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A systematic review of interventions for Hispanic women with or at risk of Gestational diabetes mellitus (GDM):

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Abstract

Background and objective: Gestational Diabetes Mellitus (GDM) is a serious health concern for pregnant women, with Hispanic women at particular risk for developing the condition. The aim of this review was to critically examine GDM intervention programs for Hispanic women, in the United States of America (US).

Methods: English and Spanish electronic databases were searched for relevant studies published between 1995-2015. Eligible study designs included randomized controlled trial, pre/post-test and quasi experimental methods.

Results: Findings indicated that there was a dearth of literature reporting on GDM interventions for Hispanic women and just seven papers met inclusion criteria. These seven studies were included in the review and they reported on interventions for: (1) pregnant women at high risk of developing GDM; (2)

pregnant women with GDM. Results suggest that a combination of intensive counselling over a prolonged period of time, together with a low calorie, possibly low glycemic index diet, produces best results.

Conclusion: The review found that intensive nutritional counselling approaches which promote low calorie/low GI diets appear to be most effective in BGL management in this population. Interventions that are delivered in Spanish and culturally tailored may be more acceptable to participants. More research is needed to develop suitable interventions to improve GDM management among Hispanic women.

Introduction

Gestational diabetes mellitus (GDM) is a serious health challenge for pregnant women[1] with increased risk for caesarean birth and hypertensive disorders [2]. For infants, GDM is linked to increased mortality and morbidity including respiratory distress, macrosomia and special care admission [3]. Longer term, GDM increases women's risk for type 2 diabetes, and their infants' risk for obesity, type 2 diabetes and cardiovascular disease [2]. Recent research indicates that high glucose levels or over nutrition during pregnancy can result in a 'metabolic programming' effect on the fetus, predisposing the child to early onset diabetes and obesity [4].

Rates of GDM are increasing dramatically in the United States [1, 5] with a 10-100% increase in some ethnic groups in the past 2 decades[5]. Hispanic women are at particularly high risk [6]and in a recent US study, Hispanics had considerably higher rates of GDM (12.1%) compared to non-Hispanic whites (6.8%) [7]. The risk for recurrence of GDM in subsequent pregnancies is also significantly higher amongst Hispanic women [8]. This is of particular concern as Hispanics are the largest minority group in the US, representing approximately 17% of the total population [9] and have higher than average birthrates [9].

Hispanic women incur a disproportionate risk for GDM as they possess additional risk factors that are associated with poor pregnancy outcomes, including; birth outside the US[10]; and overweight/obesity [11]. Cavicchi et al. [11], for example, found that a BMI (Body Mass Index) of 25-29 kg/m² was associated with 14.4% of GDM cases among Hispanic women, compared to White (8.8%) and Black (7.8%) women while Hedderson et al. [12] suggested that BMI >25 kg/m² was attributable to 61.2% of GDM cases among Hispanics. Low levels of education and low socio-economic factors, which are associated with a calorie dense diet and minimal fruit/vegetables [13], may also contribute to this problem [14].

Although GDM poses serious health risks, careful management, which aims to maintain blood glucose levels (BGLs) within normal ranges, mitigates some of these risks. Recommended approaches include: gestational weight gain counselling, nutrition and exercise intervention and pharmacological approaches (oral hypoglycemics or insulin). Most studies evaluating interventions consider their approach to be successful: at reducing insulin requirements; macrosomia and hypertensive disorders, and improving knowledge and pregnancy outcomes [15]. Studies evaluating interventions for GDM that are specifically tailored to cultural groups have shown significant improvements in GDM management behaviours and health outcomes [16, 17]. Nonetheless, a systematic review of nutrition interventions tailored to Asian women with GDM found limited effects on glycemic control and overall pregnancy outcome, however diet changes made in early pregnancy were associated with reduced neonatal birthweight [18]. These findings demonstrate the inconsistencies in this area of research, and it is not clear how existing interventions address the needs of Hispanic women with GDM.

Thus, the aim of this systematic review was to critically examine existing gestational diabetes mellitus (GDM) programs for Hispanic women of Mexican origin. It was intended that the insights gained would inform the development of a GDM intervention for Hispanic Mexican women in US Border regions.

Methods

A systematic review approach was chosen for this project, using Uman's guidelines [19, p. 57-5919]:

- Formulating the review question/s
- Data searching using key search terms
- Study selection using defined inclusion/ exclusion criteria
- Data extraction and quality assessment
- Results (Analysis and interpretation of findings)

Formulating the review question/s

There were two review questions:

1. What GDM intervention programs are currently available for Hispanic women?

2. How effective are these approaches?

Data searching using key search terms

PubMed, CINAHL, Medline, MedicLatina, OvidSP, Lilacs ProQuest, and SCOPUS databases were searched to locate GDM management /educational programs. Quantitative papers were selected if they contained one key search terms for GDM such as: gestational diabetes mellitus; GDM, pregnancy diabetes, and one search term for GDM management such as: educational programs; lifestyle/ life-style intervention; exercise, diet, weight management. Search terms for ethnicity included: Mexican, Latino, Latina, Hispanic, Mexican-American. The search was limited to articles published in English and Spanish. Additional articles were located by searching the reference lists of selected articles. Search results were managed in an Endnote library. The paucity of literature led the team to broaden the search to include interventions aimed at preventing GDM onset among all Mexican Hispanic women. The rationale for broadening our search in this way, was that Mexican women residing in Mexico and in the US shared similar cultural understandings.

Criteria for considering studies for this review

Types of studies

Studies were included if they had a least one intervention and one comparison group. The comparison group could be either a control group, usual care group or alternative intervention group. Studies without a comparative method were not included.

Excluded studies

Articles were rejected if they met one or more of the following exclusion criteria: 1) did not include a group of women who identified as Hispanic or Mexican; 2) did not include human data; 3) did not have original data (i.e. meeting abstract, editorial, commentary or letter); and 4) did not compare a

nutrition, exercise or combined nutrition and exercise intervention to a control group. After non-relevant studies were excluded, potentially relevant studies were assessed independently by all three authors (MCO, MDG, JL). Significant differences in reviewer's assessments were discussed until consensus was reached.

Types of participants

Studies which included participants with the following characteristics were included in the review: pregnant women who identified as Hispanic, Mexican, Mexican-American; were aged over 18 years and diagnosed with or at high risk of GDM.

Types of interventions

Studies which incorporated interventions that lasted for one session or more which provided diet only, or diet and exercise education, nutritional counselling and insulin, nutritional counselling and metformin were included in the review. Interventions were conducted in a variety of settings, including primary care, hospitals and community settings.

Types of outcome measures

The main outcome measure of interest was blood glucose levels; however other measures such as glycosylated haemoglobin levels, GDM diagnosis, diet quality and perinatal/neonatal outcomes were also examined.

Data extraction and quality assessment

All investigators (MCO, MDG, JL) independently assessed the quality of the studies using adaptations of section A (Q1-6) Critical Appraisal Skills Program (CASP) tool (table 1) for assessing cohort studies [20] and the full CASP tool for assessing RCTs [21](table 2). Questions were modified slightly to align more closely with the intent of the review and to specifically address the following criteria: intervention, study method, GDM diagnostic criteria, BGL

measurements, outcome measures, confounding factors and follow up (table 1). For example Q.1 Did the study address a clearly focused area? Was modified to - Was the intervention clearly described? For Q.2 an additional question was included to capture methodological strength- Was an appropriate comparative method used to evaluate the intervention? For Q.4, an additional question was also included to capture blood glucose measurement, which was an important variable for this review: 4b. In studies not testing for GDM, were blood glucoses levels measured?

Studies were assessed for these criteria, and each was scored on a scale of 0-4, where 0 indicated that the criterion was not addressed and 4 indicated that all elements required of the criterion as outlined in the CASP tool were met.

Insert table 1 here

Insert table 2 here

Data synthesis

Each outcome by intervention category (diet and exercise, diet-only, diet and insulin/metformin) was summarised qualitatively. A meta-analysis of a primary outcome such as BGLs or any of the other outcomes could not be conducted due to heterogeneity in the population studied, variation in study duration and timing of intervention components, and differences in the mode of intervention delivery.

Results

Results of the search

The literature search took place in Melbourne, Australia and El Paso Texas and was conducted by (MCO, MDG, JL) in January- May 2015. A total of 189 citations were retrieved from electronic databases and hand searches (Figure 1). After reviewing abstracts and full articles, 22 unique publications related to interventions for the management or prevention of GDM were located. A further four articles were identified when the search criteria was broadened to include studies located in Mexico. After exclusion criteria were applied, seven papers remained for systematic review. Five of the included studies were RCTs assessing diet only interventions (N= 208), diet and medication interventions (N=1196) and diet and exercise interventions (N=278). The 2 remaining cohort studies assessed diet only interventions (N=205).

Study selection using defined inclusion/ exclusion criteria

After initial screening, 26 papers remained for closer examination (figure 1) and were reviewed by all authors. Papers were excluded if: (1) they focused on diabetes types 1/ 2; (2) included a general category of 'diabetes in pregnancy'; or (3) did not report on separate data for Hispanic women. Seven papers remained after this process and were included in the review [22-28].

Insert figure 1 here

Of the seven papers included in the analysis, two were written in Spanish [22, 28] and five in English. Four English language papers reported on interventions that were delivered in Spanish [24-27]. Four studies were conducted in Mexico and three in the US. Sample size ranged from 31-1535 participants. Although study focus varied, nutritional counselling was involved in each study. The most frequent methodology was randomized controlled trial [22-25, 27]. Other methods were pre/post-test design [22, 28]. Using our quality assessment tools for cohort studies (Table 1) and RCTs (Table 2), study scores ranged from 12 [25, 29] to 22 [22, 24], out of 28. In all cases, the intervention was clearly described and comparison was used to evaluate the

intervention. The timing and focus of interventions included: (1) interventions aimed at preventing GDM onset among high-risk Hispanic women; (2) interventions to promote normal BGLs among Hispanic women with GDM.

Interventions aimed at prevention of GDM

Two randomized controlled trials tested interventions targeting pregnant Hispanic women, at risk of GDM [24, 29]. Both delivered the intervention in Spanish and promoted dietary change. Keiffer et al.'s study [24] (n=275) was conducted in a low-income Latina population in Detroit, US and focussed on encouraging greater fruit and vegetable consumption, however prevalence of GDM following the intervention was not described. The intervention consisted of an 11 week intensive dietary counselling program, with exercise advice, delivered by trained Latina health workers. Final data was collected prior to the birth. The study found that women reported considerably improved diet over the period of the study in terms of reduced total fat ($p<.05$) and sugar ($p<.05$). In contrast, Reyes-Munoz et al.'s study [29], was conducted in Mexico city and tested the efficacy of medical nutrition therapy (MNT), compared to MNT plus Metformin in preventing GDM (n=58). There is no description of what the MNT involved. Outcome measure was diagnosis of GDM, using oral glucose tolerance test (OGTT) 75gr glucose and fasting/ 2hr BGLs [29]. Authors found no clear evidence of difference in outcomes between groups (RR-0.35, 95%CI 0.03–3.2). Neither study controlled for confounding factors.

Interventions to promote normal BGLs among Hispanic women with GDM

Five studies reported on interventions, which aimed to promote normal BGLs among pregnant women with GDM [22, 23, 25, 26, 28]. All but one of the interventions were conducted in Spanish [23]. Three studies were undertaken in Mexico city [22, 26, 28] and the remaining two studies in the US [23, 25].

Studies in Mexico compared variations of reduced calorie diets. Balas-Nakash et al [22], compared a diet of 24 kcal/kg between two groups of women with GDM or type 2 diabetes (n= 69). Women were screened for GDM, although diagnosis criteria were not described. Group 1 diet included all carbohydrates and group 2 diet include low glycemic index (GI) carbohydrates. Both groups received nutritional counselling and BGL measurement, but there is no mention of exercise counselling. Adherence to treatment was measured by (a) dietary analysis; (b) self-reported questionnaire; (c) self-perception of adherence ranking. Results indicated that 72% of women with GDM achieved optimal glycemic control and results were not different by study group or treatment measurement. However, a lower percentage of women in the low GI group used insulin, at the same time as consuming a larger amount of carbohydrates. Confounding factors considered included maternal age, diet type and insulin/medication use.

Perichart et al.[26], in Mexico, tested a low calorie diet, composed of 40-45% carbohydrates and compared results against a matched control group from medical records (n= 174). Women were screened for GDM, however diagnosis criteria were not described. The intervention included intensive dietary counselling with a dietician every two weeks, and there is no mention of an exercise component. Dietary recommendations were based on nutrition practice guidelines for GDM (American Dietetic Association) and the level of caloric restriction was not specified. Dietary intake was measured monthly and outcome measures included BGL, pre-eclampsia, maternal/neonatal hospital stay, stillbirth, neonatal death, preterm birth and extremes of birth weight. Confounding factors included maternal age, parity, gestational age and previous miscarriage. Results indicated no statistically significant differences in BGL between groups, however, a larger percentage of the women in the control group had raised BGLs. The largest difference was noted in pregnancy complications, and total perinatal complications were higher in the control group ($P = .005$) and fewer women in the intervention group (27.3%) had ≥ 1 perinatal complications, compared to the control group (45.3%, $P = .013$). Pre-eclampsia was less frequent (2.3% vs 16.3%; $P = .001$).

Monroy-Torres et al.[28], also in Mexico, tested a low calorie diet (1700kcal), composed of 18% protein, 30% fats and 52% carbohydrates of low/moderate

GI (n=31). Outcome measures included weight, BGLs, glycosylated hemoglobin (HgbA1c), energy and macronutrient intake. Confounding factors were not considered. At postpartum follow up, 65% of women met dietary guidelines compared to just 14% at study commencement. Glucose control improved over the course of the study (146mg \pm 37 vs 90 \pm 5 mg/dl) and average newborn size was 3,347 \pm 385gr.

Berggren et al. [23], conducted a secondary analysis (n=1535), by ethnic group, of a US intervention trial [30]. Women with mild GDM (abnormal result on OGTT but fasting BGL below 95 mg/dl) were randomly assigned to care as usual (control group) or dietary intervention, self-monitoring of BGLs, and insulin therapy, if required (intervention group). Data were collected on glucose intolerant women (OGTT 135 and 200 mg/dL). Postpartum outcomes considered included stillbirth /perinatal death or neonatal morbidity, including hyperbilirubinemia, hypoglycemia, hyperinsulinemia, and birth trauma. Confounders included maternal age, ethnic group, GDM status (glucose intolerant, mild GDM treated, mild GDM untreated). Results indicated that compared to White women, Hispanic women with glucose intolerance had more frequent composite neonatal adverse outcomes (37% vs. 27%), with raised C-cord peptide (19% vs.13%) and neonatal hypoglycemia (21% vs. 13%). Results among women with mild GDM were comparable.

The final study by Mendelson et al. [25] in California, US, compared usual care with usual care plus one hour Nurse education session on GDM, diet, activity and medical treatment (n=100). Women were screened for GDM, though diagnostic criteria for GDM were not described. Outcome measures included BGLs pre and post intervention; birth weight, maternal/ Infant hospital bed days. The study did not control for confounders. The impact of the intervention was measured by BGLs, glycosylated haemoglobin levels, macrosomia, and hospital bed days. No difference was found on any of the outcome measures (BGLs (f5-.273; p 5.602) HgbA1c levels (f5-.727; p5.402) macrosomia p<.546, maternal hospitalisation p<.893, neonatal hospitalization p<.905). However, the intervention was considered successful in improving self-reported health promoting behaviours.

Insert table 2 here

Quality assessment of studies

Studies were evaluated on methodology and clear description of the intervention, diagnostic criteria for GDM, clear description of outcome measures, follow up and confounding factors. Generally, studies performed well with the majority scoring $\geq 17/24$. The lowest scoring studies failed to provide detail on diagnosis of GDM, follow up or confounding factors.

Insert table 3 here

Discussion

Our goal was to evaluate interventions to assist Hispanic women manage their GDM. However, there is a dearth of studies aimed at this population, and limited consensus as to which approach is most likely to be successful at reducing GDM rates or improving perinatal outcomes. This is concerning as Hispanic populations incur high rates of GDM [31] and they and their infants are at greater risk of adverse perinatal outcomes.

Overall, findings suggest that: (1) intensive nutritional counselling over a prolonged period of time appears effective in reducing BGLs and pregnancy complications; (2) study populations appear to achieve better BGL control and reduced insulin use with a low calorie and possibly low GI diet; (3) Spanish language, culturally tailored interventions may be more acceptable to participants, based on their low levels of English language proficiency.

Intensive nutritional counselling over a prolonged period

Three studies considered their intervention successful [24, 26, 28]. The most successful interventions, in terms of demonstrated improvements in BGLs and outcome measures, were conducted in Mexico [26, 28]. These studies found that a reduced calorie diet [26, 28], together with comprehensive

instruction/counselling produced improved BGLs and reduced rates of pregnancy /perinatal complications, including pre-eclampsia and neonatal death. Perichart-Perera's study (n=88) controlled for a range of confounding factors, however the findings from Monroy Torres (n=31) should be interpreted with caution as only a small sample was involved and confounding factors were not considered in the analysis. The remaining intervention considered successful was conducted in the US [24]. Kieffer et al. [24] conducted a RCT including a total of 278 participants and found that the intervention resulted in improved diet, including increased fruit/vegetable consumption and reduced dietary fats. However, outcomes were measured by self-reported questionnaire without corroborating BGLs, or maternal weight changes.

Two studies reported inconclusive results [22 [Reyes-Muñoz, 2014 #817, 29] and these findings may relate to the nature of the interventions or study design. Balas-Nakash et al. [22] were concerned primarily with measuring adherence to dietary recommendations across two dietary regimes, and these were mainly evaluated by self-report which may potentially explain why 72% of participants achieved optimal glycemic control, irrespective of diet type. Although the RCT conducted by Reyes-Munoz et al. [29] found no difference in outcomes, which may also be attributable to small sample size, it is worth noting that the overall GDM incidence, was approximately 6.8%, which is relatively low for this high-risk group [12].

The final two studies reported no/limited improvements in BGLs [23, 25] and these findings may possibly be explained in two ways. Firstly, the intervention described by Mendelson et al. [25] involved a single educational session for women with GDM. This approach is in contrast to the more successful interventions, using longer and more sustained approaches. Although participants reported improved health related behaviours, no difference was noted in BGLs and it may be that the single session, described by Mendelson et al. [25], was insufficient to motivate and encourage the necessary behavioural change. Mendelson et al. [25] also did not consider confounding factors in their analysis, and this may provide an alternative explanation for their results. In the second case, Berggren et al. [23], conducted a large RCT and found that the intervention was more successful among other groups of women with GDM,

but not among Hispanic women. This finding may relate to the 'one size fits all' intervention approach, which was delivered in English. Such an approach may be at odds with the needs, cultural understandings and English language proficiency of Hispanic women [32] as other studies conducted in the US which delivered Spanish speaking interventions demonstrated that these groups are recent migrants with low levels of English literacy [24] and acculturation [25].

Calorie restriction and Low GI diet

The use of a low calorie and particularly low GI diet was generally suggestive of better glycemic outcomes, in this review, and this is consistent with the wider literature. A recent systematic review of dietary interventions (e.g., low GI, energy restriction, low carbohydrate) for GDM found that only low GI diet was associated with significant outcomes including, reduced proportions of women using insulin and reduced neonatal birth weight [33]. In contrast, a Cochrane review found that a range of dietary approaches including low GI were not associated with reduced incidences of macrosomia, large for gestational age or caesarean section in women with GDM [34]. Numerous studies have debated the efficacy of low GI diets in preventing/treating GDM and findings generally indicate improvements in weight management and BGL control, and lower insulin use [35-39]. A Cochrane review led by Tieu et al. [38], suggested that a low GI diet may reduce fasting BGLs and fetal macrosomia, while Clapp [35] found low GI diets were associated with lower maternal weight gain and lower rates of fetal macrosomia. Grant et al. [36], who piloted a Low GI diet compared to high/ intermediate GI diet, for women with GDM, found that BGL control improved on both diets, with greater improvement in postprandial BGLs on the low-GI diet. Thus, although the weight of evidence suggests improvement, there is no clear consensus on the absolute value of this dietary approach, and Moses et al.[37] who compared low GI diet with conventional healthy eating advice for pregnant women found both groups improved.

Studies examining the impact of diets high in saturated fats [40] may provide some further insight into these findings. High dietary levels of saturated fat and energy dense snacks [40] gave rise to an increased risk of GDM and it may be that dietary advice effecting any reduction in saturated fat and sugar content may generally improve glycemic outcomes. In keeping with this finding, Tobias et al. [40] found that any healthy pre-pregnancy dietary pattern, including Mediterranean, DASH (Dietary Approaches to Stop Hypertension), and alternate Healthy Eating Index significantly decreased risk of GDM. Similarly, Walsh et al. [39] who examined the use of Low GI diet to prevent fetal macrosomia, found that the women most likely to benefit from a low GI diet were women with the lowest levels of education. This finding may indicate that such women are the most in need of dietary advice.

Limitations

Limited available literature resulted in a broadening of the original search to include GDM interventions in Mexican settings. Other limitations include the quality of the studies, heterogeneity of study methods, sample size, intervention approaches, all of which limit possible comparison between studies. Variability in GDM diagnosis is a further limitation. Nonetheless, despite the limitations imposed by these incongruences, our findings offer some insights into GDM interventions targeting Hispanic Mexican women and some direction for developing new interventions.

Implications and conclusion

Our understanding that Spanish language approaches produce the best results is consistent with the literature [32, 41] and research suggests that language and culturally adapted interventions are more effective for ethnic minorities [42]. Our review indicates not only a dearth of research on GDM interventions for Hispanic women but also few culturally adapted interventions. This is an area that requires much greater attention in the future.

Overall, this review has highlighted a lack of reliable evidence on GDM interventions for Hispanic women. Greater research effort is needed to clarify which dietary approaches and behavioural interventions are likely to most effective for this group. This is an important area to address as rising rates of obesity in Hispanic populations foreshadow an ever increasing predisposition to GDM with significant implications for maternal and infant health. Spanish language approaches, offering intensive dietary counselling over a period of several weeks may prove most effective for managing GDM in Hispanic women.

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Table 1

#	Criterion	Score
1.	Was the intervention clearly described?	0-4
2.	Was an appropriate comparative method used to evaluate the intervention? (0-3) - Was the cohort recruited in an acceptable way?(0-1)	0-4
3.	In studies evaluating treatment of GDM, were the diagnostic criteria used, adequately described?	0-4
4.a	Were outcome measures clearly described and consistent with the intent of the study?	0-4

4.b	In studies not testing for GDM, were blood glucoses levels measured?	0-4
5.	Were potential confounding factors adequately addressed?	0-4
6.	Was follow up adequate in terms of: (a) for length of time, and (b) retention of study participants?	0-4

Table 2

Criteria for quality analysis adapted from CASP tool for RCTs

#	Criterion	Score
1	Was the intervention clearly described?	0-4
2	Was randomisation carried out and to what degree did blinding take place?	0-4
3	Were the groups similar at the start of the trial? - In studies evaluating treatment of GDM were diagnostic criteria used and described? Were the groups treated equally?	0-4
4	Were all participants accounted for at the end of the study?	0-4
5	Were outcome measures described and were they consistent with the intent of the study? - In studies not testing for GDM were BGLs measured?	0-4
6	Were results reported for each outcome and how precise were they?	0-4
7	Are results applicable to the context and were all clinically important outcomes considered?	0-4

Table 3 Characteristics of intervention papers
Prevention of GDM

Author (Year)	Study location Language of intervention delivery	Study Aim	Study Design	Study Population	Intervention	Outcome Measures	Reported findings		*Quality index (0-28)
Kieffer, E.C., et al. 2014	Detroit, Michigan, US Spanish	To assess the effectiveness of a community-based healthy lifestyle intervention for pregnant Latinas	Randomized controlled trial.	Pregnant Latinas aged 18 years or older, southwest Detroit residents, < 20 weeks' gestation (n=275)	An 11 week intensive dietary counselling intervention, delivered by trained Latina community health workers. The focus was on encouraging greater fruit and vegetable intake. Exercise counselling included.	Dietary assessment based on dietary recall. Controlled for maternal age, education level, years living in US, care at FQHC, food stamp participation, WIC enrollment, parity, pre-pregnancy BMI.	Intervention Reduced intake of total fat, g (P < .05) M=82.0(36.9) Reduced intake of saturated fat, g (P < .01). M=29.8(13.5) Reduced intake of added sugar, g (P = .05). M=72.0(54.6)	Control M=86.6(46.1) M=31.0(16.7) M= 74.9(48.7)	20
Reyes-Munoz, E., et al. (2014) Mexico City	Mexico City, Mexico Spanish	To assess the effectiveness of a medical nutrition intervention in preventing GDM among high risk Mexican women	Randomized controlled trial	Pregnant Mexican women with 3 of the following: > 25 years, BMI>27 kg/m ² , previous infertility, polycystic ovary syndrome, previous GDM, previous macrosomic infant, diabetes in close family member, impaired glucose metabolism(n = 58)	Medical nutrition therapy (MNT) compared to MNT plus Metformin. Diet not described. Exercise counselling not included.	Diagnosis of GDM Confounders controlled for not reported.	Intervention Incidence of GDM n=1(3.6%) (relative risk 0.35, 95% confidence interval 0.03–3.2).	Control n=3 (10%)	12

Treatment of women with GDM

Author (Year)	Study location Language of intervention delivery	Study Aim	Study Design	Study Population	Intervention	Outcome Measures	Reported findings		*Quality index (0-24)
Mendelson et al, 2008	California, US Spanish	To investigate the impact of a Parish Nurse Intervention Program (PNIP) on blood glucose control, and perinatal outcomes	Randomized controlled trial	Pregnant Mexican American women with GDM. Intervention group (n=49), routine care (n=51)	Care as usual compared to care as usual plus a one hour Parish Nurse led education session on GDM, diet, activity and medical treatment. Exercise counselling included.	BGLs pre and post intervention; birth weight, maternal/ Infant hospital bed days. The Health Promoting Lifestyle Profile II (HPLP II) Not controlled for confounders	BGLs, birth weight, or Maternal/ Infant hospital bed days were not significantly different between groups. HPLP II scores were significantly improved in the intervention group (M=2.72) in comparison to the control group (M=2.51).		16
Perichart-Perera et al, 2009	Mexico City, Mexico Spanish	To examine the impact of medical nutrition therapy (MNT) on perinatal outcomes.	Quasi-experimental design with a historical control (chosen from medical records)	Women with a diagnosis of GDM, <29 weeks gestation. Intervention group (MNT program) (n = 88). Control group (n = 86)	Reduced calorie diet, composed of 40-45% carbohydrates, with intensive dietary counselling (dietitian). Exercise counselling not included.	Pre-eclampsia, 1 st maternal hospitalization, stillbirth, neonatal death, macrosomia, prematurity, low birth weight, admission to special care. Not controlled for confounders	Intervention Lower rates of pre-eclampsia. M=2.6 less hospitalizations. M=0 less neonatal deaths. M=0	Control M=17.9 M=28.2 M=5.1	20
Balas-Nakash et al. 2010 Mexico	Mexico Spanish	To measure adherence to medical nutrition therapy (MNT) program	Randomized controlled trial	Mexican women Pregnant, < 30 weeks gestation Diagnosis of GDM or type 2 diabetes, (n=69)	Reduced calorie diet, 24 kcal/kg. Group 1 - all carbohydrates. Group 2 - low glycemic index carbohydrates. Both groups received nutritional counselling. Exercise counselling not included.	Adherence to MNT as indicated by BGLs and evaluation by: <ul style="list-style-type: none"> • Questionnaire • Women's self-perception. • Dietary 24 hr recall. Controlled for maternal age, insulin, diet type	Intervention Optimal Glycemic control: 72% of women No differences seen in the 3 evaluation methods used by the study.	Control 61.6% of women	22

Monroy Torres et al., 2008 Leon,	Guanajuato, Mexico Spanish	To examine the effectiveness of a low/moderate glycemic diet to control GDM	Longitudinal study of a single group	Mexican women Pregnant, Diagnosis of GDM, (n=31) <24 weeks gestation	1700kcal low /moderate glycemic index diet composed of: protein 18%; fat 30%; carbohydrates 52% dietary counselling Exercise counselling not included.	Dietary intake, weight gain, monthly weight and blood glucose. HBA1C measured at beginning and end of study, infant weight Not controlled for confounders	An improvement was seen from 14% to 65% adherence to recommended diet. Average infant birth weight was 3,347 ± 385gr		17
Berrgen, E. et al., (2012)	Multi-site, USA English	To test the effectiveness of a treatment program for mild gestational diabetes		Pregnant Hispanic and non-Hispanic white women with glucose intolerance (n=767) or mild GDM (n= 371).	Self monitoring of blood glucose levels, dietary counselling, insulin if deemed necessary. Exercise counselling not included.	Neonatal death, hypoglycemia, hyperbilirubinemia, hyperinsulinemia; stillbirth; birth trauma, gestational age at delivery, birthweight, and hypertensive disorders of pregnancy Confounders: parity; gestational age, BMI, maternal age ; smoking	Intervention Frequency of perinatal morbidity outcomes 37% (aOR 1.62 95%CI 1.10, 2.37) Elevated C-cord peptide 19% (aOR 1.79 95%CI 1.04, 3.08) Hypoglycemia 21% (aOR 2.04 95%CI 1.18, 3.53). No differences seen in by ethnic group among women with untreated mild GDM.	Control 27% 13% 13%	22

Legend: * Quality score: 0-9 = low quality, 10-19 moderate quality, 20-28, high quality.

Table 4 Outcome variables by study type

Study	*Study focus	Outcome Variables Maternal									Outcome Variables infant			
		Self-rated dietary	Self-rated exercise	Dietary adherence	Diagnosis of GDM	BGLS (B) HBA1C (H) Insulin (I)	Hospital stay	Pregnancy Hypertension (any)	BMI	Maternal weight-gain	Birth-weight	[^] Perinatal adverse outcome	#Perinatal morbidity	^o SCN admission
Kieffer, et al. 2014	1	X												
Reyes-Munoz et al. 2014	1				X									
Mendelson et al, 2008	2					X (B)	X				X			
Perichart-Perera et al, 2009	2						X	X		X	X (NND, SB)	X (GA)	X	
Balas-Nakash et al. 2010	2	X		X		X (B)								
Monroy Torres et al., 2008	2	X		X		X (H)				X				
Berggren et al., 2005	2					X (B)		X			X	X (NND, SB)	X (LGL, HBR, HI, BT, GA)	

Legend: * Study focus- (1) GDM prevention; (2) GDM treatment;

[^] Perinatal adverse outcome: Neonatal death- NND; Stillbirth- SB

Perinatal morbidity: Hypo-glycemia- LGL (low glucose level)-; Hyper-bilirubinemia-HBR; Hyper-insulinemia- HI ; Birth trauma- BT; Gestational age – GA

^oSCN- Special Care Nursery admission