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Feasibility of Online Nutritional Counseling and/or Remote Self Weighing in Pregnant Women With Obesity

Rebecca Mattson
University of San Diego

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Hahn School of Nursing, University of San Diego

UNIVERSITY OF SAN DIEGO

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Dissertation Committee

Mary Barger, PhD, MPH, CNM, FACNM
Chairperson

Ann M. Mayo, DNSc, RN, FAAN
Committee Member

Kathy S. James, DNSc, APRN, FAAN
Committee Member

Abstract

Purpose

The purpose of this feasibility study is to determine the magnitude of effect using a combination of weekly weights and an online registered dietician to control excessive gestational weight gain in pregnant women with obesity using a pilot randomized controlled trial.

Specific Aims

There are three specific aims. Aim 1: Describe the study population in terms of sociodemographic influences (e.g., ethnicity, age, weight, and height) and obstetrical influences (i.e., parity and pregnancy weight). Aim 2: Measure participant satisfaction with the study interventions of weekly weighing and online nutrition counselling. Aim 3: **(**a) Explore the differences in gestational weight gain from enrollment to 6 weeks later and at 28 weeks among pregnant women with obesity who were not given any special nutrition counseling or scale (historical controls) to those given scales and asked to weigh themselves weekly; (b) explore if there were any differences in gestational weight gain among the intervention group, between those who receive nutrition counseling and those who did not; (c) determine the effect size of the interventions for a future larger RCT.

Background

Approximately 1/3 of pregnancy complications are related to obesity (Ramachenderan et al., 2008). For example, the odds of developing gestational diabetes increases 7.7 times. For every 5-7 unit increase in maternal BMI the risk for preeclampsia doubles (Bautista-Castano et al., 2013), and the risk of having a cesarean delivery increases 2-3 times for women whose BMI is greater than 30 (Ovesen et al., 2011). Employing a Registered Dietician (RD) for weight

management during pregnancy has demonstrated success, although the use of online dieticians remains untested (Vincze et al., 2019).

Methods

Pregnant women between 14-36 weeks gestation, with a BMI greater than 30 will be included in the study. Recruitment will occur remotely through the use of a recruitment flyer with a QR code. Participants will scan the QR, complete a survey for eligibility, and consent for the study online. Women will be randomly assigned to either the self weighing group or self-weighing and online nutritional counseling intervention group. Self-weighing will occur through the use of a preconfigured Bluetooth scale and data will be stored and retrieved through a secure data hub. Online nutritional counseling will occur through a secure telehealth platform, and occur for 30 minutes, once a week, for six weeks. For the control group, retrospective data will be extracted from an electronic medical record. Variables measured include gestational weight gain after six weeks, at 28 weeks, and 36 weeks gestation. Adherence to the intervention will be tracked.

Results

Those in the study group (n = 11) on average comprised of a group of multiethnic pregnant women in their late 20s early 30s with an average BMI of 33.5 (5.4), with an average gestation age at recruitment 16.5 weeks. The majority were married or cohabitating (n = *1*0), with a mix of some high-school (n = *2*) to college education (n = *9*), a mix of private (n = 4) and governmental insurance (n = 7), working (n = 7) and non-working (n = 4). Online nutritional counseling was accepted in this population using the virtual provider online satisfaction survey, Cronbach's alpha of 0.55. There were no missed visits for those attending the nutritional counseling sessions. 82% (N = 9) of women adhered to self-weighing once a week. Overall

gestational weight gain was less in the study group (mean weight gain 5.8 lbs., *SD* (5.9), than in the historical control group (Mean weight gain 6.6 lbs., *SD* (3.1)), The registered dietitian group had a mean weight gain of 4.1 lbs., *SD* (5.6) compared to 6.9 lbs., *SD* (5.6) in the self-weighing alone group. The Effect size was small with a Cohen's D calculated at 0.17.

Significance:

It is feasible to provide online nutritional counseling to pregnant women with obesity while using remote weight monitoring to eliminate biases that occur with self-reporting. Further research is needed to determine the effect of this intervention within a larger sample size.

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Feasibility of Online Nutritional Counseling and/or Remote Self Weighing in Pregnant Women With Obesity

Chapter 1

One out of every four pregnant women starts pregnancy with a body mass index (BMI) equal to or greater than 30, falling under the classification of obesity (Amirkhani et al., 2013). In a study by Ukah et al. (2019), roughly 54% of the 166,000 pregnant with an elevated BMI equal to or greater than 30, gained excess weight. Pregnancy complications linked to elevated BMI and excessive gestational weight gain include gestational diabetes mellitus (GDM), preeclampsia, and cesarean delivery (Rahman et al., 2020). The prevalence of obesity in pregnancy (BMI $\geq$ 30) and associated complications pose a critical healthcare challenge (Khashan & Kenny, 2009). Interventions targeting these complications include nutritional counseling and self-weighing. Results from a meta-analysis indicate dietary interventions are successful at reducing excessive gestational weight gain in women with obesity (Vincze et al., 2019). Jeffries et al. (2009) found women who weighed themselves during pregnancy had less excessive gestational weight gain. Presently, gaps in research surround the efficacy of nutritional counseling via video telehealth and the precision of a self-weighing intervention using self-reported weight (Vincze et al., 2019). In this dissertation, the researcher studied nutritional counseling delivered via video telehealth and weekly self-weighing by the participant using a Bluetooth scale.

Background

Obesity during pregnancy is an underlying contributor to the pathophysiology of diabetes mellitus, hypertension, organ dysfunction, inflammatory response, and immune dysfunction (Garner et al., 2020; Redinger, 2007). Obesity in pregnancy has been identified as the leading contributing factor to preeclampsia, present in 30% of the cases in the United States (Roberts et

al., 2011). Additionally, in the United States, the risk of developing GDM has been found to rise as BMI increases (Kim et al., 2010). An elevated BMI during pregnancy is a major public health and healthcare concern and directing interventions to reduce excessive weight gain in this population is imperative (Flynn et al., 2016).

The American Academy of Obstetricians and Gynecologists (ACOG) recommends the involvement of other health care providers, such as a nutritionist, to provide dietary counseling to women with obesity (Stewart et al., 2009). Registered dieticians (RD) working with pregnant women follow the Institute of Medicine (IOM) BMI-based advice and nutritional orders and recommendations supplied by providers to support women and control weight management during pregnancy (Garner et al., 2020). Effective nutritional counseling includes basic information on nutrient needs, as well as tailored caloric intake information based on BMI (Kominiarek & Rajan, 2016). Varying techniques and approaches to nutritional counseling exist, but most use components of motivational interviewing which start with the patient's motivations and goals. Communication strategies differ; some occur in person, phone, or by email.

Remote healthcare services are gaining momentum, with approximately 50% of healthcare institutions and hospitals using telehealth services (Tuckson et al., 2017). During the 2019–2020 COVID-19 pandemic, the demand to use telehealth services increased in urgency. Some studies differ in differentiating telehealth from telemedicine. In the literature, telehealth refers to a variety of applied technologies. As technology advances, it is common to associate telehealth with video conferencing. Although telehealth may include teleconferencing, it also involves additional forms of telecommunication phone calls, emails, and text messages. For this dissertation, the exclusive medium of telehealth was video conferencing. Research testting the utilization of video conferencing telehealth for nutritional counseling is present for nonpregnant

populations. Video conferencing telehealth has demonstrated success in reducing weight for the nonpregnant population with an elevated BMI (Alencar et al., 2019). Video conferencing in pregnancy has successfully been used to deliver routine prenatal care (Pflugeisen et al., 2016).

The act of self-weighing during pregnancy has been shown to be successful in managing weight. Nonpregnant populations frequently use participant self-weighing for weight control (Goldstein et al., 2019; Painter et al., 2016; Sheih et al., 2016). Two studies have demonstrated success in reducing the overall gestational weight gain (Harrison et al., 2014; Jeffries et al., 2009). Implementation of participant self-weighing has potential for providing a simple, cost-effective, convenient method to involve the pregnant woman in her health and control excessive gestational weight gain (Arthur et al., 2020). Frequency of self-weighing and logging weight information varies in research, although studies in nonpregnant populations support weekly weigh-ins as the minimum frequency. Accurate and precise measurement of participant self-weighing is needed to determine the overall efficacy of this intervention for this population.

Gap in the Literature

The existing literature on the effectiveness of nutritional counseling to mitigate adverse pregnancy outcomes contains conflicting evidence. The study by Dodd et al. (2014), whose intervention required in-person nutrition counseling, had significant issues with both participant retention and uptake of the study intervention. Potential reasons for poor participation may have been inconvenience of attending nutritional counseling sessions and prenatal visits in-person due to caring for other children at home or work-related responsibilities. Emerging literature suggested using video conferencing telehealth to deliver nutritional counseling sessions is both effective and acceptable to people (Vincze et al., 2018). Video conferencing telehealth may reduce participant burden and inconvenience. Although some studies tested telehealth's role in

the postpartum period or for the nonpregnant population, limited research looked at the role of video conferencing telehealth in pregnant women with obesity. Further investigation is needed to determine the efficacy of this intervention using a video conferencing telehealth medium.

Self-weighing during pregnancy to reduce excessive gestational weight gain revealed inconsistent results in the literature. Reasons for conflicting evidence revolved around methods for obtaining and tracking participant weight. Findings on self-weighing indicated it tends to be ineffective or insignificant when participants use self-logs or researchers do not monitor or analyze participants' frequency or adherence (Arthur et al., 2020). The need for more accurate self-participant weight measurement was evident (Arthur et al., 2020; Harrison et al., 2014; Jeffries et al., 2009). Although the use of Bluetooth scales to monitor weight has been used in research with nonpregnant populations, no known research has evaluated this during pregnancy. Alencar et al. (2019) demonstrated the effectiveness of using a Bluetooth scale for weight measurement in nonpregnant people who are obese. Data are still needed to address the feasibility and practicality of the data hub and Bluetooth scale. Additional research is needed to determine the efficacy of using a Bluetooth scale in pregnant populations with an elevated BMI. This study bridges this gap and evaluates the effectiveness of using nutritional counseling through a telehealth system and monitoring weekly weights to control gestational weight gain in obesity pregnant women.

Purpose of the Study

The purpose of this feasibility study was to determine the magnitude of the effect of using a combination of weekly weights and an online RD to control excessive gestational weight gain.

Research Questions

There were two major research questions in this study. These research questions were the basis for the specific aims.

Question 1

Will participants with obesity engage in online dietician counseling to control gestational weight gain? Secondarily, what are participants' satisfaction with this modality?

Question 2

Does self-weighing alone or in combination with online nutrition counseling have an effect of gestational weight gain in pregnant women with obesity compared to historical controls?

Specific Aims

There were three specific research aims, these aims were related with the research questions.

Aim 1

Describe the study population in terms of sociodemographic influences (i.e., ethnicity, age, weight, and height) and obstetrical influences (i.e., parity and pregnancy weight).

Aim 2

Measure participant satisfaction with the study interventions of weekly weighing and online nutritional counselling

Aim 3

A. Explore the differences in gestational weight gain from enrollment to 6 weeks later among pregnant women with obesity who were not given any special nutrition counseling or scale (historical controls) to those given scales and asked to weigh themselves weekly.

B. Explore if there were any differences in gestational weight gain among the

intervention group, between those who receive nutrition counseling and those who did not.

C. Determine the effect size of the interventions for a future larger RCT.

Study Design

This study was a feasibility study testing the preliminary effect of weekly self-weighing and the use of an online dietician to control gestational weight gain in pregnant women with obesity. An RD provided nutritional counseling. The timing of counseling, one 30-minute session once a week for 6 weeks, was based on a previous study using a comparable intervention and participant sample size (Mortensen & Kam, 2012). The intervention group met once a week with an online RD via a Health Insurance Portability and Accountability Act (HIPPA) secure telehealth system called Healtie, following recommendations by Nichols (2018) on nutritional counseling and Institute of Medicine (IOM) standards for appropriate weight gain.

Theoretical Model

In her self-care deficit theory, Doretha Orem explored the meaning of self-care and dependent care (Hartweg, 1991). Self-care and dependent care shared a common goal: to meet an individual's known needs. Orem built the case that everyone has the potential to perform self-care (Hartweg, 1991). However, Orem pointed out just because individuals can meet their own needs, it does not mean they will act or seek knowledge to learn how. By contrast, dependent care occurs when a person's needs cannot be met by themselves but instead require a family member or caregiver. The theory established nurses have a unique role in determining if an individual is capable of self-care or requires dependent care (Hartweg, 1991). According to Orem, the goal of the nursing system was to determine if a self-care deficit is present and develop a plan identifying roles assigned to the individuals to care for the need (Hartweg, 1991). Using Orem's theory, a women's inability to meet the proper nutritional requirements during

pregnancy and only gain the appropriate amount of weight may constitute a self-care deficit. Lack of knowledge, lack of motivation, or environmental factors may contribute to a pregnant women's self-care deficit.

Women with obesity may consume too many calories or non-nutrient foods. Nutritional interventions have been implemented in numerous studies and women's health clinics to help address this issue. Additionally, the practice of self-weighing to promote weight management in pregnancy is supported by the American Academy of Nutrition and Dietetics (Stang & Huffman, 2016). Having participants self-monitor weight may be one way to meet this self-care deficit. Nutritional education learned through counseling sessions may provide a foundation for women to change their behavior with increased knowledge and support to becoming capable of meeting this need based on their own self-care nutritional goals in the future.

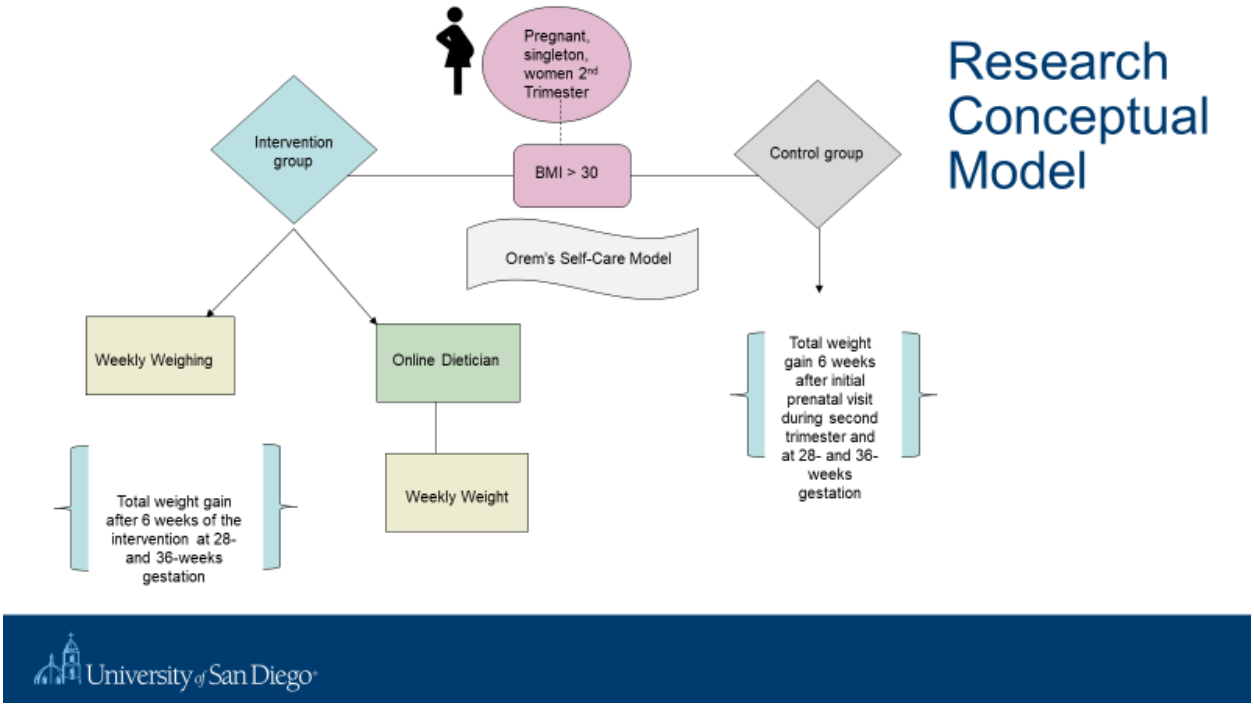
Research Conceptual Framework

This study used a conceptual research framework to represent the relationship among participants, independent variables, and dependent variables (see Figure 1). The pink circle at the top of the framework represents the study participant, a woman with a singleton pregnancy in her second and trimester. The pink box connected by the dashed line signifies the population of interest in this study is pregnant women whose prepregnancy BMI is equal to or greater than 30. Two lines are connecting outward toward two diamonds, one blue and one grey, which illustrate the historical control group, and the intervention group. The grey diamond is the control group, which is attached to a yellow box (closet documented weight after 14 weeks) by means of an arrow. The blue diamond on the left side of the graph is the intervention group. There are two subgroups in the intervention group. Everyone in the intervention group receives a scale. One subgroup did weekly weighing only (yellow box), and the other subgroup did weekly weighing

(yellow box) and on-line nutritional counseling. (green box). Weight data was also collected for the historical charts, referred to has historical control group in this dissertation, 6 weeks after the initial prenatal visit occurring the second trimester and 6 weeks from that point. Weight collected data are shown in brackets.

Figure 1

Research Conceptual Model



Note. Orem's self-care model is depicted in grey wavy box and is the theoretical model underpinning this study.

Study Implications

The maternal mortality ratio has more than doubled over the last 20 years to 16.9 deaths per 100,000 births (Center for Disease Control, 2020), the highest among developed countries. Women with obesity are at higher risk of having chronic health conditions, such as hypertension, diabetes, and heart disease, which are associated with adverse pregnancy outcomes. Pregnancy is

also a time when women are willing to make lifestyle changes for the good of their babies (Forbes et al., 2018). By identifying an effective, low-burden intervention for controlling excess weight gain in pregnancy, there is a potential to save lives and lower maternal mortality. There is also the possibility that weighing habits and healthy eating advice will continue after the pregnancy, improving both the mother's health and that of her family. During the COVID-19 pandemic, a time of physical distancing and changes to routine healthcare practice, it is imperative the effectiveness of telehealth to deliver care be examined.

Summary

The goal of nursing science must be to influence the improvement of both health healthcare delivery and outcomes (Coster et al., 2018). This dissertation focused on strengthening the evidence for effective interventions to reduce the burden of obesity in pregnancy and to promote wellbeing in this population. Research demonstrated promotion of health activities and care by nurses increased patient adherence (Coster et al., 2018). Nurse involvement in nutritional and pregnancy research may reduce the risk of patient morbidity and mortality. Nurse researchers have an important role in identifying gaps in evidence that significantly impact clinical areas (Coster et al., 2018). Investigation of online nutritional counseling via telehealth and self-weighing may help inform decisions for future research.

Chapter 2

Review of Literature

Increases in prepregnancy BMI elevate the associated risks of adverse pregnancy outcomes (Ukah et al., 2019). This issue is gaining attention with comorbidity and mortality death rates on the rise in the United States (Bauman et al., 2017). Attempts to reduce adverse pregnancy outcomes associated with elevated BMI existed within the literature.

This study seeks to build on previous research by implementing a novel approach of nutritional counseling via telehealth video conferencing and self-weighing for weight measurement via precise Bluetooth scales in the pregnant population with obesity. This chapter will review the literature related to obesity in pregnancy, nutritional counseling, self-weighing, and video conferencing telehealth to describe how these variables affect or may affect gestational weight gain among pregnant women with obesity. This chapter is divided into four sections: obesity in pregnancy, nutritional counseling, self-weighing, and telehealth. Each section includes the search strategy for the literature review, and the relevant literature is discussed by study type.

Obesity During Pregnancy and Adverse Outcomes

As prepregnancy BMI increases, so does the occurrence of pregnancy complications and poor outcomes (Ma et al., 2016). Inherent threats to health common to obesity are amplified in pregnancy when a woman is obese (Khadilkar, 2019). Problems distinct to pregnancy also increase with higher prepregnancy BMI. Some of these issues include excessive weight gain, gestational diabetes mellitus (GDM), pregnancy-induced hypertension/preeclampsia, higher rates of cesareans, and increases in maternal death (Khadilkar, 2019; Marchi et al., 2015; Yang et al., 2019). Conducting an in-depth examination of the existing research for these complications is described in the sections that follow.

Search Strategies

Identification of studies related to obesity and pregnancy outcomes involve general search headings of pre pregnancy BMI equal to or greater than 30 and adverse outcomes in PubMed and similarly in CINAHL. After examining the 87 results for relevancy, one systematic reviews containing 22 studies and two cohort studies were also included in this dissertations review of the literature.

Obesity in Pregnancy and Selected Pregnancy Outcomes: Systematic Review of Reviews

The review of reviews mentioned above was conducted by Marchi et al. (2015). These researchers identified 22 relevant systematic reviews that met their specified inclusion criteria. This systematic review of systematic reviews compared pregnancy outcomes for women of various BMIs. Marchi et al. (2015) followed the procedure of addressing methodological quality of systematic review of reviews by utilizing the AMSTAR checklist (Shea at al., 2007). A total of 573 studies were included. The study samples encompassed only pregnant women. The sample sizes within the systematic reviews ranged from 20,419 to nearly 2 million pregnant women. All types of observational studies were included (i.e., prospective, and retrospective cohort studies and case-control studies). With this large sample size considerable heterogeneity and threats to generalizability were present. However, summarizing the evidence and the population of interest, even with the heterogeneity, allowed the research question "do increases in prepregnancy BMI impact pregnancy outcomes?" to be addressed. Three associated outcomes pertinent to this dissertation are highlighted: GDM, preeclampsia, and cesarean section.

Within the systematic review of reviews, two reviews focused on the connection between GDM and obesity (Chu et al., 2012; Torloni et al., 2009). These systematic reviews included 76 case-control or cohort studies from 1992–2006/2007, including 1.4 million women. Within the

review of reviews, there were two meta-analyses that the researchers obtained similar odds ratios for the association between obesity and GDM of 3.35 and 3.76, with the former being an adjusted estimate for confounders (Torloni et al., 2009). Interventions successful in decreasing the odds of developing GDM included diet and exercise. Torloni et al. (2009) showed exercise decreased the odds of developing GDM by nearly 40% (OR 0.62, 95% CI 0.52–0.75) and hypertensive disorders (OR 0.59, 95% CI 0.37–0.90). The evidence that diet modification reduced GDM is supported by two systematic reviews and two randomized control trials (Callaway et al., 2010; Poston et al., 2013: Skouteris et al., 2014).

Concentrating on the role that obesity has on preeclampsia, the evidence from two reviews were chosen. One was a narrative synthesis and one was a meta-analysis; these two reviews included 54 case-control and cohort studies between the years of 1995–2012. The narrative synthesis by Salihu et al. (2012) estimated pregnant women with obesity were 3–10 times more likely than pregnant women of normal weight to develop preeclampsia. The meta-analysis by Wang et al. (2013) supported these findings and found pregnant women with obesity had over twice the risk of developing preeclampsia (OR 2.68; 95% CI 2.40 – 3.00). The authors of these two reviews speculated an unhealthy diet and lack of physical activity may contribute to an underlying inflammatory process, which is thought to increase preeclampsia risk (Salihu et al., 2012; Wang et al., 2013).

Examining the mode of birth in relation to prepregnancy obesity, three meta-analyses are described. A total of 62 cohort studies, case-control studies, and randomized control trials were the included with much overlap in range of years of included studies (Chu et al., 2007; Heslehurst et al., 2007; Pooblan et al., 2009). Three estimates for the unadjusted odds ratio for having a cesarean among pregnant women with obesity were very similar, 95% CI [1.86–2.27]

and 95% CI [2.28–3.79] (Chu et al., 2007; Heslehurst et al., 2008; Poobalan et al., 2009). It is unclear why pregnant women with obesity have increased risk for cesarean even when controlling for morbidities like GDM and preeclampsia. These women are more likely to have large for gestational age infants, which may partially explain the higher rate among this group of women (Chu et al., 2007). Poobalan et al. reported increases in instrumental vaginal births associated with increases in cholesterol deposits in the myometrium (2009). Additionally, Poobalan et al. (2009) determined women with an elevated BMI also had a poorer response to oxytocin due to increases in maternal adipose tissue. Additionally, a recent study examined differences in metabolic parameters among African American women with and without obesity in the late third trimester (Carlson et al., 2020). They found metabolic pathways related to tryptophan, steroid production, and lipotoxicity were associated with labor dystocia and differed by obesity classification.

In conclusion, this review of reviews provided a summary of the evidence related to obesity and pregnancy outcomes. Key findings illustrated how BMI specifically impacts GDM, preeclampsia, and mode of birth. Limitations existed from the heterogeneity resulting from including a vast number of articles and study population.

Attributable Risk for Poor Pregnancy Outcomes by Prepregnancy Weight Loss: Cohort Study

Yang et al. (2019) used an Australian territorial perinatal database of all births, both hospital and home births, of 24,000 pregnant women with BMI of 25 or more weeks gestation with a singleton between 2009–2015 to estimate the attributable risk of obesity on poor pregnancy outcomes. In the study population, 24% were overweight and 16% were obese. Compared to pregnant women with a normal BMI, those with obesity were older, had higher

parity, were more likely an aboriginal, and were more likely to have smoked. These women had an increased risk for all eight adverse outcomes measured in the study. The three largest attributable risks, adjusted for sociodemographic factors, were developing preeclampsia (aRR= 3.50; 5% CI 3.01–4.01), developing GDM (aRR= 2.66; 95% CI 2.42–2.93), and having a large for gestational age infant (aRR = 2.14; 95% CI 1.94–2.35). The authors calculated the preventable attributable factor for decreased adverse pregnancy outcomes under three hypothetical scenarios of weight loss prior to pregnancy. The first scenario described a 1-unit BMI decrease in overweight women. The second scenario calculated outcomes if there were a 2-unit decrease in BMI for those with obesity. The third scenario was a 5% weight reduction in women who are overweight and 10% reduction in women who are obese. For the three scenarios, results demonstrated 9–16% of preeclampsia, 7–13% of GDM, and that 5–11% of large for gestational age infants could be prevented (Yang et al., 2019).

This study addressed the research gap looking at the preventable attribute risk of poor outcomes associated with excess weight gain in this population. Limitations existed, as these numbers were projected to account for the attributable risk and were not from a randomized clinical trial. With a reasonably large dataset, this study provided an essential population-based perspective on the potential effect of improving perinatal outcomes through nutrition counseling and weight loss before pregnancy.

Gestational Weight Gain in Those with Obesity: Cohort Study

This cohort study by Ukah et al. (2019) was published after the systematic review (author, year) examined the association or the preventable attributable risk of gestational weight gain on pregnancy outcomes for women with obesity. This large retrospective cohort study examined both prepregnancy BMI, weight gain, and birth outcomes. The researchers offered a

unique perspective by examining the effect of both prepregnancy BMI and gestational weight gain on pregnancy outcomes as opposed to prepregnancy BMI alone. This retrospective cohort study linked a statewide birth event database to hospital discharge abstracted data for both women and their neonates for 952,212 women. Prepregnancy BMI was self-reported. The prevalence of prepregnant weight by IOM classifications was 3.1% were underweight, 49.1% had a normal weight, 25.8% were overweight, and 23.0% were obese (Ukah et al., 2019). More women who had an elevated BMI greater than 30 had prepregnancy hypertension or diabetes compared with the normal BMI group. Variations were seen in demographics among the various BMI categories. Focusing on the results related to the population of interest, findings demonstrated 54% of the nearly 166,000 pregnant women with a BMI equal to or greater than 30 prepregnancy gained excess weight according to IOM recommendations compared to 40% of women with normal prepregnancy weight. Among pregnant women with obesity, those with excess gestational weight gain had 12% increased odds for severe maternal morbidity or mortality 95% CI [0.94–1.22]. The adjusted odds ratio increased with increasing BMI, from 1.07 for Class I to 1.23 for Class III. Women with excess gestational weight gain and obesity had small increased odds of maternal death and severe maternal morbidity (adjusted OR= 1.12; 95% CI1.01–1.23; Ukah et al., 2019). The findings illustrated how both obesity and excess weight gain were associated with adverse pregnancy outcomes, including for women with lower prepregnancy BMI. Additionally, Ukah et al. (2019) described severe morbidities requiring lifesaving procedures, unlike other studies that have counted relatively less severe outcomes such as lacerations. As with any research collected from a database, there is likely to be misclassification errors. However, such errors should be nondifferential, or not dependent on the woman's BMI or gestational weight gain. This study supports future research evaluating

effective strategies to help pregnant women with a prepregnancy BMI greater than 30 limit excessive weight gain (Ukah et al., 2019).

Summary of Obesity During Pregnancy

These studies documented a clear association between BMI greater than 29 and increased rates of preeclampsia, cesareans, and maternal mortality (Marchi et al., 2015; Ukah et al., 2019; Yang et al., 2019). Additionally, women with obesity were more likely to have excess gestational weight gain, resulting in a further increase of having poor pregnancy outcomes. Authors from these studies suggested adverse pregnancy outcomes may be potentially avoided through the achievement of recommended gestational weight gain. These studies are central to this dissertation as they describe why interventions targeted at reducing excessive gestational weight gain in women who have obesity during their pregnancy are necessary.

Nutritional Interventions to Improve Pregnancy Outcomes

Search Strategies

A review of the literature on the topic of nutritional counseling interventions, weight gain, pregnancy outcomes, and obesity in pregnancy is next provided in this literature review. Identification of nutritional approaches tested among pregnant women with obesity was accomplished through a search using Academic Search Premier, PubMed, and CINAHL databases. General search terms of *dietary counseling, gestational weight gain,* and *pregnancy BMI equal to or greater than 30* in the English language with human subjects were used. This search method identified 267 studies. Of these, one systematic review and meta-analysis capturing 49 studies, and two RCTs pertinent to this dissertation were chosen for detailed review.

Nutritional Counseling to Limit Gestational Weight Gain: Systematic Review

Synthesizing evidence from relevant studies, the systematic review and meta-analysis by

Vincze et al. (2019) reported on the impact nutritional counseling has on weight gain. The Joanna Briggs Institute Meta-Analysis of Statistic Assessment and Review Instrument was used by Vincze and colleges to evaluate the quality of the systematic reviews and meta-analyses of potential included reviews. Full-text articles published from 1980–2016 that met the study criteria were reviewed by Vincze et al. (2019) For the study described by Vincze et al. (2019) one narrative synthesis which included 48 studies, and one meta-analysis that included 30 articles, all RCTs were included in this review of reviews. Twenty RCTs focused on pregnancy alone, five included both pregnancy and postpartum, and 14 were postpartum only. Of the 20 studies that looked at pregnancy alone, the total population included 5,895 women.

Considerable heterogeneity was found across all studies. The overall quality of the studies was described as moderate due to the lack of clarity within several of the study's dietary interventions. The origin studies varied, with 15 from the United States, and the others from Australia, Canada, Denmark, Finland, Italy, and Sweden, and some were unspecified. Studies differed by inclusion criteria and timing in pregnancy for recruitment and type of control groups. Most studies recruited based on BMI: five studies with a BMI equal to or greater than 30, seven with a BMI equal to or greater than 25, one with a BMI equal to 18.5–24.9, and six with all BMI categories from underweight to very obese. Seventy-two percent (72%) of studies required women be less than 27 weeks' gestation with 25% (n = 14) requiring enrollment in the first trimester. Eleven studies used routine prenatal care for the control group, but three had an added component, such as providing the control group with an exercise DVD or written educational booklet on diet and exercise. The interventions varied, with 10 of the studies having an exercise program in addition to nutritional counseling. The nutritional interventions provided in pregnancy significantly varied in delivery methods, timing, and frequency of nutritional sessions.

Only five studies during pregnancy included intensity for all intervention components. One study reported the duration of the nutritional sessions but did not include follow-up information. Women received dietary counseling individually face-to-face with a nutritionist, in group sessions, through phone calls or text messages, or in a combination of these modalities. The dose of the intervention also had a wide range from 1–2 visits with a nutritionist to more than 10. One study had women meet with a nutritionist twice and attend up to 16, 90-minute group sessions. The results of those studies using usual prenatal care as the control group showed women experiencing the intervention gained 1.25 kg less (95% 2.1–0.4). Among the 11 studies showing a significant reduction in gestational weight gain, nine met once a month, and eight met individually and in person during the intervention. In these studies, 45% of participants were all BMI categories (n = 5), but the majority were limited to women who were obese (n = 4) or overweight or obese (n = 2). The intervention itself differed among these studies with some focusing solely on diet and others including exercise along with diet. One study found that gestational weight gain was found to be significantly less for those who met with a dietician and took weekly exercise classes.

The researcher described above provided helpful information on the nutritional interventions and their efficacy. Even with differences seen between x in the study design, the meta-analysis results demonstrated dietary interventions aimed at moderating gestational weight gain can be successful for women with obesity. Inconsistencies among the intervention protocols account for the high heterogeneity among studies. The sample size of 5,895 women was large enough to make the results credible. Loss to follow up was not accounted for, many participants did not complete the intervention, and reasons for this were not reported, making it difficult to evaluate the true effectiveness of the intervention. This review highlighted a combination of

weight monitoring and remote nutritional education is an unexplored approach which may be as effective and maybe more accessible and cost-effective in limiting gestational weight gain.

Nutrition and Weight Restriction in Pregnancy: Specific Randomized Controlled Trial

From the systematic review and meta-analysis by Vincze et al. (2019), there was one study worth discussing further in detail. This was a single-blinded study because participants knew which treatment group they were assigned. The RCT by Wolff et al. (2008) provided evidence dietary interventions alone using an RD can effectively moderate the total amount of weight gain by women with obesity during pregnancy. This study differed from the proposed dissertation study as it examined weight restriction instead of weight moderation in pregnancy. This study addressed the insufficient number of studies evaluating the effect of limiting gestational weight gain on pregnancy and birth outcomes in women with obesity. The objective was to determine if gestational weight restriction could be achieved and if the weight restriction would affect increases in insulin, leptin, and glucose levels in pregnancy. The intervention was 10 total consultations lasting 1 hour each of dietary education sessions on healthy eating in pregnancy provided by an RD. Both the intervention and control groups recorded supplement use and kept food intake diaries at specified intervals. Biometric measures included weight, blood pressure, and heart rate obtained at enrollment, 27 and 36 weeks gestation. Additionally, fasting blood levels, including serum insulin, serum leptin, and blood glucose were obtained at 27 and 36 weeks gestation.

Based on the inclusion and exclusion criteria (no preexisting diabetes or development of GDM), 66 nondiabetic White women with obesity were recruited using convenience sampling from two hospitals in Denmark. Of these, 11 in the control group and five in the intervention group were not included in the final analysis. Reasons for drop out included the time-consuming

nature of the trial, disappointment in being assigned to the control group and not receiving the intervention, and development of GDM.

Study results showed randomization was successful in equally distributing both sociodemographic and biometric baseline measures. Changes in calorie intake and macronutrient patterns differed between groups providing evidence that nutrition counseling was successful in changing the eating habits of women in the intervention group. The intervention group restricted their total gestational weight gain to an average of 6.6 $\pm$ 5.5 kg, compared to a gain of 13.3 $\pm$ 7.5 kg in the control group (a mean difference of 6.7 kg; 95% CI 2.6–10.8 kg). Additionally, on average the intervention group gained 0.18 kg/week (95% CI 0.07–0.30), less than the control group from inclusion to 36 weeks gestation. Weight at 36 weeks gestation was representative of total weight gain at birth. Additionally, serum insulin and serum leptin were 20% and 23% lower in the intervention group compared to the control group at both measured time points, but no difference was found for fasting glucose between groups. There was no statistical difference in clinical outcomes of GDM, preeclampsia, prolonged pregnancy, or cesareans. Lack of improvements to these pregnancy complications may be a result of limited power, with only one to four people in both groups experiencing the outcome.

This study showed fairly intense nutritional counseling (10 hours) can result in more than 6.5 kg less gestational weight gain among women with obesity. There may be some threats to internal validity. Among the control group, several women stated their reason for dropout was disappointment related to not being in the intervention group. Therefore, the potential Hawthorne effect operating in the intervention group may have magnified the results, but it also points to the desire of women with obesity to modify their weight gain in pregnancy and their willingness to engage in a discussion of diet change. The generalizability of these results was limited to women

entering pregnancy in a healthy status who do not develop GDM. This proposed dissertation study differs from the Wolff et al. (2008) study in that the nutritional intervention was delivered via video conferencing.

Nutritional Counseling to Reduce Gestational Weight Gain: Randomized Controlled Trial

The study by Thornton et al. (2009) was a randomized, controlled parallel-group trial that was conducted in three tertiary medical centers in the United States from June 1998 to May 2005. The study population included women with obesity who were 12–28 weeks gestation with a singleton pregnancy. Pregnant women who had preexisting diabetes, renal disease, hypertension, or chronic renal diseases were excluded from the study. Both groups received one session with an RD regarding conventional prenatal nutritional guidelines, with weight measured at each prenatal visit. The primary independent variable was the intervention group alone received a detailed dietary intake protocol and a 24 kcal/kg balanced nutritional regimen consisting of 40% carbohydrates, 30% protein, and 30% fat, with no fewer than 2,000 calories. The intervention group was instructed to record their diet into a food diary notebook which was reviewed at each prenatal visit and collected at the end of the study. The researchers encouraged participants in the intervention group to not weigh themselves at home, as self-weighing at home could inflate bias toward significance in the intervention group (Thornton et al., 2009). Participants in both groups were encouraged to complete 30 minutes of exercise a day. The pertinent dependent variables of this study included the weight of participant at delivery and six weeks postpartum, type of delivery, preterm birth, GDM, and gestational hypertension. Randomization was successful in creating similar groups for women, and no blinding was mentioned for either the participant or those delivering the intervention. Convenience sampling was used to recruit 719 participants, 367 refused to participate, and 95 did not meet the study

criteria, the remaining 326 participants were randomized, with 124 assigned to the intervention group and 133 to the control group. Eight participants in the intervention group and 17 in the control group were lost to follow up, leaving 116 in each group. Data from women who received the intervention were analyzed by adherence or non-adherence group based on end of the study food diaries.

When analyzing if a nutritional regimen prescribed by the RD affected gestational weight in pregnancy and birth outcomes, women in the intervention group weighed significantly less and had less total gestational weight gain at the end of the pregnancy (p <.001). The results indicate a significant reduction of gestational hypertension in the intervention group (p = .046, 8.6%, n = 10) when compared to the control group vs. 2.6% (n = 3). A non-significant reduction difference was found for occurrence of preterm labor between the intervention group (2.6%) compared to the control group (4.3%; p = 0.472). This study demonstrated placing women with obesity on a calorie restricted healthy balanced diet was safe and likely to incur benefits in positive pregnancy outcomes.

Overall, this study's findings demonstrated how a nutritional intervention during pregnancy in a population with obesity can impact both perinatal outcomes and weight gain during pregnancy. Having participants' awareness to group assignment could create a Hawthorne effect, inflating bias toward significance. Instrument bias may be present when measuring adherence to the nutritional regimen as this is self-reported data and food diaries are known to influence weight. However, both the control and intervention group used a food diary, equalizing the effect of the intervention in both groups. The authors stated they hope to see many more studies to examine active interventions, which include nutritionally monitoring women with obesity and individualizing their prenatal management. This dissertation differs from Thornton et

al. (2009) because it used video conferencing telehealth and weekly self-weighing instead of weights collected at routine prenatal visits. Vital principles, such as using a monitored calorie suitable meal plan during pregnancy, set a foundation for the nutritional interventions to be conducted with an RD for this dissertation.

Antenatal Dietary and Lifestyle Interventions: Randomized Controlled Trial

The LIMT RCT trial aimed to examine the effects of antenatal dietary and lifestyle advice on women who are overweight or obese (Dodd et al., 2014; Dodd et al., 2011). This RCT occurred in three different maternity hospitals in Australia. Participants were not blinded to which treatment group they were assigned, but the researcher collecting data from the charts for both groups was blinded. Eligibility was determined by BMI equal or greater than 25, singleton pregnancy, and a pregnancy between 10 to 20 weeks gestation. Women were excluded if they had type 1 or type 2 diabetes prior to the pregnancy. The study population was comprised of predominantly White and highly socially disadvantaged women, limiting external validity.

The study intervention included a combination of dietary advice, physical activity, and behavioral strategies. The intervention group was given two nutritional counseling sessions in person (initial visit and at 28 weeks with an RD) and three counseling sessions over the phone. Dietary advice was individualized and included healthy meal planning based on motivational interviewing and self-identified goals of participants. Time spent in person and on the phone was not reported. Participants were asked to record their food intake and physical activity in a workbook. Physical activity advice focused on the benefits of exercise and safety concerns. Self-reporting could be a historical threat to internal validity. Women in the lifestyle advice intervention group were further separated into a walking group and non-walking group. Women in the walking group were encouraged to participate three times a week, with a support person,

and under the guidance of a trained researcher. Women were encouraged to cover 4.2 km, over 40 minutes, and have a 5-minute stretch at the beginning and end of the session. The control group received routine prenatal care.

Nutritional intervention fidelity was measured using a semi-quantitative food frequency questionnaire completed at study enrollment, at 28- and 36-weeks' gestation, and at four months postpartum by all study participants. This widely used food frequency questionnaire (Willett, 1995) consists of 126 food items, which, aside from frequency, included portion size, item preparation or cooking method, and use of supplements. It was grouped into seven categories. Open-ended questions also documented other foods consumed not specified on the questionnaire.

The study was powered to detect differences in pregnancy outcomes. The primary study outcome was the rate of large of gestation age infants. Secondary outcomes included both infant and maternal outcomes such as preterm birth, GDM, gestational hypertension. A posthoc analysis examined differences in gestational weight gain.

The total trial included 2,152 women (1,108 in the control group and 1,104 in the intervention group) and 2,142 live born infants. The drop-out rate between groups was similar, about 15%. Randomization was successful in equally distributing women by age, gestational age at entry, BMI, parity, and social disadvantage. There were differences in drop-out rates for women who identified as smokers in the intervention group (n = 124) and the control group (n = 97) with the smoker drop-out rate being x more/less than the non-smokers. The nutritional intervention resulted in little difference between groups on total glycemic index; healthy eating index; or intake of calories, macronutrients, or food groups with the exception of the intervention group eating half a serving more of vegetables by 36 weeks gestation (Dodd et al., 2011) Maybe unsurprising, there were few differences in pregnancy outcomes with no difference in the

primary outcome, percent of LGA infants (21% and 19%, controls and intervention respectively). There was a 18% decreased risk of having an infant weighing more than 4000 gm for the intervention group (aRR – 0.02; 95% CI: 0.68–0.99). There were no differences in any maternal outcomes, including no difference in gestational weight gain or the percentage of women gaining more than the IOM recommendation.

The results of this large trial argued against the effectiveness of diet and exercise counselling to improve pregnancy outcomes. The study was powered to examine a real pregnancy outcome, LGA with a baseline incidence of 14% (although the actual rate was somewhat higher) instead of using weight gain as a surrogate. The study used an intention to treat analysis and had a reasonable drop-out rate for a study lasting through pregnancy and 4 months postpartum. The lack of evidence about any effectiveness of the study intervention in contrast to evidence from other studies was concerning. A study with multiple study sites may have important differences among those delivering the intervention and information about protocol fidelity was lacking in the two written papers of results. It may also be that asking women to monitor their weight more frequently than what is done in routine prenatal care may be an important component to encouraging women to adhere to a healthier eating pattern. This dissertation aims to provide women with an online, accessible, and more intensive nutritional counseling over a shorter period of time, which may be more effective. Additionally, its inclusion of weekly self-weighing may be important to reinforcing a woman's goals for her pregnancy weight gain.

Summary of Nutritional Counseling

The meta-analysis and systematic review by Vincze et al. (2018) demonstrated how nutritional interventions could modify excess gestational weight gain during pregnancy. Within

this meta-analysis and systematic review, a study by Wolff et al. (2008) focused on how a nutritional intervention alone provided by an RD significantly modified the amount of gestational weight a woman gains during pregnancy. The study by Thornton et al. (2009) illustrated how a very intense nutritional counseling protocol provided to women with obesity with an RD, can modify gestational weight gain and improve perinatal outcomes. The LIMIT trial by Dodd and colleagues was a large RTC that looked beyond just weight gain during pregnancy but targeted perinatal outcomes as a measure for nutritional counseling. Although this was a large study, it is unclear if the results are due to a lack of effectiveness of the intervention or internal validity issues with how the intervention protocol was carried out. The differences between the Wolff study done among Danish participants and the Dodd et al. study done with Australian women may also be due to differences in women's overall motivations or self efficacy and cultural norms related to diet and exercise and therefore may not be generalizable in other countries such as the United States.

Role of Self-Weighing in Excessive Weight Gain Prevention

In the adult population, self-weighing was an important predictor of weight change (Ross et al., 2019). Weight is continually changing in pregnant women, and providers routinely monitor this change during prenatal visits, which occur monthly until the last trimester. For women with elevated BMI, researchers wondered if self-weighing at more frequent intervals may provide a simple, cost-effective solution to managing weight gain. Precise measurement of self-weighing was lacking in current research. Self-weighing is typically done as part of another study or intervention and is logged by the participant. An in-depth literature review describing these practices was conducted.

Search Strategies

To establish the effect that self-weighing has on excess gestational weight gain for women with obesity, a search using the general terms self-weighing, and gestational weight gain was conducted. Recent peer-reviewed published work on this topic in PubMed and CINAHL brought up 2,283 results. After analyzing the articles for relevancy, 3 RCTs were reviewed in depth.

Monitoring Weight Gain With a Visual Graph: Randomized Controlled Trial

Jeffries et al. (2009) conducted a single blinded RCT with the study objective to assess what effect regular self-measured weight had on total weight gain during pregnancy. This Australian study recruited participants at less than 14 weeks of pregnancy regardless of their BMI. Individuals who were non-English speaking, less than 18 years of age, or had a twin pregnancy were excluded from the study. Participants in the intervention group recorded their weight on a tabular or graphical chart provided to them at 16, 20, 24, 28, 30, 31, and 34 weeks gestation obtained during their antenatal visit or by self-measurement with a digital scale at home. Participants were told their optimal gestational weight gain in pregnancy based on the IOM guidelines. The control group was weighed at recruitment and 36 weeks; no other instruction was given on optimal weight gain or regular self-weighing. Both participants and researchers were blinded to the group assignment.

Of the 286 participants, 138 were randomized to the control group and 148 to the intervention group. Randomization successfully evenly distributed participants by mean weight, gestational age at recruitment, and mean BMI index. Originally 148 women were in the intervention group and 138 women were allocated to the control group. After 50 (18%) participants were lost to follow up, there were 125 in the intervention group and 111 participants in the control group. Data for 17 participants could not be included because the hospital was

unable to weigh the participants on the same scale.

The overall results showed no statistical difference in weekly weight gain between groups. Women in the intervention group had a mean per week gain of 0.44 (0.173) kg compared to 0.46 (0.156kg) per week in the control group using an unpaired T test with a mean difference of 0.02 kg/week 96% CI [-0.02kg to 0.07kg/week]. However, among those who were overweight, the intervention group gained 0.12 kg/week less (95% CI 0.03 to 0.22 kg/week).

This study provided an indication that a combination of self-monitoring and recording of weight may decrease gestational weight gain. However, weights were either recorded at antenatal visits or at home. Having participants weigh-in either at home on a digital scale or on the hospital scale may weaken internal validity. This study sought to address this issue by sending data from the digital scales directly to the researcher and RD from the device. This study provided supporting evidence for this dissertation, as it demonstrated self-weighing can improve adherence to IOM guidelines for recommended weight gain.

Self-Weighing in Women At-Risk for GDM: Randomized Controlled Trial

Harrison et al. (2013) conducted a triple blinded RCT of a lifestyle intervention aimed at limiting gestational weight gain among pregnant women at risk for developing GDM in Victoria, Australia. A secondary analysis of these data aimed to evaluate the effect that self-weighing in pregnancy had on weight gain compared to routine prenatal care visit weigh-ins (Harrison et al., 2014). Women who were classified as overweight or obese between 12–15 weeks' gestation were recruited to the study. Women who had type 1 or type 2 diabetes, BMI equal to or greater than 45, existing medical conditions, or did not speak English were excluded from the study.

The intervention group received four sessions of behavior lifestyle change advice provided at the antenatal clinic at 14–16, 20, 24, and 28 weeks gestation. These sessions were

implemented by an exercise physiologist. Pregnancy-specific dietary advice, healthy eating, guidance physical activity messages, behavioral change strategies, and an aid in self-identifying goals were provided during the sessions. Participants were encouraged to use a pedometer and refer to a chart identifying appropriate weight gain based on IOM guidelines. Both groups received written information on promoting optimal health, gestational weight gain, and lifestyle advice.

The total study population was 228 (107 in the control group and 121 in the intervention group) with a 9% and 12% loss to follow-up in the control and intervention groups, respectively. Both groups were similar based on sociodemographic factors, weight, and BMI. In the intervention group of 106 women all completed the baseline and anthropometrics questionnaire. In the control group, the data from 97 women were analyzed, with all women completing the anthropometrics and baseline questionnaire. By 28 weeks gestation, the intervention group gained an average of 0.9 kg or 14% less than the control group [6.0 (2.8) vs 6.9 (3.3) kg; (96% CI-1.7 to -0.1). Women in the intervention group had a significantly lower estimated rate of weekly gestational weight gain compared those in the control group [0.43 (0.22) vs 0.51 (0.22) kg/week]. Women with obesity gained less weight in the intervention group although this was statistically significant (5.2 (2.6) vs 5.9 (3.5) kg (95% CI -0.7 to 2.1).

This study provides some evidence for the efficacy of self-weighing in limiting gestational weight gain in overweight women of various ethnic groups with risk factors for GDM. Whether the results were generalizable to all pregnant women who are overweight was unclear. Implications for future research means that self-weighing can be considered a possible strategy for controlling excessive gestational weight gain.

Daily Weighing: Randomized Controlled Trial

Arthur et al. (2020) conducted a non-blinded parallel randomized control trial aimed to assess if a daily weighing intervention would control excessive weight gain in pregnant nulliparous women. The study population included women in their second trimester of a singleton pregnancy, and participants were recruited from a single hospital in Australia. Women who were not proficient in English; were multiparous; had pre-existing diabetes, hypertension, or renal disease; or smoked were excluded from the study. The intervention was a single session instructing participants to record daily weights in a weight diary and weigh themselves each day. As an incentive to join the study, participants in the intervention group were each given a scale. The researchers did not provide a standardized scale, nor did they collect data on weight obtained from the scale provided. Both the intervention and the control group were given a single educational session describing the IOM weight guidelines.

Randomization successfully equally distributed baseline sociodemographic and obstetrical characteristics as well as BMI. Four hundred women were randomized to either the control or intervention group, with 326 in the final analysis (160 in the control group and 166 in the intervention group). The 17.5% lost to follow-up was similar between groups. There was no difference between groups of the percentage with excessive weight gain (93% control group and 87% intervention group; p=0.31) Change in weight per week during the study period was also not significant, with a 0.59 kg difference for the intervention group (SD 0.30) vs. 0.63 kg in the control group (SD 0.31; p = 0.22).

This study had significant validity issues. Internal validity was poor because there was no measure of fidelity to the intervention among those assigned to daily weighing. Therefore, it is unknow what proportion weighed themselves daily or even weekly. Generalizability to Australian women may also be limited due to enrollment of few Aboriginal women, and as

indicated earlier, generalizability to ethnically diverse U.S. population may also be problematic. This study differed from the proposed dissertation study, which is asking women to weigh only weekly, and data was automatically uploaded avoiding issues of self-report bias.

Summary

Self-weighing as an intervention to control excessive gestational weight gain has mixed findings in the current literature. Some evidence supports the use of self-weighing in combination of other interventions to control excess gestational weight gain (Harrison et al., 2014). Differences in study findings may result from varying sample size or lacking intervention strength and rigor such as weak methods in participant reporting of weight (Arthur et al., 2020). From this literature search, there are no known studies in pregnancy that used a smart scale to record self-monitored weight in pregnancy. This study is different from other studies as it was the first known study to collect and record self-weighing data on pregnant women with obesity using a smart scale. This method has the potential to reduce participant bias, and empirically determine the frequency of weight measurement.

Telehealth

Remote healthcare services are gaining momentum with approximately more than 50% of healthcare institutions and hospitals using telehealth services (Tuckson et al., 2017). According to the American Academy of Nutrition and Dietetics (2020), telehealth uses electronic information and communication technology to implement long distance health care and education. Telehealth is possible via the internet, video conferencing, email, fax, or broader distance communications. This dissertation evaluates telehealth explicitly via video conferencing, and therefore this literature review also analyzes studies using the same type of telehealth technology. Amidst the 2019–2020 COVID-19 pandemic, and the necessity for

physical distancing, the demand to use telehealth services has urgently increased (Bikson et al., 2020).

Search Strategies

Identification of appropriate studies of video conferencing telehealth included general search terms of telehealth and video conferencing limited to the topics on pregnancy, obesity, and nutrition, which brought up 87 results in PubMed and CINAHL. After examining the articles for relevancy, one feasibility study, one RCT, and one cohort study are examined in detail.

Use of Telhealth Nutritional Counseling of Posptartum Women: Feasbility Study

The study by Vincze et al. (2018) was a feasibility study evaluating the implementation, acceptability, and preliminary effects of a tailored nutritional and exercise program delivered via video-consultations. The study population included women who were 3–12 months postpartum living in Australia. Recruitment of participants took place through a medical research center's website via Facebook and twitter. An online survey was utilized for screening participants for the inclusion and exclusion criteria Women who were 3–12 months postpartum, had a BMI equal to or greater than 25, and were medically cleared for exercise participation were eligible for the study. Additional eligibility requirements included internet access and connection speed of 300 kbps, ability to attend two in-person assessment sessions, not on insulin or hypoglycemic medications, and not pregnant or trying to conceive. The intervention included a 60-minute initial live video consultation with an exercise physiologist and a 60-minute initial video consultation accredited RD within the first 2 weeks of the study. Following the initial visit, a 30-minute session was provided again by the exercise physiologist and RD on live video conferencing. All participants received four sessions with an option to book one more appointment with either the exercise physiologist or the RD for 30 minutes on live video. These

sessions occurred over the course of five weeks. The RD collected a 3-day, image-based food record for personalized discussion of portion size, meal composition, and timing during the counseling sessions. Participants also wrote out their individualized goals that were included in video consultations. Of 71 participants expressing an interest in the study, 30 women correctly completed study materials and were enrolled in two cohorts.

Of the 30 women enrolled in the 8-week study, 27 (90%) completed it. Nearly all participants (n = 26) completed the four consultations sessions, and 11 participants opted for the supplemental session of their choice. Women indicated they were comfortable with interacting with the healthcare professional online [4.5(.8) out of 5] and were overall satisfied with the video-consultations [4.4 (0.9)]. The mean weight loss was not significant, and women reported wanting more support to attain weight management goals with both the RD and the exercise physiologist [4.3 (.9) and 4.1 (.9) out of 5].

In summary, Vincze et al. (2018) demonstrated postpartum women found video telehealth to control weight both acceptable and helpful. This study is important to this dissertation as it sought to describe the feasibility of diet and exercise interventions provided through a telehealth platform for a similar study population. This dissertation differs from the study as its study population are pregnant women, not those postpartum.

Telehealth to Promote Weight Loss Among Those With Obesity: Randomized Controlled Trial

Alencar et al. (2019) conducted a single-blinded RCT to assess change in body weight from a 12-week, telehealth-based weight loss program integrating health coaching using video conferencing. Convenience sampling was used to recruit participants. A total of 12 men and 13 women between the ages of 23–64 volunteered. Participants were described to be weight stable,

non-tobacco users, free of metabolic or renal disease, and not on any metabolism altering medications but may have been on antihypertensives. Additional eligibility requirements included residence in the state of California, ownership of an iPhone or smart phone, and access to an internet connection. Individuals were excluded from the study if they had type 1 or type 2 diabetes mellitus, had a serious medical condition, were taking medications for weight loss, or were participating in a medical weight loss program.

The intervention group met once a month with a medical doctor via telehealth who prescribed a caloric deficit diet to induce a weight loss of 1–2 lbs. a week and then weekly with the RD via telehealth. Tracking of weight occurred using a Bluetooth scale, a Bluetooth activity tracking watch, and a blood pressure cuff. Assuming all participants attended the sessions and sessions occurred monthly for the medical doctor and weekly for the RD sessions, there would be three total sessions with the medical director and 12 sessions with the RD. Online educational modules were given to the virtual care group, which included single video and handout to watch once a week. The total number of sessions and duration of sessions by the medical doctor was not included in the study details.

Prior to eligibility assessment 127 individuals were screened. From those, 71 declined to participate. Thirty eligible participants were randomized into two groups of 15 each: intervention and control. Neither the reliability of the devices or their ability to produce valid data to track measurements was provided in this paper. Of the 30 participants recruited to the study, 25 (83%; 12 men and 13 women) completed the study of 12 weeks. The intervention group had a significantly larger mean decrease in overall body weight loss (7.3 ± 4.4 kg) compared to the control group (1.5 ± 4.4 kg, $p \leq .005$).There was also a greater mean reduction in percentage of

body fat in the intervention group (-9.0 ±8.3%) compared to the control group (1.3 ±7.7%, p ≤.005).

This study provided evidence that the use of video conferencing to deliver nutritional counselling with a RD can be effective in achieving weight goals, at least in the short term. However, this study included the use of a medical doctor to also provided counseling sessions, something that differs from the proposed dissertation study, which is using just an RD. Within the discussion section, the authors mentioned there were technical challenges with hardware and connectivity that contributed to missing data with no further explanation. A defective or inconsistent scale, blood pressure cuff, or watch could also cause instrument bias and potentially invalidate findings of the study (Shuttleworth, 2009). The reliability and validity of the devices used to track measurements was not provided in this paper. This dissertation sought to mitigate this issue by eliminating the need for the participant to connect to wireless internet for data retrieval of weight information by using a data hub. All the participant needed to do was plug in the hub and then start using the scale. Additionally, in this dissertation those eligible for the intervention were screened prior to the study to ensure adequate internet connection existed to support telehealth communication.

Virtual Visit Prenatal Appointments: Cohort Study

Pflugeisen and colleagues (2017) conducted a descriptive observational cohort study that aimed at implementing and exploring the satisfaction with a new model of prenatal care that combined traditional and online visits using video conferencing. The study sample was comprised of 30 women who initiated prenatal care in the first trimester of a singleton pregnancy. Unfortunately, the demographics between the two cohorts were different with women in the new model more likely to have a partner, not participate in a government nutrition

program, and more likely for this not to be their first pregnancy. Twelve women were ineligible for the virtual prenatal care group because they were deemed as a high-risk pregnancy.

The intervention was virtual prenatal care, where five of the 14 prenatal visits and one postpartum visit were conducted via video conferencing. Women receiving virtual visits were provided a fetal doppler and blood pressure monitoring device. Women used their own technology for video conferencing and self-weighing. An advanced practice nurse practitioner provided a 10–15-minute session discussing diet, weight gain, and preparing women for upcoming tests. Topics of domestic violence were also covered. If women did not speak English, translators who spoke up to 60 languages were provided to translate medical information. If an additional follow-up visit was needed, an in-person office visit with the physician was scheduled. All virtual track patients had access to online resources on the topics of pregnancy, breastfeeding, and parenting. All groups received prenatal lab work and an ultrasound at 20 weeks gestation.

This study analyzed data from low-risk women, identified through the electronic medical record, who used traditional care (n = 941) and compared them to women who chose virtual visits (n = 117). Women picked which group they wanted to be in and could change groups during the study, although 98.1% of women stayed in the group they originally chose. From those who switched, eight transferred from the virtual group to the traditional group, and 12 switched from the traditional group to the virtual group.

The results showed no difference in pregnancy and birth outcomes between the virtual prenatal group and traditional prenatal group for GDM, cesarean rate, newborn birth weight, NICU admissions, and gestational age at birth. The only difference found was a higher number of preeclampsia cases in the intervention group compared to the control group (OR 2.70 [1.21–

6.02]). Additionally, there was no increase in general encounters, remote encounters, ED, or hospital encounters between groups. Both groups had high satisfaction with their care, but satisfaction was overall higher in the virtual prenatal care model.

Generally, the study findings demonstrated using telehealth to deliver a portion of prenatal care is highly acceptable and satisfying to pregnant women. Although prenatal care has traditionally been delivered through one-on-one, face-to-face visits or through in-person group prenatal care, there are many potential barriers to this model for women, such as a lack of transportation, distance to travel, lack of childcare, or ability to take time off from work.

Summary

The demand for telehealth has increased in urgency since the 2019–2020 COVID-19 pandemic. Few studies exist exploring video conferencing telehealth in the maternal population (Bikson et al., 2020). Studies have tested the effectiveness and feasibility of using this technology to reduce postpartum weight gain. These studies showed telehealth is possible for the population of interest and provide support for this dissertation. Additionally, emerging literature illustrates the effectiveness of using telehealth video conferencing to reduce weight gain in the obese population (Alencar et al., 2019). Study findings supported a telehealth medium's ability to effect weight gain (Alencar et al., 2019). The study conducted by Pflugeisen and colleagues demonstrated the efficacy of applying video conferencing telehealth to routine prenatal care. Although the population for virtual prenatal care utilized low-risk women, findings are significant as they support the use of video conferencing telehealth in the pregnant population. There was a vast gap in the literature evaluating the use of video conferencing telehealth in pregnancy. Based on this extensive literature review, no study exists looking at the use of video conferencing to moderate gestational weight gain in women with obesity. Overall, women were

satisfied with virtual prenatal care and highly valued providers attending their concerns.

Conclusion

This literature review highlighted the health effect of elevated maternal BMI, previously tested solutions to improve gestational weight gain, and provided justification for testing a newer intervention. The topics of prepregnancy BMI, excessive gestational weight gain, and pregnancy outcomes, being reviewed in detail here, have laid the foundation for this dissertation. Relevant articles on existing interventions, such as nutritional counseling and self-weighing, were critiqued. Comparing the strengths and weaknesses of these studies provided both justifications for testing these interventions and insights for improvements. Innovative approaches to advancing strategies at improving gestational weight gain in this population included using video conferencing telehealth. Using a feasibility study design was consistent with methodologies employed by the formerly discussed articles.

Chapter 3 Methodology

Purpose of the Study

The purpose of this feasibility study was to determine the magnitude of the effect of using a combination of weekly weights and an online RD to control excessive gestational weight gain.

Research Questions

There were two major research questions in this study. These research questions were the basis for the specific aims.

Question 1

Will participants with obesity engage in online dietician counseling to control gestational weight gain? Secondarily, what are participants' satisfaction with this modality?

Question 2

Does self-weighing alone or in combination with online nutrition counseling have an effect of gestational weight gain in pregnant women with obesity compared to historical controls?

Specific Aims

There are three specific research aims, these aims are associated with the research questions.

1. Describe the study population in terms of sociodemographic influences (i.e., ethnicity, age, weight, and height) and obstetrical influences (i.e., parity and pregnancy weight).
2. Describe participant satisfaction with the study interventions of weekly weighing and online nutrition counselling.
3. a) Compare the differences in gestational weight gain from enrollment to 6

weeks among pregnant women with obesity who were not given any special nutrition counseling or scale (historical controls) to those given scales and asked to weigh themselves weekly.

b) Compare if there were any differences in gestational weight gain among the intervention group, between those who receive nutrition counseling and those who did not.

c) Determine the effect size of the interventions for a future larger RCT.

Study Design

This study was a feasibility study aimed at determining the magnitude of the effect of weekly self-weighing and the use of an online dietician to reduce gestational weight gain in pregnant women with obesity. Once randomized to one of two groups, nutritional counseling was provided by a RD to the intervention group. The timing of counseling, one 30-minute session once a week for six weeks, was based on a previous study using a comparable intervention and participant sample size (Mortensen et al., 2012). The intervention group met once a week with an online RD via a HIPPA secure telehealth system called Healtie, following recommendations by Nichols (2018) on nutritional counseling and IOM standards for appropriate weight gain.

Methods

This section describes how the research question was answered, provides justification for feasibility study, and explains how the results were analyzed.

Recruitment

Pregnant women were recruited from women's health centers located in San Diego County. The women's health center's staff were notified, and the flyer was printed and placed at

the front desk for participants to access a QR code for virtual enrollment screening for participants who are at least 12–14 weeks gestation. A few participants were recruited using the online flyer through social media after 2 months from the start of the study when recruitment and enrollment was delayed due to restrictions from COVID-19 pandemic.

The recruitment occurred via two methods: patient self-identification and direct invitation from the providers office. Flyers were posted in the waiting rooms of the women's health center offices one to two weeks before the start of the study, and during the study women were provided the flyer and invited to fill out the enrollment survey. Women interested in participating in the study scanned the QR code on the flyer to determine if they were eligible. After the individual scanned the QR code from the flyer, a short questionnaire populated. This survey asked questions to determine if the women met the eligibility criteria. A second method included participant selection by the women's health center staff, based on the eligibility criteria, who allowed the principal investigator to speak with potential participants and briefly discuss the study. Women were able to use the QR code or phone number to contact the researcher. These two methods at the selected health centers failed to meet enrollment numbers after 2 months, and the utilization of social media was necessary. Recruitment of participants from social media followed previously developed guidelines for the use of social media recruitment for research (Gelinas et al., 2017). One women's health center provided historical charts with a comparable study population based on the eligibility requirements to serve as a historical control to compare weight gain in women with routine prenatal care.

Informed Consent

Written informed consent in English was provided to participants describing the nature of the study and identifying any potential risks and benefits. Education on nutrition in pregnancy

was provided to participants, informing them they may withdraw their consent at any time. Participants had an opportunity to review the informed consent and ask questions. Because all procedures and interventions took place remotely, consent forms were signed electronically and stored by the researcher.

Sample

This section includes elements that describe the study population being recruited.

Inclusion Criteria

Inclusion criteria included pregnant women who: (a) were 18 years of age or older, (b) were at least 14 weeks gestation but not more than 27 weeks gestation, (c) had a pre pregnancy BMI equal to or greater than 30, (d) had a singleton fetus, and I spoke English.

Exclusion Criteria

Exclusion criteria consisted of: (a) no access to the internet or (b) type 1 or type 2 diabetes, history of gestational diabetes, history of gestational hypertension or history of preeclampsia.

Study Variables

This section describes the specific study variables starting with the dependent variables followed by the independent variables.

Dependent Variables

Gestational weight gain

The primary dependent variable was total gestational weight gain from enrollment to six weeks later. Weight was recorded in pounds. For the historical controls, women's weights at the visit were recorded based on gestational age similar to the intervention group, and any interval weights between this identified enrollment research date and six weeks later.

For the intervention group, weight gain was measured using the Withing's Body Scale, an advanced smart Wi-Fi and Bluetooth enabled device that allowed for accurate measurement. All intervention participants were given this digital Bluetooth enabled scale free as part of their study participation. The company website states that the scale is highly reliable, providing accurate measurements up to 0.2 pounds (Withings, 2019). The Withing's data hub allows for data to be securely transmitted through cellular networks. With this software, participants' data were available 99.95% of the time (Withings, 2019). Recent studies evaluating weight and pregnancy outcomes have used the Withing's Body Scale and technology to assess outcomes and remote patient monitoring (Lanssens et al., 2017; Treskes et al., 2020).

Before the start of data collection, the principle investigator completed a survey through a link on the company's website specific for researchers interested in using the device. After completing the survey, the company contacted the researcher. The corporation offered detailed information and device support needed to conduct clinical studies (Withings, 2020). With technology support, the scales were set up for participants with the correct settings and ability to transmit weight data through the cellular card.

Participant Satisfaction

Participant satisfaction was a secondary dependent variable obtained only on participants assigned to the RD intervention. Plugeisen and Mou's (2017) Patient Satisfaction with Virtual Obstetric Care Survey was used to assess patient satisfaction with the video counseling with the RD in this study. The survey is comprised of two main parts; the first part is divided into five domains*: A (scheduling), B (technology), C (virtual visit provider), D (personal issues), and E (overall assessment).* These domains are rated using a 5-point Likert scale (very poor, poor, fair, good, very good). An example of a question under the scheduling domain was "Ease of your

scheduling visits," and participants are asked to rate of the Likert scale. The instrum'nt's internal consistency for Plugeisen and Mou's study was a Cronb'ch's alpha ≥ 0.7 for all domains, and Pear'on's correlation of ≥0.4 for domains.

An RD provided nutritional counseling which involved motivational interviewing, screening of food, provision of sample menus and review of food choices. The RD provided six, 30-minute sessions. These sessions took place once a week for six weeks. Topics discussed with participants included individual goals, food choice recommendations, breakdown of needed nutrients, and review of diet from the previous week.

Independent Variables

Historical Controls

The researcher extracted information comparable to that of the intervention group retrospectively from 11 records of women who met study eligibility criteria at a women's health office. The historical control participants were proportional to the number of intervention participants in the study used as an unmatched comparison to all intervention groups.

Weighing Intervention

All participants in the study intervention group received the Withing scale in the mail. To make the scale easy to use and have the data readily accessible to the study investigator the Withing's Data Hub was supposed to be preconfigured for each participant so that no set up or WIFI was needed on the participant's part. Preconfigured scales were not supposed to require further installation by the participant. Once the Data Hub that came with the scale was plugged into an outlet, it automatically connects to the Withing's cellular data network. The setup for the scale was automatic, and the participant used it normally. Connection status feedback was continuous. A well-established cellular connection would show a green light. The exchange of

data information would show a blinking light on the device. Red light only appeared when the Data Hub was unable to reach the network and synchronize the data. In the case that network synching issues occurred, the data hub would show an error message. Smartphone and Wi-Fi networks were not required as the data hub used cellular data intended to reach diverse populations (Withings, 2019).

Nutritional Counseling plus Weighing Intervention

Half of study participants were assigned to have nutritional counseling by a RD in addition to weekly self-weighing. An RD provided nutritional counseling which involved motivational interviewing, screening of food, provision of sample menus and review of food choices. The RD provided six, 30-minute sessions. These sessions took place once a week for six weeks. Topics discussed with participants included individual goals, food choice recommendations, breakdown of needed nutrients, and review of diet from the previous week. The RD followed the IOM BMI-standards recommendations for weight, and nutritional education included suggestions for low glycemic carbohydrates, adequate proteins, healthy fats, and a variety of fruits and vegetables (Nichols, 2018). Additionally, the RD provided nutritional education tailored to the participant's diet history from the previous week, sample nutritional meal plan, coaching to support understanding of food choices, and strategies for healthy eating.

Number of Weekly Weight Measurements

Data for participants in the intervention study group was also analyzed by weighing frequency. Participants were categorized by as those who weighed themselves at least six times or more for six weeks and those who weighed themselves less than six times in six weeks. The frequency with which a research participant weighed herself was automatically uploaded to the

study database. This information determined the proportion of the six weekly weights for each participant.

Covariates

The following terms describe sociodemographic covariates measured in this feasibility study.

Age. Age at initial visit was recorded in years. Pregnancy outcomes differ based on the age of the pregnant person.

Ethnicity. Ethnicity described the degree of diversity of the study population and was self-reported as non-Hispanic White, non-Hispanic Black, Hispanic, Asian, or Other. Existing literature supports the findings that women who have a pre pregnancy BMI ≥ 30 tend to gain more or less gestational weight gain depending on their ethnicity (Singh & DiBari, 2019).

Partner Status. Partner status was collected as a dichotomous variable. *Coresident* was defined as married or cohabitating with a romantic partner. *Single* was defined as never married, divorced, widowed, or separated. Research showed women with obesity are less likely to be married and/or have a cohabiting partner (Ng et al., 2014).

Education. Years of schooling was measured by categories of less than high school graduate, high school graduate, some college, college graduate, or greater degree. According to Ng et al. (2014), women with obesity have lower education levels.

Employment and Health Insurance Status. Employment status and health insurer were used as proxy measures of economic status. Economic factors have been associated with gestational weight gain (Huynh et al., 2014). The status of a worker was described in terms of self-identification of working or non-working. Employment level has been known to be a potential confounder in research (Molyneaux et al., 2016). The effects of the COVID-19

pandemic may affect job status. Insurance was collected as governmental or not.

Parity. Parity was described as the number of pregnancies a woman has completed past 20 weeks, including both live and still birth deliveries. Ng (2014) found there was a relationship between maternal elevated BMI and parity. Data was described as dichotomous: first pregnancy, yes or no.

Gestational age. Gestational age was calculated from the first day of the last menstrual cycle to the current due date or by the first trimester ultrasound. Weight gain recommendations differ depending on the gestational age.

Study Protocol

After International Review Board (IRB) approval, the study recruitment begun. The researcher contacted local women and birth centers to recruit participants. Flyers were posted in the study sites informing women about the study. The principal investigator asked eligible women if they had an interest in the study. Flyers had the phone number of the principal investigator and a QR that participants could scan using their mobile device. After participants scanned the QR code, a short questionnaire was available to the participant. The researcher was available by phone or email if eligible women had any questions regarding the study. Before the participant completed the questionnaire, a video was available regarding the study. Choosing *I accept* meant the participant provided consent for the study on the online form. An electronic copy of the consent was sent to the participant. After providing consent, participants had the option to complete the online survey to obtain needed study data. At this time, the participant was sent through the mail the Bluetooth Withing's Body scale and received help on the device if problems occurred. The device and data hub were setup ahead of time, so participants needed only to stand on the scale and plug in the data hub. Participants were instructed to weigh

themselves at least weekly. They were able to keep the scale after the study and all remote access monitoring was turned off after the conclusion of the study and extraction of the data.

Once women were enrolled in the study, they were randomly assigned using random sequence done by a third party to either weighing alone or weighing and the nutritional counseling intervention. Those randomized to nutritional counseling were provided a link to Healtie, the online telehealth portal. Participants met individually with the RD once a week via a HIPPA secure telehealth system called Healtie. The telehealth portal allows for all appointments to be scheduled, providing a calendar reminder and link to the video conferencing appointment.

For the historical control group, retrospective data was extracted from an electronic medical record. The historical controls were approximately matched according to age, and gestational age at recruitment in the intervention group. Weight information at different gestational ages and sociodemographic and obstetric factors were recorded from the chart, with each person assigned a study ID number saved into an Excel sheet. For the intervention group, the variable information regarding weight was obtained by using the Withing's Data Hub, allowing for a secure PDF to be directly downloaded from the device. Data for the independent variable were extracted from the telehealth portal. Healthie provides for the scheduling of all telehealth nutritional counseling appointments to be tracked, including those missed, securely in a downloadable PDF. This information was imported into an Excel datasheet as well.

Recruitment occurred from January through May. Weight information at 28 and 36 weeks gestation was not analyzed for this study but is ongoing until women meet those targets and information was analyzed separately.

Analysis

Descriptive statistics were conducted on the demographics between the groups using means, and standard deviations and unpaired t-test for continuous variables. Differences in gestational weight gain after six weeks and change in weight over six weeks was examined with an independent t-test. Significant associations between groups such demographic differences and weight differences assumed a two-tailed test to calculate the p-value.

Protection of Human Subjects

Approval to conduct this study and a decision of level of oversight was obtained from the IRB at the University of San Diego (USD). A letter of approval was acquired from the chief of medical office(s) at the women's health center(s) and submitted with the letter of IRB approval. If a center had its own IRB, that IRB approval was obtained first before being submitted to the USD IRB. Written electronic informed consent was obtained from all eligible participants prior to the start of enrollment. All data collected for the control group were deidentified for each case and recorded using a separate study identification number such that none of these data were linked backed to an individual woman. Any identifying information was properly deleted. A computer in the home of the researcher securely stored all PDFs associating the scale weights with a participant with weight data downloaded from the data hub. After the study was complete, all documentation will be properly stored for 5 years. At the time of analysis, data were deidentified and processed in SPSS. As an incentive to thank participants for their time in the study, the Withing's Body scale was gifted for them to keep. This study was a voluntary, feasibility study and offered minimal intervention risk.

Study Timeline

The IRB at USD took 3 months to be approved. Data collection took up to 6 months, and data analysis and writing required another month.

Chapter 4 Results

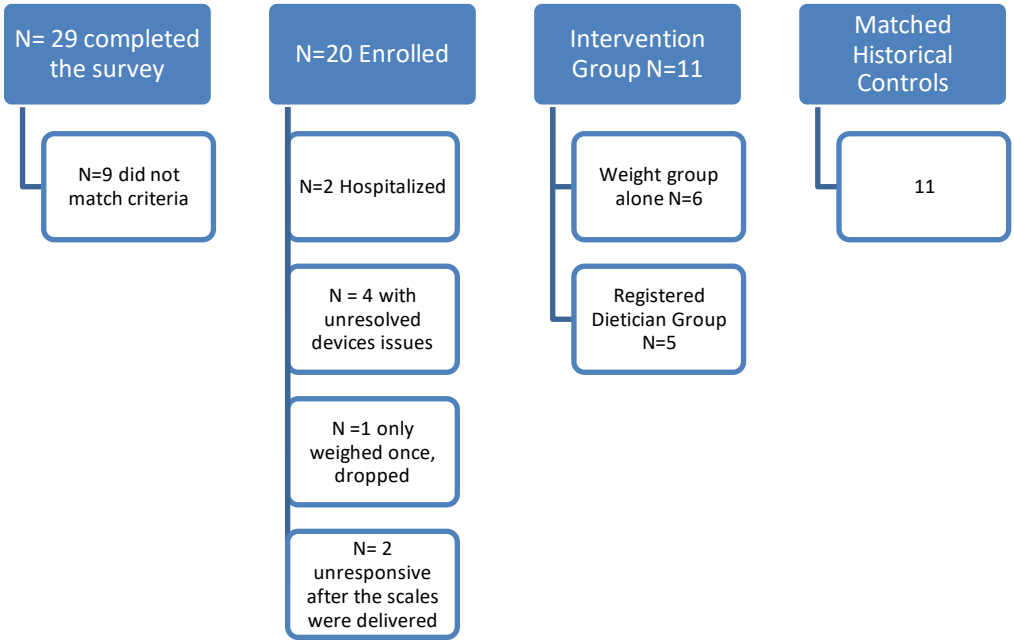
Purpose of the Study

The purpose of this feasibility study was to determine the magnitude of effect of using a combination of weekly weigh-ins and an online registered dietician to control excessive gestational weight gain.

Twenty-nine individuals filled out the study survey and 11 people completed the intervention (see Figure 1). Eleven individuals were also selected for the retrospective study also referred to historical controls.

Figure 1

Recruitment and Enrollment



Aim 1 Sociodemographic and Obstetrical Influences

Describe the study population in terms of sociodemographic influences (i.e., race/ethnicity, partner status, health insurance, employment status, education level) and

obstetrical influences (i.e., gestational age, parity, and BMI).

In this section the sociodemographic and obstetrical differences between the study group and the historical control group, the registered dietician group and the weight alone group, and those who weighed themselves six times or more and those who did not will be described in the tables.

The study group participants were divided evenly between non-Hispanic White and non-Hispanic Black, there were slightly less Hispanic, or Latino's (see Table 1). The historical controls had fewer non-Hispanic Whites, non-Hispanic Blacks, and more Latino or Hispanics. Differences found in ethnicity between the study group and historical controls (P =0.055) are likely attributed to the number of participants who fell within the Latino/Hispanic or other category. Participants in the study group were similar in age to the retrospective controls (P = 1.0, T= 1.038); both group averages were in their late twenties/early thirties. Participants in the study and historical controls were similar in their insurance and employment statuses (P =0.238), with approximately half self- identified as working, with the other half not working or unknown. Unfortunately, level of education was missing for nearly half of the retrospective cohort, so it is unclear if there were any true differences by education between the two groups.

The prepregnancy BMI between the study group and the historical controls were essentially the same (P =0.349, T =.001), classifying as category I obesity. In both the study group and the historical controls, both started weight measurements in the middle of their second trimester of pregnancy on average. In the study group, participants were evenly split between nulligravidas and multigravidas. For the historical controls, the majority were multigravida women. The historical control group gained more gestational weight than the intervention group on average.

Adherence and Cost

Device issues were a consider barrier in this study. Of the N = 20 enrolled, N = 4 had cellular hub issues causing the scale to not communicate with hub or remote data reporting. Additionally, N = 2 received scales and never set them up, even after communication attempts. N = 1 weighed themselves once and then stopped weighing, and N = 2 dropped from the study due to hospitalization during the study period. The consort figure (See Figure 1) depicts those (N = 29_who completed the survey, were screen and enrolled (N = 20) and then completed the study (N = 11). Overall cost for the scales included $50 per device, $500 a month for the remote software for the scales, $150 a month for the telehealth platform for the RD, and $2,000 overall for the RD to provide counselling sessions.

Table 1

Demographics Between the Intervention and Historical Controls

	Intervention Group N (%) or mean (SD) N = 11 n (%)	**Historical Controls N (%) or mean (SD) N = 11 n (%)**	**Statistical Value**
Race/Ethnicity			P = 0.055
Non-Hispanic White	4 (36)	1 (9)	
Non-Hispanic Black	4 (36)	1 (9)	
Hispanic or Latino	3 (27)	6 (55)	
Other	0 (0)	3 (27)	

		30.5	
Age	29.6 (5.6)	(4.6)	T = .001, P = 1.0
Partner Status			P = 0.329
Married/Cohabitating	10 (91)	8 (73)	
Single	1 (9)	1 (9)	
Unknown	0 (0)	2 (18)	
Health Insurance			P = 0. 095
Governmental or Self-pay	7 (64)	6 (64)	
Private	4 (36)	5 (45)	
Employment Status			P = 0.011
Working	7 (64)	6 (55)	
Nonworking	4 (36)	0 (0)	
Unknown	0 (0)	5 (45)	
Education Level			P = 0.238
Some High School	2 (18)	0 (0)	
High School graduate	0 (0)	2 (18)	
Some college	0 (0)	3 (27)	
College graduate or more	9 (73)	1 (9)	
Unknown	0 (0)	5 (45)	
		33.4	T = -1.038, P = 0.349
Pregnancy BMI	33.5 (5.4)	(3.3)	
Gestational Age at	16.5 (5.9)	21.0	T = .001, p= 1.0

Recruitment		(4.3)	
Prima Multi			P = 0.193
Nulligravid	6 (55)	3 (27)	
Multigravida	5 (45)	8 (73)	
Mean Total Weight Gain			T = .001, p = 1.0
(TWG)	5.8 (5.9)	6.6 (3.1)	

Differences in Demographics Between Intervention Group

The study group was next divided into the registered dietitian (RD) group and the self - weighing alone (WA) group (N = 5 and N = 6 respectively). The baseline demographics were similar between the RD and the self-weighing alone group (see Table 2). In terms of race and ethnicity, half of the participants self-identified as nonHispanic White in the RD group, with a smaller percentage who self -identified as non-Hispanic black or Hispanic or Latino. A smaller percentage self -identified as non-Hispanic White for the WA intervention group, half identified as non-Hispanic Black, and the remaining few stated they were Hispanic or Latino (see Table 2). The average age between both intervention groups differed slightly with those in the RD group a few years younger than the WA group. The partner status between groups was similar, with all but one in the RD group stating they were married or cohabitating. All in the WA group said they were married or cohabitating. Health insurance status was similar between intervention groups where both groups mainly were split evenly between those who have private vs. governmental health insurance. There were more workers in the RD group, and the self-weighing alone group was split evenly between working and non- working.

The RD group had a higher average BMI than the WA group with the RD averaging as a class II obesity, and the WA group averaging as a class I obesity. The mean gestational age at recruitment was similar, with the RD group being slightly earlier in their gestation than the WA group. Parity was approximately the same between the two groups, with half in their first pregnancy and the other half being in the second or more pregnancies.

Table 2

Baseline characteristics of the Study Population between the RD or WA groups

	RD Group N = 5 n (%) or mean (SD)	**Weight Group N = 6 n (%) or mean (SD)**	**Statistical Value**
Ethnicity			
Non-Hispanic White	3 (60)	1 (17)	P = 0.323
Non-Hispanic Black	1 (20)	3 (50)	
Hispanic or Latino	1 (20)	2 (33)	
Age	27.8 (1.6)	31.2 (7.1)	T= 1.028, P = 0.346
Partner Status			P = 0.346
Married/Cohabitating	4 (80)	6 (100)	
Single	1 (20)	0 (0)	
Health Insurance			P = 0.740
Governmental or self-pay	3 (60)	4 (67)	
Private	2 (40)	2 (33)	
Employment Status			P = 0.237

Working	4 (80)	3 (50)	
Nonworking	1 (20)	3 (50)	
Education Level			P = 0.303
Completed some High School	2 (40)	0 (0)	
Completed college	3 (60)	5 (83)	
Completed some Postgraduate	0 (0)	1 (17)	
Pregnancy BMI	35.7 (7.0)	30.8 (3.1)	T = -1.129, P = 0.288
Gestational Age at Recruitment	17.0 (5.6)	16.0 (6.1)	T = -2.53, P = 0.904
Prima Multi			P = 0.740
Primiparous	3 (60)	3 (50)	
Multiparous	2 (40)	3 (50)	
Mean TWG	4.1 (5.6)	7.0 (5.6)	T = 0.692, P = 0.507

Aim 2 Differences In the study group demographics between those who weighed themselves once a week and those who did not

The average number of weights for the sample during the 6 weeks of the intervention was 6.2 (*SD* = 2.4). Nine (82%) participants weighed themselves at least once a week during the intervention time period with only two weighing less than weekly. There was not a significant difference in weight found between the two groups (*t* = x; *p* = 0.58). Participants who weighed themselves once a week were multiethnic, whereas those who did not weigh themselves at least once a week were all non-Hispanic White (see Table 3).

Table 3

Sociodemographic for study participants weighing themselves at least 6 times compared to those weighing themselves less than 6 times

	≥ 6 times N = 9 n (%) or mean (SD)	**< 6 times N = 2 n (%) or mean (SD)**	**Statistical Value**
Ethnicity			
Non-Hispanic White	2 (22)	2 (100)	P = 0.118
Non-Hispanic Black	4 (44)	0 (0)	
Hispanic or Latino	3 (33)	0 (0)	
Age	30.2 (6.0)	27 (1)	T = 1.78, P = 0.324
Partner Status			P = 0.621
Married/Cohabitating	8 (89)	2 (100)	
Single	1 (11)	0 (0)	
Health Insurance			P = 0.658
Governmental or self-pay	6 (67)	1 (50)	
Private	3 (33)	1 (50)	
Employment Status			P = 0.237
Working	5 (56)	2 (100)	
Nonworking	4 (44)	0 (0)	
Education Level			P = 0.632
Completed some High School	2 (22)	0 (0)	
Completed college	6 (67)	2 (100)	

Completed some Postgraduate	1 (11)	0 (0)	
Pregnancy BMI	33.5 (5.8)	30.4 (0.0)	P = 0.274
Gestational Age at Recruitment	17.4 (6.0)	12.0 (2.0)	P = 0.664
Prima Multi			P = 0.887
Primiparous	5 (56)	1 (50)	
Multiparous	4 (44)	1 (50)	
Mean TWG	4.6 (5.6)	8.1 (5.4)	T = 2.658, P = 0.38

Aim 3 Participant satisfaction with the study interventions of weekly weighing and online nutrition counselling

Overall, participants were satisfied with their virtual nutritional counseling (see Table 4). In all five domains the majority of participants rated their care as ‘very good’ or’ good.’ There were two times ’fair’ was selected: regarding the ease of use of Withing’s body scale, and the explanation or support provided by the RD regarding the telehealth system or body scale.

Table 4

Ratings of Satisfaction with Virtual Care

Domain/ Question	**Likert Rating* N = 5 Mean (SD)**
Scheduling	
Ease of Scheduling virtual visits	5 (0)
Frequency of starting virtual visits on time	5 (0)

Convenience of Virtual Visits	5 (0)
Technology	
Ease of connecting for virtual visits	4.6 (0.55)
Quality of Connecting during the virtual visits	4.6 (0.55)
Ease of Using Healthie (telehealth portal)	4.2 (0.94)
Ease of Using the Withing's blue tooth scale	3.6 (0.89)
Virtual Visit Provider	
How well did the virtual visit provider explain her role in your care?	5 (0)
Friendliness/ Courtesy of the virtual visit provider	5 (0)
Missing = 2	
Explanations about how to use the telehealth and the body scales	3.8 (0.84)
Skill and knowledge of the virtual visit provider	5 (0)
Degree to which the virtual visit provider took the time to listen to you	5 (0)
Virtual visit providers concern for you questions and worries?	5 (0)
Missing = 2	
Personal Issues	
Our concern for your privacy	5 (0)
Our sensitivity to your needs	5 (0)
Response to concerns made during your virtual visit	5 (0)
Ease of accessing the virtual visit provider when necessary	5 (0)
Ease of accessing your OB when necessary	5 (0)
Overall Assessment	

Overall rating of care received during the virtual visits	5 (0)
Your satisfaction of virtual visits	5 (0)
Likelihood that you would recommend virtual visits	5 (0)

* 5= Very good, 4= Good, 3= Fair, 2= Poor, 1=Very Poor

Open ended comments on the survey (see Table 5) were positive regarding the nutritional counseling. Two comments spoke to issues with the body scale, or Wi-Fi problems.

Table 5

Qualitative comments of Satisfaction with Virtual Care

"She worked with me through time zones and technical difficulties! It was great to have someone available to message when needed as well!"
"(RD) is supportive and informative! Exactly who I needed to hear from in my first pregnancy."
"My weight (increased) based on the scale, but my doctor said I lost weight"
"My WiFi goes out sometimes so I'm not sure if it was the app or my WiFi but we did most of our sessions over a phone call instead of the app. I loved the messaging app for scheduling and in between session questions. The scale my husband set up for me and was easy except when it decided to not send my data through several weeks in a row. I'm not sure if that was because the data hub was too far away or what. It was relatively close but in my experience, I always had to move the scale closer to see the sending action. The scale itself worked beautifully and is very light/easy to move around as needed."
"(RD) was amazing"

"(RD) was amazing"

Determine the reliability of the participant satisfaction questionnaire when using it in an online modality

To determine the internal consistency of the virtual care satisfaction survey a Cronbach's alpha was performed. The inter item reliability was fair, with a Cronbach's Alpha of 0.5, with N = 22 items.

The key differences in gestational weight gain from enrollment to 6 weeks

Differences between pregnant women with obesity who were not given any special nutrition counseling or scale (historical controls) and those given scales and asked to weigh themselves weekly are described in Table 6. The intervention group and the historical control group on average had a similar mean weight gain. There was a larger *SD* in the intervention group compared to the historical control group. There was not a significant difference in weight change among the groups (p = .605).

Table 6

Differences in gestational weight gain from enrollment to 6 weeks Later

	Weight gain over 6 weeks	**Statistical Value**
Compared groups	**Mean (SD)**	
Intervention Group (n = 11)	5.8 (5.9)	T = 0.402, P = 0.692
Historical Control Group (n = 11)	6.6 (3.1)	

The nutritional counseling group on average gained less weight than the historical controls (see Table 6). Additionally, the nutritional counseling group had a larger *SD* in weight compared to the historical control group. Overall, there was not a significant difference in weight gain between the nutritional counseling group and the historical control group ($p = 0.35$). There calculated effect size using Cohen's d for the intervention was small, 0.17.

Table 6

Differences in RD vs Historical Control Group TWG

Study Group	Total weight gain over 6 weeks Mean (SD)	Statistical Value
Nutritional Counseling ($n = 5$)	4.4,(6.0)	T = 0.978, P = 0.345
Historical Controls (n = 11)	6.6 (3.1)	

Summary

Demographic and obstetrical influences between groups were compared in Table 1, 2, and 3. The overall participant satisfaction with their virtual care is shown in Table 4. Differences in total weight gain over six weeks are described in tables 5 and 6.

Chapter 5

Purpose of the Study

The purpose of this feasibility study was to determine the magnitude of effect of using a combination of weekly weights and an online registered dietician to control excessive gestational weight gain. This study highlights the viability of conducting online nutritional counseling during pregnancy, remote monitoring of weight, and automated weight data collection. The main benefits and issues with the application of this technology are described in this chapter.

Overview of Findings

This study demonstrated the feasibility of providing online nutritional counseling to pregnant women with obesity while using standardized weight scales with remote weight data collection. Women from multiple ethnic groups, differing education levels and insurance, both working and non -working, participated and completed the study intervention. Participants adhered to the intervention and the 81% self- weighed once a week during their enrollment time in the study. From the findings, it is realistic to have pregnant women with obesity receiving nutritional counseling online. Women in this study did not miss any nutritional counseling visits. Additionally, they reported acceptance of receiving nutritional counseling via this methodology through their positive responses on the satisfaction survey. Evidence of the intervention on the effects of gestational weight gain over the six weeks was not significant. On average the group who weighed themselves once a week gained 4 pounds less than those who did not weigh themselves once a week but again the sample size is extremely small. Additionally, the generalizability of the results is limited due to the small sample size and the limited timeframe.

Consideration of Findings in Context of Current Literature

U.S Preventative Task Force (USPSTF) published in a recommendation statement in May 2021 stating there is a need for research targeting interventions to prevent excessive gestational weight gain during pregnancy, especially in multiethnic groups and women with obesity (Davidson et al., 2021). This study supports these recommendations by investigating and reporting on nutritional counseling interventions in this population.

Self-Weighing

This feasibility study provides unique data describing the use of remote weight monitoring from an individual's home; therefore, removing self-reporting bias. Weight data was obtained directly from the scale, instead of reported from the participant. Previous studies have shown women with obesity tend to report a lower weight than their actual weight (Rowland, 1990; Scribani et al., 2014). Although there is evidence evaluating the use of self-weighing with Bluetooth technology in non-pregnant populations, there is literature lacking the study of the viability of using these kinds of scales for pregnant women with obesity (Alencar et al., 2019). Findings from this feasibility study were similar to a larger study conducted by Arthur et al. (2020) that had nearly 400 women, occurring over 2 years, which did not find self-weighing to significantly change weight gain during pregnancy. Another study by Harrison et al. (2013) evaluating weight gain during the second trimester which included approximately 100 women, also had similar findings

Online Nutritional Counseling

In this feasibility study the registered dietician group demonstrated overall less gestational weight gain compared to the self-weighing alone group or the historical control group by approximately 2.5 lbs. in six weeks.

A major strength of this feasibility study is that it contributes to the scarce literature on the role of online nutritional counseling of pregnant women with obesity in the United States. Recent literature suggests that women have positive experiences when receiving care through a telehealth provider (Pflugeisen & Mou, 2017). Supporting these findings, this feasibility study observed overall women were satisfied with online nutritional counseling. The Cronbach's alpha for the Satisfaction with Virtual Care Scale was lower than that reported by Pflugeisen and Mou (2017). Reasons for this difference may be the implementation of using an online survey compared to a survey being mailed on paper or that this study had a small sample size.

Adherence

Davidson and colleagues (2021) draw attention to the need for studies to report their intensity and adherence to nutritional interventions. Adherence and intensity of the nutritional interventions are often not reported according to a recent meta-analysis conducted by Vincze et al. (2019). This feasibility study achieved 100% adherence to the dietary intervention. The findings that nutritional counseling interventions did not significantly reduce gestational weight gain over 6 weeks, differ from the reported changes in weight gain found in the meta-analysis by Vincze et al. (2019). Comparatively, Vincze et al. (2019) found among studies of interventions to limit gestational weight group, those in the intervention group gained 1.25 kg less over that last 12 weeks of pregnancy compared to the control group. This feasibility study found the intervention group gained 2.02 kg less than the control group which was statistical insignificant due to the larger *SD* in the intervention group and small size of the sample. Additionally, the timeframe was only six weeks, so results may be more robust if measurements continued to the end of pregnancy.

Nutritional counseling interventions started on average at 17 weeks gestation which was

the same as Opie et al. (2016). More recent recommendations suggest starting interventions targeting excessive gestational weight gain at the beginning of the second trimester or around 5 weeks earlier (Davidson et al., 2021). Additionally, the literature identifies interventions, a mix of nutrition and/or exercise, are more effective if they are considered to have a higher intensity (from early second trimester to 36 weeks this would be twice a month or 10-12 contacts) compared to lower frequency (Davison et al., 2021). With only six nutritional counseling sessions, this study would then be considered a moderate intensity nutritional intervention in the Davidson et al., framework and they found no difference in outcomes at this level. However, other studies in this category included 3-5 face-to-face meetings occurring throughout the pregnancy which means the counseling was not as concentrated as in this study which may make a difference in helping women change their food choices.

Study Limitations

There were several limitations of this feasibility study. Some of these limitations were due to location, timing, and application of new technology. As a result of restrictions placed by the COVID-19 pandemic, recruitment was initiated remotely.

Location

Because this study required the participant's trust to provide personal information, such as a home address through an online form, only two individuals were recruited through this methodology. All the other participants were recruited through a physician's office or birth center.

Timing

Trying to recruit women in the second trimester proved to be challenging. As a result of the COVID-19 pandemic, many doctor's appointments were conducted online initially, and they

were spaced at least monthly. This made it much more challenging for the primary investigator to be at their prenatal appointment to request participation; if the time did not match up, the primary investigator had to wait another month to seek the participant. Additionally, limiting participants to only those with obesity decreased the number of participants in the study that may have benefited from the interventions. A future study should include people with a history of or risk factors for gestational diabetes or hypertension as this will increase the generalizability of the potential effect of the interventions on this population.

Application of New Technology

Other limitations in the study were attributed to the scales. The cellular card technology used with the scales for remote monitoring was in its primitive stages. The Withing's company team members stated this was the first time the cellular data hub was used for research, and a new team within the company managed the programing, delivery, and support of the scales. The company sent the scales to the participant's house with directions that were inaccurate and described equipment that was not inside the box nor a part of the study. Many participants were confused from incorrect directions provided, and after attempting to setup the scale and not succeeding, they became disinterested. Four participants' scales could not be fixed even with a new scale mailed to their homes due to problems connecting to the cellular card. Two participants received the scales but did not set them up or respond to the primary investigator via email or phone. Two participants were hospitalized, one before the scale could be set up and other could not complete the 6 week weighing. Once participant weighed in once, and then stopped weighing. All participants enrolled in the study needed some form of additional contact with the principal investigator to answer questions regarding setup or help with the device. Expense of the scale was another limitation of the study; price of the scales was $50 per

participant. Although every participant received a scale, the cost was high overall. Additional cost for the scale included remote monitoring software to view participant's weight. Overall, the technology issues with the scale were the largest obstacles for participants either beginning or completing the study and completion rates would have increased 20% if these were solved as N = 4 device issues of the original 20 enrolled.

There were essentially no limitations with the remote software for the telehealth nutritional counseling; participants were able to meet and schedule appointments with the dietician via the telehealth platform. The cost for this platform was moderate, at approximately $150 a month. Although the study found positive attitudes toward online nutritional counseling, there were limitations. Having a small sample size precludes the generalization of results without a more extensive study.

Recommendations for Future Literature

Future research is needed to determine the effectiveness of this intervention among pregnant populations with obesity. It is important to note limiting the study population based on BMI may not be the best approach for future studies. Based on the specificity of this population and the restricted timing of office visits, it was challenging to sample this population. Future research may benefit from including all pregnant individuals and then conducting further sub-analysis on this specific population.

Self-weighing has the potential to provide standardized and accurate weight measurements from participants. Although this study did not find self- weighing alone to significantly impact gestational weight gain, it did demonstrate the feasibility of remote monitoring of weight in pregnant women with obesity. The cellular hub methodology eliminates the inaccuracy and inconsistences of self- reporting. Once the scales were properly set up, data

was directly imported. However, being in the early stages, the data hub, and scales had several issues needing to be addressed for initial setup. A Small Business Technology Transfer program (STTR) is recommended for development and potential commercialization of this technology to address the issues and implement a larger randomized control trial. Alternatives to the scale with Bluetooth and cellular hub could include the use of low cost scales and participants take a picture of the scale and send results to the principal investigator through text message or some other communication method. While this could be beneficial if a lower cost option is needed, it may introduce error from self- reporting. Future studies may also consider implementing the weekly weigh- ins starting at the beginning of the second trimester through the end of the pregnancy to increase the intensity of the intervention.

Implications for Professional Practice

Online nutritional counseling has real implications for practice. The use of nutritional counseling using a registered dietician to provide sessions online through a telehealth platform has potential to improve both access to a nutritionist and to limit gestational weight gain in pregnant women with obesity. Conceivably, women who may not have attended face-to-face sessions due to work or childcare issues may be better able to schedule counseling sessions at their convenience. Providing nutritional support during pregnancy, especially in high-risk pregnancy, seems to have real benefit (Vincze et al., 2019).

Participants were satisfied with online nutritional counseling; this method appears practical and doable for women during their pregnancy. Self-weighing with remote reporting is appropriate and supplements nutritional counseling. Using a scale that automatically reports weights to the clinician eliminates error from self-reporting. In practice, utilization of remote weight monitoring with an online dietician may be a feasible and practical way to determine if

nutritional counseling interventions are effective for weight management.

Conclusion

Findings from this current study indicate online nutritional counseling and remote monitoring of weight is feasible for pregnant populations with obesity. Attitudes toward online nutritional counseling were positive and indicate a potential application for this type of intervention. Utilization of telehealth platforms for nutritional counseling may widen the accessibility of nutritional counseling. Additionally, combining this with remote monitoring of weight may allow for unbiased reporting. Further research is needed to determine the effectiveness of this approach on gestational weight gain and the needed intensity of the intervention to make a difference.

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