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Diabetes after pregnancy prevention trials: Systematic review for core outcome set development

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Abstract

Diabetes prevention intervention studies in women with previous gestational diabetes have increased, but no consensus exists on core outcomes to support comparisons and synthesis of findings. We aimed to systematically catalogue outcomes in diabetes after pregnancy prevention interventions with the goal of developing a core outcome set. Embase, Medline, Cochrane Library, Cochrane Pregnancy and Childbirth Trials Register, and CINAHL were searched from inception to October 2017. Postpartum lifestyle and diabetes screening intervention studies in women with previous gestational diabetes and/or their families were eligible. No limits were placed on intervention type, duration, or location. Two authors independently screened and performed data extraction on outcomes, measurement tools, and relevant study characteristics. We analysed data from 38 studies (29 randomised controlled trials and 9 pre–post intervention evaluations) comprising 12,509 participants. Most publications (80%) occurred between the years 2012 and 2017. Among 172 outcomes, we identified 36 outcome groups and classified them under three domains: health status (body weight, body composition, diabetes risk, cardiometabolic risk, diabetes development, mental health, pregnancy outcomes, and fitness), health behaviours (dietary, physical activity, diabetes screening, behaviour change, and breastfeeding), and intervention processes (implementation). The health status domain contained the most commonly reported outcomes, but measurement tools were very heterogeneous.

Despite the recent explosion in diabetes after pregnancy prevention studies, large variation in outcomes and measurement methods exists. Research is needed to define a core outcome set to standardise diabetes after pregnancy prevention interventions. The core outcome set should engage a wide group of stakeholders to identify impactful indicators for future trials.

KEYWORDS

core outcome set, diabetes prevention, gestational diabetes

1 | INTRODUCTION

Gestational diabetes mellitus (GDM) currently affects 5–15% pregnancies and increases the risk of complications such as shoulder dystocia and caesarean delivery (Nguyen, Pham, Binns, Duong, & Lee, 2018). The risk associated with GDM does not end once the woman gives birth; research indicates that women with previous GDM have eightfold higher risk of developing type 2 diabetes (Song et al., 2018) and are more likely to have another GDM pregnancy (Nguyen et al., 2018) and that the woman's partner and offspring are also at risk of type 2 diabetes (Boney, Verma, Tucker, & Vohr, 2005; Dasgupta et al., 2015). The incidence of GDM is predicted to dramatically rise in coming years due to the growing rates of obesity (Nguyen et al., 2018). It is thus imperative that any interventions that are designed to reduce a woman's risk make best use of resources available.

The U.S. diabetes prevention programme provided evidence that intensive lifestyle modification could reduce the risk progression to diabetes after pregnancy (DAP) by more than half; moreover, the intervention was similarly beneficial in the subgroup of women with a GDM history as in the overall study population (Aroda et al., 2015; Ratner et al., 2008). The diabetes prevention programme participants had already developed impaired glucose tolerance, and women were enrolled an average of 12 years after their first GDM pregnancy. These women were much further along the trajectory to develop DAP and at a different life stage compared with women within 5 years of GDM pregnancy (Kragelund Nielsen, Groth Grunnet, & Terkildsen Maindal, 2018; Nielsen, Kapur, Damm, de Courten, & Bygbjerg, 2014). Importantly, at least half of women with a GDM history who develop DAP do so within 5 years of a GDM pregnancy (Kim, Newton, & Knopp, 2002; Pace, Brazeau, Meltzer, Rahme, & Dasgupta, 2017). A systematic review indicates that the highest risk period is 3 to 6 years post-partum (Song et al., 2018). The difference that this time frame brings to delivering a health behaviour change intervention cannot be underestimated as it results in a well-documented lowering of prioritisation and perceived time (Nielsen et al., 2014) to engage in DAP prevention activities for women with young families.

An increasing number of DAP prevention trials seek to find the balance between the demands of daily life with a young family, alignment with relevant healthcare systems and intervention effectiveness. The degree of variation in reported trials appears to be stifling growth in how we might understand what works best, where, and for whom. As a response, we proposed the development of a core outcome set (COS) for DAP prevention trials. COSs are consensus-driven minimum sets of outcomes for measuring and reporting in trials for a given health issue (Williamson et al., 2012). COS selection is a four-stage process, where the first stage consists of a systematic review to collate all trial outcomes measured at the time of registration with the Core Outcome Measures in Effectiveness Trials Initiative (COMET number 1083) (Kirkham et al., 2017). In the present investigation, we aimed to identify core outcomes in DAP prevention interventions, systematically report their evolution over time, and characterise outcomes into key domains that will form a framework for the COS development.

Key Messages

- Intervention studies in women with previous gestational diabetes focused on diabetes prevention have increased. However, there is no agreed set of outcomes across studies, limiting comparisons and synthesis of findings.
- We identified 36 outcome groups and classified them under three domains: health status; health behaviours; and implementation processes. The health status domain had the most commonly reported outcomes but measurement tools were very heterogeneous.
- Despite the recent growth in intervention numbers, outcomes and methods of measurement are varied. A core outcome set is needed to standardise intervention reporting and identify useful indicators for future trials.

2 | METHODS

2.1 | Eligibility criteria, information source, and search strategy

We searched five citation indices (OVID Medline, Embase, CINAHL, Cochrane Central Register of Controlled Trials, and Cochrane Pregnancy and Childbirth Group Trials Register) from inception to October 25, 2017. Subject headings and key words included “gestational diabetes” and/or “diabetes in pregnancy,” “postpartum period” and related words, “diabetes reduction” and/or “diabetes prevention,” and various terms related to the intervention (e.g., “diet,” “body mass index,” “weight reduction,” “exercise,” “lifestyle,” and “cognitive therapy”; see Table S1 for details). Citation lists of meta-analyses and systematic reviews were reviewed to identify any intervention reports missed by the search strategy. The search was performed by Y. L. after review by the University College Dublin systematic review librarian and S. O'R.

2.2 | Study selection

Studies were required to include an intervention report (randomised, non-randomised, pre–post design, and quasi-experimental studies) or protocol published in a peer-reviewed journal. Where both a protocol and results publication were identified, only the results publication was included. Excluded studies were reviews, case reports, meta-analyses, systematic reviews, observational studies, letters, guidelines, commentaries, historical articles, and editorials. Only English language studies were retained due to resource constraints.

2.3 | Data extraction

Screening of titles and abstracts occurred independently by two investigators (S. O'R. and Y. L.). Disagreements were resolved by consensus. After this initial screening, full texts of potentially relevant articles were reviewed by a minimum of two investigators (among K. D., K. K. M., H. T. M., Y. L., and S. O'R.). Studies retained were required to include post-partum outcomes, but no restrictions were placed on the time since delivery. Interventions that commenced during pregnancy were included, provided that they included post-partum outcomes. Interventions focused on changing diabetes screening behaviours or health behavioural outcomes (i.e., eating and physical activity) were included, whereas those focused on pharmacological treatments or supplements were excluded. The data extracted included study design, duration, setting, recruitment, target population, numbers invited and/or contacted, numbers assessed and/or eligible, numbers enrolled, numbers participating, effectiveness reported, intervention description, measurement tools, duration of follow-up, randomisation, blinding, population demographics, and contextual factors.

2.4 | Assessment of risk of bias

No assessment of risk of bias was undertaken as the purpose of the COS is to collate trial outcomes and evaluate their definition and evolution over time.

2.5 | Data synthesis

A comprehensive list of outcomes was generated, and this was subsequently organised into outcome subdomains and summarised in table format. For each outcome, we calculated the proportion of studies reporting them and organised these into 5-year blocks to capture changes over time. The reporting of outcomes was then condensed into a matrix with the outcomes as rows and their frequency plotted in greyscale over a time axis. We did not perform a study quality assessment, as this review sought to evaluate only outcome measures and definitions. Similarly, no analysis of effect size was performed, as it was not appropriate for a review aiming to tabulate potentially important outcomes.

3 | RESULTS

3.1 | Study selection

In total, 4,343 records with three additional articles identified through citation tracking (Figure 1) were examined. Following duplicate removal, 2,859 titles were screened, resulting in the exclusion of 2,724 articles. Of the final 135 abstracts that were screened, 57 full-text articles were subsequently reviewed. Nineteen articles were excluded after full-text review (six incorrect study design [Azen et al., 1998; Carmody, Egan, & Dunne, 2015; Frazzitta, Anderson, & Egan, 2013; McManus, Giroux, Zhou, McLaren, & MacLellan, 2012; Paez,

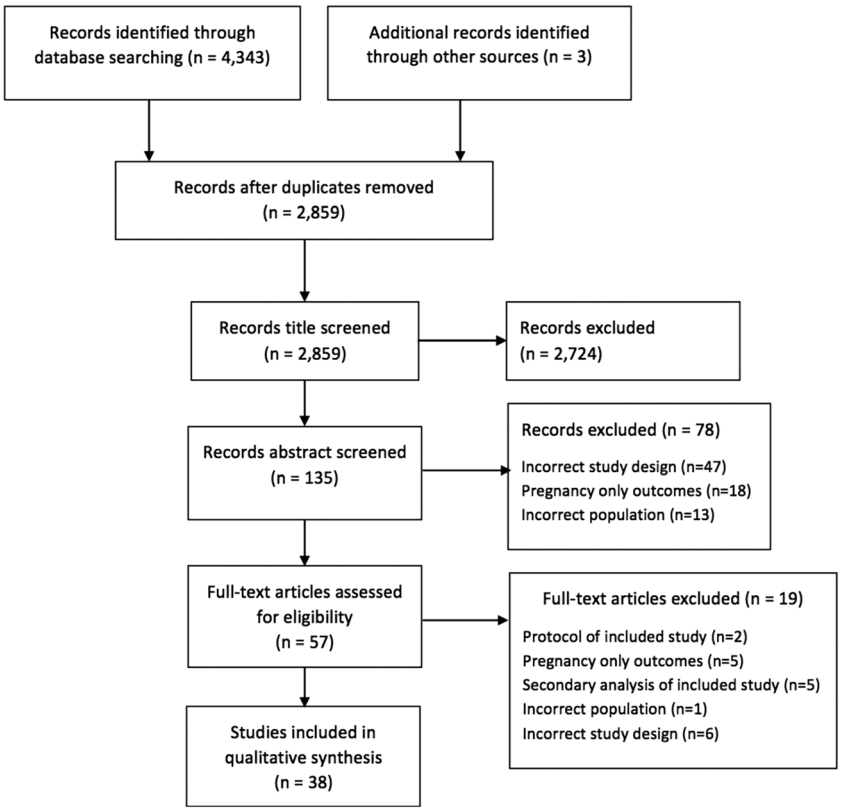

FIGURE 1 PRISMA flow chart for assessment of diabetes after pregnancy prevention trials in women with previous gestational diabetes

Griffey, Thompson, & Gillman, 2014]; five pregnancy-only outcome [Guelfi et al., 2016; Koivusalo et al., 2016; Louie, Markovic, Ross, Foote, & Brand-Miller, 2015; Puhkala et al., 2017; Tawfik, 2017]; five secondary analysis of a study already included [Aroda et al., 2015; Ehrlich et al., 2014; Ghani et al., 2014; Nicklas et al., 2016; Shyam et al., 2016]; two protocol papers of included studies [Ferrara et al., 2014; Heatley, Middleton, Hague, & Crowther, 2013]; and one incorrect population [Lewis, Martinson, Sherwood, & Avery, 2011]), resulting in 38 articles included in the final analysis. Figure 1 demonstrates the study selection process and reasons for exclusion at each review stage.

3.2 | Study characteristics

In total, 12,509 women participated with 49% randomised to placebo (Table 1). Most articles were published after 2007 (95% trials), and the median duration of follow-up was 26 weeks. The time point at which trials were started varied (during pregnancy, 9 trials; 6–8 weeks post-partum, 4 trials; within 12 months post-partum, 3 trials; up to 5 years post-partum, 11 trials; and unspecified time since GDM, 3 trials) as did the duration of intervention (6 weeks to 5 years). Eight trials addressed diabetes screening, and 30 trials examined health behaviour change interventions. The type of trials designed for diabetes screening was split evenly between randomised controlled trials and pre–post interventions, whereas most health behaviour change trials had a randomised control design (87% trials; Table S2). Health behaviour change and diabetes screening interventions had an average of 9 and 5 outcomes, respectively, per trial. Typically, pilot health behaviour trials with smaller participant numbers had less outcomes, but diabetes screening trials had a relatively consistent number of outcomes. The smallest trial included 23 women (Nicholson et al., 2016), the largest 2,280 (Ferrara et al., 2016), and the average was 329. Close to half of the trials were conducted in the United States (45%); Canada (13%) and Australia (24%) were the other main site countries. A total of 172 outcomes were identified. These were condensed into 36 groups and then categorised into domains (Table S3). Additional information on how the outcomes were measured and defined was also collected (Table S3).

3.3 | Synthesis of results

3.3.1 | Health status outcomes

Health status outcomes were the most numerous out of the different domains (Figure 2). The health behaviour change trials all included at least one health status outcome, and a spread of outcome subdomains occurred across trials regardless of size. The most commonly recorded outcome subdomain (97% trials) was body weight (Table 2). In second place was direct measurement of diabetes risk, using dysglycaemia and insulin resistance measures (90% trials). Direct measures of cardiovascular risk such as blood pressure or lipids were the third most commonly recorded outcomes, but their frequency was much lower (59% trials). All other health status outcomes had a lower and varied prevalence across trials. Within the body weight subdomain, a variety of definitions were used for post-partum weight reduction. In contrast, weight was standardised, and the measures used included digital scale, electronic health record data, and self-reported weights. The diabetes risk subdomain's most commonly measured outcome was change in fasting plasma glucose (88% of trials measuring diabetes risk), followed closely by change in 2-hr plasma glucose (85% trials), which demonstrates that an oral glucose tolerance test is

TABLE 1 Trial characteristics in diabetes prevention for women with previous gestational diabetes

Characteristics	Health behaviour change trials (*n* = 30)	Diabetes screening trials (*n* = 8)	All trials (*n* = 38)
Trial participants, number (%)			
Total participants	9,575	2,934	12,509
Intervention participants	4,302 (45)	2,130 (73)	6,432 (51)
Trial publication year, number (%)			
2007–2017	28 (93)	8 (100)	36 (95)
1996–2006	2 (7)	0	2 (5)
Trial design, number (%)			
Randomised controlled	26 (87)	4 (50)	30 (79)
Pre–post intervention	4 (13)	4 (50)	8 (21)
Country, number (%)			
United States	13 (43)	4 (50)	17 (45)
Australia	8 (27)	1 (13)	9 (24)
Canada	2 (7)	3 (37)	5 (13)
Other (Spain, China, Finland, Ireland, and Malaysia)	7 (23)	0	7 (18)
Follow-up (weeks), median (interquartile range)	28 (13–52)	26 (13–52)	26 (13–52)

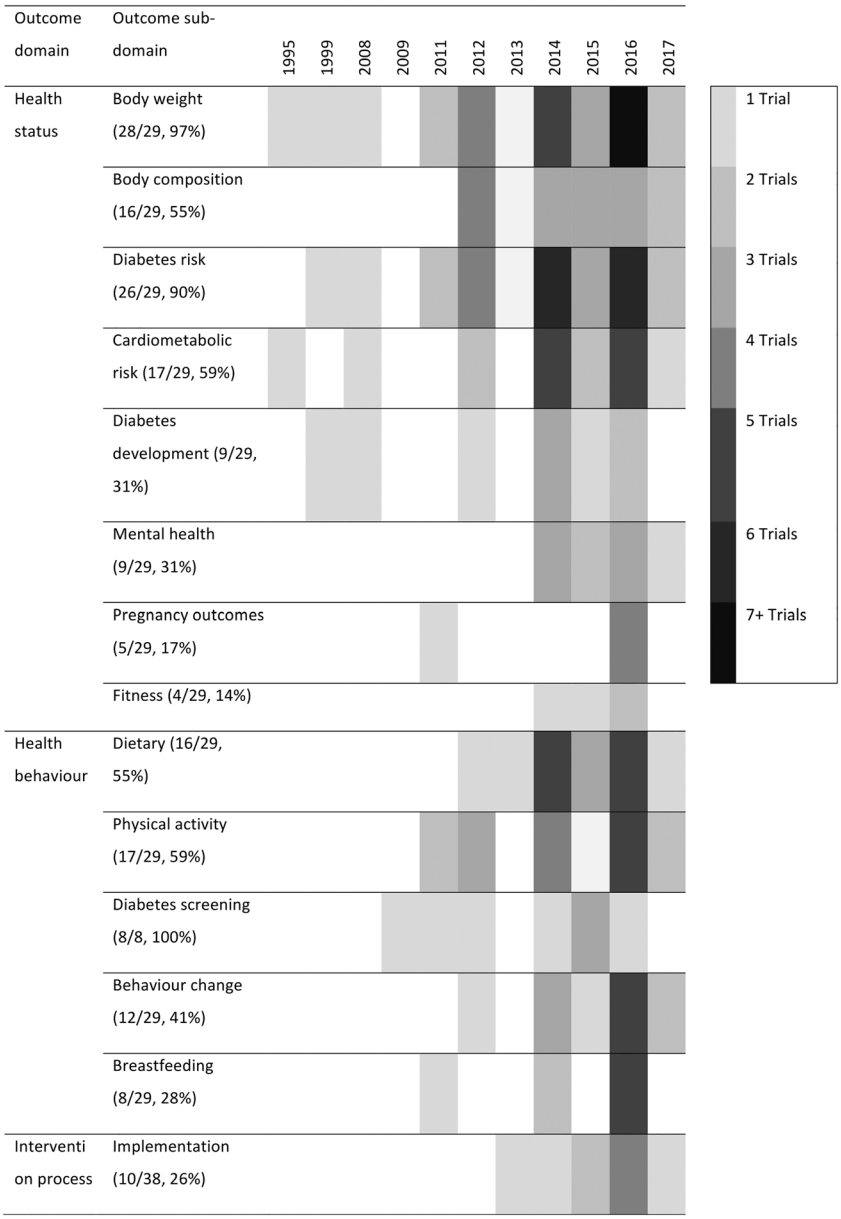

FIGURE 2 Outcomes reporting matrix for trials to prevent diabetes after pregnancy in women with previous gestational diabetes

performed in most trials and haemoglobin A1c (35% trials) at a much lower frequency. Diabetes development was measured in only nine trials, all of which had over 200 participants and a follow-up duration of over 3 years. The measurement of outcomes in mental health, body composition, and fitness outcomes has only occurred in the past 5–7 years.

3.3.2 | Health behaviour outcomes

The most commonly reported outcome for health behaviour change trials was physical activity (59% trials), followed closely by dietary outcomes (55% trials). The physical activity outcomes measured frequency and volume of activity (16 trials) more often than level of intensity (six trials). The dietary outcomes tended to be focused on macronutrient-level assessment (12 trials); dietary quality received less attention (seven trials), and just under half of dietary quality outcome measures were unvalidated. For diabetes screening trials, every single study had a diabetes screening outcome but the degree of variation in definition used was large, as there were a wide variety of tests being used, for example, any blood glucose test, haemoglobin A1c, oral glucose tolerance test, fasting blood glucose, and time frames being used in the measurement, for example, 3 months after delivery, 6 months post-partum, and within 12 months post-partum. Breastfeeding was an outcome that was largely unmeasured with only 28% of the larger to medium-sized lifestyle modification trials reporting breastfeeding outcomes, but this may be impacted by the time frame over which the trials were conducted, for example, immediately post-partum versus women with older weened children.

TABLE 2 Outcome domains and measurement tools for prevention of diabetes after pregnancy trials in women with previous gestational diabetes

Outcome domain	Outcome subdomain	Primary outcomes	Secondary outcomes	Measurement
Health status	Body weight	• Weight • Post-partum weight retention	• Weight • Post-partum weight retention	• BMI • Weight (self-reported, health records and actual) • Height (self-reported, health records and actual)
	Body composition	• Body composition	• Body composition	• Waist/hip circumference (self-reported and actual) • Body fat (DEXA, CT scan, and bioelectrical impedance analyser) • Basal metabolic rate (metabolic cart)
	Diabetes risk	• Glycaemic control	• Glycaemic control	• Fasting blood glucose • Oral glucose tolerance test • Glucose AUC • HbA1c • Urine glucose
			• Insulin	• Serum fasting insulin • Insulin AUC
			• Insulin resistance and sensitivity	• Matsuda index • HOMA-IR • Insulin: Glucose ratio
	Cardiometabolic risk		• Blood pressure	• Systolic and diastolic (automated and health records)
			• Blood lipids	• Total cholesterol • LDL cholesterol • HDL cholesterol • Triglycerides
			• Inflammation	• Fetuin-A • Albumin: Creatinine ratio • Apolipoprotein B • Plasma uric acid • TNF-α • Plasma gamma-glutamyl transferase • Adiponectin • C-reactive protein • C-peptide • Leptin
	Diabetes development	• Incidence	• Incidence	• Diagnosis (WHO, ADA guidelines)
	Mental health		• Depression • Quality of life • Anxiety • Stress • Well-being	• Questionnaires (detail) • Health records
	Pregnancy outcomes		• Maternal	• Gestational hypertension • Labour induction • Caesarian section • Maternal length of stay
			• Infant	• Gender • Birth weight and length • Jaundice • Neonatal length of stay
	Fitness		• Fitness • Flexibility • Strength	• VO2 max • 6-min walk test • Handgrip strength

(Continues)

TABLE 2 (Continued)

Outcome domain	Outcome subdomain	Primary outcomes	Secondary outcomes	Measurement
				• Sit and reach test
Health behaviour	Dietary	• Macronutrients	• Macronutrients	• Total energy and energy from fat and saturated fat • Fibre intake • Carbohydrate intake • Glycaemic load (food frequency questionnaire/dietary recall/food diaries/self-reported questionnaires)
			• Dietary quality • Eating behaviours	• Food group servings • Eating out frequency • Diet quality questionnaire • Mediterranean diet score
	Physical activity	• Volume	• Volume	• Steps/distance (pedometer) • Activity counts (accelerometer) • Time (questionnaires) • Sitting time • Sedentary behaviour (<5,000 steps/day)
		• Intensity	• Intensity	• Level of exertion sedentary/moderate/vigorous (questionnaire and accelerometer)
	Diabetes screening	• Completing post-partum test • Sending of reminders	• Completing post-partum test • Sending of reminders	• Attending test • Completion of OGTT/blood glucose/HbA1c • Number of reminders/test orders sent
	Behaviour change	• Beliefs	• Beliefs	• Motivation to change • Fatalism and cultural beliefs • Perceived body image and diabetes risk
			• Self-efficacy	• Perceived self-efficacy • Exercise self-efficacy • Diet self-efficacy • Weight self-efficacy
			• Barriers and enablers	• Identifying and addressing barriers and enablers • Perceived barriers • Social support • Sleep quality
		• Knowledge	• Knowledge	• Diabetes knowledge • Healthy lifestyle behaviours • Diabetes prevention behaviours
	Breastfeeding		• Duration • Exclusivity	• Feeding type • Feeding duration
Implementation process	Implementation	• Engagement • Feasibility	• Engagement • Feasibility	• Intervention components engaged with/duration • Completion of targets/activities • Recruitment, retention, acceptability • Adverse events
			• Health economics	• Health status for cost evaluation • Health service utilisation and cost

Abbreviations: AUC, area under the curve; BMI, body mass index; CT, computed tomography; DEXA, dual-energy X-ray absorptiometry; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; HOMA-IR, homeostatic model assessment of insulin resistance; LDL, low-density lipoprotein; OGTT, oral glucose tolerance test; TNF-α, tumour necrosis factor alpha.

3.3.3 | Implementation process outcomes

Implementation process outcome measures were the least commonly reported domain. These measures typically covered intervention engagement from a participant or healthcare professional perspective (eight trials), the feasibility of the intervention (four trials), or health economics assessment (three trials). Only about a quarter of trials reported these outcomes with the spread relatively even between health behaviour change (31% trials) and diabetes screening (25% trials). Health economic outcomes were reported in a single study (Ferrara et al., 2016), although these were measured in two additional trials (O'Reilly et al., 2016; Schmidt et al., 2016).

4 | DISCUSSION

The majority of DAP prevention trials that met our inclusion criteria focused on health behaviour change (30 trials, 79%) rather than diabetes screening (eight trials, 21%). Among the former, 97% evaluated body weight and 90% examined a measure of glycaemic control or insulin resistance, as an indicator of DAP risk, and roughly 60% examined other cardiometabolic outcomes. One third of studies were able to capture incident DAP as an outcome measure. Although interventions focused on changes in physical activity and/or eating behaviours, these behaviours were not measured in 40–50% of trials. Breastfeeding outcomes were infrequently assessed as an outcome measure (14%). Approximately one third assessed mental health outcomes, and one quarter examined implementation process measures. There were substantial variation in measurement methods for weight (self-report, digital scales, and balances), glycaemic control and insulin resistance, and health-related behaviour. The timing of when interventions were commenced (during pregnancy, immediately postpartum, and within a certain number of years post-partum) and the duration of intervention and follow-up varied substantially across studies. The next stage in this COS development was a two-round online Delphi survey aimed at prioritising the identified outcomes (completed in 2018) and a consensus meeting with key stakeholders to review, discuss, and refine suitable COS measures, using nominal group technique, completed in 2019 (Kragelund Nielsen, O'Reilly, Wu, Dasgupta, & Terkildsen Maindal, 2018).

The use of a systematic review as a starting point for a COS process, although methodologically accepted, (Kirkham, 2015) has the limitation of potentially restricting considered outcomes to those measured in previous studies. Consequently, the use of a systematic review as the initial stage to inform the subsequent ones will mean that the perspective of the researcher is the foundation of the COS, and other stakeholders will only influence the latter half of its development. Consistent with this challenge, among the studies that we identified, only 26% reported patient-reported outcome measures, and a single study reported a co-design approach to intervention development—but not to outcome selection (Handley et al., 2016). In addition, none of the identified studies included data on children postnatally nor did they include partners, yet we know both groups are integral parts of the family unit, and both have increased risk of developing diabetes and other types of cardiometabolic ill health, as we have demonstrated (Dasgupta et al., 2015). This adds further strength to the argument for a COS development that includes a variety of stakeholders, including patients, and that provides them with an opportunity to add to the list of possible outcomes.

The field of DAP prevention is relatively new and evolving, as the learning emerges from trials. Understanding the direct impact of DAP interventions is crucial to determining their effectiveness, and the only way to accomplish this definitively is by examining the incidence of DAP and its related complications. The challenge for the researcher is that this requires a long duration of follow-up and sufficiently large populations to meaningfully examine these outcomes. Within our systematic review, there were nine trials reporting diabetes incidence as an outcome and none reporting diabetes-related complications. The average number of participants and duration in those trials were 827 and 124 weeks, respectively, which is feasible only when an intervention is embedded within a health system. However, the challenge to funding these large-scale initiatives is persuading funders and health service providers that the intervention being offered is a sound option that should be effective for DAP prevention and improving cardiometabolic health—herein lies the potential benefit presented by an effective COS.

The development of diabetes has long been understood to compose of a preceding period of increasing dysglycaemia and insulin resistance, often concurrent with lipid abnormalities and increases in blood pressure (Kim, 2014). It is no surprise that a large proportion of the identified studies included these measures as outcomes especially when looking at smaller participant numbers or shorter time horizons because these measures are continuous, and examining their change over time is likely to be useful in demonstrating intervention efficacy (Aroda et al., 2015). This review identified four outcomes that were commonly measured (body weight, body composition, diabetes, and cardiometabolic risk), but within those outcomes, there were 31 separate measurements, and within some measurements, three different ways of collecting that data, each with different sources of error. The degree of variability in the measurements used to identify these biomarkers is a major challenge presented and the identification of a consensus on which ones to choose will be immediately useful for the development of the field.

The reporting of health behaviour and implementation process outcomes is a more recent domain compared with health status ones. In addition to cardiometabolic and diabetes risk measures, process outcomes and context are arguably equally important when the ultimate aim is to reduce population risk, especially due to the variation in the settings delivering the interventions. Our survey of the literature suggests that these process measures are often not measured, rendering replication and understanding of the interventions more difficult to achieve across setting and countries. This aligns with our previous examination of other research examining the penetration and participation rates of interventions in women with previous gestational diabetes, highlighting that contextual and process-related factors are crucial if we want to optimise intervention implementation

(Dasgupta, Terkildsen Maindal, Kragelund Nielsen, & O'Reilly, 2018). As studies move towards implementation at scale, measures of process become critical. The COS process enables these measures to be highlighted as important when designing interventions, whether they be large scale or small pilots.

Another behavioural aspect to diabetes prevention after pregnancy is offering and engaging women in diabetes screening, which is known to be low to very low in women with previous gestational diabetes (Boyle et al., 2018). Among the eight screening studies identified, only two reported process outcomes unrelated to the screening activity itself and none reported the perceived level of diabetes risk, which could arguably impact a woman's engagement in the screening process. In fact, only four DAP prevention studies reported including an outcome measure of perceived diabetes risk even though the literature supports this being an important factor in influencing health behaviours through its effect as an internally motivating factor, which can subsequently impact action (Kim et al., 2007; Mukerji et al., 2015). Similarly, only about half of the health behaviour change studies reported dietary and physical activity behaviours, although nearly all recorded body weight. An intervention may successfully impact glycaemic control, insulin resistance, or cardiometabolic risk without impacting body weight substantively (Jeon, Lokken, Hu, & van Dam, 2007), and if we are not measuring health behaviours, we will miss an opportunity to unpack the population behaviours we need to change to effectively reduce DAP.

5 | CONCLUSIONS

In summary, most DAP prevention trials are not sufficiently powered to examine DAP itself as an outcome measure. Their duration is simply too short. We identified for the first time that the clear majority examine weight and glycaemic control and/or insulin resistance, but there is broad variation in methods and specific measurements for a series of outcome subdomains. Another important aspect identified in this systematic review is the inconsistent reporting of significant public health outcomes associated with behavioural changes and implementation process measures that are key to understanding mechanisms and improving the intergenerational impact of interventions. There is a need to establish the specific outcomes critical to meaningful comparisons across DAP prevention studies. Further, outcomes that have not previously been incorporated warrant consideration, including outcomes in offspring and other family members, patient-reported outcomes, and contextual factors. This systematic review provides a novel conceptual framework for a COS development in DAP prevention.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

CONTRIBUTIONS

SO'R, KD, and HTM conceived the project and sought funding for the work; SO'R, KD, YL, and HTM defined the search strategy; Y. L. conducted the search; SO'R, KD, HTM, and YL analysed the data; SO'R. wrote the first draft; HTM, YL, and KD contributed to revisions.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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