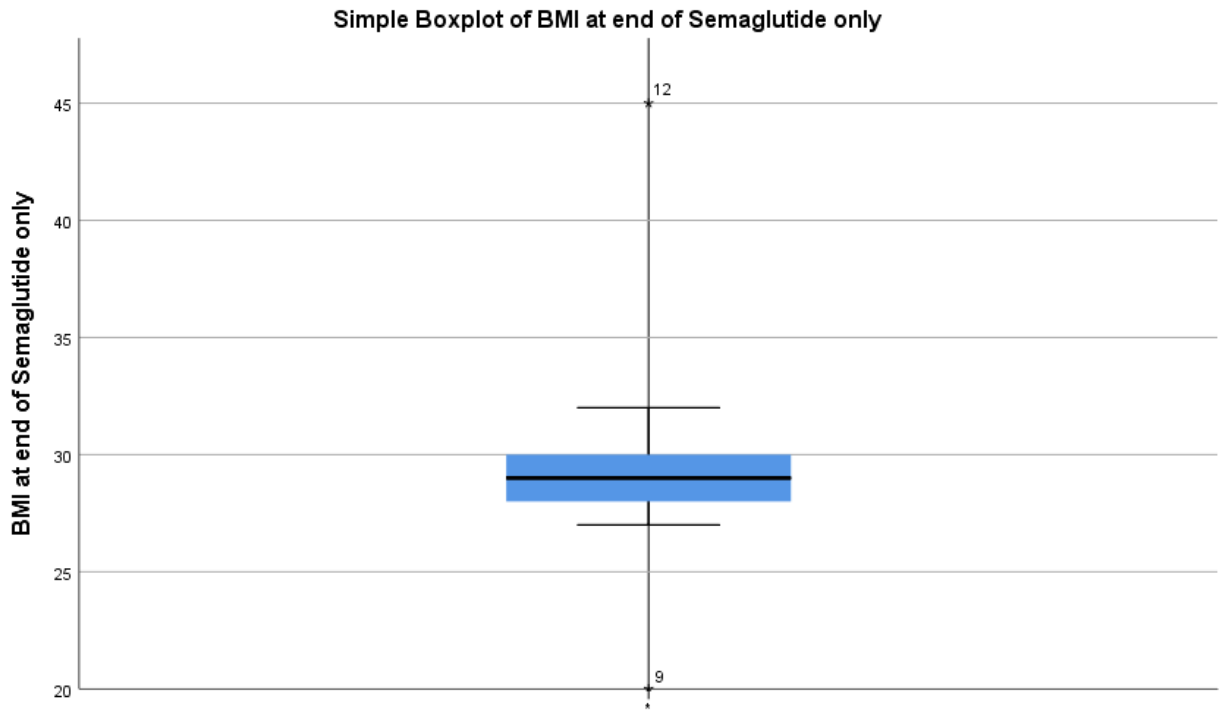
Figure 2:

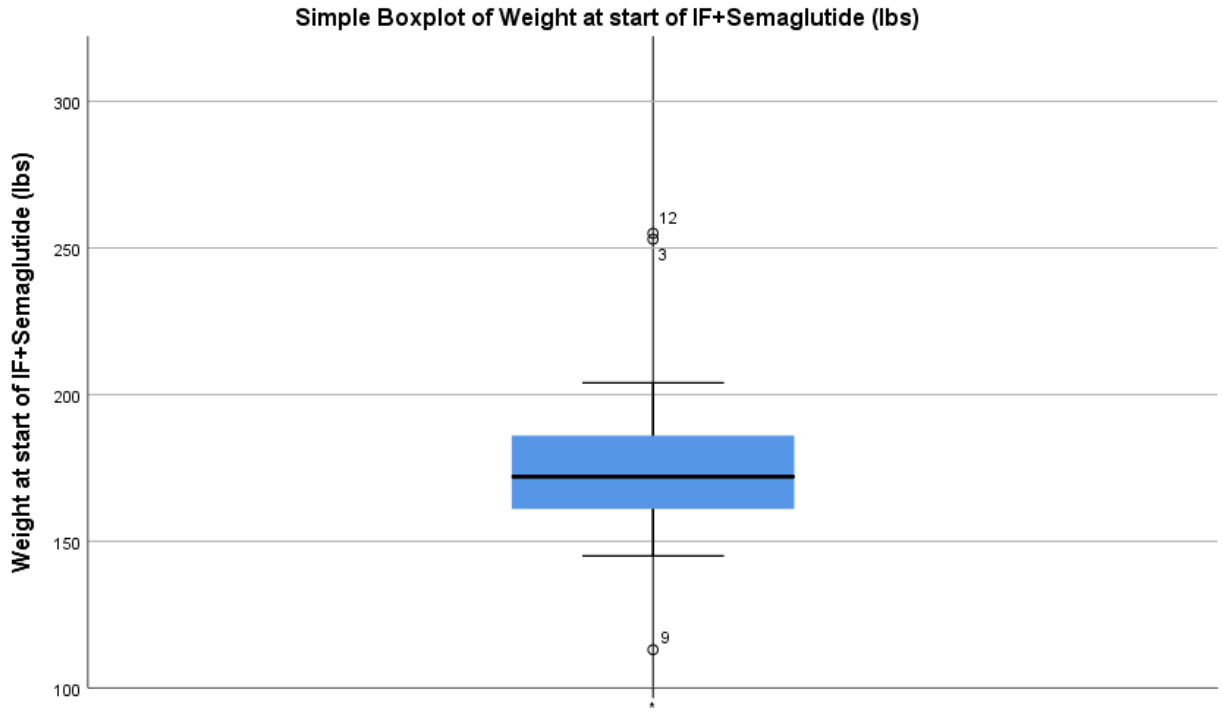
Box Plots

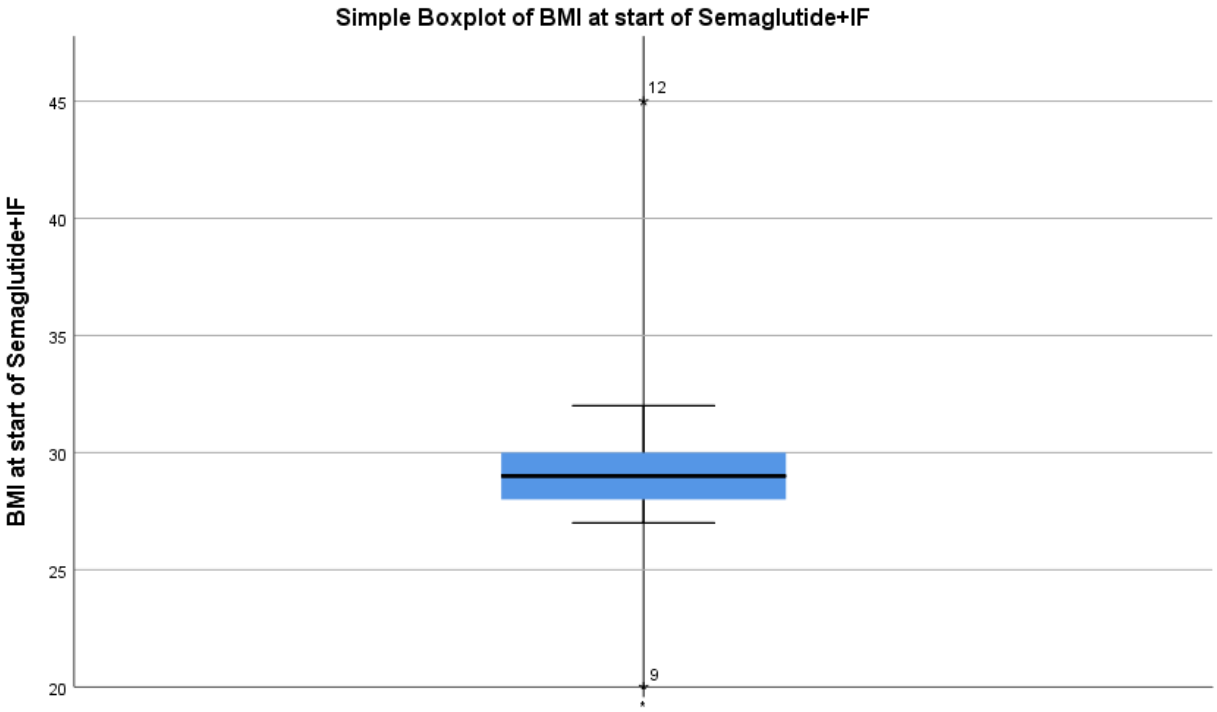


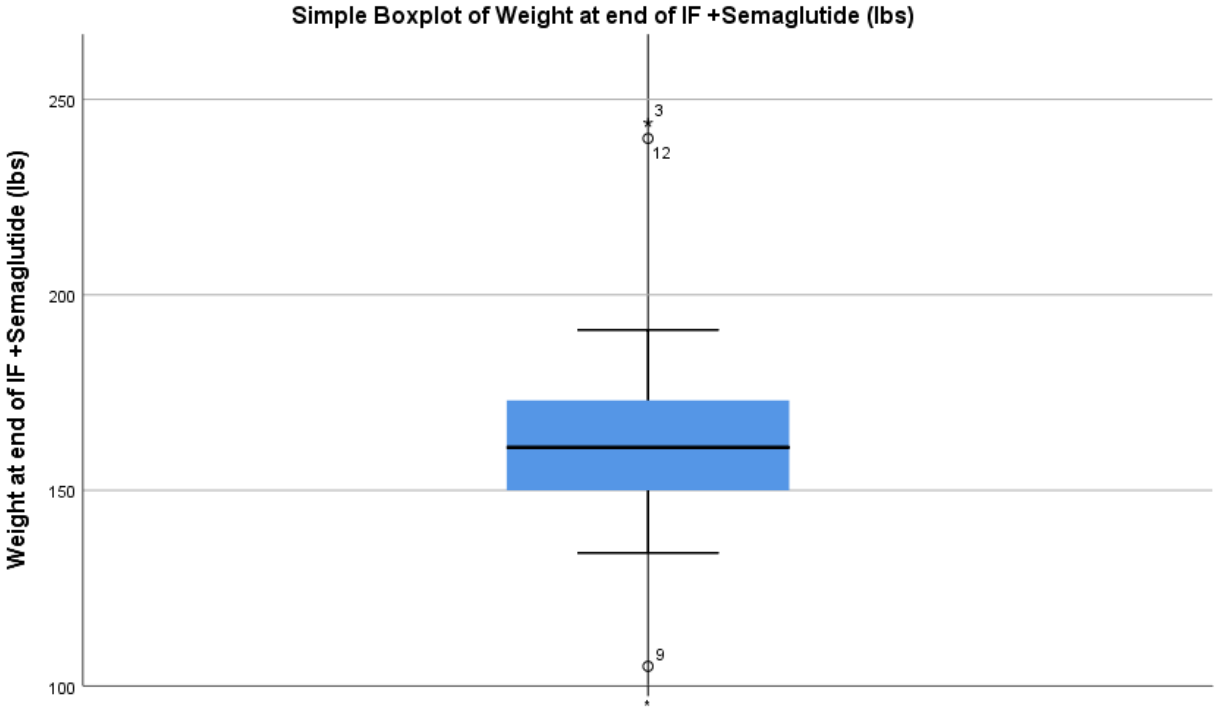

Simple Boxplot of BMIt at start of Semaglutide only Treatment
BMIt at start of Semaglutide only Treatment
50
45
40
35
30
25
12

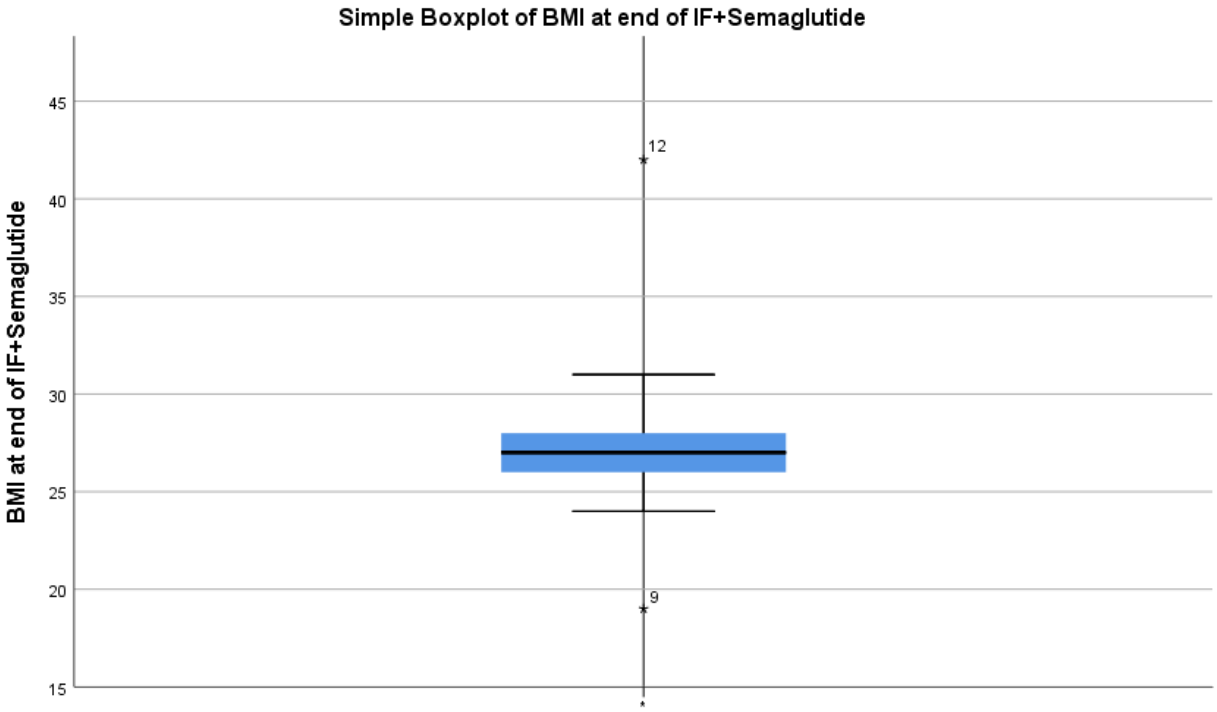

Simple Boxplot of Weight at end of Semaglutide only (lbs)
Weight at end of Semaglutide only (lbs)
300
250
200
150
100
12
3
9


Simple Boxplot of BMI at end of Semaglutide only
BMI at end of Semaglutide only
45
40
35
30
25
20
12
9


Simple Boxplot of Weight at start of IF+Semaglutide (lbs)
Weight at start of IF+Semaglutide (lbs)
300
250
200
150
100
12
3
9


Simple Boxplot of BMI at start of Semaglutide+IF
BMI at start of Semaglutide+IF
45
40
35
30
25
20
12
9


Simple Boxplot of Weight at end of IF +Semaglutide (lbs)
Weight at end of IF +Semaglutide (lbs)
250
200
150
100
3
12
9


Simple Boxplot of BMI at end of IF+Semaglutide
BMI at end of IF+Semaglutide
45
40
35
30
25
20
15
12
9