Physical Activity in Women Diagnosed with Gestational Diabetes Mellitus

Submitted by

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Supplementary materials:

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List of Abbreviations

ACOG	American College of Obstetricians and Gynecologists
ADA	American Diabetes Association
AIHW	Australian Institute of Health and Welfare
ANCOVA	Analysis of Covariance
BGL	Blood Glucose Level
BMI	Body Mass Index
CI	Confidence Interval
Con	Control Group
CONSORT	Consolidated Standards of Reporting of Trials
COREQ	Consolidated Criteria for Reporting Qualitative Studies
Elig	Eligibility Range
ENTREQ	Enhancing Transparency in reporting the Synthesis of Qualitative Research
Ex	Exercise
Exp	Experimental Group
GDM	Gestational Diabetes Mellitus
IADPSG	International Association of Diabetes and Pregnancy Study Groups
IDF	International Diabetes Federation
Indiv	Individual
Kg/m^2	Kilograms per metre squared
MD	Mean Difference

mmol/L	Millimoles per Litre
OR	Odds Ratio
n	Number
NHMRC	National Health and Medical Research Council
n/s	Not Stated
PA	Physical Activity
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
RCT	Randomised Controlled Trial
SD	Standard Deviation
SREQ	Standards for Reporting Qualitative Studies
Superv	Supervised
TIDieR	Template for Intervention Description and Replication
Unsuperv	Unsupervised
WHO	World Health Organisation

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Summary

This thesis comprises of four studies investigating the role of physical activity in women with gestational diabetes mellitus.

Study 1, a systematic review of eight randomised controlled trials showed exercise, additional to standard gestational diabetes mellitus care, improved postprandial glycaemic control (MD -0.33 mmol/L, 95% CI -0.49 to -0.17) and fasting blood glucose (MD -0.31 mmol/L, 95% CI -0.56 to -0.05) compared to standard care alone.

Study 2, a systematic review of 47 quantitative and qualitative studies, explored attitudes and perceptions of pregnant women to physical activity. Meta-analyses of proportions showed pregnant women had positive attitudes towards physical activity, identifying it as important (0.80, 95% CI 0.52 to 0.98), beneficial (0.71, 95% CI 0.58 to 0.83) and safe (0.86, 95% CI 0.79 to 0.92). This was supported by thematic analysis from 15 qualitative studies. Little information was available about physical activity perceptions for women with gestational diabetes mellitus.

Study 3, a qualitative study exploring the attitudes and perceptions of 27 women diagnosed with gestational diabetes mellitus towards physical activity found the process of communicating information about physical activity (messaging) was the main theme.

Study 4, a randomised controlled trial with 69 participants, evaluated a consumer co-designed infographic about physical activity on knowledge and self-efficacy in women with gestational diabetes mellitus. A **c**linically important, between-group, difference at post-intervention in knowledge (MD 12.0%, 95% CI 9.5 to 14.5) and self-efficacy (MD 2.5 units, 95% CI 1.9 to 3.0) favoured women receiving the infographic.

In conclusion, this thesis provides evidence that adding exercise to usual-care is beneficial for improving glycaemic control in women with gestational diabetes mellitus. Also, short-term knowledge and self-efficacy about physical activity can be improved in women with gestational diabetes mellitus by involving them in co-design of an intervention that addresses their identified barriers to physical activity participation.

Statement of Authorship

This thesis includes work by the author that has been published as described in the text. Except where reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma. No other person's work has been used without due acknowledgement in the main text of the thesis.

This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

All research reported in this thesis was approved by the Mercy Health Human Research Ethics Committee and the La Trobe University Human Ethics Committee (Appendix A).

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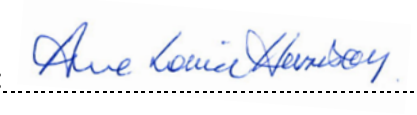
Signature: 

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Dated: 1 November 2020

Preface

This thesis comprises chapters that may be read independently or in the order they appear as part of the entire thesis. Chapters 2 to 5 are presented in the format they were published. These chapters all use the referencing and citation style of the journal in which they are published / submitted for publication.

The remaining sections of this thesis are written in Australian English and use the American Psychological Association (APA) 6th edition referencing and citation style.

All research studies involving recruitment of participants were approved by the La Trobe University and Mercy Health Human Research Ethics Committees, with details provided in Appendix 1.

List of Publications

1. **Harrison, A. L.,** Shields, N., Taylor, N. F., & Frawley, H. C. (2016). Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. *Journal of Physiotherapy*, *62*(4), 188–196.

2. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley, H. C. (2018). Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *Journal of Physiotherapy*, *64*(1), 24–32.

3. **Harrison, A. L.,** Taylor, N. F., Frawley, H. C., & Shields, N. (2019). Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study. *Journal of Physiotherapy*, *65*(1), 37–42.

4. **Harrison, A. L.**, Taylor, N. F., Frawley, H. C., & Shields, N. (2020). A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial. *Journal of Physiotherapy*, *66*(4), 243–248.

List of Conference Presentations and Awards

Conference Presentations

1. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley H. C. *'Move Baby Move' Exercise improves glycaemic control in women with gestational diabetes mellitus.* Victorian Allied Health Research Conference, Melbourne, Australia, March 31, 2017 (Oral presentation)

2. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley H. C. *'Move Baby Move' Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review.* National Allied Health Conference, Sydney, Australia, August 26-29, 2017 (Poster presentation)

3. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley H. C. '*Move Baby Move' Exercise improves glycaemic control in women with gestational diabetes mellitus: a systematic review*. Australian Physiotherapy Association Conference, Sydney, Australia, October 19-21, 2017 (Oral presentation)

4. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley H. C. '*Move Baby Move' Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review*. Australian Physiotherapy Association Conference, Sydney, Australia, October 19-21, 2017 (Poster presentation)

5. **Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley H. C. *Exercise improves glycaemic control in women with gestational diabetes mellitus: a systematic review*. Australasian Diabetes in Pregnancy Society Scientific Meeting/Conference, Adelaide, Australia, August 24-26, 2018 (Oral presentation)

6. **Harrison, A. L.,** Taylor, N. F., Frawley H. C., & Shields, N. '*Move Baby Move' Physical activity 'messaging' needs of women with GDM.* Australasian Diabetes in Pregnancy Society Scientific Meeting/Conference, Adelaide, Australia, August 24-26, 2018 (Poster presentation)

7. **Harrison, A. L.,** Taylor, N. F., Frawley H. C., & Shields, N. *Physical activity 'messaging' needs of women with gestational diabetes mellitus.* Victorian Allied Health Research Conference, Melbourne, Australia, March 22, 2019 (Oral presentation)

8. **Harrison, A. L.,** Taylor, N. F., Frawley H. C., & Shields, N. *Engaging with women with GDM to improve physical activity 'messaging'.* National Allied Health Conference, Brisbane, Australia, August 5-8, 2019 (Oral presentation)

Awards

'Best Student Oral Presentation' Award in the Women's, Men's and Pelvic Health category for oral presentation titled '*Move Baby Move' Exercise improves glycaemic control in women with gestational diabetes mellitus: a systematic review*, at the Australian Physiotherapy Association Conference, Sydney, Australia, October 19-21, 2017.

Research Student Travel Grant Award for oral presentation titled '*Move Baby Move' Exercise improves glycaemic control in women with gestational diabetes mellitus: a systematic review*, at the Australasian Diabetes in Pregnancy Society Scientific Meeting/Conference, Adelaide, Australia, August 24-26, 2018.

Chapter 1: Introduction

1.1 Problem Statement

Physical activity is recommended for women with gestational diabetes mellitus, a common complication of pregnancy. It is thought to assist in improving glycaemic control, a critical factor in combatting the short and longer-term adverse effects of poorly controlled gestational diabetes mellitus. However, most pregnant women with gestational diabetes mellitus are inactive.

Little is known about the attitudes, barriers and facilitators to physical activity for women with gestational diabetes. This information could inform the development of interventions to increase these women's participation in physical activity. This thesis aims to address this knowledge gap by confirming the benefits of physical activity on glycaemic control in gestational diabetes mellitus, investigating the perceptions of women with gestational diabetes mellitus about physical activity and exploring strategies to address their physical activity participation.

1.2 Background

1.2.1 *Gestational diabetes mellitus and importance of glycaemic control*

Gestational diabetes mellitus is carbohydrate or glucose intolerance of variable severity that has its onset during pregnancy (American Diabetes Association [ADA], 2019; Metzger, 1991). In pregnancy many physiological systems adapt, including the metabolic and endocrine systems, to support the pregnancy and foetus. Throughout pregnancy, insulin sensitivity changes to meet the differing needs of each stage of the pregnancy. In the first trimester, insulin sensitivity increases to enable greater glucose storage in preparation for the second and third trimesters. As pregnancy progresses, the associated hormonal changes lead to insulin resistance and elevation of blood glucose levels necessary to feed foetal growth (Phelps, Metzger, & Freinkel, 1981). Evidence in animal models suggests in a normal pregnancy pancreatic beta-cells change to adapt to the metabolic needs of the various stages of pregnancy to enable maintenance of blood glucose levels within normal limits (Parsons, Brelje, & Sorenson, 1992). However, it is

thought that in most cases of a pregnancy complicated by gestational diabetes mellitus, beta-cells fail to respond appropriately to the surge of placental pregnancy hormones in the second and third trimesters and so are unable to compensate for the demands of pregnancy including altered insulin production and sensitivity, which results in a state of chronic hyperglycemia during the pregnancy if left untreated (Plows, Stanley, Baker, Reynolds, & Vickers, 2018).

Gestational diabetes mellitus is a common complication of pregnancy, with an incidence in pregnancy ranging from 3.5 to 15% (AIHW, 2019; Jacqueminet & Jannot-Lamotte, 2010; Serlin & Lash, 2009). With increasing rates of obesity, the prevalence of gestational diabetes mellitus is increasing (American College of Obstetricians and gynaecologists [ACOG], 2018; ADA, 2019; Serlin & Lash, 2009). In 2017, it was reported that 14% of pregnancies globally were affected by gestational diabetes mellitus; women living in South-East Asia were highest at 24.2% (International Diabetes Federation, 2017). Risk factors for developing gestational diabetes mellitus include specific race / ethnic backgrounds (Southern and East Asian, Pacific-Islander, Aboriginal, African-American, Hispanic and Middle Eastern), being overweight, having a history of gestational diabetes mellitus, having previously delivered a macrosomic baby ($\geq$ 4000 grams), family history of diabetes mellitus and polycystic ovarian syndrome (Diabetes Australia, n.d.; Kjos, 1999; Nankervis et al., 2014; National Institute for Health and Care Excellence [NICE], 2015).

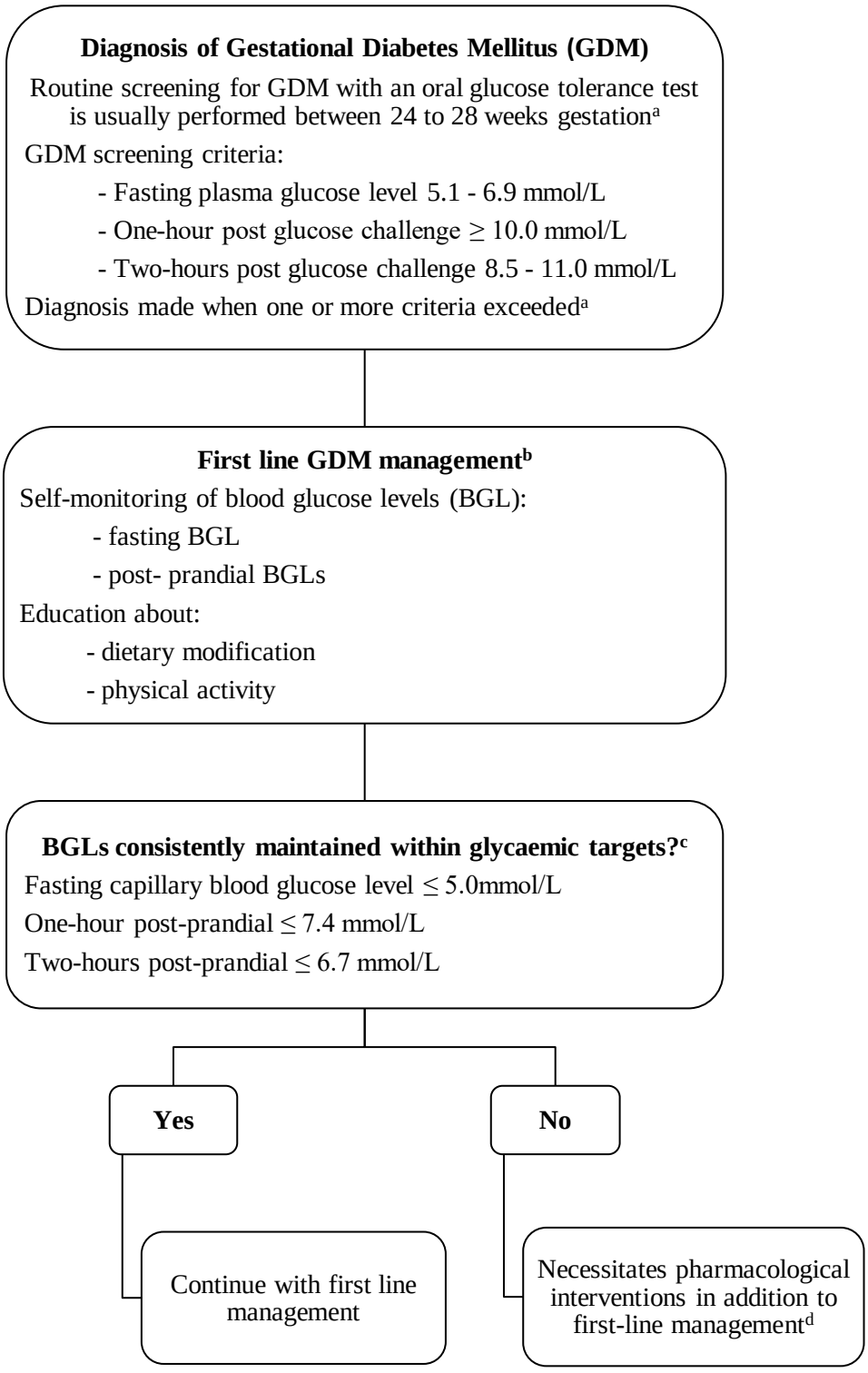
Gestational diabetes mellitus is diagnosed through routine oral glucose tolerance testing, with accompanying blood tests, usually between 24 and 28 weeks gestation (ADA, 2019; Diabetes Australia, n.d., Nankervis et al., 2014). A diagnosis of gestational diabetes is made when one or more of the following plasma glucose levels is exceeded: fasting level 5.1 to 6.9 mmol/L; one-hour post glucose challenge $\geq$ 10.0 mmol/L; two-hour post glucose challenge 8.5 to 11.0 mmol/L (International Association of Diabetes and Pregnancy Study Group Consensus Panel 2010; Nankervis et al., 2014; World Health Organisation [WHO], 2014, 2016).

Hyperglycaemia associated with poorly controlled gestational diabetes mellitus affects both the mother and the baby (ADA, 2019; Garrison, 2015; Metzger, 1991). The short-term adverse consequences of hyperglycaemia may include maternal pre-eclampsia (ACOG, 2018; ADA, 2019), higher incidence of caesarean birth and birth trauma from

foetal macrosomia (ACOG, 2018; ADA, 2019; Serlin & Lash 2009). For the baby, adverse effects may include jaundice, breathing difficulties and shoulder dystocia due to macrosomia causing difficulty and possible trauma if delivered vaginally (ACOG, 2018). Gestational diabetes mellitus also has longer-term health implications. For the mother, these include a 35 to 70% increase in risk of recurrence of gestational diabetes mellitus in subsequent pregnancies (England et al., 2015; Kim, Berger, & Chamany, 2007; Moses, 1996) with a seven-fold increased risk of developing type 2 diabetes mellitus (Bellamy, Casas, Hingorani, & Williams, 2009). For the child of a gestational diabetes mellitus pregnancy, there is an increased risk of obesity and type 2 diabetes mellitus later in life, and those born with macrosomia have an increased lifetime risk of cardiovascular disease and an increased risk of leukaemia (Harder et al., 2009; Kral, 2004). For these reasons, the increasing rate of gestational diabetes mellitus is of concern and has public health ramifications.

Glycaemic control is a critical factor in combatting the adverse effects of hyperglycaemia that results from poorly controlled gestational diabetes mellitus (ADA, 2019). The aims of gestational diabetes management are to maintain blood glucose levels within a safe target range (Figure 1). Self-monitored blood glucose targets are based on information about blood glucose levels in normal pregnancy and recommend a fasting capillary blood glucose level of ≤ 5.0 mmol/L, one-hour postprandial ≤ 7.4 mmol/L and two-hour postprandial ≤ 6.7 mmol/L (Hernandez, Friedman, Van Pelt, & Barbour, 2011; Nankervis & Conn, 2013; Nankervis et al., 2014). Management of gestational diabetes mellitus is typically led by endocrinologists in conjunction with obstetricians, general practitioners, or midwives, with input from diabetes educators and dieticians (ADA, 2019). Guidelines recommend first-line management of self-monitoring of fasting and postprandial acute capillary blood glucose levels, dietary modification, and physical activity (ACOG, 2018; ADA, 2019). However, anecdotal evidence suggests that some health providers and women with gestational diabetes mellitus concentrate their focus more on the regular glucose monitoring and dietary changes with less time and emphasis devoted to improved physical activity. In as many as 39% of women with gestational diabetes, dietary modification alone does not achieve glycaemic control within recommended target levels (Langer, Berkus, Brustman, Anyaegbunam, & Mazze, 1991). This necessitates pharmacological management most commonly of insulin therapy as this does not cross the placenta. Metformin or glyburide may be used if appropriate and not contraindicated

but is less popular because it crosses the placenta (ACOG, 2018; ADA, 2019; Jacqueminet & Jannot-Lamotte 2010; Langer 1998).



GDM = Gestational Diabetes Mellitus; BGL = Blood Glucose Level
[a] Nankervis et al., 2014; WHO, 2016; [b] ACOG, 2018; ADA, 2019; [c] Hernandez et al., 2011; Nankervis et al., 2014; [d] ACOG, 2018; ADA, 2019

Figure 1. Flow chart of key steps in gestational diabetes mellitus pathway

1.2.2 Benefits of physical activity for pregnant women including those with gestational diabetes mellitus

Physical activity is any movement produced by skeletal muscle that results in energy expenditure and broadly encompasses not only the subset of exercise that is planned, structured and repetitive but also occupational, sports, household and leisure time physical activity (Caspersen, Powell, & Christensen, 1985). Physical activity has substantial benefits and minimal risks for pregnant women (ACOG, 2020; Evenson et al., 2014; Mottola et al., 2018) including those diagnosed with gestational diabetes mellitus (ACOG, 2018; Colberg, Castorino, & Jovanovi, 2013; Nascimento Surita, & Cecatti, 2012; NICE, 2015). The benefits of regular physical activity during pregnancy include a reduced risk of excessive weight gain (Muktabhant, Lawrie, Lumbiganon, & Laopaiboon, 2015; Wang et al., 2017) and premature birth (Di Mascio, Magro-Malosso, Saccone, Marhefka, & Berghella, 2016; Hegaard, Pedersen, Nielsen, & Damm, 2007), lower incidence of preeclampsia and caesarean birth (Magro-Malosso, Saccone, Tommaso, Roman, & Berghella, 2017), lower risk of low back pain (Liddle & Pennick, 2015), anxiety and depressive symptoms (Da Costa, Rippen, Dritsa, & Ring, 2003; Davenport et al., 2018a; Robledo-Colonia, Sandoval-Restrepo, Mosquera-Valderrama, Escobar-Hurtado, & Ramirez-Vélez, 2012), and improved physical fitness (Kramer & McDonald 2006; Ramirez-Velez et al., 2011), postnatal recovery (Price, Amini & Kappeler, 2012), sleep (Youngstedt, 2005), health perception (Barakat, Pelaez, Montejo, Luaces, & Zakynthinaki, 2011) and self-reported body image (Marquez-Sterling, Perry, Kaplan, Halberstein, & Signorile, 2000).

The benefits from increased physical activity for pregnant women include a 38% decrease in the odds of developing gestational diabetes mellitus (Odds Ratio 0.62; 95% CI 0.52 to 0.75) (Davenport et al., 2018b). Physical activity was also reported to decrease the odds of developing pre-eclampsia by 41% (Odds Ratio 0.59; 95% CI 0.37 to 0.9) (Davenport et al., 2018b; Davenport et al., 2019a), ante-natal depression by 67% (Odds Ratio 0.33; 95% CI 0.21 to 0.53) (Davenport et al., 2018a) and having a caesarean delivery (Relative Risk 0.69, 95% CI 0.42 to 0.82) (Barakat, Pelaez, Lopez, Montejo, & Coteron, 2012). These benefits have been shown without any increase in odds of adverse obstetric outcomes such as miscarriage, premature birth, low birth weights or perinatal mortality (Davenport et al., 2019b; Davenport et al., 2018c). In overweight and obese women the benefits of regular aerobic exercise included significant decreases in gestational weight gain at 25 weeks gestation (4.1 ± 3.0 kg in intervention group compared to 5.9 ± 2.6 kg in the

control group), at delivery (8.4 ± 3.7 kg compared to 10.5 ± 3.3 kg) and a significantly lower incidence of gestational diabetes mellitus (22% exercise intervention group compared to 41% in control group, $P < .001$; Relative Risk Reduction 0.46; 95% CI 0.21 to 0.63) (Wang et al., 2017). Additionally, for the sub-group of women diagnosed with gestational diabetes mellitus, preliminary evidence suggests physical activity may assist with glycaemic control (Artal, 2003; Jovanovic-Peterson, Durak, & Peterson, 1989).

Given these substantial benefits, guidelines recommend pregnant women participate in physical activity (ACOG, 2020; Mottola et al., 2018), including those women diagnosed with gestational diabetes mellitus as part of the first-line management of gestational diabetes mellitus (ACOG, 2018; ADA, 2019; NICE, 2015). In the absence of contraindications, pregnant women are encouraged to be physically active and engage in aerobic and strengthening type activities (ACOG, 2020; Mottola et al., 2018). Types of physical activity considered safe include walking, swimming, water exercises, dancing, stationary cycling, modified yoga or pilates, resistance exercises and stretching (ACOG, 2020; Berghella & Saccone, 2017; Mottola et al., 2018). To achieve benefits and reduce complications, pregnant women are recommended to participate in 30 minutes of moderate intensity physical activity most days of the week with the goal of accumulating at least 150 mins per week (ACOG, 2020; Davenport et al., 2018b; Mottola et al., 2018). There is strong evidence supporting recommendations that physical activity in pregnancy should include both aerobic and strengthening exercises and stretching or yoga may also be beneficial (Mottola et al., 2018). Inclusion of pelvic floor exercises is also recommended to assist with decreased risk of developing urinary continence (Mottola et al., 2018). Guidelines for management of gestational diabetes mellitus recommend women diagnosed with gestational diabetes be encouraged to walk after meals for 15 to 30 minutes to assist glycaemic control (ACOG, 2018; NICE, 2015) and, consistent with guidelines for pregnant women generally, participate at least five times per week in 30 minutes of moderate intensity aerobic exercise (ACOG, 2020).

1.2.3 Physical activity to improve glycaemic control.

There is a plausible physiological explanation to support exercise as a therapeutic adjunct for improving glycaemic control, including postprandial blood glucose levels, in women with gestational diabetes mellitus. In management of type 2 diabetes, there is strong evidence that exercise, particularly structured aerobic and/or resistance training, is a beneficial, adjunctive therapy through its ability to increase glucose uptake and improve

insulin sensitivity (Colberg et al., 2010; Dela, Mikines, Sonne, & Galbo, 1994; Santos, Ribeiro, Gaya, Appell, & Duarte, 2008; Umpierre et al., 2011; Winnick et al., 2008). Exercise, particularly activation of large muscles such as the quadriceps, stimulates glucose uptake in muscle, increasing energy expenditure and improving glucose transportation, resulting in improved glucose tolerance (Richter, Kiens, Saltin, Christensen, & Savard, 1988; Santos et al., 2008). Exercise is associated with a reduction of glycated haemoglobin (HbA1c), a measure of the average plasma glucose in the longer term (2 to 3 months), in people with type 2 diabetes mellitus (Boule, Haddad, Kenny, Wells, & Sigal, 2001; Irvine & Taylor, 2009; Nathan, Turgeon, & Regan, 2007;), which is optimised by meeting physical activity guidelines (Thomas, Elliott, & Naughton, 2006; Umpierre et al 2011).

Although dietary modification is the treatment basis of first-line gestational diabetes mellitus management (ACOG, 2018; ADA, 2019), in as many as a third of women with gestational diabetes diet therapy alone is not sufficient to consistently maintain postprandial glycaemic levels within glycaemic targets (Langer et al., 1991; ADA, 2019). This triggers the prescription of pharmacological agents such as insulin (ACOG, 2018; ADA, 2019; Metzger et al., 2007) however; insulin administration does not address insulin resistance *per se* as it simply provides more insulin without addressing the insulin receptor issue. In contrast, an acute bout of exercise increases insulin action by stimulating glucose uptake in muscle, via activation of intracellular glucose transporters, and increasing use of intracellular fatty acids (Barnard & Youngren 1992; Turcotte & Fisher 2008). Exercise also alters expression of muscle proteins involved in insulin responsiveness (Hayashi & Wojtaszewski 1997) and with large muscle activation improves glucose uptake (Santos et al., 2008; Richter et al., 1988). In type 2 diabetes, a bout of aerobic exercise has immediate effects to regulate fat and glucose metabolism (Turcotte & Fisher 2008). This improves insulin sensitivity, promoting glucose uptake and resulting in a decrease in blood glucose levels for up to 72 hours afterwards (Boule et al., 2001). Glucose uptake is also influenced by the duration and intensity of exercise performed; the more intense the exercise the stronger the glycaemic lowering effect (Richter, Derave, & Wojtaszewski, 2001).

Although guidelines recommend physical activity in the form of exercise as an adjunct to standard gestational diabetes mellitus care, this recommendation has not been supported by evidence from a systematic review with meta-analysis. To date, the evidence regarding

the benefits of regular exercise for the management of gestational diabetes mellitus has been equivocal, derived from individual studies often with small sample sizes and heterogeneity of exercise type and outcome measures. In addition, the synthesis of the evidence on the benefits of exercise for the management of gestational diabetes mellitus was previously limited to a review focusing on pregnancy outcomes completed more than a decade ago (Ceysens, Rouiller, & Boulvain, 2006), and subsequently updated after commencement of this thesis (Brown, Ceysens & Boulvain, 2017). As glycaemic control is a critical factor in combatting the adverse effects of poorly controlled gestational diabetes, the evidence supporting adjuvant physical activity to assist in improving glycaemic control in gestational diabetes mellitus is important to determine.

1.2.4 *Women with gestational diabetes mellitus do not exercise as recommended.*

Despite well-documented health benefits (ACOG, 2020; Mottola et al., 2018; Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2019), 60 to 85% of pregnant women (Amezcua-Prieto et al 2013; Evenson & Wen, 2011; Gaston & Vamos, 2013; Hesketh & Evenson, 2016), including those who are overweight or obese (Hesketh & Evenson, 2016), do not participate in recommended levels of physical activity (Gaston & Vamos, 2013). The most common form of physical activity reported by pregnant women is walking, followed by household tasks / gardening (57%) and just over 40% engaged in swimming or home exercises (Gaston & Vamos, 2013; Wang et al. 2017). Pregnant women from backgrounds other than Caucasian, or who are single, divorced, have a lower level of education (not completed high school) or from lower socio-economic backgrounds are less likely to engage in physical activity (Gaston & Vamos, 2013).

Women diagnosed with gestational diabetes, are also typically inactive (Anjana et al., 2016; Symons Downs & Ulbrecht, 2006). Anjana et al., (2016) reported as many as 86% of women with gestational diabetes mellitus were sedentary (behaviour exerting ≤ 1.5 metabolic equivalents) with only 14% participating in moderate intensity physical activity of 20-30mins most days of the week. For these women the most common forms of physical activity were household tasks and walking.

As physical activity is recommended because it is considered to have potential to assist glycaemic control, a critical factor in managing gestational diabetes, it is important to

explore ways to improve levels of physical activity participation in women diagnosed with gestational diabetes mellitus. Women with gestational diabetes have more frequent contact with health professionals and combined with the concern pregnant women have for their health and that of their baby, this may provide a window of opportunity to promote physical activity (Phelan, 2010). As many factors have potential to both encourage and hinder participation in physical activity, it is helpful to understand the perceptions of pregnant women to inform design of relevant and effective physical activity interventions to facilitate positive behaviour change.

1.2.5 *Involving women with gestational diabetes to better understand the problem of physical inactivity and to inform consumer-relevant strategies to affect behaviour change.*

Physical activity behaviour in pregnant women is influenced by many factors across multiple domains (McLeroy, Bibeau, Steckler & Glanz, 1988; Symons Downs, Chasan-Taber, Evenson, Leiferman, & Yeo, 2012; Thompson, Vamos, & Daley, 2017). As such, it is recommended that development of physical activity interventions for pregnant women be based on appropriate theoretical frameworks to assist in informing behaviour change techniques to address the multi-level physical activity determinants specific to pregnancy (Currie, Sinclair, Murphy, Madden, Dunwoody, & Liddle, 2013; Thompson et al., 2015) and to increase the likelihood of effectiveness (Craig et al., 2008). Health behaviour theories can provide a systematic, scientific approach to addressing the issue of physical activity participation in pregnant women (Glanz, Rimer & Lewis, et al., 2002; Rimer & Glanz 2005).

Health behaviour theories (e.g. Theory of Planned Behaviour and Social Cognitive Theory), theoretical models (e.g. Transtheoretical Model and Health Belief Model) and frameworks (e.g. Social-ecological Model) have previously been applied to inform interventions aimed at improving physical activity participation in pregnant women (Chan, Yeung & Law, 2019; Thompson et al., 2017). A social-ecological framework considers that behaviour may be influenced by numerous factors across multiple levels, including intrapersonal, interpersonal, and environmental (Bronfenbrenner, 1994; Stokols, 1996). Many health behaviour theories focus on factors at the intrapersonal level including attitudes, beliefs, motivation, and knowledge. For example, the Theory of Planned Behaviour explores an individual's attitudes as well as additional factors such as barriers, enablers and social factors which may influence intention and subsequent

behaviour (Ajzen, 1991; Armitage & Conner, 2001). Social Cognitive Theory, with key constructs including learning through observation, reinforcement and self-efficacy, proposes there are continual, dynamic interactions occurring between a person, environmental factors and behaviour that influence a person's subsequent behaviour (Bandura, 1986a, 1986b, 1997). The Transtheoretical Model proposes stages of behaviour change in terms of motivation and readiness to change (Prochaska & DiClemente, 1983; Prochaska & Velicer, 1997). The Health Belief Model also approaches behaviour from an individual angle and explores the interaction between a person's perception of potential threat from a health condition, the benefit of taking action to avoid the threat and the influence of factors such as self-efficacy (Rosenstock, 1974; Rosenstock, Strecher, & Becker, 1988).

The inclusion of appropriate behaviour change techniques as part of health interventions can help improve physical activity levels during pregnancy (Currie et al., 2013). In pregnant women, behavioural change techniques such as goal setting, planning and education to shape knowledge, appear most effective when delivered with feedback about goal achievement (Currie et al., 2013). Effective physical activity interventions for improving level of activity seem to be those that provide specific information and/or face to face sessions and reminders (Chan et al., 2019). A person-centred approach that tailors information or goals so it is more relevant and specific to the target group is recommended and is consistent with a health behaviour theoretical approach that aims to address influencing factors (Currie et al., 2013; NICE 2006).

Therefore, to design appropriate and effective physical activity behaviour change interventions, clinicians first need to understand the barriers, enablers and attitudes common among women with gestational diabetes mellitus, and consider this alongside relevant health behaviour theoretical modelling so they can effectively design education and evidence-based behaviour change strategies. Based on health behaviour theory, strategies targeted at addressing the specific factors influencing women with gestational diabetes mellitus may assist in facilitating positive behaviour change and thereby be effective in improving physical activity participation in this group. Therefore, filling this knowledge gap about the physical activity perceptions of women with gestational diabetes mellitus, is important.

Current literature recommends consumer involvement in healthcare, '*doing it with us not for us*' (Department of Health Victoria, 2011, p.1) (Cochrane Community, 2018; Miller et al., 2017; National Health and Medical Research Council [NHMRC], 2016; Sydney Health Partners, 2017; Todd & Nutbeam, 2018). This is based on the principle that consumers at whom the research is targeted have a right to provide input into the research, to ensure the research meets their needs (Miller et al., 2017; NHMRC, 2016) and translates more readily into practice thereby reducing research waste (Chalmers et al. 2014). Rather than clinicians or researchers deciding what might be required, involving consumers in research can improve its quality and relevance as outcomes are more likely to be useful (Miller et al., 2017; NHMRC, 2016; National Institute for Health Research INVOLVE, 2012). Therefore, research that explores the physical activity perceptions, and opens a dialogue with women with gestational diabetes mellitus, is needed to increase understanding of their lived experience. Input from these women is also needed to inform intervention development to ensure it is appropriate and relevant to their needs.

1.3 Aims

Therefore, the overarching aim of this thesis was to investigate the role of, and factors influencing participation in, physical activity in women with gestational diabetes mellitus.

The specific objectives of this thesis were:

1. To determine the effect of physical activity on glycaemic control in women diagnosed with gestational diabetes mellitus
2. To explore the attitudes, barriers and enablers of pregnant women about physical activity during pregnancy
3. To explore the attitudes, barriers and enablers of women diagnosed with gestational diabetes mellitus about physical activity during pregnancy
4. To develop and trial a consumer informed intervention that addresses an identified barrier and/or facilitator of physical activity in women with gestational diabetes mellitus

To address this aim and achieve the objectives, four studies were conducted and form the chapters of this thesis. Chapters that have been published are presented in their published format. Each chapter is outlined below and may be read independently or in order as part of the entire thesis.

Chapter 2 reports a systematic review to collate available data about the effect of physical activity on glycaemic control in women diagnosed with gestational diabetes mellitus.

Chapter 3 reports a systematic review to synthesise available evidence about attitudes, barriers and enablers of pregnant women and those diagnosed with gestational diabetes mellitus about participating in physical activity during pregnancy.

Chapter 4 reports a qualitative study conducted to gain deep insight into the attitudes, barriers and enablers of women diagnosed with gestational diabetes mellitus about physical activity in pregnancy.

Chapter 5 reports a randomised controlled trial completed to evaluate the effect on knowledge and self-efficacy of a consumer co-designed infographic about physical activity for women with gestational diabetes mellitus.

Chapter 6 provides a discussion of findings, key issues arising from the work of this thesis and clinical implications, strengths and limitations of the research, implications for future research and provides a summary from this thesis overall.

Chapter 2:
Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review

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2.1 Preface

Chapter 2 presents a systematic review and meta-analysis to collate available data about the effect of physical activity on glycaemic control in women diagnosed with gestational diabetes mellitus. The aim of the review was to investigate whether exercise improves postprandial glycaemic control in women diagnosed with gestational diabetes mellitus. Secondary aims were to explore if exercise improves fasting blood glucose levels and HbA1c in women diagnosed with gestational diabetes mellitus and identify characteristics of exercise programs that are effective in lowering their postprandial blood glucose levels.

2.2 Study one

Chapter 2 is presented in its published format as (Harrison, Shields, Taylor, & Frawley, 2016):

Harrison, A. L., Shields, N., Taylor, N. F., & Frawley, H. C. (2016). Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. *Journal of Physiotherapy*, *62*(4), 188–196.

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Research

Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review

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KEY WORDS

Exercise
Gestational diabetes
Blood glucose
Pregnancy
Systematic review

ABSTRACT

Question: Does exercise improve postprandial glycaemic control in women diagnosed with gestational diabetes mellitus? **Design:** A systematic review of randomised trials. **Participants:** Pregnant women diagnosed with gestational diabetes mellitus. **Intervention:** Exercise, performed more than once a week, sufficient to achieve an aerobic effect or changes in muscle metabolism. **Outcome measures:** Postprandial blood glucose, fasting blood glucose, glycated haemoglobin, requirement for insulin, adverse events and adherence. **Results:** This systematic review identified eight randomised, controlled trials involving 588 participants; seven trials (544 participants) had data that were suitable for meta-analysis. Five trials scored $\geq$ 6 on the PEDro scale, indicating a relatively low risk of bias. Meta-analysis showed that exercise, as an adjunct to standard care, significantly improved postprandial glycaemic control (MD –0.33 mmol/L, 95% CI –0.49 to –0.17) and lowered fasting blood glucose (MD –0.31 mmol/L, 95% CI –0.56 to –0.05) when compared with standard care alone, with no increase in adverse events. Effects of similar magnitude were found for aerobic and resistance exercise programs, if performed at a moderate intensity or greater, for 20 to 30 minutes, three to four times per week. Meta-analysis did not show that exercise significantly reduced the requirement for insulin. All studies reported that complications or other adverse events were either similar or reduced with exercise. **Conclusion:** Aerobic or resistance exercise, performed at a moderate intensity at least three times per week, safely helps to control postprandial blood glucose levels and other measures of glycaemic control in women diagnosed with gestational diabetes mellitus. **Registration:** PROSPERO CRD42015019106. **[Harrison AL, Shields N, Taylor NF, Frawley HC (2016) Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. *Journal of Physiotherapy* 62: 188–196]**

Introduction

Gestational diabetes mellitus (GDM) is carbohydrate or glucose intolerance of variable severity that has its onset during pregnancy.[1,2] It is diagnosed through laboratory screening, using a pregnancy oral glucose tolerance test that is performed between 24 and 28 weeks gestation.[1,3] GDM is a common complication of pregnancy, with an incidence ranging from 3.5 to 12%; it also has an increasing prevalence.[1,4–7] If poorly controlled, GDM results in hyperglycaemia,[1,2] which affects both the mother and the developing baby. The short-term adverse consequences of hyperglycaemia may include hypertension and pre-eclampsia for the mother, and birth trauma from macrosomia (ie, excessive birth weight) for the baby.[1,7] GDM also has longer-term health implications. For the mother, these include a 35 to 50% increase in risk of recurrence of GDM in subsequent pregnancies,[8] with a seven-fold increased risk of developing type 2 diabetes mellitus.[9] For the child of a GDM pregnancy, there is an increased risk of obesity and type 2 diabetes mellitus later in life,[10,11] and those born with macrosomia have an increased lifetime risk of cardiovascular disease[12] and an increased risk of leukaemia.[13] For these reasons, the increasing rate of GDM has public health ramifications.[14,15]

Glycaemic control is a critical factor in combatting the adverse effects associated with poorly controlled GDM.[6] Management of GDM typically consists of dietary modifications, regular self-monitoring of postprandial (ie, post-meal) acute capillary blood glucose levels[3] and – where diet modification does not achieve euglycaemia – insulin therapy.[16–18] There is strong evidence that exercise, particularly structured aerobic and/or resistance training, is a beneficial adjunctive therapy in the management of type 2 diabetes mellitus through its ability to increase glucose uptake and improve insulin sensitivity.[19–24] Exercise, particularly activation of large muscles such as the quadriceps, stimulates glucose uptake in muscle, increases energy expenditure and improves glucose transportation, which results in improved glucose tolerance.[22,25] Exercise is associated with a reduction of glycated haemoglobin (HbA1c), a measure of the average plasma glucose in the longer term (2 to 3 months), in people with type 2 diabetes mellitus;[26,27] it is optimised by training of 150 minutes or more per week at moderate intensity.[21,28] Exercise is also recommended as beneficial for women with uncomplicated pregnancies.[29–31]

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However, to date, the evidence regarding the benefits of exercise for the management of GDM has been equivocal – largely due to small sample sizes and heterogeneity of exercise type and outcome measures. In addition, the synthesis of the evidence on the benefits of exercise for the management of GDM has been limited to a review completed almost a decade ago.[32]

Several international guidelines and reviews recommend exercise in the management of GDM.[4,16,33–35] While these guidelines recommend exercise as an adjunct to standard GDM care, there has not been supporting evidence from a systematic review with meta-analysis of the effects of exercise on postprandial blood glucose levels. There is good justification for postprandial glucose levels to be the main outcome of interest among this population due to the continuous relationship with macrosomia and birth defects.[1,2,7,16] Fasting blood glucose levels and HbA1c are, however, important as secondary outcomes because, other than their established physiological relevance to complications of diabetes,[15] some trials may only include these measures rather than an oral glucose tolerance test (OGTT).

Therefore, the research questions for this systematic review were:

1. Can adjunctive exercise improve the acute postprandial control of blood glucose in women diagnosed with GDM when compared with standard GDM care?
2. Does adjunctive exercise improve fasting blood glucose levels and the longer-term measure, HbA1c, in women diagnosed with GDM when compared with standard GDM care?
3. What are the characteristics of exercise programs that are effective in lowering postprandial blood glucose levels for women with GDM and the variables affecting adherence to exercise?

Box 1. Inclusion criteria.

Design
- Randomised, controlled trial
- Full-text articles published in English in a peer-reviewed journal

Participants
- Pregnant women diagnosed with GDM [a] during the current pregnancy

Intervention
- Cardiovascular exercise or strengthening exercises sufficient to achieve aerobic effect or changes in muscle metabolism [b]
- Exercise performed more than once a week [c]
- Exercise in any setting

Primary outcome measure
- Self-monitored postprandial blood glucose levels

Secondary outcome measures
- Fasting blood glucose levels
- HbA1c
- Requirement for insulin

Comparisons
- Standard care of GDM, including diet and/or insulin

[a] GDM, as diagnosed by a pregnancy oral glucose tolerance test performed at 24 to 28 weeks[1,3]
[b] Based on the American College of Sports Medicine & American Diabetes Association joint position statement[19]
[c] Chosen to exclude single bouts of exercise but to keep search broad, as aiming to identify sufficient exercise to improve self-monitored postprandial blood glucose levels.

Method

The review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[36]

Identification and selection of studies

One reviewer (AH) performed a search of the following electronic databases from the earliest possible date (ie, from database inception) until November 2015: AMED, CINAHL, Medline, Embase, PsycInfo, Cochrane Library, PEDro, SPORTDiscus, Joanna Briggs Institute and Trip. To ensure full representation of the evidence, no search limitations were used. The search strategy consisted of four key concepts: GDM, physical activity, blood glucose and randomised, controlled trials. For each concept, key words and MeSH search terms were combined with the 'OR' operator. The results of the searches of the four key concepts were combined with the 'AND' operator. An example of the search strategy is presented in Appendix 1 on the eAddenda. Reference lists from the included studies were manually searched and relevant articles were screened and reviewed for possible inclusion. Using Google Scholar and Web of Science, citation tracking was also performed on the included articles to identify any additional, relevant articles.

Two reviewers (AH and HF or NT) independently reviewed the title and abstracts of the articles yielded by the search, according to the inclusion criteria presented in Box 1 and the exclusion criteria outlined below. If eligibility was unclear from the review of title and abstract, full text was obtained and reviewed by two researchers working independently. Disagreements were resolved by discussion between reviewers.

Assessment of characteristics of studies

Participants

Trials were excluded if the participants had existing type 1 or type 2 diabetes. This was because the aetiologies are somewhat different or, at least, the aetiology may be only transient in GDM and because the chronic physiological effects of longer-term diabetes could confound findings.[1,35]

Intervention

As the minimum level of exercise to improve self-monitored postprandial blood glucose levels is not well established, the inclusion criteria for this review were set broadly to include trials of interventions with exercise frequency greater than weekly. If individual studies provided an exercise intervention dosage that met the recommended guidelines,[19] then it was considered that the exercise intervention would provide sufficient stimulus to achieve aerobic effect or changes in muscle metabolism. It was acceptable for the exercise intervention to be combined with dietary modification and insulin, as required, along with self-monitoring of blood glucose; this is considered standard care for women diagnosed with GDM.[7,16,33,35]

Outcome measures

As outlined in Box 1, postprandial glucose levels, fasting blood glucose levels and HbA1c were the outcome measures chosen to reflect treatment of existing GDM. Because the primary aim of this review was to evaluate the treatment effect of exercise on postprandial control of glycaemia in women with GDM, not to prevent it, trials were excluded if prevention of GDM was an outcome measure.

Risk of bias

Risk of bias was assessed using the Physiotherapy Evidence Database (PEDro) scale.[37] This scale scores the risk of bias of studies out of 10, providing a comprehensive description for each item to improve inter-rater reliability[37] and is considered a valid and reliable tool for measuring methodological quality.[38,39] For the purposes of this review, trials achieving a PEDro score of ≥ 6 were considered as being at low, or slightly greater than low, risk of bias.[40] Two reviewers (AH and NS) assessed the risk of bias independently. Disagreements between allocated scores were resolved by discussion.

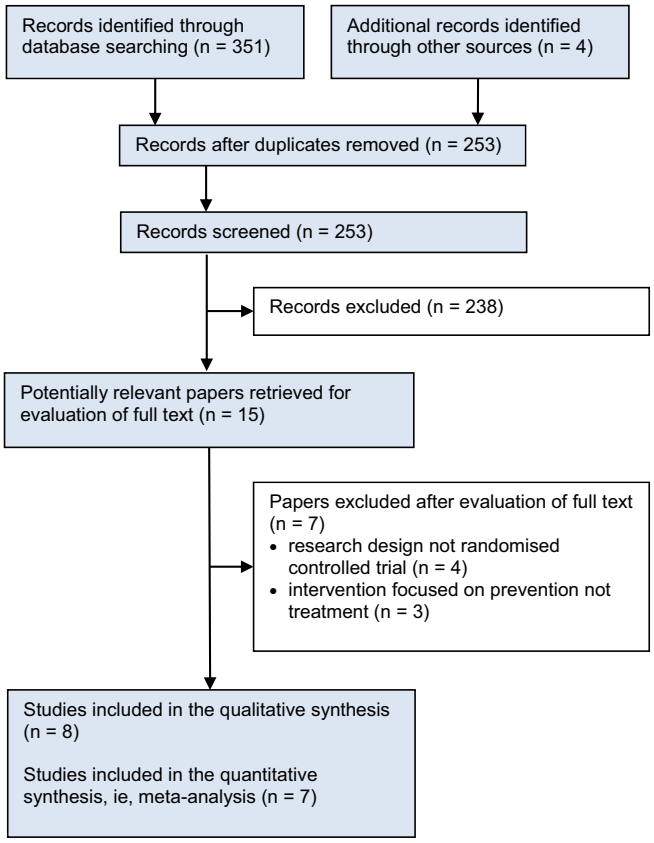

Figure 1. Flow of studies through the review.

Data extraction and analysis

Data were extracted from each included article using a standardised data extraction form. Data were extracted by one reviewer (AH), and checked by a second reviewer (HF). The extracted data included: authors, year of publication, sample size, demographic information about the participants (age, gestation at inclusion, parity, history of previous GDM, body mass index, socio-economic status, cultural background/ethnicity), the intervention (exercise type, frequency, intensity, session duration, mode, duration of intervention program), results (postprandial blood glucose levels, fasting blood glucose levels, glycated haemoglobin levels, adverse events, adherence rates) and study conclusions. Authors were contacted for missing data when it was related to the primary outcome of the review. To provide homogeneous unit measures, postprandial blood glucose levels and fasting blood glucose levels were converted using an online blood sugar conversion calculator[41] from mg/dL units into mmol/L.

Meta-analyses were conducted using RevMan[42] to pool the data. As the units of the measure within each outcome were common, a mean difference (MD) measure of effect was calculated. A random-effects model was used to ensure a conservative estimate of the meta-analysed effect estimate of the MD with 95% confidence intervals (95% CI).[43] A meta-analysis using odds ratios (OR) with a random-effects model was conducted to compare the effect of adjunctive exercise versus standard GDM care on the proportion of participants requiring insulin therapy. The characteristics of exercise programs and adherence to the exercise programs were synthesised descriptively.

Results

Flow of studies through the review

The initial search yielded 351 articles (Figure 1). The yield included three papers that were published in languages other than English; however, as titles and abstracts for all three papers were available in English, they were included in the screening process. None of these three papers was a randomised, controlled trial and therefore all were ineligible. Through reference checking and citation tracking, four additional articles were identified by title. On review of these abstracts, all were excluded: two because they were not randomised, controlled trials, one because the outcomes related to the foetus, and the other because the intervention was a single bout of exercise. Following the screening process, eight trials were included in the review (Figure 1).

Characteristics of included studies

Risk of bias

Table 1 provides the details of the PEDro scoring for risk of bias. These trials involved an exercise intervention, so it was not anticipated that it would be possible to blind either participants or therapists; therefore, the maximum score expected was 8/10. Five of the eight trials scored ≥ 6 on the PEDro scale, representing a low, or slightly greater than low, risk of bias.

Participant characteristics

The mean age of participants in the included trials ranged from 31 to 33 years (Table 2, and for more detailed data about the characteristics of the participants, see Table 3 on the eAddenda).[44–51] Consistent with standard diagnostic testing for GDM occurring between 24 to 28 weeks, participants were recruited from 24 weeks gestation through to 31 weeks gestation. Parity and past history of GDM (with previous pregnancies) were reported in two of the trials.[46,51] Five trials provided mean pre-pregnancy body mass index with a range of 25.4 to 27.6 kg/m^2.[44–47,50]

Intervention characteristics

The exercise interventions were all low impact, but the type of exercise varied (Table 2, and for more detailed data about the characteristics of the interventions, see Table 4 on the eAddenda). Two trials used circuit-type resistance training,[44,45] two trials used cycling on upright cycle ergometers[46,47] (one of which combined cycling with walking[47]), one trial used a recumbent cycle ergometer[48] and another trial used an arm ergometer.[49] Of the two remaining trials, one used brisk walking[50] and the other used yoga as the exercise intervention.[51]

Table 1
Risk of bias assessment - PEDro scores of included studies.

Trial	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	<15% dropouts	Intention-to-treat analysis	Intergroup comparison reported	Point estimate and variability measures	Total Score (0 to 10)
Avery[47]	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4
Bo[50]	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	6
Brankston[45]	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	6
Bung[48]	Yes	No	Yes	No	No	No	No	No	No	Yes	3
de Barros[44]	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8
Halse[46]	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	6
Jovanovic-Peterson[49]	Yes	No	No	No	No	No	Yes	No	Yes	Yes	4
Youngwanichsetha[51]	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7

Table 2
Summary of included studies (n = 8).

Study	Participants [a]	Intervention [b]	Outcome measures
Avery[47] USA	n = 29 Age *(yr)* = 31 (SD 5) Gestation *(wk)* = 28 (SD 4) BMI *(kg/m²)* = 26.5 (SD 6.3) BGL *(mmol/L)* = 10.3 (SD 1.1)	Exp = cycle ergometer, indiv, superv, 30 min x 2/wk x 6 wk (70% predHR$_{max}$) and walking, indiv, unsuperv, 30 min x 2/wk x 6 wk (70% predHR$_{max}$ via Borg Scale) Con = usual activity Both = usual diet	• Postprandial BGL • Fasting BGL • Need for insulin
Bo[50] Italy	n = 200 Age *(yr)* = elig 18 to 50 Gestation *(wk)* = elig 24 to 26 BMI *(kg/m²)* = 27.6 (SD 4.2) BGL *(mmol/L)* = n/s	Exp = brisk walking, indiv, unsuperv [c], 20 min x 7/wk x ~25 wk (Borg 12 to 14) ± behavioural advice [d] Con = ± behavioural advice [d] Both = individually prescribed diet	• Postprandial BGL • Fasting BGL • HbA1c • Need for insulin
Brankston[45] Canada	n = 32 Age *(yr)* = 31 (SD 5) Gestation *(wk)* = 29 (SD 2) BMI *(kg/m²)* = 26.5 (SD 4.1) BGL *(mmol/L)* = 9.8 (SD 1.2)	Exp = circuit resistance ex, indiv, superv for 3 sessions then unsuperv [c], 2 to 3 sets x 15 to 20 reps x 3/wk x ~8 wk ('somewhat hard') Con = usual activity Both = prescribed diet	• Postprandial BGL • Fasting BGL • Need for insulin
Bung[48] USA	n = 34 Age *(yr)* = 31 (SD 5) Gestation *(wk)* = 30 (SD 2) BMI *(kg/m²)* = n/s BGL *(mmol/L)* = n/s	Exp = recumbent cycle ergometry, indiv, superv, 45 min x 3/wk x ~10 wk (50% VO_{2max}) Con = insulin Both = prescribed diet	• Fasting BGL
de Barros[44] Brazil	n = 64 Age *(yr)* = 32 (SD 5) Gestation *(wk)* = 31 (SD 2) BMI *(kg/m²)* = 25.4 (SD 4.0) BGL *(mmol/L)* = 9.1 (SD 1.4)	Exp = circuit resistance ex, indiv, superv 2/wk and unsuperv 1/wk, 30 to 40 min x 3/wk x ~8 wk ('somewhat heavy') Con = usual activity Both = prescribed diet	• Postprandial BGL • Need for insulin
Halse[46] Australia	n = 40 Age *(yr)* = 33 (SD 4) Gestation *(wk)* = 29 (SD 1) BMI *(kg/m²)* = 25.8 (SD 6.9) BGL *(mmol/L)* = 8.8 (SD 1.1)	Exp = home cycle ergometer, indiv, superv 3/wk and unsuperv 2/wk, 25 to 45 min x 5/wk x ~6 wk (55 to 85% predHR$_{max}$) Con = usual activity Both = dietary advice	• Postprandial BGL • Fasting BGL • HbA1c • Need for insulin
Jovanovic-Peterson[49] USA	n = 19 Age *(yr)* = 32 (SD 5) Gestation *(wk)* = n/s BMI *(kg/m²)* = n/s BGL *(mmol/L)* = 10.2 (SD 0.9)	Exp = arm ergometer [e], 20 min x 3/wk x 6 wk (70% predHR$_{max}$) Con = usual activity Both = diet	• Postprandial BGL • Fasting BGL • HbA1c • Need for insulin
Youngwanichsetha[51] Thailand	n = 170 Age *(yr)* = 32 (5) Gestation *(wk)* = elig 24 to 30 BMI *(kg/m²)* = n/s BGL *(mmol/L)* = 9.9 (SD 1.1)	Exp = yoga breathing, postures and movements, indiv, some superv, 15 to 20 min x 5/wk x 8 wk (intensity n/s) + mindfulness eating Con = usual care, including dietary advice	• Postprandial BGL • Fasting BGL • HbA1c

BGL = blood glucose level, BMI = body mass index, con = control group, elig = eligibility range, ex = exercise, exp = experimental group, indiv = individual, superv = supervised, unsuperv = unsupervised.

[a] Age and gestation are at enrolment, BMI is pre-pregnancy, and BGL is postprandial at enrolment. Where participant characteristics are not stated but similar measures were reported (eg, BMI at enrolment instead of pre-pregnancy), these are reported in Table 3 on the eAddenda.

[b] For more detailed characteristics of the interventions, see Table 4 on the eAddenda.

[c] Occasional phone call and/or visit.

[d] This trial was factorially randomised, meaning that half the participants in the exp and con groups were randomly allocated behavioural recommendations.

[e] It was unclear whether the arm ergometry was individual or group exercise and whether it was supervised or unsupervised.

The frequency of exercise ranged from three to seven sessions per week. Exercise intensity was variable: four trials used an age-predicted heart rate maximum varying from 50 to 70%,[46–49] two trials used Borg exertional scale ratings of 12 to 14,[47,50,52] one trial used the OMNI exertional scale[44,53] and one trial did not state the exercise intensity.[51] Where descriptors of exertion were used, they were generally between 'moderate' and 'somewhat hard'. Exercise session durations ranged from 20 to 45 minutes, which included short warm-up and cool-down periods. Where specified, all of the exercise interventions were delivered in individual sessions. Two interventions were centre-based with direct supervision,[47,48] four interventions were predominantly home-based with a combination of direct supervision, indirect supervision (phone monitoring) and unsupervised,[45,46,50,51] and two interventions were a combination of both home and centre-based.[44,47] The duration of the exercise programs, where specifically stated, was 6 weeks, although others were until 38 weeks gestation[50] or to the end of pregnancy.[44]

In seven trials, the exercise intervention was an adjunct to standard care and was compared with standard care alone. The exception to this was the trial by Bung et al, which evaluated an intervention group receiving exercise without insulin, compared with insulin therapy.[48]

Baseline comparability of the randomised groups

Baseline data, where reported, showed that the control and intervention groups were similar at baseline (see Table 3 on the eAddenda). Baseline data were reported for mean postprandial blood glucose measures by six trials,[44–47,49,51] fasting blood glucose by seven trials,[44–49,51] and HbA1c by three trials.[46,47,49]

Effect of adding exercise to standard care

Postprandial blood glucose

Data from seven trials,[44–47,49–51] with a total of 554 participants, compared the effect of exercise plus standard care with the effect of standard care alone on postprandial blood glucose levels (Figure 2, see Figure 3 on the eAddenda for a detailed forest plot). There was a significant between-group difference in postprandial blood glucose levels favouring exercise (MD −0.45 mmol/L, 95% CI −0.68 to −0.22, I^2 = 76%). One trial[49] with a relatively high risk of bias (PEDro score = 4/10) and a small sample of 19 participants had a larger favourable mean difference and wider confidence interval compared to the other six trials (Figure 2). The I^2 value reduced to 48% when this study[49] was removed in a sensitivity analysis, but the new pooled effect (MD −0.33 mmol/L, 95% CI −0.49 to −0.17)

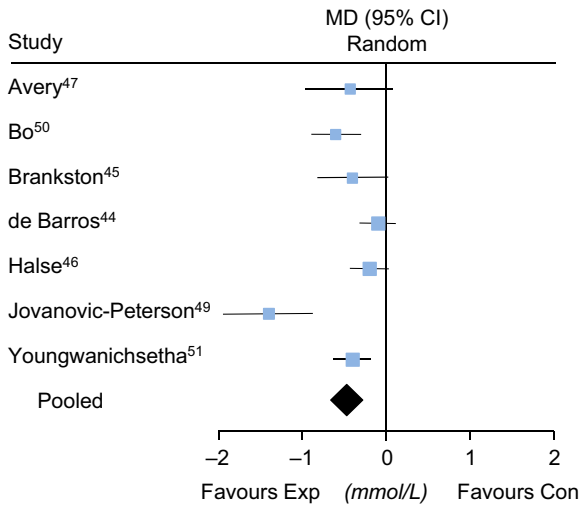

Figure 2. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on postprandial blood glucose (mmol/L) in women with gestational diabetes mellitus.

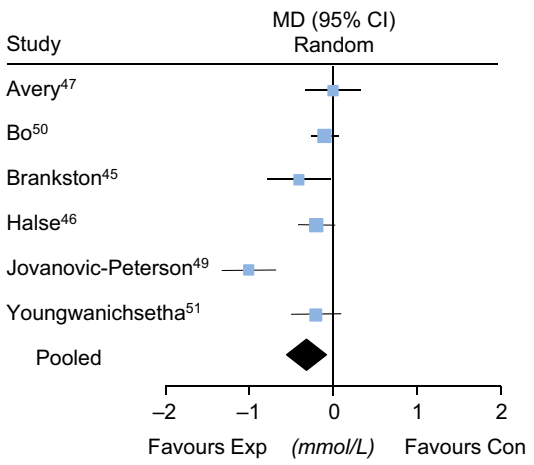

Figure 6. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on fasting blood glucose (mmol/L) in women with gestational diabetes mellitus.

still significantly favoured exercise (Figure 4, see Figure 5 on the eAddenda for a detailed forest plot).

Fasting blood glucose

Data from six trials,[45–47,49–51] with a total of 500 participants, compared the effect of exercise plus standard care with the effect of standard care alone on fasting blood glucose (Figure 6, see Figure 7 on the eAddenda for a detailed forest plot). There was a significant between-group difference in fasting blood glucose favouring exercise (MD –0.31 mmol/L, 95% CI –0.56 to –0.05, I^2 = 82%). A seventh trial measured fasting blood glucose, but did not report data with standard deviations and so was unable to be included in the meta-analysis.[44]

Glycated haemoglobin

Data from four trials,[46,49–51] with a total of 439 participants, compared the effect of exercise plus standard care with the effect of standard care alone on glycated haemoglobin (Figure 8, see Figure 9 on the eAddenda for a detailed forest plot). There was a significant between-group difference in glycated haemoglobin favouring exercise (MD –0.33%, 95% CI –0.48 to –0.18, I^2 = 60%).

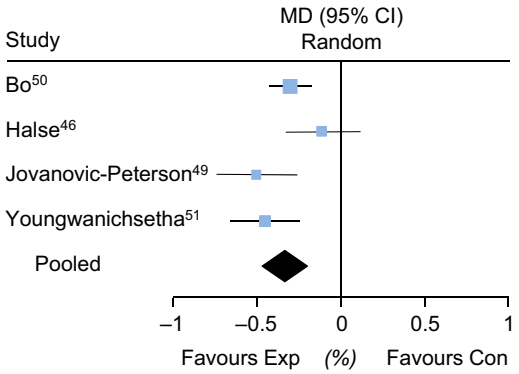

Figure 8. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on glycated haemoglobin (%) in women with gestational diabetes mellitus.

Need for insulin therapy

Data from six trials,[44–47,49,50] with a total of 384 participants, compared the effect of exercise plus standard care with the effect of standard care alone on the proportion of participants requiring insulin therapy (Figure 10, see Figure 11 on the eAddenda for a

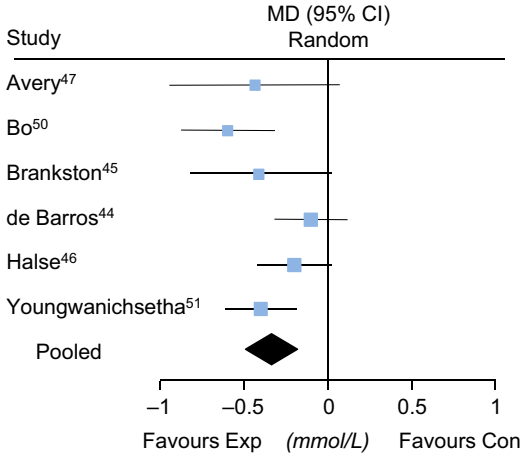

Figure 4. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on postprandial blood glucose (mmol/L) in women with gestational diabetes mellitus, in a sensitivity analysis excluding the study by Jovanovic-Peterson et al[49] due to heterogeneity.

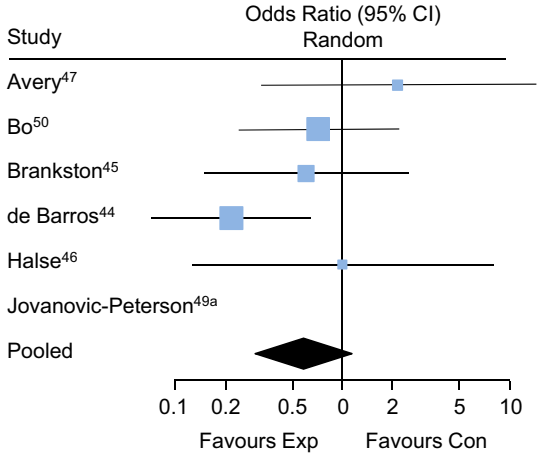

Figure 10. Odds ratio (95% CI) for insulin requirement with exercise plus usual care versus usual care only in women with gestational diabetes mellitus.
[a] An odds ratio and 95% CI for the study by Jovanovic-Peterson[49] could not be calculated because there was no insulin use in either group.

Table 5
Reported information about measures of safety considered in the included studies (n = 8).

Trial	Measures of safety mentioned	Reported results
Avery[47]	Apgar scores, gestational age at birth, infant birth weight, caesarean births	Similar scores in both groups
	'Complications' [a]	No complications in either group
Bo[50]	Maternal: pregnancy-induced hypertension, infectious diseases, cholestasis during pregnancy, and peri- and post-partum complications	Reduced maternal/infant complications: OR 0.50 (95% CI 0.28 to 0.89)
	Neonate: birth weight > 90th percentile, pre-term birth, and any neonatal conditions requiring a specific treatment or a prolonged in-hospital stay	
	Other 'adverse events' [a]	No adverse events in either group
Brankston[45]	An investigator 'made weekly contact to ensure the safety of participants' [a]	n/s
Bung[48]	Premature rupture of membranes, premature labour, birth weights	'Similar rate of complications in each group' [a]
de Barros[44]	Post-exercise hypoglycaemia, capillary glycaemia > 250 mg/dL	No events in either group
	BMI, pregnancy weight gain, gestational age at delivery, caesarean sections	No significant difference between groups
Halse[46]	n/s	'No adverse effects were reported in response to exercise'
Jovanovic-Peterson[49]	Maternal: uterine activity, hypoglycaemia (< 60 mg/dL), maternal morbidity	No complications in either group
	Neonate: foetal bradycardia, gestational age at birth, infant morbidity	
Youngwanichsetha[51]	n/s	No adverse events occurred during practice

n/s = not stated.
[a] Not specified further.

Table 6
Reported information about exercise adherence among participants in the experimental group in the included studies (n = 8).

Trial	Exercise *(sessions/week)* mean (SD)	Mean adherence *(% of prescribed)*
Avery[47]	3.0 (0.6)	75% [a]
Bo[50]	n/s	66% [a]
Brankston[45]	2.0 (0.9)	67% [a]
Bung[48]	n/s	> 90%
de Barros[44]	2.4 (0.4)	80% [a]
Halse[46]	Superv 2.8 (n/s) [a]	Superv 96%
	Unsuperv 2.0 (1.0)	Unsuperv 100% [a]
Jovanovic-Peterson[49]	3 (n/s)	100%
Youngwanichsetha[51]	Classes 2 (0) Home ex n/s	Classes 100% Home ex > 80%

Ex = exercise, n/s = not stated, superv = supervised, unsuperv = unsupervised.
[a] Calculated from data in the paper.

detailed forest plot). Meta-analysis of these six trials favoured exercise, but did not reach statistical significance (OR 0.59, 95% CI 0.28 to 1.22).

Adverse events

Adverse events were defined and analysed in varying detail in the included trials, as presented in Table 5. One trial[50] reported significantly reduced maternal/neonatal complications due to exercise (OR 0.50, 95% CI 0.28 to 0.89). Some trials reported no adverse events in either group. Other trials reported that maternal and neonatal outcomes were similar or not significantly different between the randomised groups. None of the trials reported that exercise caused a significant increase in adverse events or a significant worsening of maternal/neonatal outcomes.

Effect of exercise versus insulin therapy

One trial[48] evaluated the effect of exercise and diet compared with insulin therapy and diet. There was no statistical difference in the weekly fasting blood glucose levels between the exercise group and the insulin group. This trial reported a similar rate of complications (premature rupture of membranes, premature labour, birth weights) in each group.

Adherence

All of the included trials reported some information about the level of adherence to exercise in the experimental group (Table 6), although the method of collecting these data was not well described. Two trials reported 'satisfactory' adherence, with participants exercising 2 to 2.4 times a week.[44,45] Another trial[50] stated 'good' adherence, as reported by participants in surveys; however, actual exercise attendance was 66%. Three trials reported a specific percentage of adherence with exercise: one trial reported > 90% attendance for centre-based exercise;[48] one trial reported 96% adherence to home-based stationary cycling;[46] and one trial reported 100% attendance at centre-based training then 80% adherence to the home-based yoga exercise program.[51]

Discussion

Evidence from seven randomised, controlled trials found that exercise as an adjunct to standard care significantly improved postprandial control of glycaemia and lowered fasting blood glucose for women with GDM compared with standard care alone. There was no increase in adverse events in the exercise groups. A previous systematic review conducted a decade ago concluded that there was insufficient evidence to determine whether exercise should be prescribed to reduce maternal and perinatal morbidity in women with GDM.[32] The current systematic review provides evidence that exercise is beneficial for postprandial control of glycaemia in women diagnosed with GDM. This evidence is likely to be robust because it relies on multiple meta-analyses; the included studies examined various exercise types, and the studied populations were representative of the wider target population of women with GDM. The current systematic review therefore provides strong new comprehensive evidence to support the many recommendations in the literature to use exercise in this population;[4,6,15,16,33–35] the recommendations were based on other forms of evidence such as narrative reviews, physiological rationales, consensus opinion or systematic reviews of fewer studies.

Lower postprandial blood glucose levels are associated with fewer perinatal complications.[16] These results are clinically important because they indicate the potential of exercise to assist in reducing acute blood glucose levels to within the normal range: postprandial blood glucose (MD −0.45 mmol/L, 95% CI −0.68 to −0.22) and fasting blood glucose levels

(MD –0.31 mmol/L, 95% CI –0.56 to –0.05). Glycated haemoglobin levels, which measure longer-term (2 to 3 months) glycaemic control,[26] also improved significantly for the exercise group when compared with standard care.[46,49–51]

It remains uncertain whether adjunctive exercise, in controlling glycaemic levels in women with GDM, has the potential to reduce or delay the need for insulin therapy, which can be costly, invasive and poorly accepted by women.[45,54] This is relevant because high insulin levels, as occur in hyperglycaemia, may be associated with vascular damage; so the lower the dose of insulin required, the better.[55] In the exercise intervention groups, it was observed that there were fewer women requiring insulin (26 out of 194, 13%) compared with those receiving standard care (39 out of 190, 21%), although the meta-analysis of the studies contributing to these pooled data did not identify a statistically significant difference. A larger cohort would provide greater power to determine whether exercise decreases the number of women requiring insulin. One trial[44] found that participants who exercised were prescribed less insulin ($p < 0.01$) and another[48] concluded that adjunctive exercise was as effective as insulin in maintaining normoglycaemia and could therefore be useful in obviating the need for insulin therapy.

There is a plausible physiological explanation to support exercise as a therapeutic adjunct for improving postprandial control of glycaemia in women with GDM. Although dietary modification is the basis of standard GDM management for maintaining normal postprandial glycaemic levels and optimising maternal and foetal outcomes, postprandial control of glycaemia is not maintained with diet therapy alone in as many as 39% of women with GDM.[56] Poor control leads to fasting and/or postprandial hyperglycaemia triggering the prescription of insulin.[57] However, insulin administration does not address insulin resistance per se. In contrast, an acute bout of exercise increases insulin action by stimulating glucose uptake in muscle, via activation of intracellular glucose transporters, and increasing use of intracellular fatty acids.[24,58] Exercise training also alters expression of muscle proteins involved in insulin responsiveness.[59]Activation of large muscles, such as the quadriceps, improves glucose uptake.[22,25] In type 2 diabetes, the acute effects of a bout of aerobic exercise are to regulate fat and glucose metabolism.[24] This improves insulin sensitivity, promotes glucose uptake and results in a decrease in blood glucose levels for up to 72 hours afterwards.[27] Glucose uptake is also influenced by the duration and intensity of exercise performed: the more intense the exercise, the stronger the glycaemic lowering effect.[60]

The variation of exercise prescription across the trials hinders the identification of an optimal exercise regimen. However, the results from these trials suggest that a program of either aerobic exercise or resistance training appears equally effective, as long as it is performed at least at a moderate intensity or greater, for 20 to 30 minutes, three to four times a week, to provide a repeated stimulus that facilitates improved blood glucose uptake and induces increases in insulin sensitivity. Consistent with the findings of a previous systematic review on type 2 diabetes,[28] this suggests that as long as the dosage is similar, there is flexibility in type of exercise. This is relevant to translation into a person-centred model of care. This would enable exercise programs to be tailored to suit an individual's preference, which may help adherence.

Although the ideal situation is prevention, a recent review investigating the effect of exercise combined with diet for the prevention of GDM reported that there was little difference between the exercise plus diet group and the control group who received no intervention; however, limitations with the available evidence were acknowledged.[61] Therefore, with increasing prevalence of GDM,[4–7] improved management of GDM is important. As maintaining acute postprandial blood glucose levels within the recommended targeted range is associated with improved perinatal outcomes in women diagnosed with GDM,[16] and as exercise appears to improve HbA1c in the longer-term,[46,49–51] this suggests that commencement of adjunctive exercise as early as possible in pregnancies complicated by GDM may be beneficial. Larger and more rigorous studies are needed to further investigate the effect of exercise earlier in pregnancy in relation to GDM onset and blood glucose control.

Not all studies in this review reported on each outcome. Generally, however, exercise with greater levels of frequency and/or intensity, combined with some form of supervision to improve adherence, appeared to confer better overall outcomes.[50,51] Further research is needed to provide better understanding of the exercise dose-response relationship and more systematic reporting of levels of adherence to exercise.

Although adherence is considered necessary to realising the potential of the intervention and achieving optimal clinical benefit,[62] none of the trials systematically investigated or evaluated adherence determinants, mediators or adherence strategies. Level of exercise adherence appeared to be collected through attendance and participation, but this was not consistently or well described. Participants in the trial of Bo et al[50] self-reported good adherence, but attendance was 69%. This highlights that self-reporting is liable to overestimation due to the possibility of social desirability bias; this reduces the level of confidence in the actual adherence to the intervention and, thereby, the certainty of the optimal exercise dosage required to achieve the physiological effect. Greater supervision, either face-to-face or via phone follow-up, appeared to be associated with higher levels of adherence.[46,48,49,51] The convenience of a supervised, home-based exercise program was suggested as a reason for good adherence.[46,51] Home-based exercises involving little or no equipment, such as brisk walking,[50] resistance exercises with exercise bands[44,45] or yoga,[51] are more accessible for most women and less expensive in terms of access costs compared with clinic attendance; and they have equivalent beneficial effects on blood glucose control. All interventions were individually delivered, which has the advantage of tailoring to the individual, thereby facilitating adherence. Future research is needed to explore determinants of exercise adherence in women with GDM and to subsequently evaluate the effect of exercise adherence strategies on glycaemic control outcomes.

No trials reported using group exercise interventions, which may provide social support and be a cost-effective healthcare option. In the reviewed trials, neither socio-economic status nor cultural characteristics were well reported. These factors may influence a woman's attitude, health literacy level and acceptability of the intervention, which may affect clinical outcomes and are therefore important considerations in future research. One trial[51] provided culturally appropriate exercise, and when combined with supervision achieved good compliance and positive results across the reported outcomes. Although reporting of cultural background and socio-economic details was scant, the geographical breadth of the trial locations (Canada, United States of America, Brazil, Thailand and Australia) and reported cultural backgrounds (Caucasian, South-East Asian and Spanish) improve the generalisability of the findings.

The differing types of exercise among the included studies could be seen as a potential limitation. A previous systematic review[28] concluded that aerobic or resistance exercise, or a combination, were similarly effective in improving glycaemic control in people with type 2 diabetes mellitus; therefore, the present study deemed it acceptable to combine different types of exercise, provided they were similar in dosage. As no trial included a follow-up phase, the lasting effects of exercise and lifestyle modification on long-term prevention of type 2 diabetes mellitus in this population is unknown.

In conclusion, the results of this review provide evidence to support the recommendation that exercise, as an adjunct to standard GDM care, is beneficial in controlling postprandial blood glucose levels and in glycaemic control in women diagnosed with GDM. Programs of either aerobic or resistance exercise appear effective. Characteristics of effective exercise programs for management of GDM appear to be exercise performed at a moderate intensity and for a minimum of three times a week.

What is already known on this topic: Poorly controlled gestational diabetes mellitus may have adverse consequences for the mother and the developing baby. Gestational diabetes mellitus management includes dietary modification, self-monitoring of blood glucose levels, exercise and, if necessary, use of insulin. Although exercise improves various measures of blood glucose, its effect on postprandial blood glucose requires explication.

What this study adds: Adding exercise to usual care of gestational diabetes mellitus reduces postprandial blood glucose, fasting blood glucose and glycated haemoglobin. Exercise is safe and may reduce maternal and neonatal complications in gestational diabetes mellitus.

eAddenda: Figures 3, 5, 7, 9 and 11, Tables 3 and 4, and Appendix 1 can be found online at: doi:10.1016/j.jphys.2016.08.003.

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2.3 Study one - Supplementary material (tables, figures and search strategy example) included on Journal of Physiotherapy e-Addenda

Table 3 Detailed participant characteristics at baseline.

Trial	Age *(y)* Mean (SD)		Gestation at b/l (*wk*) Mean (SD)		Parity Mean (SD) or n/N, %		History GDM n/N, %		Pre-pregnancy BMI (kg/m^2) Mean (SD)		Postprandial BGL *(mmol/L)* Mean (SD)		Fasting BGL *(mmol/L)* Mean (SD)		HbA1c *(%)* Mean (SD)	
	Con	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp
Avery[47]	30.4 (5.1)	32.2 (4.9)	26 (8.0)	29 (3.0)	0.4	1.5	n/s	n/s	25.5 (5.5)	28.4 (7.6)	10.4 (1.4)	10.3 (1.0)	4.7 (0.6)	4.7 (0.4)	5.0 (0.3)	5.0 (0.4)
Bo[50]	Elig 18 to 50		Elig 24 to 26		n/s	n/s	n/s	n/s	27.5 (4.4)	27.6 (4.1)	n/s	n/s	n/s	n/s	n/s	n/s
Brankston[45]	31.3 (5.0)	30.5 (4.4)	30 (2)	29 (2)	n/s	n/s	n/s	n/s	28.0 (5.7)	25.9 (3.4)	9.6 (1.4)	9.9 (1.0)	5.5 (0.6)	4.8 (0.6)	n/s	n/s
Bung[48]	32.0 (5.7)	31.0 (4.5)	30 (2)	30 (2)	n/s	n/s	n/s	n/s	b/l wt *(kg)* 79.2 (9.5)	b/l wt *(kg)* 75.8 (23.5)	n/s	n/s	6.4 (0.4)	6.4 (0.5)	n/s	n/s
de Barros[44]	32.4 (5.4)	31.8 (4.9)	31 (2)	32 (2)	n/s	n/s	n/s	n/s	25.4 (3.8)	25.3 (4.2)	9.0 (1.1)	9.4 (2.4)	5.2 (0.8)	5.1 (1.0)	n/s	n/s
Halse[46]	32 (3)	34 (5)	29 (1)	29 (1)	1 (1)	1 (1)	3/20 15%	2/20 10%	26.4 (7.1)	25.2 (6.7)	8.7 (1.5)	8.8 (0.9)	4.6 (0.6)	4.3 (0.4)	5.3 (0.5)	5.2 (0.4)

Jovanovic-Peterson[49]	31.1 (2.8)	29.5 (2.5)	n/s	n/s	n/s	n/s	n/s	n/s	b/l wt *(kg)* 75.3 (8.2)	b/l wt *(kg)* 78.4 (9.7)	10.1 (0.7)	10.8 (1.9)	5.4 (0.7)	5.6 (0.5)	4.9 (0.4)	4.8 (0.3)
Youngwanichsetha[51]	31.2 (4.5)	32.6 (5.0)	Elig 24 to 30	65/85 76%	64/85 75%	33/85 39%	28/85 33%	b/l BMI 27.1 (4.1)	b/l BMI 27.1 (3.6)	9.8 (1.0)	10.0 (1.3)	5.0 (0.5)	5.0 (0.5)	n/s	n/s	

BMI = body mass index, b/l = baseline, con = control group, elig = eligibility criterion, exp = experimental group, GDM = gestational diabetes mellitus, n/s = not stated, wt = weight.

Table 4 Detailed characteristics of the interventions.

Trial	Control intervention	Experimental exercise intervention						
		Type	Frequency	Intensity	Duration	Format	Site	Program duration
Avery[47]	Diet/standard care	Cycle ergometer	Twice weekly	70% age-predicted HR_{max}	30 mins	Individual Supervised	Centre	6 weeks
		Walking	Twice weekly	a/a via Borg scale 30 mins	30 mins	Individual Unsupervised	Home	
Bo[50]	Diet ± behavioural education	Brisk walking	Daily	Borg scale rating 12 to 14	20 mins	Individual (weekly phone calls and fortnightly visits)	Home	24 to 26 weeks to 38th week or before delivery
Brankston[45]	Diet/standard care	Circuit-type resistance exercise	Three times weekly	'To level that felt somewhat hard' Exercises progressed weekly	2 sets 15 reps week 1 progressed to 3 sets 20 reps	Individual 3 x Supervised then weekly phone calls	Home	29 weeks gestation to delivery (˜ 8 weeks)
Bung[48]	Insulin therapy	Cycling on recumbent bike	Three times weekly	50% of the $Vo_{2\ max}$ test	45 mins	Individual Supervised In lab	Centre (exercise lab)	˜8 weeks

de Barros[44]	Diet/standard care	Circuit-type resistance training - eight exercise stations	Three times weekly	OMNI exertional scale 5 to 6 corresponding to 'somewhat heavy'	15 reps 8 exercises Initially 2 circuits progressed to 3 lasting 30 to 40 mins	Individual	Both	31 weeks to end pregnancy (˜8 weeks)
Halse[46]	Diet/standard care	Stationary upright cycle ergometer plus exercise of choice	Three times weekly supervised + two unsupervised	Variable intensity 55% age predicted HR_{max} to bursts 75 to 85% age predicted HR_{max}	25 mins week 1 progressed to 45mins	Individual Some supervision	Home	6 ± 1 week
Jovanovic-Peterson[49]	Diet/standard care	Aerobic exercise on arm ergometer	Three times weekly	70% age-predicted HR_{max} or 140 bpm, whichever lower	20 mins	Not clearly reported	Centre	6 weeks
Youngwanichsetha[51]	Diet/standard care	Yoga pranayama and asanas (postures and movements)	Five times weekly	Each posture repeated 10 times Otherwise n/s	15 to 20 mins	Individual Some initial supervision	Home	8 weeks

Centre = centre-based exercise program, Home = home-based exercise program, n/s = not stated.

2.3 Study one - Supplementary figures (as included on Journal of Physiotherapy publication e-Addenda)

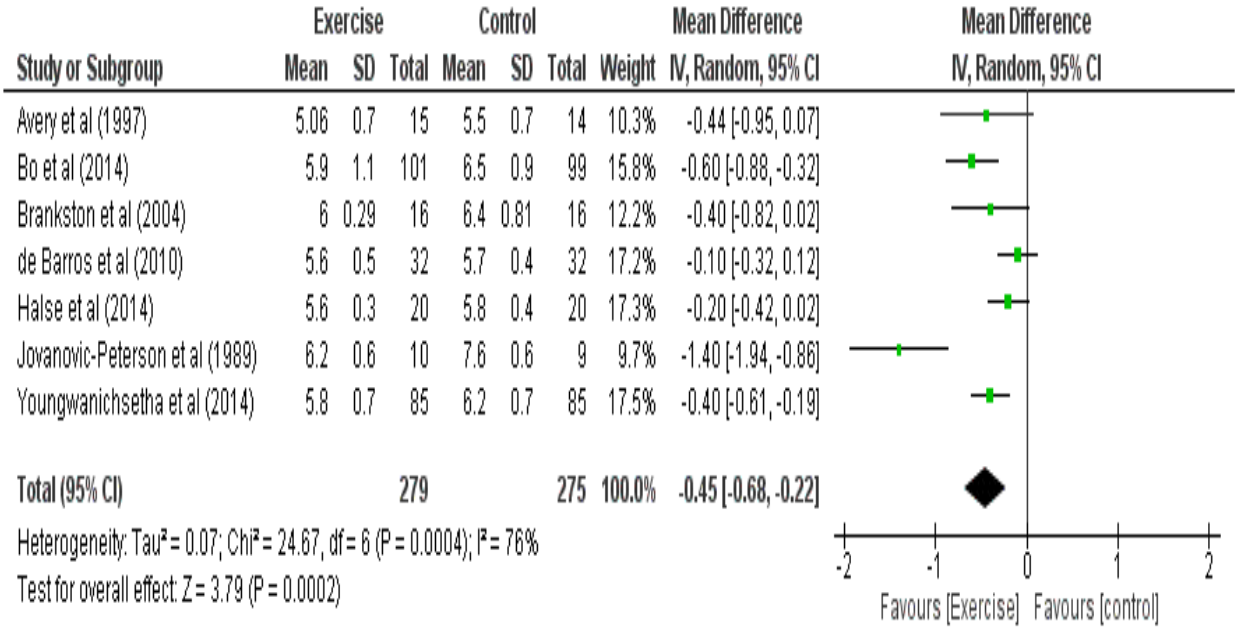

Figure 3. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on postprandial blood glucose (mmol/L) in women with gestational diabetes mellitus.

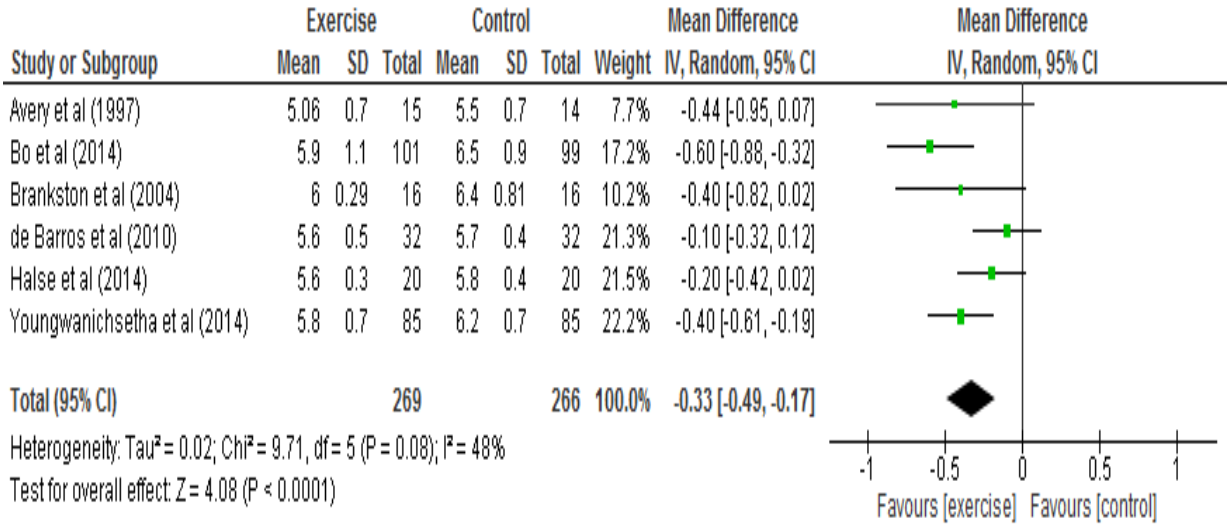

Figure 5. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on postprandial blood glucose (mmol/L) in women with gestational diabetes mellitus, in a sensitivity analysis excluding the study by Jovanovic-Peterson et al[49] due to heterogeneity.

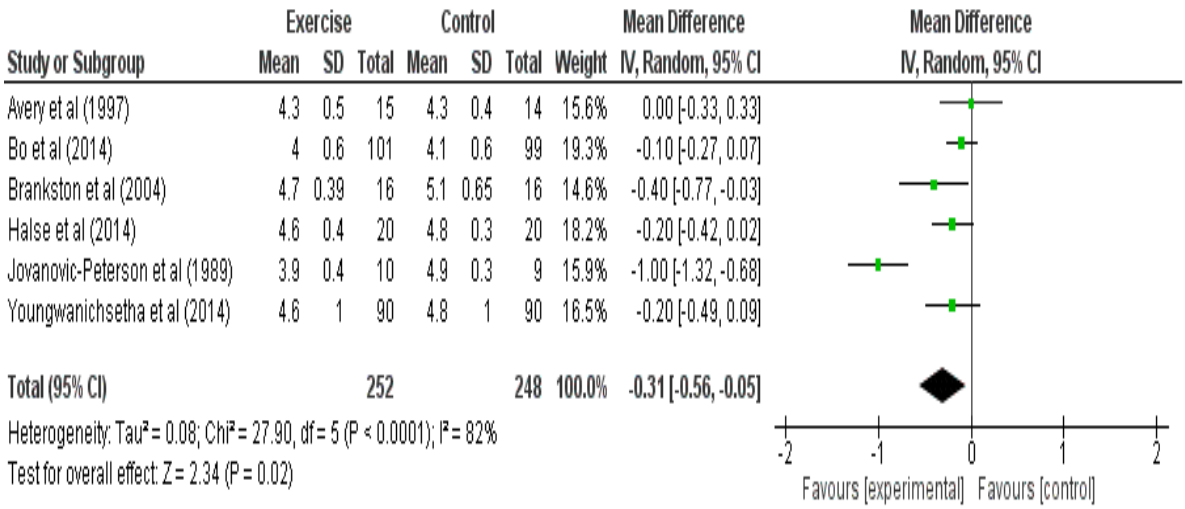

Figure 7. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on fasting blood glucose (mmol/L) in women with gestational diabetes mellitus.

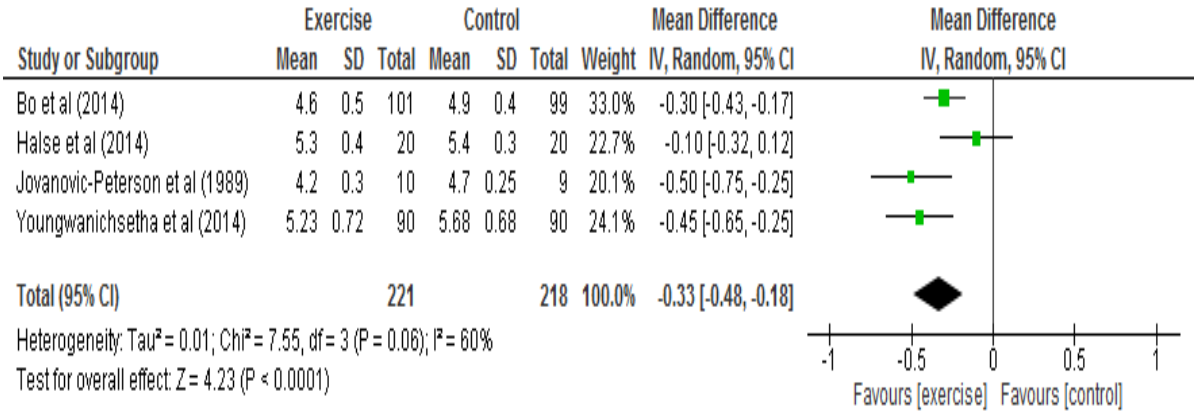

Figure 9. Mean difference (95% CI) in effect of exercise plus usual care versus usual care only on glycated haemoglobin (%) in women with gestational diabetes mellitus.

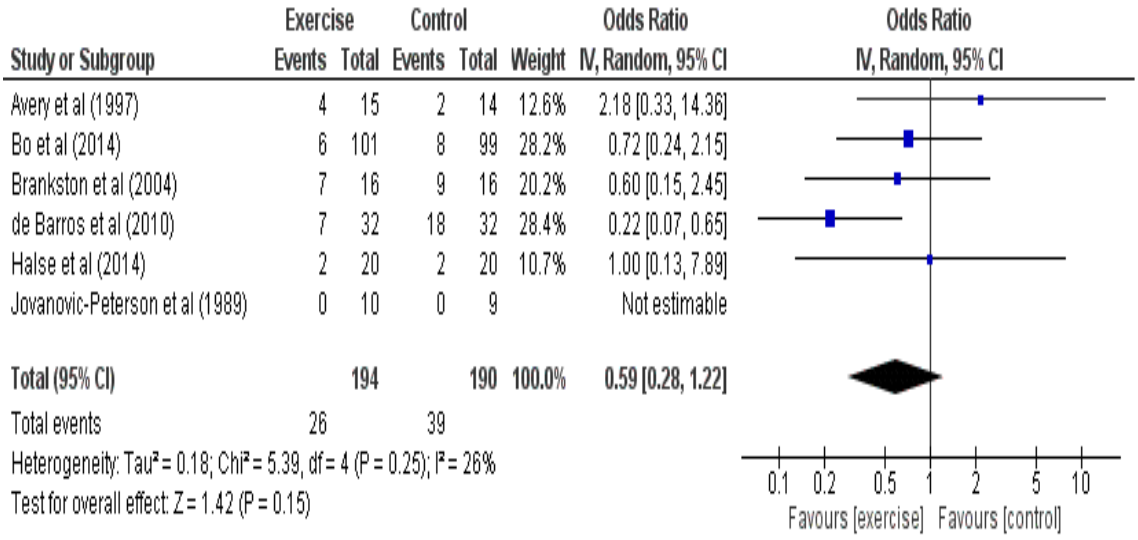

Figure 11. Odds ratio (95% CI) for insulin requirement with exercise plus usual care versus usual care only in women with gestational diabetes mellitus.

2.3 Study one - Search strategy example (as included as appendix 1 on Journal of Physiotherapy e-Addenda)

Database: CINAHL

S26	S15 AND S25	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	22
S25	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	193,782
S24	TI trial	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	33,505
S23	AB randomly	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	30,532
S22	(MH "Clinical Trials+") OR "Clinical trials" OR (MH "Randomized Controlled Trials") OR (MH "Cochrane Library")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	146,710
S21	placebo	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	23,100
S20	randomi?ed	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	87,240
S19	"controlled clinical trial"	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search	1,732

			Database - CINAHL	
S18	"randomi?ed controlled trial"	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	16,708
S17	(MH "Randomized Controlled Trials") OR (MH "Clinical Trials+") OR (MH "Cochrane Library")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	135,725
S16	"randomised controlled trial.pt."	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	0
S15	S3 AND S10 AND S14	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	117
S14	S11 OR S12 OR S13	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	40,896
S13	"Glyc?mic control" or "normoglyc?mia" or "glucose control" or "blood sugar levels" or "oral glucose tolerance test" or "insulin"	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	33,622
S12	(MH "Blood Glucose Self-Monitoring") OR (MH "Blood Glucose Monitoring+") OR (MH "Blood Glucose")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	16,374
S11	(MH "Glycemic Control")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	6,818
S10	S4 OR S5 OR S6 OR S7	**Search modes** -	**Interface** - EBSCOhost	132,850

	OR S8 OR S9	Boolean/Phrase	Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	
S9	"Physical activit*" or "exercis*" or exercise therap*" or "exercise intervention" or "resistance training" or resistance exercis*" or "walking" or "cycling" or "swimming" or aerobic training" or aerobic exercis*" or "strength training" or "strength exercis*"	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	123,528
S8	(MH "Exercise+") OR (MH "Resistance Training") OR (MH "Therapeutic Exercise+") OR (MH "Aquatic Exercises") OR (MH "Group Exercise") OR (MH "Aerobic Exercises+")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	65,224
S7	(MH "Exercise+") OR (MH "Therapeutic Exercise+") OR (MH "Group Exercise") OR (MH "Aquatic Exercises") OR (MH "Aerobic Exercises+")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	65,224
S6	(MH "Resistance Training")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	407
S5	(MH "Exercise+")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	53,868
S4	(MH "Physical Activity") OR (MH "Self Care: Activities of Daily Living (Iowa NOC)") OR (MH "Activity and Exercise Enhancement (Iowa NIC)") OR (MH "Physical	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	31,760

	Endurance") OR (MH "Physical Performance") OR (MH "Physical Fitness")			
S3	S1 OR S2	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	2,604
S2	"Diabetes, Gestational" or "Diabetes Mellitus, Gestational" or Diabetes, Gestational/therap*" or "Gestational Diabetes" or "Gestational Diabetes Mellitus" or "Gestational Diabetes Mellitus" or "GDM"	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	2,604
S1	(MH "Diabetes Mellitus, Gestational")	**Search modes** - Boolean/Phrase	**Interface** - EBSCOhost Research Databases **Search Screen** - Advanced Search **Database** - CINAHL	2,588

2.4 Addendum

After publication of this systematic review (Harrison et al., 2016), a systematic review investigating the effect of exercise on outcomes in women diagnosed with gestational diabetes mellitus was published by Brown et al., (2017). In the Brown et al., (2017) review, primary maternal outcomes were measures of hypertension, pre-eclampsia, induction of labour, caesarean delivery and development of type 2 diabetes. Primary neonatal outcomes were macrosomia, neonatal mortality and morbidities, and neurosensory deficits. One of the 16 secondary maternal outcomes was glycaemic control. The review reported exercise improved glycaemic control in women with gestational diabetes mellitus supporting findings of this review (Chapter 2) and cited Harrison et al., (2016).

Glycaemic control is a critical factor in combatting the adverse effects of poorly controlled gestational diabetes and subsequently for improving maternal and neonatal outcomes (ACOG, 2018; ADA, 2019). Therefore, the evidence provided by this systematic review (Chapter 2), supporting adjuvant physical activity as effective in assisting to improve glycaemic control in gestational diabetes mellitus, is important and useful for clinicians.

Chapter 3:
Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review

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3.1 Preface

The systematic review and meta-analysis in Chapter 2 (Harrison et al., 2016) provided evidence to support clinical guideline recommendations that, as an adjunct to standard care, adding aerobic or resistance exercise, performed at a moderate intensity at least three times per week, is beneficial in safely reducing postprandial blood glucose and for improving glycaemic control in women diagnosed with gestational diabetes mellitus.

Despite documented health benefits many pregnant women, including those with gestational diabetes mellitus, do not participate in physical activity as recommended. To improve pregnant women's participation in physical activity (i.e. leisure time physical activity or structured exercise programs), there is a need to understand their attitudes toward physical activity, the reasons why they do not engage in it, and enablers that could be utilised to design effective physical activity interventions that facilitate behaviour change and thereby lead to improvement in physical activity participation during pregnancy.

In Chapter 3 a systematic review, including quantitative and qualitative studies, was completed to identify the attitudes, barriers and enablers to physical activity perceived by pregnant women, including those diagnosed with gestational diabetes mellitus.

3.2 Study two

Chapter 3 is presented in its published format as (Harrison, Taylor, Shields, & Frawley, 2017):

Harrison, A. L., Taylor, N. F., Shields, N., & Frawley, H. C. (2018). Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *Journal of Physiotherapy*, *64*(1), 24–32.

Journal of Physiotherapy 64 (2018) 24–32

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Research

Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review

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KEY WORDS

Pregnancy
Diabetes gestational
Attitudes
Barriers
Enablers
Systematic review

ABSTRACT

Question: What are the attitudes, barriers and enablers to physical activity perceived by pregnant women? **Design**: In a systematic literature review, eight electronic databases were searched: AMED, CINAHL, Embase, Joanna Briggs Institute, Medline, PsycInfo, SPORTDiscus (from database inception until June 2016) and PubMed (from 2011 until June 2016). Quantitative data expressed as proportions were meta-analysed. Data collected using Likert scales were synthesised descriptively. Qualitative data were analysed thematically using an inductive approach and content analysis. Findings were categorised as intrapersonal, interpersonal or environmental, based on a social-ecological framework. **Participants**: Pregnant women. **Intervention**: Not applicable. **Outcome measures**: Attitudes and perceived barriers and enablers to physical activity during pregnancy. **Results**: Forty-nine articles reporting data from 47 studies (7655 participants) were included. Data were collected using questionnaires, interviews and focus groups. Meta-analyses of proportions showed that pregnant women had positive attitudes towards physical activity, identifying it as important (0.80, 95% CI 0.52 to 0.98), beneficial (0.71, 95% CI 0.58 to 0.83) and safe (0.86, 95% CI 0.79 to 0.92). This was supported by themes emerging in 15 qualitative studies that reported on attitudes (important, 12 studies; beneficial, 10 studies). Barriers to physical activity were predominantly intrapersonal such as fatigue, lack of time and pregnancy discomforts. Frequent enablers included maternal and foetal health benefits (intrapersonal), social support (interpersonal) and pregnancy-specific programs. Few environmental factors were identified. Little information was available about attitudes, barriers and enablers of physical activity for pregnant women with gestational diabetes mellitus who are at risk from inactivity. **Conclusion**: Intrapersonal themes were the most frequently reported barriers and enablers to physical activity during pregnancy. Social support also played an enabling role. Person-centred strategies using behaviour change techniques should be used to address intrapersonal and social factors to translate pregnant women's positive attitudes into increased physical activity participation. **Registration**: PROSPERO CRD42016037643. **[Harrison AL, Taylor NF, Shields N, Frawley HC (2018) Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *Journal of Physiotherapy* 64: 24–32]**

Introduction

Physical activity has substantial benefits for women with uncomplicated pregnancies, minimal risks, and is recommended in pregnancy guidelines.[1–3] The benefits of physical activity during pregnancy include improved physical fitness,[3–5] reduced risk of excessive weight gain,[6] reduced risk of pre-eclampsia and pre-term birth,[7] reduced low back pain,[8,9] improved sleep,[10] reduced anxiety and depressive symptoms,[11,12] and improved health perception[13] and self-reported body image.[14]

Physical activity is also important for pregnant women with comorbidities and complications such as obesity[1] or gestational diabetes mellitus (GDM).[15–17] Physical activity assists with weight control and reduces the risk of GDM in obese pregnant women.[1] In women diagnosed with GDM (a common pregnancy-related complication occurring in 3.5 to 12% of pregnancies),[15,16] physical activity is beneficial as an adjunctive intervention in the management of glycaemic control.[15,17–20] Managing glycaemic control is critical for reducing adverse effects associated with poorly controlled GDM.[21] Consequently, aerobic exercise performed at moderate intensity for 30 minutes on most days of the week is recommended for healthy pregnant women,[1,3] those with GDM[15,22,23] and those who are overweight or obese.[24]

Despite well-documented health benefits,[1,3–17,24–27] 60 to 80% of pregnant women[28–31] – including those who are overweight or obese[31] – and more than 60% of women with GDM[32] do not participate in physical activity as recommended. Pregnant women from backgrounds other than Caucasian are also less likely to engage in physical activity.[29] However, to improve pregnant women's participation in physical activity (ie, leisure time physical activities or structured exercise programs), we need to understand their attitudes to it, the reasons why they do not engage in physical

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activity, and enablers that could be harnessed to design effective physical activity interventions or programs that facilitate behaviour change and thereby improve their participation in physical activity during pregnancy.

The inclusion of behaviour change techniques into physical activity interventions has been reported as helpful in improving physical activity levels during pregnancy.[33] Behaviour change techniques such as goal setting, planning and education to shape knowledge appear most effective when delivered with face-to-face feedback about goal achievement.[33] However, to facilitate uptake of these effective physical activity interventions, clinicians need to know which barriers, enablers and attitudes are common among pregnant women, so they can effectively target their education and evidence-based behaviour change strategies. A systematic review of barriers, enablers and attitudes of pregnant women to physical activity would provide valuable information to enable clinicians to effect a positive behaviour change of increased physical activity in this group.

Identification of women's attitudes and perceptions of barriers and enablers to physical activity in pregnancy could be informed by quantitative or qualitative research approaches. A review that collates data from studies using either method would benefit from the advantages of each: improving generalisability and providing deeper insights into pregnant women's beliefs and perceptions about physical activity during pregnancy. Inclusion of qualitative findings may assist in better understanding the factors that can influence women's attitudes and perceptions. Such deeper understanding would provide valuable insight that clinicians can use to plan strategies to encourage pregnant women – in particular at-risk groups of women such as those with GDM – to participate in physical activity. It would also inform the design of realistic and acceptable interventions to be tested in an effectiveness study. No systematic review has collated quantitative data or provided a meta-summary of attitudes and perceptions of barriers and enablers to physical activity in pregnant women.

Therefore, the research question for this review was:

> What are the attitudes, barriers and enablers to physical activity perceived by pregnant women, including women diagnosed with gestational diabetes mellitus?

Method

The review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines,[34] the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ),[35] and guided by information from the Cochrane Qualitative and Implementation Methods Group.[36]

Identification and selection of studies

One reviewer (AH) searched eight electronic databases: AMED, CINAHL, Embase, Joanna Briggs Institute, Medline, PsycInfo, and SPORTDiscus from database inception until June 2016; and PubMed from 2011 until June 2016. The search strategy comprised three key concepts: attitudes, barriers and facilitators/enablers; physical activity; and pregnancy. For each concept, key words and MeSH terms were combined with the 'OR' operator and the results were combined with the 'AND' operator (see Appendix 1 on the eAddenda). No limits were applied to the search. Reference lists from included studies were manually searched for additional relevant articles. Using Google Scholar and Web of Science, citation tracking was performed on the included articles to identify any other relevant articles.

Two reviewers (AH and HF/NS/NT) independently reviewed the title and abstracts of articles yielded according to the inclusion criteria presented in Box 1. If eligibility was unclear based on the title and abstract, a full-text version was obtained and reviewed by two reviewers independently. Disagreements were resolved by discussion between reviewers.

Box 1. Inclusion criteria.

Design
- Qualitative or quantitative studies
- Full-text article published in a peer-reviewed journal

Participants
- Pregnant women whose pregnancy was not high risk [a]

Outcome measures
- Pregnant women's attitudes to physical activity [b] during pregnancy
- Pregnant women's perceived barriers and enablers to physical activity during pregnancy

[a] High-risk pregnancy was defined as premature labour, incompetent cervix, persistent bleeding, ruptured membranes, growth retardation, pre-eclampsia, severe anaemia, placenta previa after 26 weeks gestation, haemodynamically significant heart disease or restrictive lung disease.[1,2]

[b] Physical activity was defined as leisure time physical activities and structured exercise programs.

Studies using qualitative or quantitative methods were included. This integrated approach was used to enable thorough exploration of the women's perceptions, given the potential for qualitative data to complement and add greater meaning to quantitative findings.[36] This was intended to maximise the value of the findings for those designing interventions to promote physical activity in pregnant women.[37]

Assessment of characteristics of studies

Quality

Adapted from the McMaster Critical Review Forms for qualitative and quantitative research,[38,39] which include guidelines for interpreting the criteria[40,41] to facilitate inter-rater reliability,[42] the rating method for key criteria for quantitative and qualitative studies developed by Imms[43] was used to assess validity and rigor of included studies (Table 1 on the eAddenda). This form has been used previously in a study exploring similar phenomena in a different cohort.[44] Quantitative studies were rated on sample, measure and analysis. Qualitative studies were rated on credibility, transferability, dependability and confirmability, consistent with the criteria for trustworthiness.[45] A rating of one (no evidence of study meeting criterion), two (some evidence or unclear reporting) or three (evidence of study meeting criterion) was used to rate each criterion.

All included studies were assessed by two reviewers independently (AH and HF/NT) and any disagreements resolved by discussion until an agreement was reached. Where agreement could not be reached the findings were discussed with a third reviewer (NS). In appreciation that studies rated as lower methodological quality on rating scales can still provide useful insights based on the data,[36] all studies were included regardless of assessment of methodological quality but study quality was taken into account in interpretation of the results.

Participants

Data were extracted from each study regarding sample size, age, body mass index, ethnicity, education, gestation, parity, comorbidities (GDM, obesity) and physical activity level, where available. See Table 2 on the eAddenda.

Data extraction and analysis

Data were extracted from the included articles using a standardised form. Data were extracted by one reviewer (AH),

summarised into tables and independently checked by a second reviewer (HF/NT). Qualitative and quantitative data were analysed separately.

Analysis of qualitative data

Qualitative data on attitudes, barriers and enablers were synthesised using an inductive approach and synthesised into themes and sub-themes providing a meta-summary. An inductive approach provides a systematic process for analysing qualitative data, thereby deriving and summarising findings that are reliable, valid and linked to the research objectives.[46]

In preparation for analysis, two reviewers (AH and NS) independently read, re-read, reviewed and made notes to familiarise themselves with the content and the context from which the data arose. The data were transcribed verbatim into an electronic spreadsheet. Following this, the two reviewers independently derived initial coding categories, based on emerging themes. This coding was derived directly from words, phrases or paragraphs, as the primary aim was to identify the expression of attitudes and perceptions consistent with the review objectives. To facilitate consistency of coding, a 'code-book' of code names based on emerging themes and accompanying definitions to guide consistent interpretation was developed. To enhance the trustworthiness of the analysis, an audit trail was kept and an iterative process was followed involving: independently coding data; comparing inter-coder agreement; discussing and refining the coding scheme; and augmenting with interpretive memos. This iterative process was continued until sufficient coding consistency and agreement were achieved. Following this, the agreed coding rules were applied to all of the data by one reviewer/coder (AH) and independently checked by a second reviewer/coder (NS).

The themes were grouped in three categories: intrapersonal (eg, physical, psychological), interpersonal (eg, influences from family, friends, health professionals, social and cultural norms) and environmental (eg, access to facilities, built environment, policy and program such as cost), based on a social-ecological model.[47,48] An inductive approach was used to categorise the data into themes and sub-themes under this framework. Data were included under more than one theme if it was considered that the data satisfied the definition of more than one theme. For example, 'participants considered physical activity important for self and baby'[49] with an accompanying description of benefits was included under the themes of 'important' and 'beneficial'. Once all data were analysed, a count for each theme was conducted, checked and recorded.

Analysis of quantitative data

As the majority of quantitative studies reported data expressed as percentages, these data were synthesised by meta-analyses of proportions using a random-effects model to account for heterogeneity. Statistical heterogeneity in each meta-analysis was reported using the I^2 statistic with values $> 50\%$ considered indicative of statistical heterogeneity. The quantitative data were grouped under the categories: intrapersonal, interpersonal and environmental, consistent with qualitative analysis. Data collected using Likert scales were synthesised descriptively.

Results

Flow of studies through the review

The search strategy yielded 3045 articles, including papers in languages other than English. After screening of titles and abstracts, 99 full-text articles were retrieved and following reference checking and citation tracking, four additional articles were identified totalling 103 articles for full-text review. After review of these 103 full texts, 54 articles were excluded. Following this process, 49 articles presenting the results of 47 discrete studies were included in the review (Figure 1).[49–97]

Characteristics of included studies

Quality

Twenty-two articles reporting data from 21 discrete studies used qualitative methods, and seven studies used mixed methods.[60,61,66,75,83,91,97] Three[49,53,68] of these 28 studies provided evidence to satisfy all four quality criteria for qualitative studies. Six studies (reported in seven articles)[52,61,66,82,85,91,92] satisfied three criteria with some evidence of meeting the fourth (see Table 2 on the eAddenda). These studies reported evidence of prolonged engagement, a variety of data collection methods, member checking, detailed descriptions of participants, settings, processes, analyses, audit trails, reflection, peer review, and triangulation. All qualitative or mixed-methods studies demonstrated at least some evidence of trustworthiness.

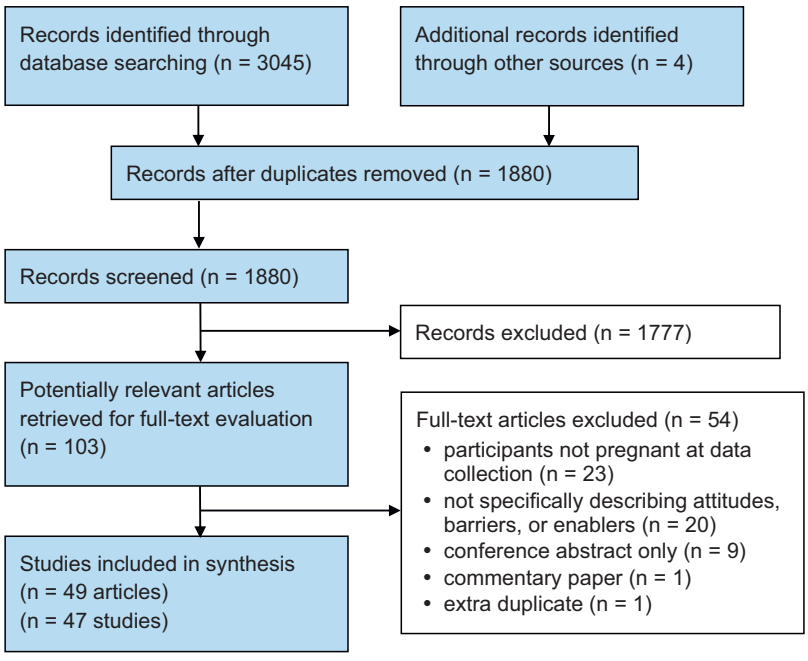

Figure 1. PRISMA flow diagram showing identification and selection of studies.[34]

Table 3
Content analysis summary of qualitative data on attitudes, barriers and enablers to physical activity during pregnancy from 28 studies (reported in 29 articles) that used qualitative methods.

Attitudes (15 studies)	n	Barriers (27 studies)	n	Enablers (21 studies)	n
Important		Intrapersonal		Intrapersonal	
Important/necessary	12	*Fatigue*	20	*Easier labour/delivery*	13
As important as diet in pregnancy	1	*Safety/fears*	20	*Maternal health and wellbeing*	12
Important for self and baby	1	*Pregnancy symptoms/discomforts*	19	*Weight control*	9
		Lack of time	17	*Ease pregnancy symptoms/discomforts*	7
Beneficial		*Lack of motivation*	13	*Confidence/physical activity habit*	7
Beneficial for women		*Lack of confidence*	8	*Baby's health*	6
For healthy pregnancy	10	*Lack of knowledge*	4	*Appearance*	5
Fitness and staying in shape	4				
For labour/birth	3	Interpersonal (social)		Interpersonal (social)	
Wellbeing/enjoyment	2	*Social support*		*Social support*	
For pregnancy symptom relief	1	Lack support of family/friends/others	9	Support of partner	10
Beneficial for baby	4	Lack support of partner	3	Support of family/friends/others	9
		Lack company	1	Socialisation with other pregnant women	5
Safety		*Informational*		Company for walks	1
Need to modify physical activity in pregnancy	2	Lack physical activity information	2	*Informational*	
Walking considered best/safest	1	Conflicting advice	2	Advice from doctor	4
		Lack of advice from professionals	2	Unambiguous advice	3
		Norms		Reassuring advice	3
		Social norms	2	*Social influence*	
		Cultural influence	1	Socialisation	4
		Responsibilities		Peer pressure	1
		Work commitments	7	*Responsibilities*	
		Childcare	5	Fewer commitments, more time	3
		Families	2	Childcare support	1
		Environmental		Environmental	
		Access		*Access*	
		Lack access to facilities/resources	11	Access to facilities/resources	9
		Lack safe place to be physically active	3	*Weather*	
		Weather		Good weather	4
		Bad weather, hot weather	9	*Policy/programs*	
		Policy/programs		Pregnancy-specific programs	6
		Affordability	7		
		Lack of pregnancy-specific programs	2		

Categories (unindented) contain themes (in italics) and subthemes. n = number of studies reporting each theme or subtheme.

Twenty articles reporting data from 19 discrete studies used quantitative methods. All of these studies and the seven mixed-methods studies provided some evidence toward meeting at least one of the three criteria (See Table 2 on the eAddenda). Four[58,64,70,80] studies met all three quality assessment criteria for quantitative studies and 11 studies met two criteria and provided some evidence toward the other.[50,54,60–62,72,74,76,87,91,97]

Participants

The characteristics of the participants in the included studies are detailed in Table 2 (see the eAddenda for Table 2). These studies included 7655 women representing a range of age groups, gestational age, parity, body mass index, countries and cultural, educational and socioeconomic backgrounds. Race/ethnicity and socio-economic background were broad and women were from rural, metropolitan, lower socio-economic and more affluent areas, accessing care in public and private health systems. Six studies (776 participants), reported in seven articles, studied only pregnant women who were overweight or obese.[56,63,67,87,91,92,95]

The range of gestational age reported across studies was from 4 to 41 weeks gestation, providing good representation of women from across the three trimesters of pregnancy. From the 35 studies reporting on parity, an average of 55% of participants were expecting their first baby. Although studies may have potentially included women with GDM, four studies (77 participants) explicitly included only pregnant women diagnosed with GDM, and measured and reported findings for this specific group of pregnant women.[51,55,57,72]

Attitudes to physical activity in pregnancy

Attitudes to physical activity in pregnancy were reported in 29 studies (5275 participants): 13 qualitative, 14 quantitative and two mixed-methods studies. The only attitudes reported in the 13 qualitative studies were that physical activity in pregnancy is important, beneficial and safe (Table 3). The majority of participants reported a positive attitude to physical activity in pregnancy. Based on pooling of the proportion data from 11 quantitative studies, most women identified physical activity as important (0.80, 95% CI 0.52 to 0.98), beneficial (0.71, 95% CI 0.58 to 0.83) and safe (0.86, 95% CI 0.79 to 0.92), as presented in Figure 2. (The numerical data used to generate Figure 2 are available in Table 4 on the eAddenda. The individual meta-analyses of proportions for each attitude are available in Appendix 2 on the e-Addenda.) The meta-analyses had high I^2 values with most $> 90\%$. Five studies used Likert scales to rank attitude, and all reported a positive attitude to physical activity during pregnancy.[54,70,72,74,87] A positive attitude to the importance and benefits of physical activity during pregnancy was also consistent across studies reporting this outcome for overweight and obese pregnant women (n = 4),[63,87,91,95] specific race or ethnic populations (n = 3)[70,77,89] and women with GDM (n = 1).[72]

Barriers to physical activity in pregnancy

Barriers to physical activity in pregnancy were reported in 41 studies (6771 participants; 20 qualitative, 14 quantitative and 7 mixed methods). The most frequent barriers cited were intrapersonal: fatigue, lack of time and pregnancy discomforts such as nausea, pain and awkwardness due to weight gain and increasing size as pregnancy progressed, and less frequently safety concerns such as the type and intensity of physical activity that is considered safe during pregnancy and fears for self, the pregnancy and the baby (Table 3 and Figure 2). (The numerical data used to generate Figure 2 are available in Table 4 on the eAddenda. The individual meta-analyses of proportions for each barrier are available in Appendix 2 on the e-Addenda.) These same barriers

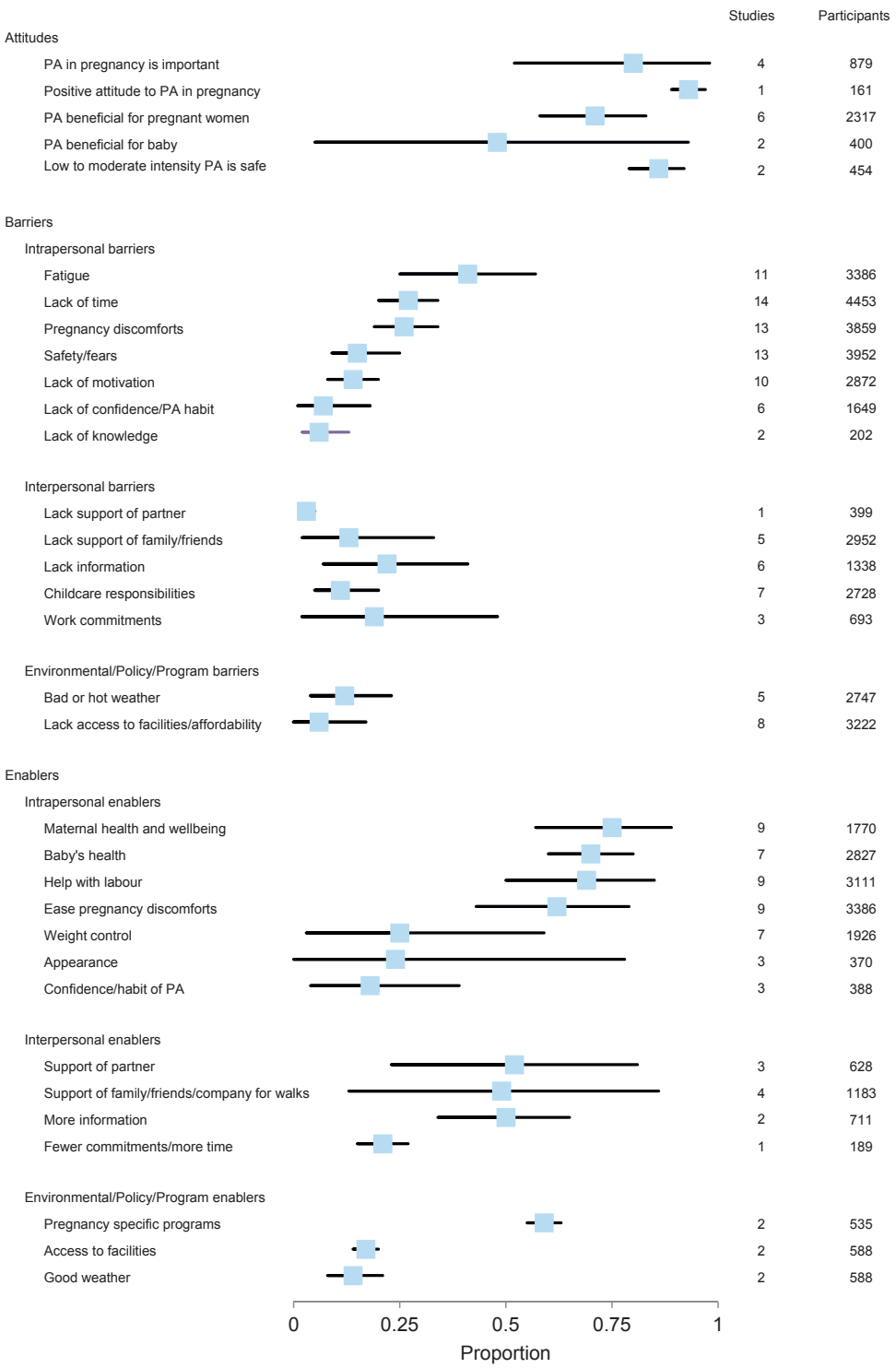

Figure 2. Forest plot of estimates of the proportion of pregnant women that report each attitude, barrier or enabler in relation to physical activity during pregnancy. Each estimate is the result of a 'meta-analysis of proportions' including the number of studies shown. Each meta-analysis of proportions is reported in detail in Appendix 2 (see eAddenda for Appendix 2). PA = physical activity.

were also highlighted in four quantitative studies that collected data using Likert scales.[58,62,70,87]

These themes also arose consistently across studies including: participants from particular races or ethnic populations (2371 participants);[51,70,71,73,77,80,81,89,93] overweight and obese pregnant women (802 participants);[56,63,67,87,91,92,95] and women with GDM (77 participants).[51,55,57,72] (For more detailed data on barriers in women with GDM, see Tables 5 and 6 on the eAddenda). In addition, for women from ethnic backgrounds other than Caucasian, safety concerns for their pregnancy and baby emerged as a theme.[51,70,71,73,81,89,93] One study[77] of low-income African-American women reported the cultural norm of lack of exercise habit and socio-economic factors of lack of affordable and safe places for physical activity as specific barriers for them. Lack of safe and affordable places to be physically active and suitable exercise classes also emerged as a barrier to physical activity in one study[95] that included overweight and obese pregnant women, while another study[67] reported lack of confidence, motivation and knowledge as important barriers. Lack of access to facilities was identified as a barrier to physical activity in pregnancy by a greater proportion of women with GDM (18%, 7 of 40 participants in one study)[72] compared to the whole sample (0.06, CI 0.00 to 0.17; 245 of 3222 participants).

Fewer sub-themes for barriers emerged in the interpersonal (social) and environmental or policy/programs categories. Lack of social support from family or friends, lack of information and work responsibilities were the most frequently cited interpersonal barriers. Environmental barriers were lack of access and (unfavourable) weather.

Enablers to physical activity in pregnancy

Enablers to physical activity during pregnancy were reported in 36 studies (5730 participants; 17 qualitative, 15 quantitative and 4 mixed methods). Intrapersonal factors were the most frequently reported enablers (Table 3 and Figure 2). (The numerical data used to generate Figure 2 are available in Table 4 on the eAddenda. The individual meta-analyses of proportions for each enabler are available in Appendix 2 on the e-Addenda.) The intrapersonal factors included maternal and foetal health and wellbeing, easing pregnancy discomforts, and an easier labour and birth. Two studies[62,87] reported data using Likert scales and found maternal health and wellbeing, decreasing stress, improving fitness and improving appearance were strong enablers of physical activity. These findings were consistent with the data reported by pregnant women who: were overweight or obese;[56,63,67,87,91,92,95] were from particular ethnic or racial groups;[71,81,89,93] or had been diagnosed with GDM.

Interpersonal enablers were often cited. Social support was the most frequently cited interpersonal enabler of physical activity, particularly partner support and family/friend's support. This was also a specific theme among overweight and obese women,[67] and the predominant theme in two studies (416 participants)[51,80] of particular racial groups and in three studies (72 participants)[51,55,72] including women with GDM (for more detailed data on enablers in women with GDM see Tables 5 and 6 on the eAddenda). In these studies, interpersonal enablers such as support from others (eg, walking with a partner) were reported more frequently than intrapersonal factors.

Six qualitative studies[49,53,67,77,82,96] and participants from quantitative studies[81,94] reported group exercise sessions for pregnant women as an enabler to physical activity, including one study[81] of Nigerian women (294/500) that reported a preference for exercise sessions performed at the antenatal clinic by an expert. One study[72] including women with GDM also reported blood glucose control (8/40 participants) as an important enabler to activity.

Discussion

Physical activity in pregnancy was identified by women as beneficial and important, with acknowledgement of safety considerations. Intrapersonal factors of maternal health and wellbeing, pregnancy symptoms, and safety of self and baby were most frequently identified as barriers and enablers to physical activity in pregnancy. Social support was a frequently identified enabler of activity. Across studies and designs with a range of methodological quality, there was strong similarity of emergent themes. This meta-summary with convergence of findings from 47 qualitative and quantitative studies suggests that pregnant women appear to have a strong internal focus on their health and wellbeing and that of their baby. This knowledge provides valuable insight for health professionals to help inform the design of physical activity interventions for pregnant women.

The attitude that physical activity is important and beneficial is a key finding because as suggested by theory,[98–101] attitude influences intention to action behaviour (physical activity). This finding spanned studies, including those solely focusing on specific populations such as particular racial/ethnic groups, women with obesity and those diagnosed with GDM. Therefore, women's positive attitude and knowledge about benefits of physical activity during pregnancy provides an important message to healthcare providers that, for many pregnant women, effort and resources may not need to be focused on increasing current levels of education. Rather, as physical activity participation rates for pregnant women are low despite positive attitudes to physical activity, this suggests a disconnect between the women's intention about physical activity and her action – a knowledge-action gap. Theory of Planned Behaviour[102] suggests factors additional to attitudes, such as barriers, enablers and social factors may also influence intention and subsequent behaviour.[102,103] Efforts to overcome intrapersonal barriers to physical activity may be directed at utilising enablers such as maternal health and wellbeing and interventions like pregnancy-specific exercise groups that incorporate social support, time efficiency for women if paired with antenatal visits, as well as fun and enjoyment critical to initiating and maintaining behaviour change.[104] This may facilitate the shift from intention to action needed in order to create behaviour change and may be more effective in improving pregnant women's participation in physical activity than knowledge or education strategies alone.

Intrapersonal themes emerged as both key barriers and key enablers to women's participation in physical activity in pregnancy, suggesting that strategies need to be person-centred and interventions need to be tailored to women's individual needs, including their stage of pregnancy. A person-centred approach may facilitate translation of the positive attitudes of pregnant women into increased physical activity participation during pregnancy and therefore may be more effective than education alone. As the type of intrapersonal barriers changed with stage of pregnancy (fatigue and nausea in early pregnancy and changes in size and shape later in pregnancy),[53,59,61,72,75] this suggests that physical activity interventions during pregnancy need to be flexible to accommodate physical changes during pregnancy, such as transitioning from land-based to water-based physical activity as pregnancy progresses. Therefore, there is an argument for ongoing review and encouragement of physical activity during pregnancy by exercise professionals to appropriately tailor interventions to suit physical changes during pregnancy to address intrapersonal barriers, and in doing so, maintain women's participation in physical activity.

Although the key findings across all studies were similar, some less frequent themes appeared to be more closely related to particular socio-cultural groups and are important and relevant to consider if caring for women from these groups. For women from low-income areas, addressing affordability and access to a safe place for physical activity are key to enabling these women to participate in physical activity.[77] Social interaction and support from other pregnant women, such as pregnancy-specific exercise groups, were also cited as important for women from specific socio-cultural backgrounds,[77,81] those who were overweight or obese,[67,92,95] and women generally.[49,53,82,94,96] If paired with antenatal visits and conducted by exercise professionals such as physiotherapists, pregnancy-specific exercise groups may offer not only a timely physical activity option but also the reassurance that some women need to overcome their concerns about physical activity in pregnancy.

Exercise professionals with specific skill sets in physical activity prescription and behaviour change may be well positioned to help facilitate physical activity interventions for pregnant women. Primary maternity care providers such as doctors, midwives and nurses appropriately focus on ensuring the health of the mother and baby, and planning for the birth.[105] However, healthcare professionals with physical activity training and skills in managing and educating about musculoskeletal changes occurring during pregnancy may be required to address the issue of physical inactivity during pregnancy by helping shift a pregnant woman's attitude from intention to action. Women in studies focusing on specific ethnic and cultural groups expressed concerns about safety of physical activity.[51,70,71,73,81,89,93] This reinforces the need for healthcare professionals to apply a person-centred approach, in order to work in partnership with the woman identifying and responding to her specific cultural needs or concerns such as

safety. Exercise professionals such as physiotherapists can provide valuable input to address important lifestyle factors, develop safe and appropriate physical activity programs suitable to women's personal needs, stage of pregnancy, any co-existing musculoskeletal limitations, physical activity preferences and socio-cultural needs. The system-level challenge is how to incorporate this intervention into local models of antenatal care, and address funding and access issues.

Little is known about the attitudes, barriers and enablers to physical activity for the at-risk group of pregnant women with GDM. Only four studies of mixed quality involving 77 pregnant women with GDM were found. This is a significant gap in the literature given they are an at-risk group for significant health consequences during pregnancy and beyond, and who have much to benefit by increasing their participation in physical activity. Safety concerns and lack of time were barriers for women with GDM, with social support the strongest enabler and maternal health and wellbeing other key enablers. The small number of studies explicitly including women with GDM suggests that further research is necessary to provide deeper insight into factors influencing physical activity participation in these women.

The strength of this review was that an extensive search identified 49 articles of 47 discrete studies with 7655 participants from a range of ethnic, cultural and educational backgrounds as well as specific health needs. The convergence of key themes across studies, using qualitative and/or quantitative methods, improves the generalisability of the findings and provides in-depth insights that emerged from the women's narratives with which to inform healthcare of pregnant women and the development of strategies to increase physical activity participation in pregnant women. Heterogeneity of data across quantitative studies was a potential limitation of this review but was accounted for by use of a random-effects model with the meta-analyses of proportions.

In conclusion, qualitative and quantitative data, interpreted through a social-ecological framework, identified key attitudes and perceived barriers and enablers of pregnant women to physical activity during pregnancy. Pregnant women had a strong, positive attitude toward physical activity during pregnancy. Intrapersonal factors – including maternal health and wellbeing, managing pregnancy symptoms, time and safety – were frequently cited as both barriers and enablers to physical activity during pregnancy. Social influences, particularly partner and family support, appeared to be important enablers. This knowledge will assist health professionals providing antenatal care to design physical activity interventions for pregnant women that respond to individual needs, optimise enablers and overcome barriers to shift women's exercise behaviour from intention to action. Due to the limited number of studies including women with GDM, further research is needed to confirm and extend understanding of attitudes and perceptions towards physical activity participation in women with GDM.

What is already known on this topic: Physical activity is recommended for women with uncomplicated pregnancies. Despite recommendations to be active many pregnant women are inactive.

What this study adds: Pregnant women believe that physical activity in pregnancy is important and beneficial. Many attitudes, barriers and enablers to physical activity were identified, which physiotherapists can use to guide their discussions with pregnant women about strategies to increase physical activity. Selection of optimal behaviour change techniques (eg, goal setting, education) and person-centred strategies able to respond to intrapersonal and social factors are needed to translate the positive attitude of pregnant women into increased physical activity participation. Data are lacking on attitudes, barriers and enablers to physical activity for pregnant women with GDM.

eAddenda: Appendices 1 and 2, and Tables 1, 2, 4, 5, 6 can be found online at https://doi.org/10.1016/j.jphys.2017.11.012.

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3.3 Study two – Supplementary material (tables, figures and example of search strategy) on Journal of Physiotherapy e-Addenda

Table 1 Quality assessment criteria for assessing internal validity as adapted by Imms[43] and used in Shields et al.[44]

Study design	Criteria	Description
Qualitative	Credibility	• Collection of data over a prolonged period and from a range of participants • Use of a variety of methods to gather data • Use of a reflective approach through keeping a journal of reflections, biases, or preconceptions and ideas • Triangulation used to enhance trustworthiness through multiple sources and perspectives to reduce systematic bias. Main types of triangulation are by: sources (people, resources); methods (interviews, observation, focus groups); researchers (team of researchers versus single researchers); or theories (team bring different perspectives to research question) • Member checking
	Transferability	• Can the findings be transferred to other situations? • Are the participants and settings described in enough detail to allow for comparisons with your populations of interest? • Are there concepts developed that might apply to your clients and their contexts? • Were there adequate (thick) descriptions of sample and setting?
	Dependability	• Is there consistency between the data and the findings? • Is there a clear explanation of the process of research including methods of data collection, analysis and interpretation often indicated by evidence of an audit trail or peer review? • An audit trail described the decision points made throughout the research process
	Confirmability	• What strategies were used to limit bias in the research, specifically the neutrality of the data not the researcher? For example, was the researcher reflective and did they keep a reflective journal, peer review such as asking a colleague to audit the decision points throughout the process (peer audit) and checking with expert colleagues about ideas and interpretation of data, checking with participants (participant audit) about ideas and interpretation of data and having a team of researchers.

Quantitative	Sample	• Sample is representative • Selection bias reduced: population based/representative/convenient • Size of study in relation to design and question (power)
	Measure	• Measure is valid for purpose and reliable • Measurement bias is reduced: validity of tools for purpose/reliability of tool/recall/memory
	Analysis	• Analyses are appropriate to the research question and outcome measure • Statistical significance reported • Point estimates and variability provided and clinical importance discussed

Table 2 Summary of included studies.

Study (year) and country	Design	Sample size	Participant details						Quality assessment [a]
			Participants and race/ethnicity	Mean age and/or range (years)	Mean BMI and/ or range (kg/m^2)	Education	Mean gestation and/or range (weeks)	Parity	
Babbar and Chauhan (2015) [50] USA	Survey Questionnaire	422	Pregnant 43% African-American 43% White 15% other	Range < 19 to 35+	Range: < 18 to 30 44%; > 30 56%; > 40 18%	6% < high school; 33% high school; 60% ≥ high school	Median 27 Range 6 to 41	30% nulliparous	Sample: 3 Measure: 2 Analysis: 3
Bandyopadhyay et al (2011) [51] Australia	Face-to-face in-depth interviews	17	Pregnant South Asian migrated to Australia; with GDM	Median 28 Range 23 to 33	NR	Range: high school to Master degree level	NR	47% nulliparous	Credibility: 2 Transferability: 2 Dependability: 2 Confirmability: 1
Beckham et al (2015) [52] USA	Demographic questionnaire and focus groups	50	Pregnant underserved (low-income); Caucasian and African-American	24.5 Range 18 to 36	Range: 25 to 30 35%; > 30 25%	79% ≥ high school	26 Range 12 to 38	Mean 1.2 (0 to 5)	Credibility: 2 Transferability: 3 Dependability: 3 Confirmability: 3
Bennett et al (2013) [53] Canada	Semi-structured interviews	9	Pregnant physically active 89% White 11% Latina	Range 20 to 44	NR	100% > high school	Range 10 to 39	100% primiparous	Credibility: 3 Transferability: 3 Dependability: 3 Confirmability: 3
Canella et al (2010) [54] USA	Questionnaire	179	Pregnant 67% White 12% African-American 11%Latino/Hispanic; Other 6%	Range 18 to 45	NR	9% ≤ high school; 91% > high school	6 to 39	32% primiparous	Sample: 2 Measure: 3 Analysis: 3

Carolan et al (2012)[55] Australia	Choice of Semi-structured interview (phone or face-to-face) or focus group	15	Pregnant with GDM Caucasian 33%; Indian 27%; Asian 33%; Arabic 7%	32 ± 5 Range 23 to 40	NR	73% high school; 27% > high school	NR	60% primiparous	Credibility: 2 Transferability: 3 Dependability: 2 Confirmability: 2
Chang et al (2015)[56] USA	Cross sectional design; focus groups	96	Pregnant Low-income, overweight or obese; African-American 46%; Non-Hispanic white 54%	26 ± 5	Range: 25 to 30 35%; 30 to 40 65%	22% ≤ high school; 78% ≥ high school	NR	NR	Credibility: 2 Transferability: 2 Dependability: 2 Confirmability: 2
Chavez-Courtois et al (2014)[57] Mexico	In-depth Interviews	5	Pregnant with GDM; ethnicity NR	Range > 18 27 to 39	NR	40% high school; 60% < high school	Range 30 to 34	100% Multiparous	Credibility: 2 Transferability: 2 Dependability: 1 Confirmability: 1
Choi et al (2016)[58] USA	RCT Used surveys to collect barriers data	30	Pregnant; sedentary; Asian 40%; Black 7%; Hispanic/Latina 10%; White 43%	34 ± 3	Mean = 28 ± 4	3% high school; 97% > high school	17 ± 3 Range 10 to 20	57% primiparous	Sample: 3 Measure: 3 Analysis: 3
Cioffi et al (2010)[59] Australia	Small group and individual face-to-face interviews	19	Ethnicity NR	Median age 35 Range 18 to 40	NR	5% < high school; 95% ≥ high school	Range 1 to 30+	42% primiparous	Credibility: 1 Transferability: 2 Dependability: 1 Confirmability: 1

Clarke and Gross (2004) [60] UK	Survey and semi-structured interviews	57 of 69	Pregnant; nulliparous Ethnicity NR	26 ± 5 Range 16 to 38	NR	55% < high school; 25% high school; 19% > high school	Range 16 to 38	100% primiparous	Sample: 2 Measure: 3 Analysis: 3 Credibility: 2 Transferability: 2 Dependability: 2 Confirmability: 1
Cramp and Bray (2009) [61] Canada	Questionnaire	160	Pregnant; 95% white	31± 3.5	NR	88% > high school	NR	57% primiparous	Sample: 2 Measure: 3 Analysis: 3 Credibility: 2 Transferability: 3 Dependability: 3 Confirmability: 3
Da Costa and Ireland (2013) [62] Canada	Questionnaire	84	Pregnant; first trimester; 78% Caucasian	Inactive:33 ± 4 Active: 34 ± 4	Inactive: 24 ± 4 Active: 25 ± 5	Mean of 16 years education	Inactive: 13 ± 3 Active: 14 ± 3	Inactive: 51% primiparous Active: 46% Primiparous	Sample: 2 Measure: 3 Analysis: 3
Denison et al (2015) [63] UK	In-depth semi-structured interviews	13	Pregnant; class III obesity; ethnicity NR	Range 25 to 34	Range: ≥ 40	NR	Range 17 to 37	46% primiparous	Credibility: 2 Transferability: 3 Dependability: 2 Confirmability: 2
Duncombe et al (2009) [64] Australia	Questionnaire	158	Pregnant; first trimester; 87% Australian; 6% European; 7% Other	32 ± 4 Range 21 to 42	NR	1% < high school; 17% high school; 82% > high school	T1: 19 T2: 27 T3: 35 Range 16to38	45% primiparous	Sample: 3 Measure: 3 Analysis: 3

Evenson and Bradley (2010) [65, b] USA	Survey and self-administered questionnaire	1306 (of 2006 enrolled in PIN study)	Pregnant; Non-Hispanic white 72%; Non-Hispanic black 17%; Other 11%	Median 30	Range: < 20 to 26 66%; 26 to ≥30 44%	19% ≤ high school; 81% > high school	Range 24 to 29 (self-administered beliefs survey)	52% primiparous	Sample: 2 Measure: 2 Analysis: 2
Evenson et al (2009) [66, b] USA	Phone survey and additional focus groups	1535 (of 2006 in PIN study for survey plus additional / separate recruitment 58 for focus groups). Total 1593	Pregnant; Survey: Non-Hispanic white 76%; Non-Hispanic African-American 19% Hispanic 5% Focus groups: Non-Hispanic white 24%; Non-Hispanic African-American 33% Hispanic 43%	Survey: median 30; Range 18 to 36+ Focus groups: median 26 Range 18 to 35	Range: Survey: < 26 66% 26 to > 29 34% Focus groups: < 26 50% 26 to >29 47%	Survey: 19% ≤ high school; 81% > high school Focus groups: 48% ≤ high school; 52% > high school	Survey: Median 29 Focus Groups: Median 29 Range 1st interview: < 20 weeks; 2nd interview; 27 to 30 weeks	NR	Sample: 2 Measure: 2 Analysis: 2 Credibility: 3 Transferability: 3 Dependability: 3 Confirmability: 2
Furness et al (2011) [67] UK	Semi structured focus groups	6	Pregnant; obese; White 95%	Range 18 to 40	Range > 30	NR	Range Observed to be approx. 18 to 40	Not Collected (range 1 to 4)	Credibility: 1 Transferability: 2 Dependability: 2 Confirmability: 2
Goodwin et al (2000) [68] Australia	Semi to structured interviews x 2	65	Pregnant; 85% Australian born	30 ± 4 Range 23 to 39	Range < 30	66% > high school	Range 14 to 20 (on entry to study); data collected at 17 weeks and at 30weeks (range 27to32)	100% primiparous	Credibility: 3 Transferability: 3 Dependability: 3 Confirmability: 3

Groth and Morrison-Beedy (2013) [69] USA	Focus groups	26	Pregnant; Low-income Hispanic 4%; Non-Hispanic 88%; Other 8%	Range 18 to 39	NR	35% < high school; 46% high school; 19% > high school	NR 60% in first 20 weeks Range 10 to 40	NR	Credibility: 2 Transferability: 2 Dependability: 3 Confirmability: 2
Guelfi et al (2015) [70] China and Australia	Questionnaire	China 240; Australia 215	Pregnant; China: Asian 100%; Australia: Caucasian 76%, Asian 16%, indigenous 1%, other 7%	China: 30 ± 3 Australia: 32 ± 4	China: 24 ± 3 Australia: 25 ± 4	NR	China: 22 ± 1 Australia: 21 ± 3 Range 18 to 26	China: 70% Australia: 54% primiparous	Sample: 3 Measure: 3 Analysis: 3
Haakstad et al (2009) [71] Norway	53-item self-administered questionnaire	467	Pregnant; Scandinavian	32 ± 4	24 ± 4	83% > high school	Range 32 to 36	1.3 ± 0.5	Sample: 2 Measure: 2 Analysis: 3
Halse et al (2015) [72] Australia	Questionnaire	40 (Control 20; Ex 20)	Pregnant with GDM Ethnicity: NR	Control: 32 ± 3 Ex: 34 ± 5	Control: 30 ± 7 Ex: 28 ± 7	NR	Control: 29 ± 1 Ex: 29 ± 1 Range 26 to 30	1 ± 1	Sample: 2 Measure: 3 Analysis: 3
Hanghoj (2013) [73] Denmark	Semi-structured in-depth interviews	5	Pregnant; Danish	Range 26 to 36	NR	Average or advanced education	Range 28 to 40	60% primiparous	Credibility: 2 Transferability: 2 Dependability: 3 Confirmability: 2
Hausenblas et al (2008) [74] USA	Questionnaire (postal) self-administered with rating scales	61	Pregnant; Non-Hispanic white 86% Other 14%	29 ± 5 Range 20 to 40	NR	44% > high school	NR	44% primiparous	Sample: 2 Measure: 3 Analysis: 3

Hausenblas et al (2011)[75] USA	Questionnaire (postal) self-administered	38	Pregnant; Caucasian 75% Other 25%	28 ± 5	NR	42% > high school	NR	NR	Sample: 2 Measure: 2 Analysis: 3 Credibility: 2 Transferability: 1 Dependability: 2 Confirmability: 2
Kolt and Nicholl (1999)[76] Australia	Questionnaire self-administered	131	Pregnant	32 ± 4 Range 24 to 34	NR	NR	25 ± 7 Range 9 to 38	NR	Sample: 2 Measure: 3 Analysis: 3
Krans and Chang (2011)[77] USA	Focus groups	34 of 40	Pregnant; African American women	23 Range 18 to 30	Mean = 33 Range 22 to 46	67% high school; 33% > high school	NR Range 1st to 3rd trimester	53% primiparous	Credibility: 2 Transferability: 3 Dependability: 3 Confirmability: 2
Krans et al (2005)[78] USA	Questionnaire self-administered	211	Pregnant; Caucasian, African-American and Hispanic	29 ± 5 Range 16 to 43	26 ± 7 Range 16 to 57	NR	25 ± 9 Range 4 to 40	51% primiparous	Sample: 2 Measure: 1 Analysis: 2
Leiferman et al (2011)[79] USA	Individual and paired interviews	25	Pregnant; White 36% African-American 28%; Other 32%	18 to 46	NR	16% < high school; 44% ≤ high school 40% > high school	17 to 40	NR	Credibility: 2 Transferability: 2 Dependability: 2 Confirmability: 2
Leppanen et al (2014)[80] Finland	Questionnaire self-administered	399	Pregnant; Finnish-speaking	30 ± 5	26 ± 5	34% ≤ high school; 66% > high school	NR	44% primiparous	Sample: 3 Measure: 3 Analysis: 3
Makinde et al (2014) Nigera[81]	Questionnaire researcher administered	500	Pregnant; Attending ante-natal clinic in Nigeria	Range 16 to 46+	NR	81% ≤ high School; 19% > high school	NR	19% primiparous	Sample: 2 Measure: 2 Analysis: 2

Marquez et al (2009) USA[82]	Focus groups	20	Pregnant; Latina and non-Latina white	Latina: 25 ± 5 Non-Latina: 29 ± 6	Latina: 28 ± 8 Non-Latina: 24 ± 4	50% ≤ high school; 50% > high school	< 28	NR	Credibility: 2 Transferability: 3 Dependability: 3 Confirmability: 3
Marshall et al (2013) USA[83]	Questionnaire Self-administered	30	Pregnant; rural; White 60%; Black 34%; Hispanic 2%; Other 2%	26 Range 18 to 36	26 ± 5	34% ≤ high school; 66% > high school	Range 1st to 3rd trimester	61% primiparous	Sample: 1 Measure: 3 Analysis: 1 Credibility: 1 Transferability: 2 Dependability: 2 Confirmability: 2
Mudd et al (2009) USA[84]	Face-to-face interviews	296	Pregnant; White 58%; Black 17%; Hispanic 21%; Other 4%	Range 18 to 30+	NR	25% < high school	11 Range 2 to 36	40% primiparous	Sample: 2 Measure: 1 Analysis: 3
Muzigaba et al (2014) South Africa[49]	Focus groups	34	Pregnant; underprivileged areas; Black 62%; Mixed ancestry 38%	26 ± 5 Range 17 to 36	NR	44% < high school	Range 1st to 3rd trimester	35% primiparous	Credibility: 3 Transferability: 3 Dependability: 3 Confirmability: 3
Padmanabhan et al (2015) UK[85]	Semi-structured face-to-face interviews	19	Pregnant; White 94%; Other 6%	30 ± 6 Range 19 to 38	47% < 25; 37% 25 to 30; 11% > 30	68% high school; 11% > high school; 21% other	Range 3rd trimester	42% primiparous	Credibility: 3 Transferability: 2 Dependability: 3 Confirmability: 3
Petrov Fieril et al (2014) Sweden[86]	Semi-structured face-to-face interviews	17	Pregnant; Swedish 82%; Finnish, French, Canadian (18%)	Range 25 to 35+	NR	12% high school; 88% > high school	Range 15 to 35	52% primiparous	Credibility: 2 Transferability: 2 Dependability: 3 Confirmability: 2

Poston et al (2013) UK[87]	Questionnaire researcher administered	183	Pregnant obese; White 56%; Black 38%; Other (6%)	Control: 31 ± 5 Intervention: 30 ± 6	36	NR	Range Approx. 15 to 28	44% primiparous	Sample: 3 Measure: 2 Analysis: 3
Poth and Carolan (2013) Australia[88]	Semi-structured face-to-face Interview	6	Pregnant; At risk of GDM Most migrants from culturally diverse backgrounds	Range > 30	NR	100% 'well educated'	Range < 24	100% primiparous	Credibility: 1 Transferability: 2 Dependability: 2 Confirmability: 1
Put et al (2015) China[89]	Questionnaire self-administered	534	Pregnant; Chinese	30.5 Range < 20 to 40+	NR	3% < high school; 58% high school; 39% > high school	NR	48% primiparous	Sample: 2 Measure: 2 Analysis: 3
Ribeiro and Milanez (2011) Brazil[90]	Individual, face-to-face, researcher administered structured questionnaire	161	Pregnant; White 27%; Non-white 73%	25 Range 18 to 30+	NR	45% < high school; 53% high school; 2% > high school	32 Range 28 to 36+	35% primiparous	Sample: 3 Measure: 2 Analysis: 2
Sui et al (2013a) Australia[91, c]	Mixed methods. Questionnaire self-administered and semi-structured face-to-face interviews	464 (Questionnaire 464 Nested in LIMIT study and within this Interviews 26)	Pregnant; overweight and obese Caucasian 91%; Others 9%	< 20 to 40+	Quantitative: 46% 25 to 30; 54% > 30 Qualitative 54% 25 to 30; 46% > 30	NR	NR Range Approx. 10 to 28	42% primiparous	Sample: 3 Measure: 2 Analysis: 3 Credibility: 3 Transferability: 2 Dependability: 3 Confirmability: 3

Sui et al (2013b) Australia[92, c]	Semi-structured face-to-face interviews	26 (nested within the LIMIT study a/a)	Pregnant; overweight and obese Most Caucasian	32 ± 1 Range 20 to 40	33 ± 6	NR	28	50% primiparous	Credibility: 3 Transferability: 2 Dependability: 3 Confirmability: 3
Sujindra et al (2015) India[93]	Questionnaire	200	Pregnant; South-Indian Hindu (81%)	25 ± 4.5 Range 18 to 35	NR	63% < high school; 29% high school; 6% > high school	NR	NR	Sample: 2 Measure: 1 Analysis: 2
Ussher et al (2007) UK[94]	Telephone questionnaire	88	Pregnant; smokers majority Caucasian	28 ± 7	NR	NR	20 ± 6	NR	Sample: 2 Measure: 2 Analysis: 2
Weir et al (2010) UK[95]	Semi structured in-depth interviews	14	Pregnant; overweight and obese White 93%	NR	≥ 25	33% > high school	Late pregnancy	47% nulliparous	Credibility: 2 Transferability: 1 Dependability: 2 Confirmability: 2
Whitaker et al (2016a) USA[96]	Interviews	30	Pregnant; African-American 50% White 50%	27 ± 6 Range 18 to 41	28 ± 7 Range 19 to 45	17% < high school; 33% high school; 50% > high school	Range 20 to 30	57% primiparous	Credibility: 2 Transferability: 3 Dependability: 3 Confirmability: 2
Whitaker et al (2016b) USA[97]	Internet-based questionnaire	189	Pregnant; White 82% African-American 11% Other 7%	30 ± 4 Range 21 to 43	26 ± 6 Range 19 to 42	6% high school; 94% > high school	26 ± 3 Range 20 to 30	52% primiparous	Sample: 3 Measure: 2 Analysis: 3 Credibility: 2 Transferability: 3 Dependability: 2 Confirmability: 2

NR = not reported; BMI = body mass index (at baseline)

[a] As adapted by Imms[43] from Law et al[38,40] and Letts et al[39,41] and used in Shields, Synnot and Barr.[44]

1 = no evidence of meeting criteria; 2 = some evidence or unclear reporting; 3 = evidence of study meeting criteria.

[b] Potential overlap of participants across articles nested within same study therefore these two articles considered one mixed study

[c] Sui et al (2013a)[91] and Sui et al (2013b)[92] appear to report data from the same study therefore these two articles considered one mixed study.

Table 4 Summary of meta-analyses of proportions (random effects model) for quantitative data on attitudes, barriers and enablers to physical activity during pregnancy from 26 discrete studies (27 articles) that used quantitative methods.[a]

	Themes	Number of studies (proportion participants responding)	Pooled effect[b]	95% CI
Attitudes				
	PA in pregnancy important	4 (735/879)	0.80	0.52 to 0.98
	Positive attitude to PA in pregnancy	1 (151/161)	0.93	0.89 to 0.97
	PA beneficial for pregnant women	6 (1904/2317)	0.71	0.58 to 0.83
	PA beneficial for baby	2 (200/400)	0.48	0.05 to 0.93
	Low to moderate intensity PA considered safe in pregnancy	2 (393/454)	0.86	0.79 to 0.92
Barriers				
Intrapersonal barriers				
	Fatigue	11 (1299/3386)	0.41	0.25 to 0.57
	Lack of time	14 (1125/4453)	0.27	0.20 to 0.34
	Pregnancy discomforts	13 (917/3859)	0.26	0.19 to 0.34
	Safety/fears	13 (616 /3952)	0.15	0.09 to 0.25
	Lack of motivation	10 (333/2872)	0.14	0.08 to 0.20
	Lack of confidence/PA habit	6 (158/1649)	0.07	0.01 to 0.18
	Lack of knowledge	2 (11/202)	0.06	0.02 to 0.13
Interpersonal barriers				
	Lack of partner support	1 (12/399)	0.03	0.02 to 0.05
	Lack of support family/friends	5 (203/2952)	0.13	0.02 to 0.33
	Lack of information	6 (198/1338)	0.22	0.07 to 0.41
	Childcare responsibilities	7 (174/2728)	0.11	0.05 to 0.20
	Work commitments	3 (70/693)	0.19	0.02 to 0.48
Environmental/policy/programs barriers				
	Bad weather/hot weather	5 (253/2747)	0.12	0.04 to 0.23
	Lack of access facilities/affordability	8 (247/3222)	0.06	0.00 to 0.17

Enablers			
Intrapersonal enablers			
Maternal health and wellbeing	9 (1371/1770)	0.75	0.57 to 0.89
Baby's health	7 (2081/2827)	0.70	0.60 to 0.80
Help with labour	9 (2577/3111)	0.68	0.52 to 0.82
Ease pregnancy discomforts	9 (2625/3386)	0.62	0.43 to 0.79
Weight control	7 (782/1926)	0.25	0.03 to 0.59
Appearance	3 (119/370)	0.24	0.00 to 0.78
Confidence/habit of PA	3 (80/388)	0.18	0.04 to 0.39
Interpersonal enablers			
Support of partner	3 (291/628)	0.52	0.23 to 0.81
Support of family/friends/company for walks	4 (719/1183)	0.49	0.13 to 0.86
More information	2 (375/711)	0.50	0.34 to 0.65
Less commitments/more time	1 (39/189)	0.21	0.15 to 0.27
Environmental/policy/programs enablers			
Pregnancy specific programs	2 (316/535)	0.59	0.55 to 0.63
Access to facilities	2 (97/588)	0.17	0.14 to 0.20
Good weather	2 (88/588)	0.14	0.08 to 0.21

PA = Physical activity; CI = Confidence interval

[a] Barriers and enablers organised into the categories of intrapersonal, interpersonal and environmental

[b] Random effects model used to account for the heterogeneity of data across studies; Meta-analyses were characterised by high I^2 values with most > 90%

Table 5 Content analysis of data on attitudes, barriers and enablers to physical activity during pregnancy from studies that used qualitative methods and included participants with gestational diabetes mellitus. [a b]

Attitudes [c]	n	Barriers (three studies)[51,55,57]	n	Enablers (two studies)[51,55]	n
Not reported		Intrapersonal		Intrapersonal	
		Safety/fears	2	*Baby's health*	1
		Lack of time	2		
		Fatigue	1		
		Pregnancy symptoms/discomforts	1		
		Interpersonal (social)		Interpersonal (social)	
		Not reported		*Social support*	
				Walk with partner	2
		Environmental		Environmental	
		Not reported		Not reported	

n = number of studies reporting each theme/subtheme; GDM = gestational diabetes mellitus

[a] Themes (*in italics*) and sub-themes and for barriers and enablers organised into the categories of intrapersonal, interpersonal and environmental

[b] Three studies using qualitative methods conducted with women with GDM[51, 55, 57]

[c] No study using qualitative methods and including GDM reported specifically on attitudes to physical activity in pregnancy

Table 6 Summary of data on attitudes, barriers and enablers to physical activity during pregnancy from one study[72] including women with gestational diabetes mellitus that used quantitative methods. [a b]

Attitudes	Proportion of participants	%	Barriers	Proportion of participants	%	Enablers	Proportion of participants	%
			Intrapersonal			Intrapersonal		
	Not reported		*Lack of time*	8/40	20%	*Maternal health*	15/40	38%
			Pregnancy discomforts	6/40	15%	*Maternal wellbeing*	10/40	25%
			Fatigue	5/40	13%	*Control blood glucose*	8/40	20%
			Complications/safety	5/40	13%	*Help with labour*	5/40	13%
			Lack of motivation	3/40	8%	*Baby's health*	3/40	8%
			Interpersonal (social)			Interpersonal (social)		
			Responsibilities			*Social Support*		
			Childcare responsibilities	4/40	10%	Partner support	19/40	48%
			Lack of information/advice	1/40	3%			
			Environmental			Environmental		
			Lack of access facilities/affordability	7/40	18%	Not reported		

% = percentage of participants with that response

[a] Barriers and enablers organised into the categories of intrapersonal, interpersonal and environmental

[b] One study,[72] with 40 participants reported quantitative findings (expressed as percentages) on barriers and enablers to physical activity during pregnancy for women with gestational diabetes mellitus

3.3 Study two – Search strategy example (included as appendix 1 on Journal of Physiotherapy e-Addenda)

Embase database search

Search History (8)

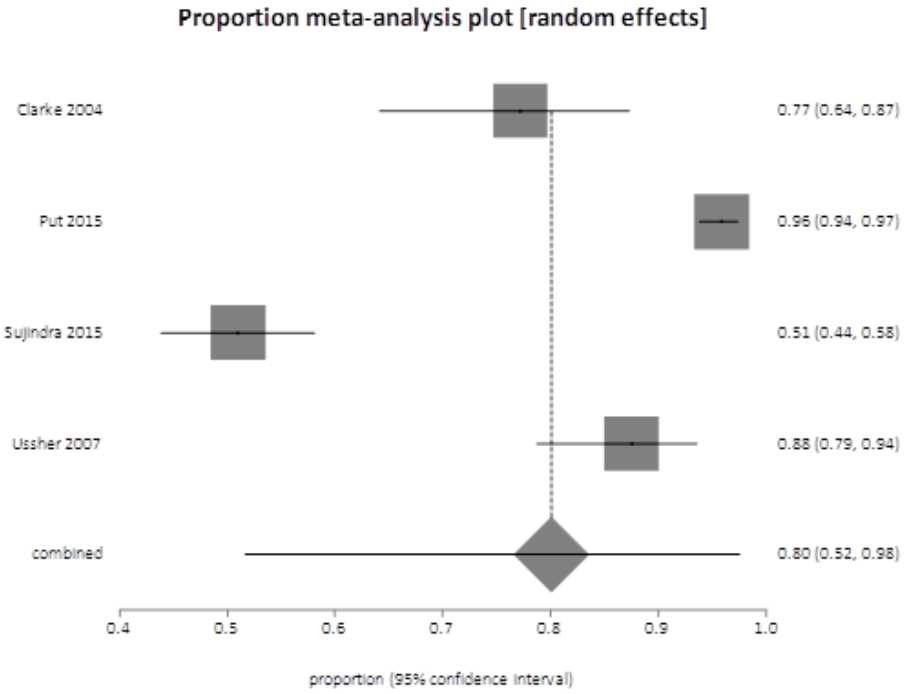
# ▲	Searches	Results	Type
1	(Pregnancy or gestational diabetes mellitus or diabetes, gestational or GDM).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]	857654	Advanced
2	(Physical activit* or exercis* or exercise therapy or resistance exercis* or recreational exercis* or leisure exercis* or fitness training or physical fitness or aerobic exercis* or aquatic exercis* or walking or swimming or cycling).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]	671759	Advanced
3	(Attitude* or perception* or view* or barrier* or enabler* or facilitator* or adherence).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]	1562704	Advanced
4	1 and 2 and 3	1177	Advanced

3.3 Study two –Individual meta-analyses of proportions for each attitude, barrier and enabler (included as appendix 2 on Journal of Physiotherapy e-Addenda)

Pregnant women's attitudes to physical activity in pregnancy

For meta-analysis of "identify exercise in pregnancy as important & necessary"

Clarke and Gross (2004)	44/57
Put et al (2015)	512/534
Sujindra et al (2015)	102/200
Ussher et al (2007)	77/88



The estimated population proportion is 0.80 (95% CI 0.52 to 0.98)

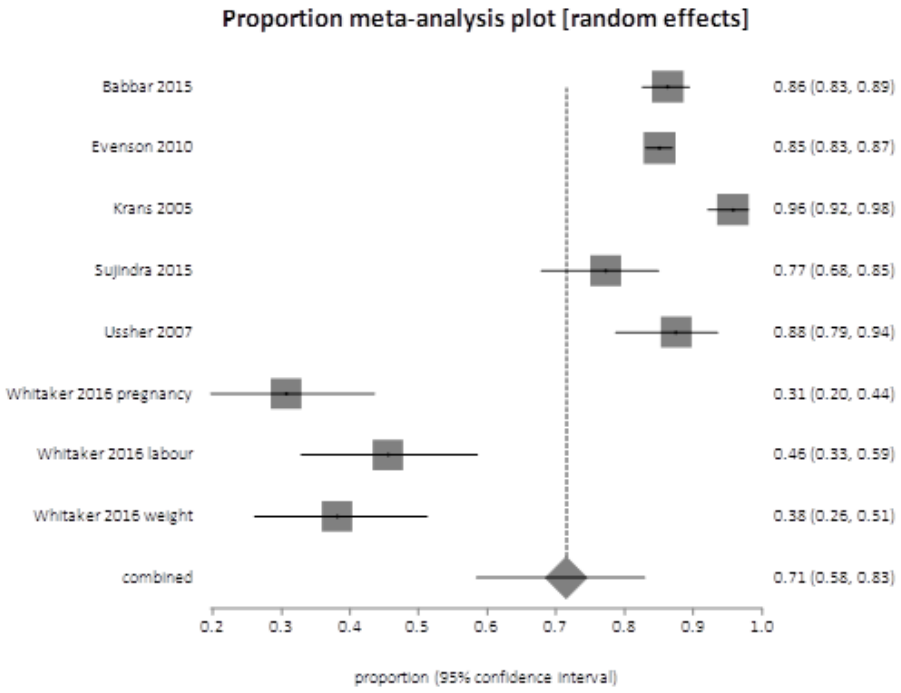
For meta-analysis of "positive/favourable attitude to physical activity"
Ribeiro and Milanez (2011) 151/161

The estimated population proportion is 0.93 (95% CI 0.89 to 0.97)

For meta-analysis of "physical activity in pregnancy is beneficial/beneficial for self"

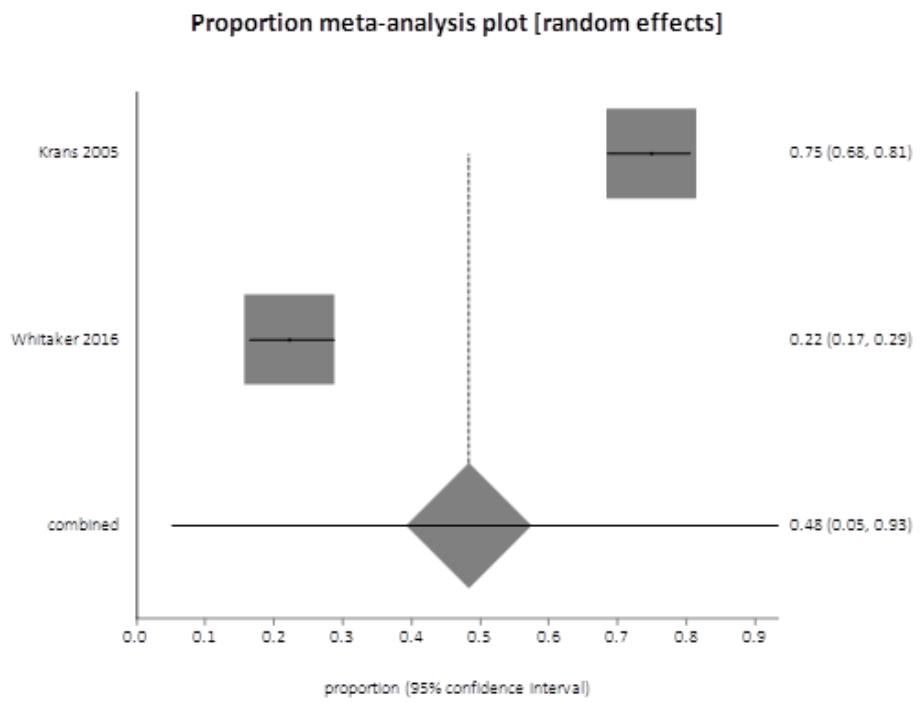
Babbar et al (2015)		364/422
Evenson and Bradley (2010)		1111/1306
Krans et al (2005)		202/211
Sujindra et al (2015)		78/101
Ussher et al (2007)		77/88
Whitaker et al (2016)	Beneficial for healthy pregnancy	58/189
	Beneficial for labour	86/189
	Beneficial for weight control	72/189

Note: For this meta-analysis, three domains from one study (Whitaker) were eligible. To avoid a unit-of-analysis error, the proportions were scaled down to so that the sample size for each domain was reduced to one-third.



The estimated population proportion is 0.71 (95% CI 0.58 to 0.83)

For meta-analysis of "physical activity in pregnancy is beneficial for the baby"
Krans et al (2005) 158/211
Whitaker et al (2016) 42/189

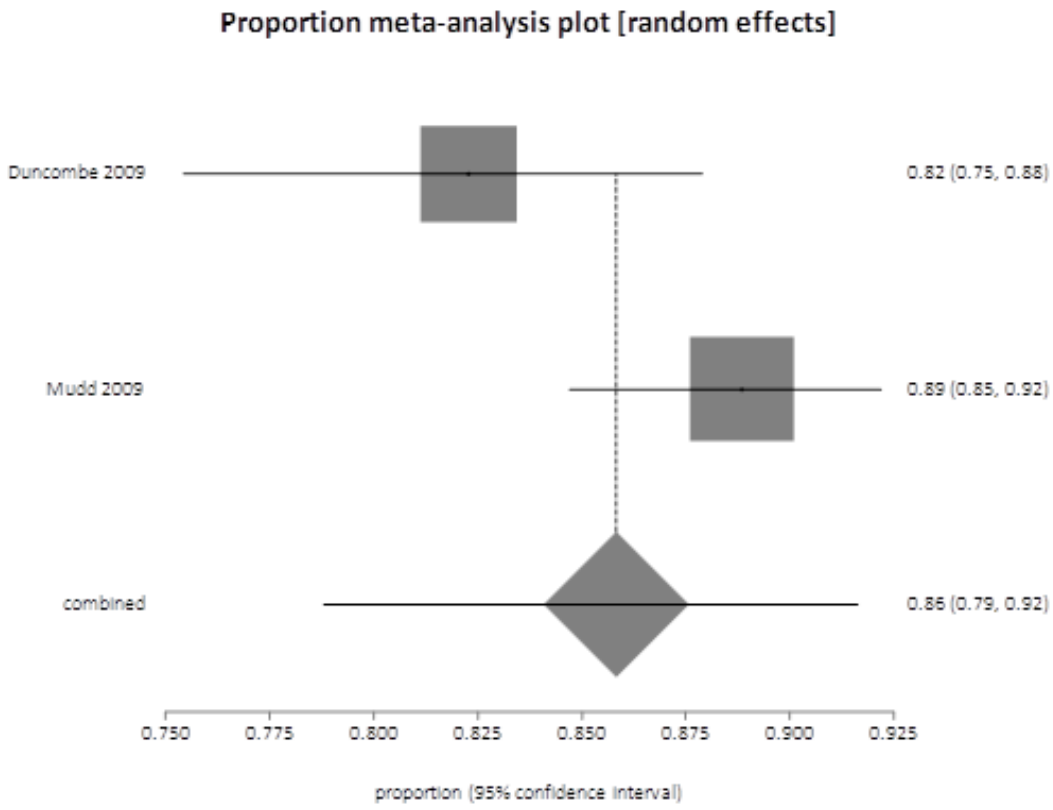


The estimated population proportion is 0.48 (95% CI 0.05 to 0.93)

For meta-analysis of "physical activity in pregnancy is safe"

Duncombe et al (2009) 130/158

Mudd et al (2009) 263/296



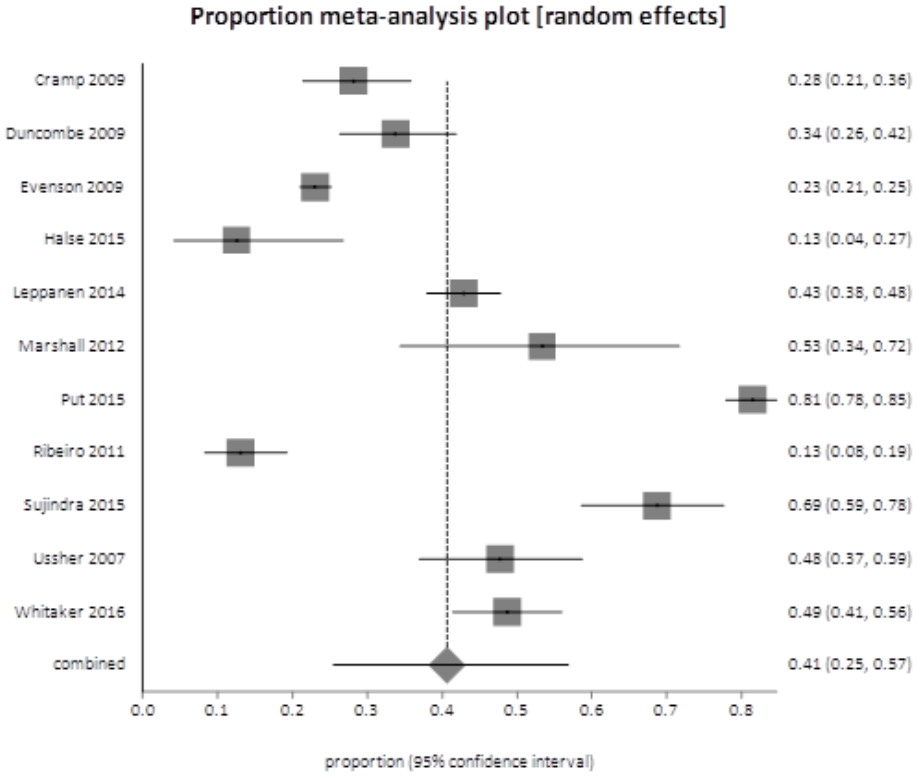
The estimated population proportion is 0.86 (95% CI 0.79 to 0.92)

Pregnant women's perceived barriers to physical activity in pregnancy

Intrapersonal barriers

For meta-analysis of "Fatigue as a perceived barrier to physical activity in pregnancy"

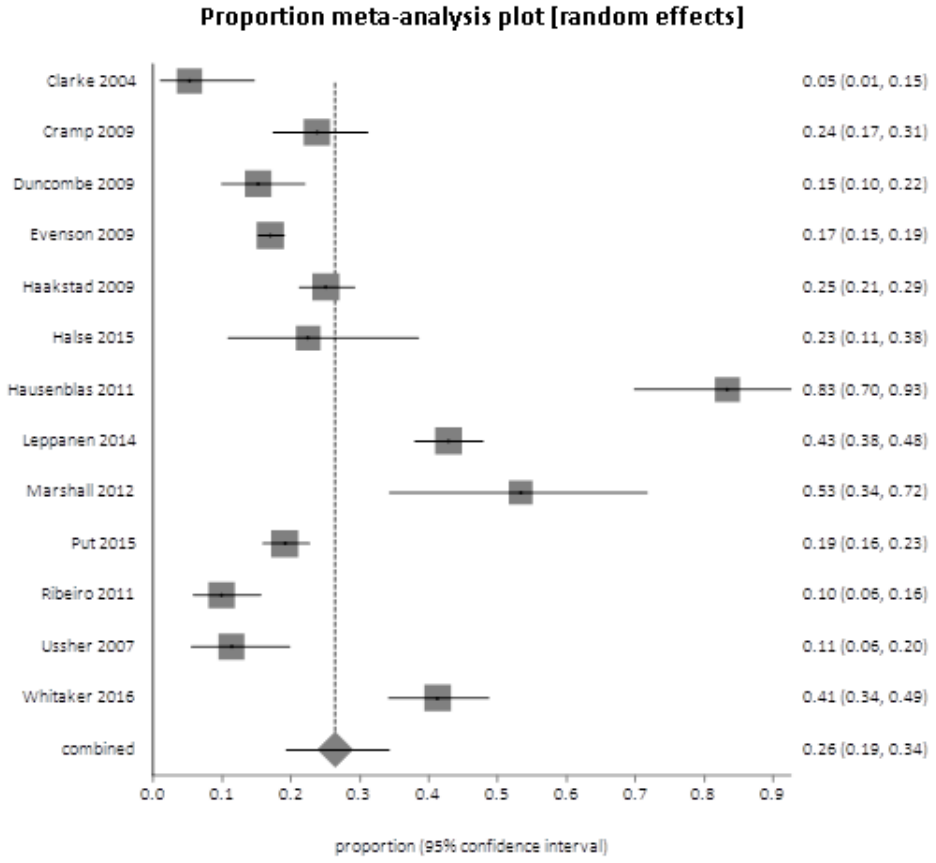
Cramp and Bray (2009)	45/160
Duncombe et al (2009)	51/151
Evenson et al (2009)	353/1535
Halse et al (2015)	5/40
Leppanen et al (2014)	171/399
Marshall et al (2012)	16/30
Put et al (2015)	435/534
Ribeiro and Milanez	21/161
Sujindra et al (2015)	68/99
Ussher et al (2007)	42/88
Whitaker et al (2016)	92/189



The estimated population proportion is 0.41 (95% CI 0.25 to 0.57)

For meta-analysis of "Pregnancy symptoms/discomforts as a perceived barrier to physical activity in pregnancy"

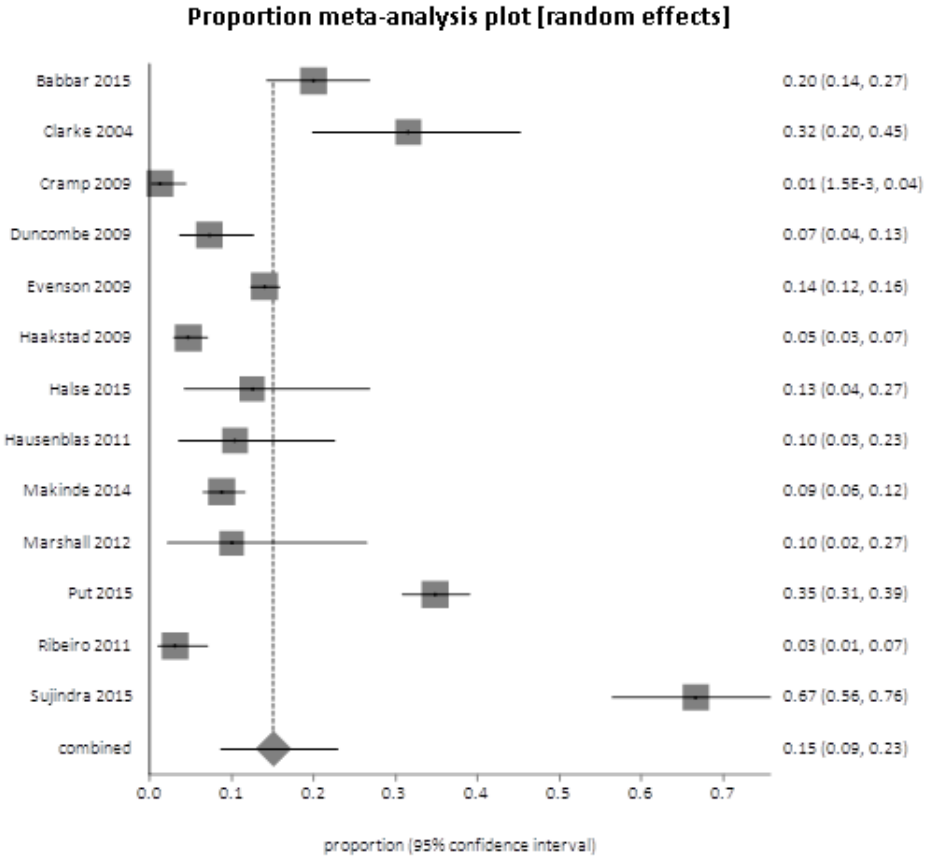
Clarke and Gross (2004)	36/57
Cramp and Bray (2009)	38/160
Duncombe et al (2009)	23/151
Evenson et al (2009)	261/1535
Haakstad et al (2009)	117/467
Halse et al (2015)	9/40
Hausenblas et al (2011)	40/48
Leppanen et al (2014)	171/399
Marshall et al (2012)	16/30
Put et al (2015)	102/534
Ribeiro and Milanez (2011)	16/161
Ussher et al (2007)	10/88
Whitaker et al (2016)	78/189



The estimated population proportion is 0.26 (95% CI 0.19 to 0.34)

For meta-analysis of "Safety concerns as a perceived barrier to physical activity in pregnancy"

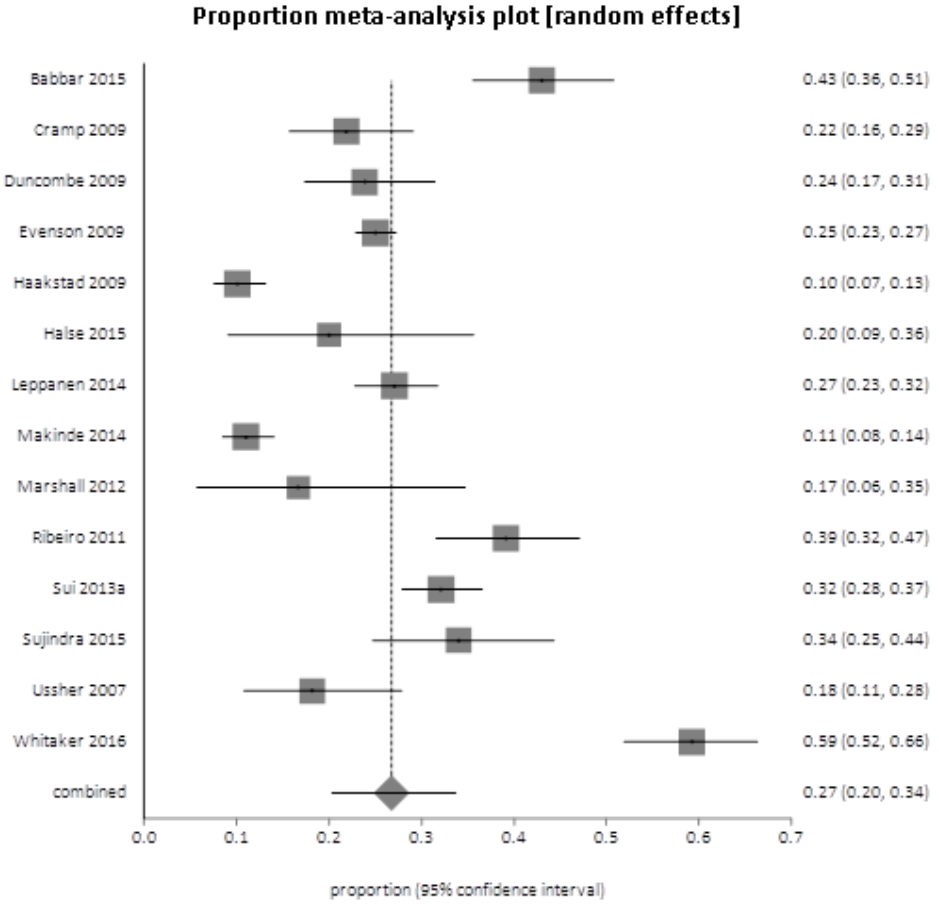
Babbar et al (2015)	34/170
Clarke and Gross (2004)	18/57
Cramp and Bray (2009)	2/160
Duncombe et al (2009)	11/151
Evenson et al (2009)	215/1535
Haakstad et al (2009)	22/467
Halse et al (2015)	5/40
Hausenblas et al (2011)	5/48
Makinde et al (2014)	44/500
Marshall et al (2012)	3/30
Put et al (2015)	186/534
Ribeiro and Milanez (2011)	5/161
Sujindra et al (2015)	66/99



The estimated population proportion is 0.15 (95% CI 0.09 to 0.25)

For meta-analysis of "Lack of time as a perceived barrier to physical activity in pregnancy"

Babbar et al (2015)	74/172
Cramp and Bray (2009)	35/160
Duncombe et al (2009)	36/151
Evenson et al (2009)	384/1535
Haakstad et al (2009)	47/467
Halse et al (2015)	8/40
Leppanen et al (2014)	108/399
Makinde et al (2014)	55/500
Marshall et al (2012)	5/30
Ribeiro et al (2011)	63/161
Sui et al (2013a)	149/464
Sujindra et al (2015)	33/97
Ussher et al (2007)	16/88
Whitaker et al (2016)	112/189

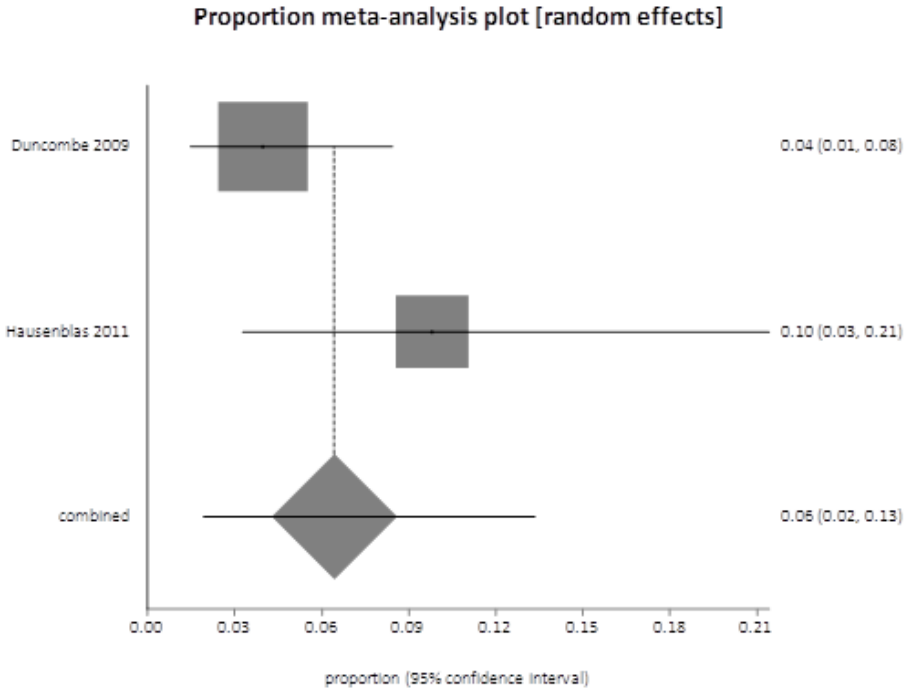


The estimated population proportion is 0.27 (95% CI 0.20 to 0.34)

For meta-analysis of "Lack of knowledge/ understanding as a perceived barrier to physical activity in pregnancy"

Duncombe et al (2009) 6/151

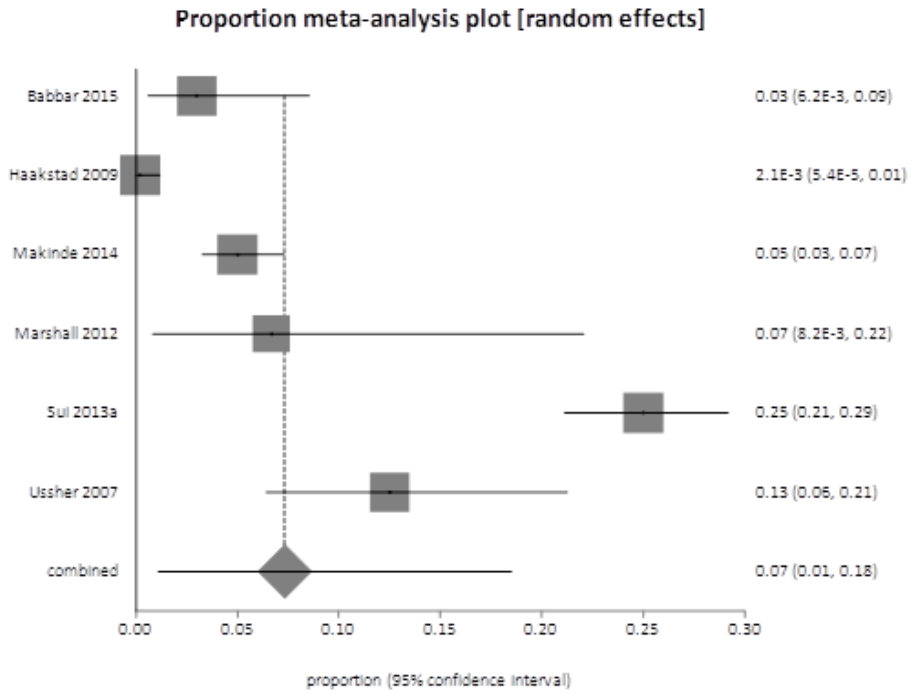
Hausenblas et al (2011) 5/51



The estimated population proportion is 0.06 (95% CI 0.02 to 0.13)

For meta-analysis of "Lack of confidence/PA habit as a perceived barrier to physical activity in pregnancy"

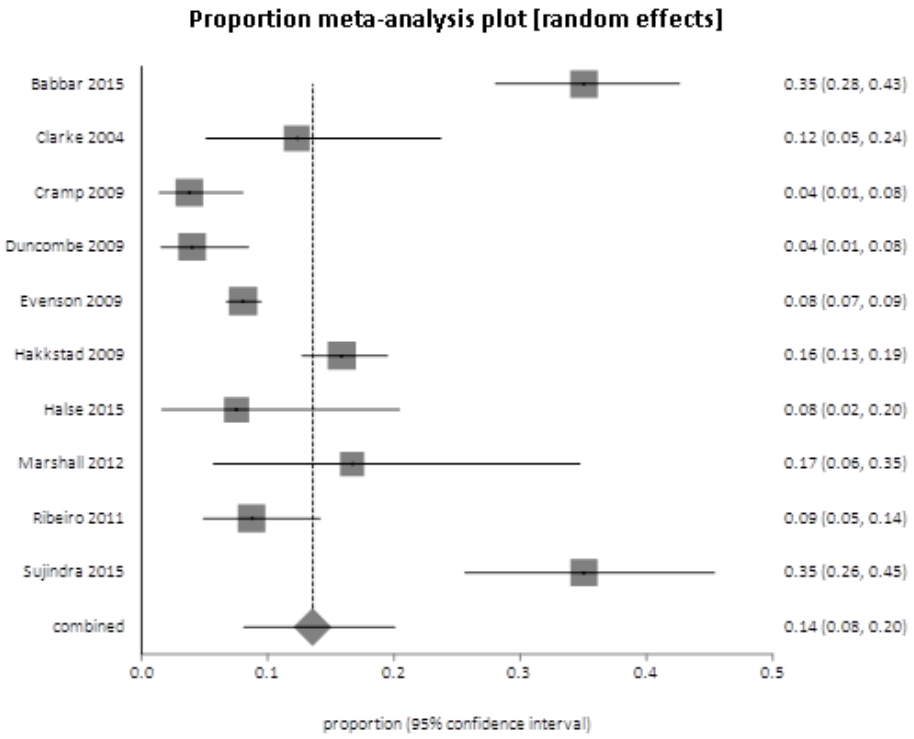
Babbar et al (2015)	3/100
Haakstad et al (2009)	1/467
Makinde et al (2014)	25/500
Marshall et al (2012)	2/30
Sui et al (2013a)	116/464
Ussher et al (2007)	11/88



The estimated population proportion is 0.07 (95% CI 0.01 to 0.18)

For meta-analysis of "Lack of motivation as a perceived barrier to physical activity in pregnancy"

Babbar et al (2015)	61/174
Clarke and Gross (2004)	7/57
Cramp and Bray (2009)	6/160
Duncombe et al (2009)	6/151
Evenson et al (2009)	123/1535
Haakstad et al (2009)	74/467
Halse et al (2015)	3/40
Marshall et al 2012	5/30
Ribeiro et al (2011)	14/161
Sujindra et al (2015)	34/97



The estimated population proportion is 0.14 (95% CI 0.08 to 0.20)

Interpersonal barriers

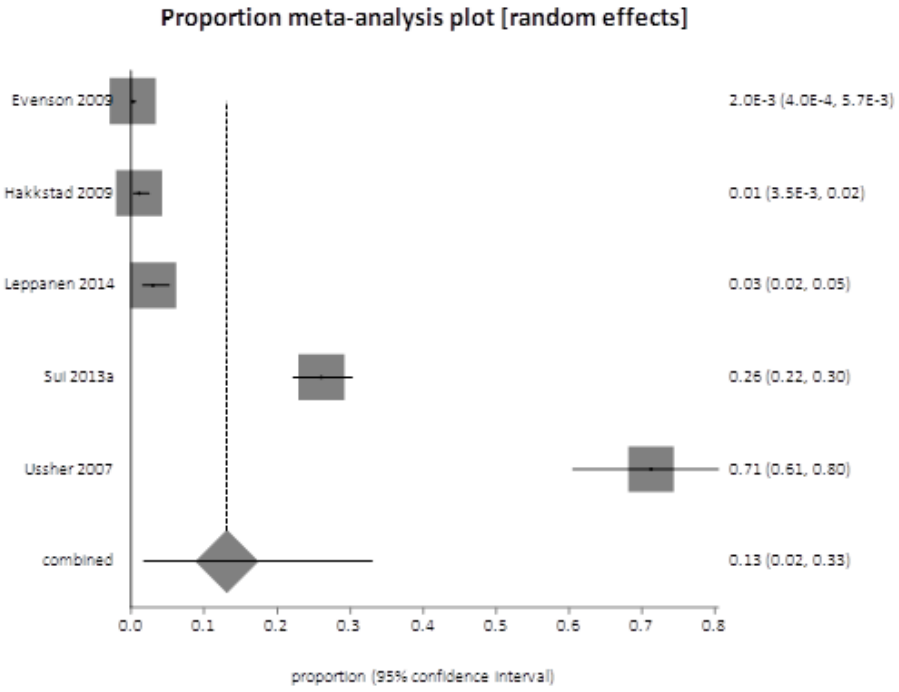
For meta-analysis of "Lack of partner support as a perceived barrier to physical activity in pregnancy"

Leppanen et al (2014) 12/399

The estimated population proportion is 0.03 (95% CI 0.02 to 0.05)

For meta-analysis of "Lack of support family/friends/others as a perceived barrier to physical activity in pregnancy"

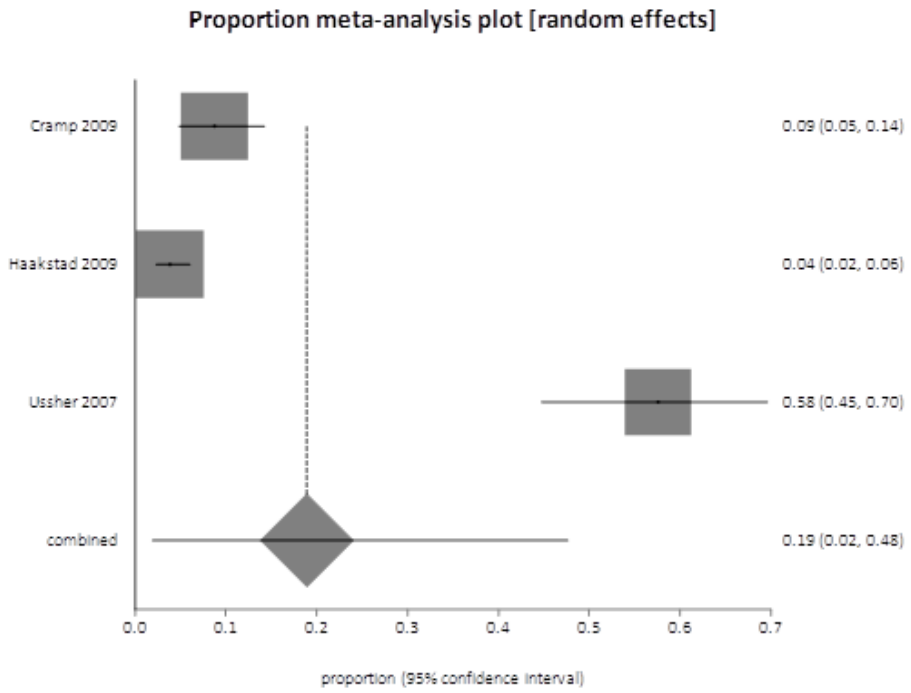
Evenson et al (2009)	3/1535
Haakstad et al (2009)	5/467
Leppanen et al (2014)	12/399
Sui et al (2013a)	121/464
Ussher et al (2007)	62/87



The estimated population proportion is 0.13 (95% CI 0.02 to 0.33)

For meta-analysis of "Work responsibilities as a perceived barrier to physical activity in pregnancy"

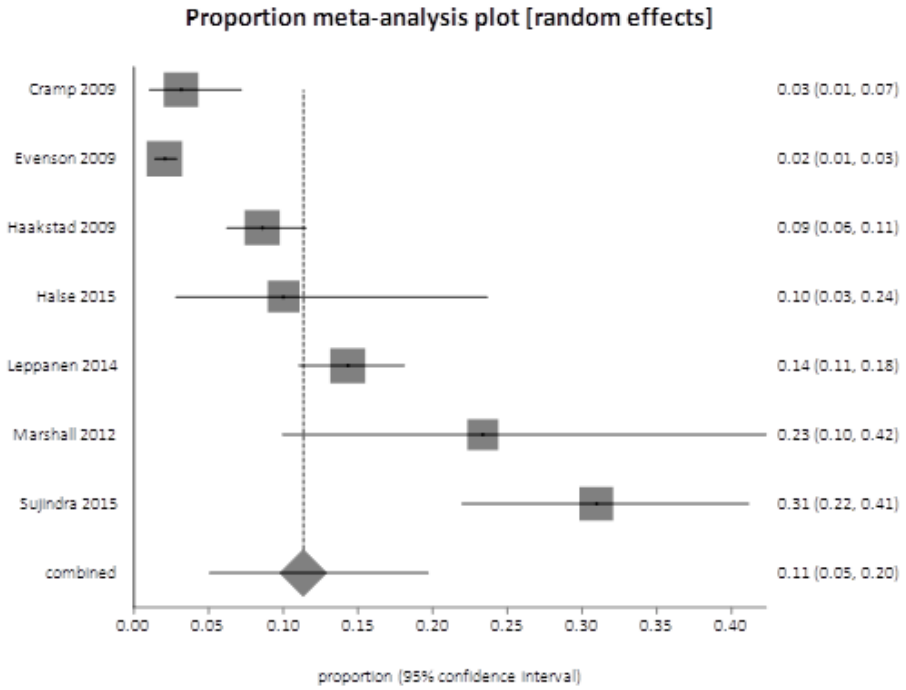
Cramp and Bray (2009)	14/160
Haakstad et al (2009)	18/467
Ussher et al (2007)	38/66



The estimated population proportion is 0.19 (95% CI 0.02 to 0.48)

For meta-analysis of "Child caring responsibilities as a perceived barrier to physical activity in pregnancy"

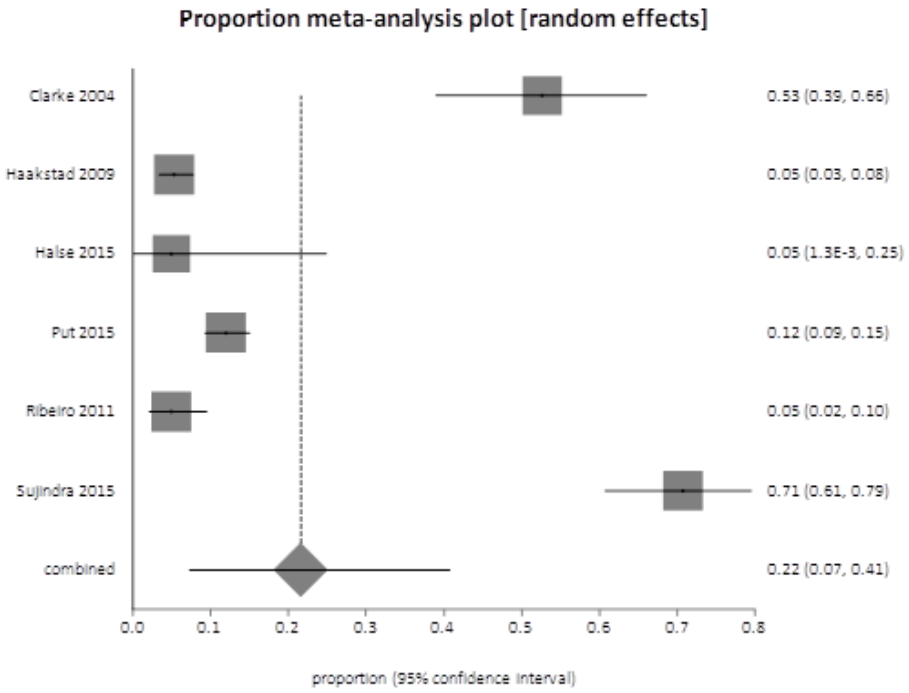
Cramp and Bray (2009)	5/160
Evenson et al (2009)	31/1535
Haakstad et al (2009)	40/467
Halse et al (2015)	4/40
Leppanen et al (2014)	57/399
Marshall et al (2012)	7/30
Sujindra et al (2015)	30/97



The estimated population proportion is 0.11 (95% CI 0.05 to 0.20)

For meta-analysis of "Lack of information/ misleading advice as a perceived barrier to physical activity in pregnancy"

Clarke and Gross (2004)	30/57
Haakstad et al (2009)	25/467
Halse et al (2015)	1/20
Put et al (2015)	64/534
Ribeiro et al (2011)	8/161
Sujindra et al (2015)	70/99

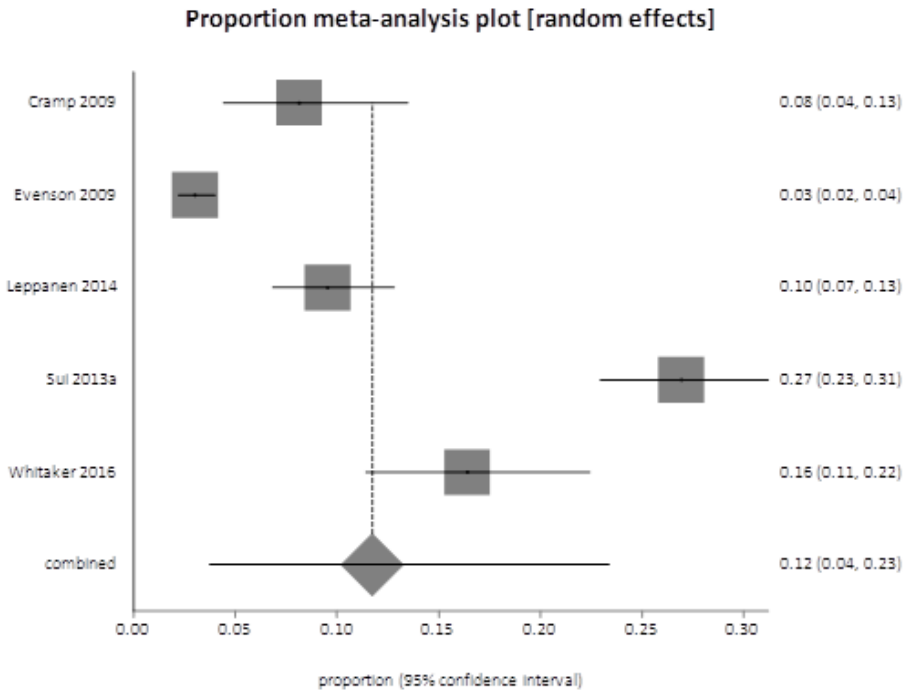


The estimated population proportion is 0.22 (95% CI 0.07 to 0.41)

Environmental/policy/programs barriers

For meta-analysis of "Bad weather as a perceived barrier to physical activity in pregnancy"

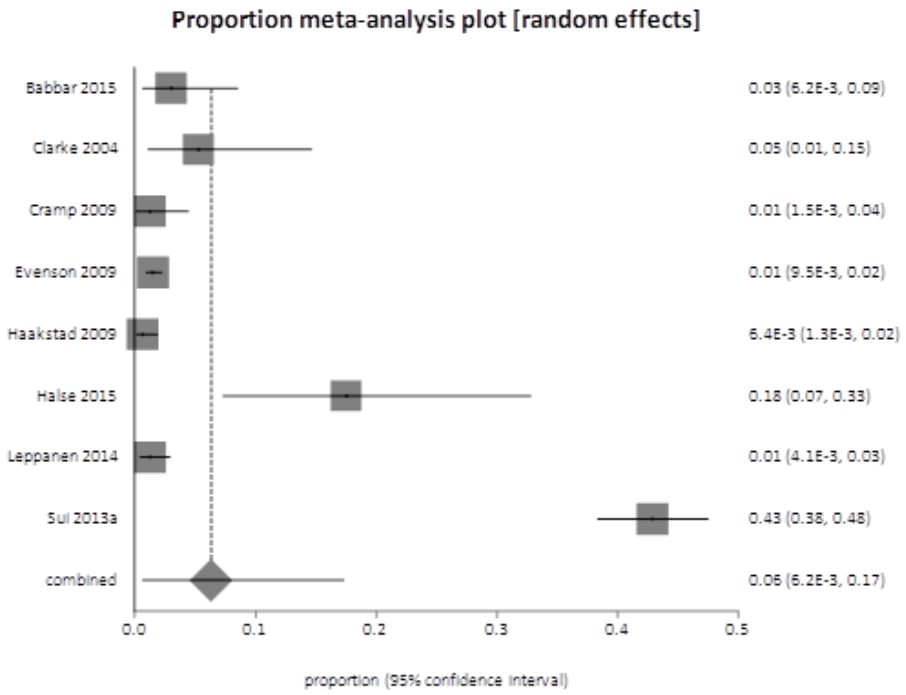
Cramp and Bray (2009)	13/160
Evenson et al (2009)	46/1535
Leppanen et al (2014)	38/399
Sui et al (2013a)	125/464
Whitaker et al 2016	31/189



The estimated population proportion is 0.12 (95% CI 0.04 to 0.23)

For meta-analysis of "lack of access to facilities/affordability as a perceived barrier to physical activity in pregnancy"

Babbar et al (2015)	3/100
Clarke and Gross (2004)	3/57
Cramp and Bray (2009)	2/160
Evenson et al (2009)	23/1535
Haakstad et al (2009)	3/467
Halse et al (2015)	7/40
Leppanen et al (2014)	5/399
Sui et al (2013a)	199/464



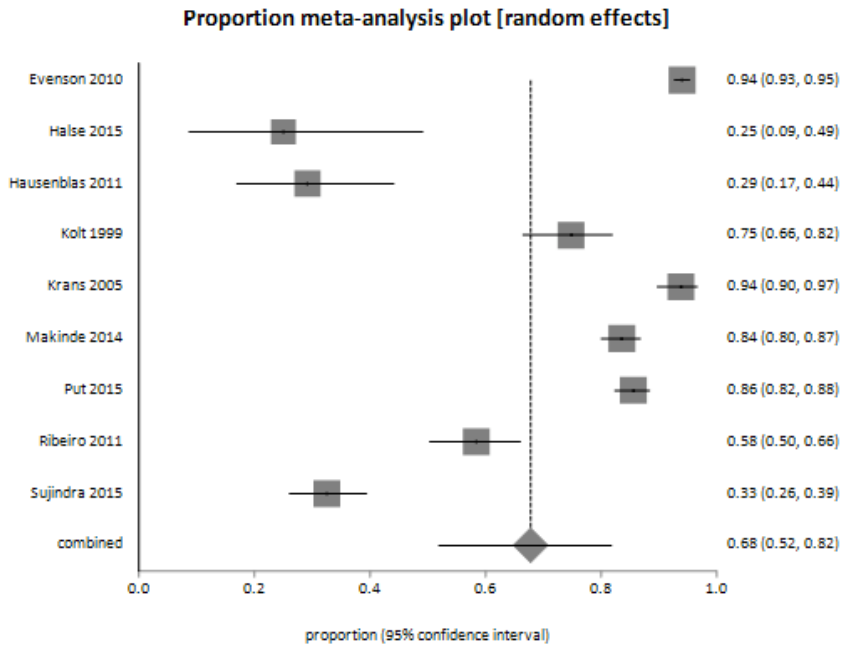
The estimated population proportion is 0.06 (95% CI 0.00 to 0.17)

Pregnant women's perceived enablers to physical activity in pregnancy

Intrapersonal enablers

For meta-analysis of "Helps with labour as a perceived enabler to physical activity in pregnancy"

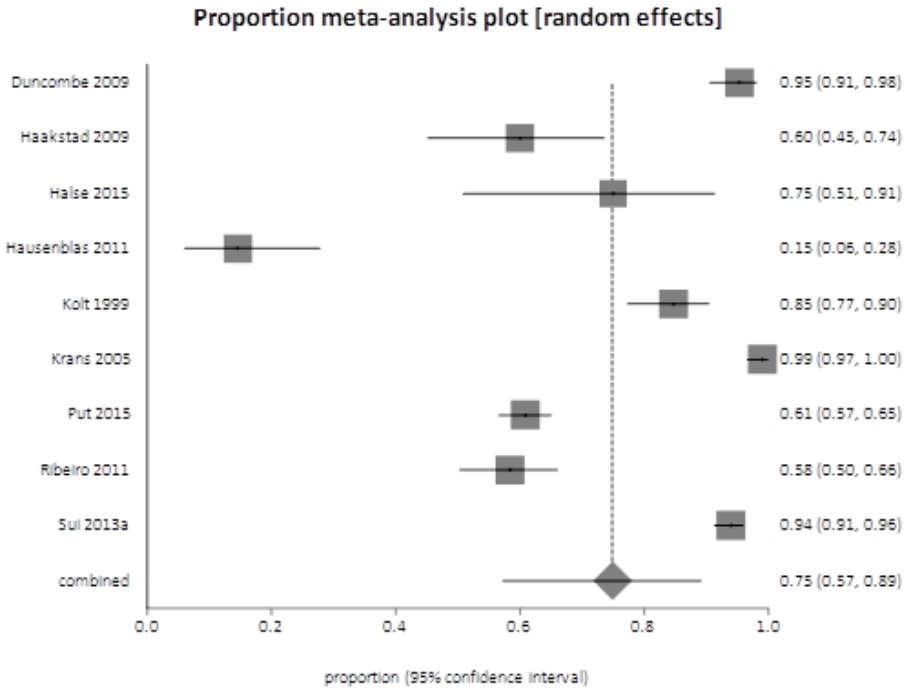
Evenson and Bradley (2010)	1228/1306
Halse et al (2015)	5/20
Hausenblas et al (2011)	14/48
Kolt and Nicoll (1999)	98/131
Krans et al (2005)	198/211
Makinde et al (2014)	418/500
Put et al (2015)	457/534
Ribeiro and Milanez (2011)	94/161
Sujindra et al (2015)	65/200



The estimated population proportion is 0.68 (95% CI 0.52 to 0.82)

For meta-analysis of "Maternal health and wellbeing as a perceived enabler to physical activity in pregnancy"

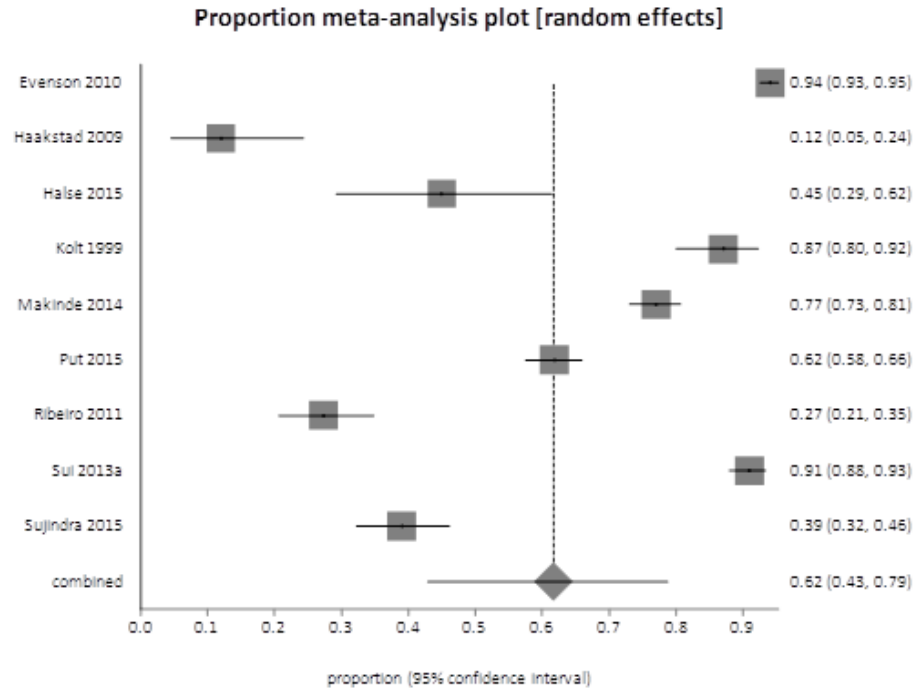
Duncombe et al (2009)	144/151
Haakstad et al (2009)	30/50
Halse et al (2015)	15/20
Hausenblas et al (2011)	7/48
Kolt and Nicoll (1999)	111/131
Krans et al (2005)	209/211
Put et al (2015)	325/534
Ribeiro and Milanez (2011)	94/161
Sui et al (2013a)	436/464



The estimated population proportion is 0.75 (95% CI 0.57 to 0.89)

For meta-analysis of "Easing pregnancy discomforts as a perceived enabler to physical activity in pregnancy"

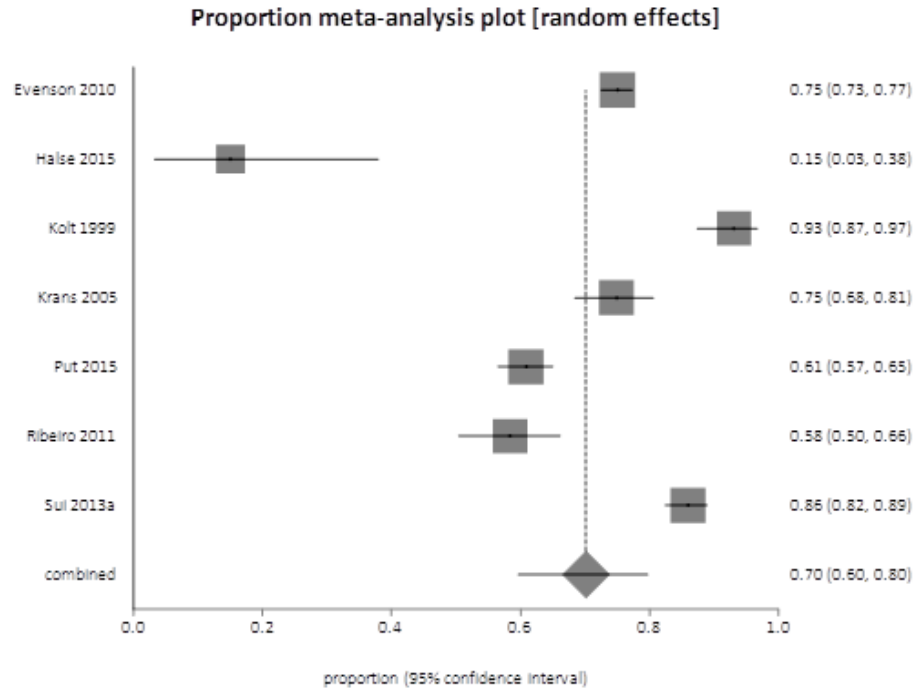
Evenson and Bradley (2010)	1228/1306
Haakstad et al (2009)	6/50
Halse et al (2015)	18/40
Kolt and Nicoll (1999)	114/131
Makinde et al (2014)	385/500
Put et al (2015)	330/534
Ribeiro and Milanez (2011)	44/161
Sui et al (2013a)	422/464
Sujindra et al (2015)	78/200



The estimated population proportion is 0.62 (95% CI 0.43 to 0.79)

For meta-analysis of "Baby's health as a perceived enabler to physical activity in pregnancy"

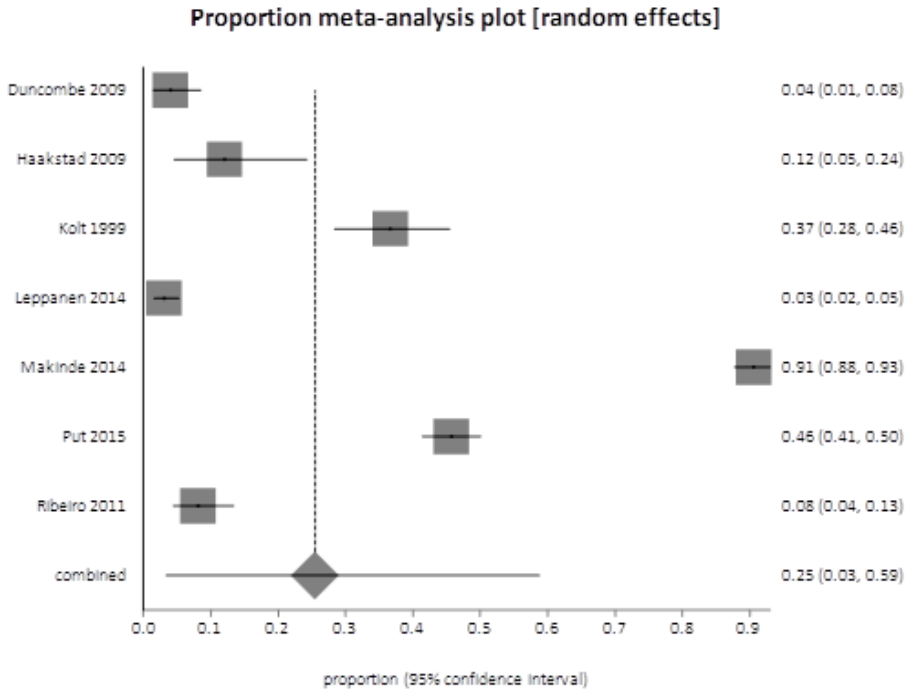
Evenson and Bradley (2010)	980/1306
Halse et al (2015)	3/20
Kolt and Nicoll (1999)	122/131
Krans et al (2005)	158/211
Put et al (2015)	325/534
Ribeiro and Milanez (2011)	94/161
Sui et al (2013a)	399/464



The estimated population proportion is 0.70 (95% CI 0.60 to 0.80)

For meta-analysis of "Weight control as a perceived enabler to physical activity in pregnancy"

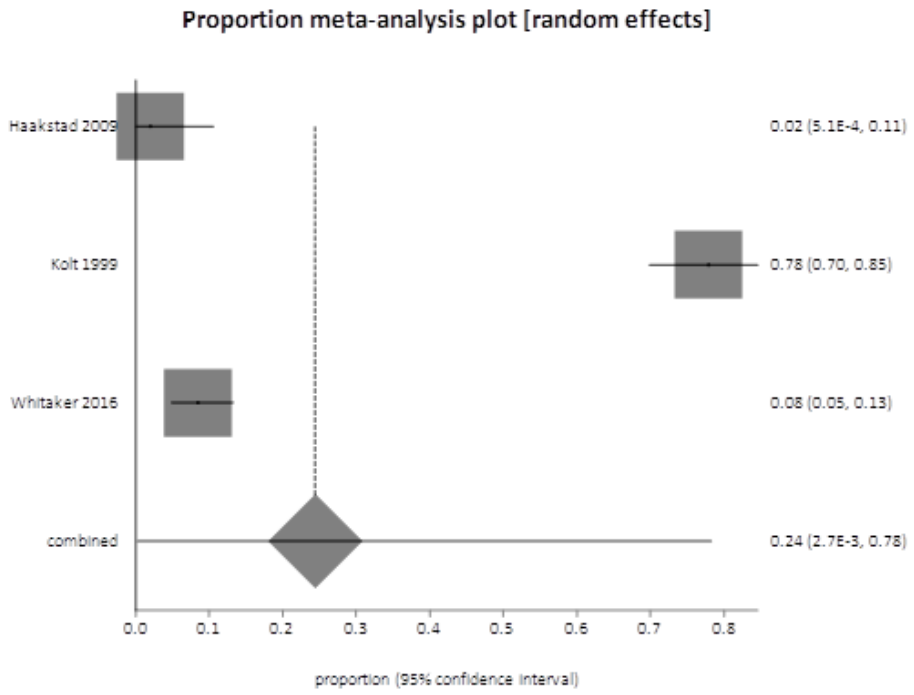
Duncombe et al (2009)	6/151
Haakstad et al (2009)	6/50
Kolt and Nicoll (1999)	48/131
Leppanen et al (2014)	12/399
Makinde et al (2014)	453/500
Put et al (2015)	244/534
Ribeiro and Milanez (2011)	13/161



The estimated population proportion is 0.25 (95% CI 0.03 to 0.59)

For meta-analysis of "Appearance/concerns about body image as a perceived enabler to physical activity in pregnancy"

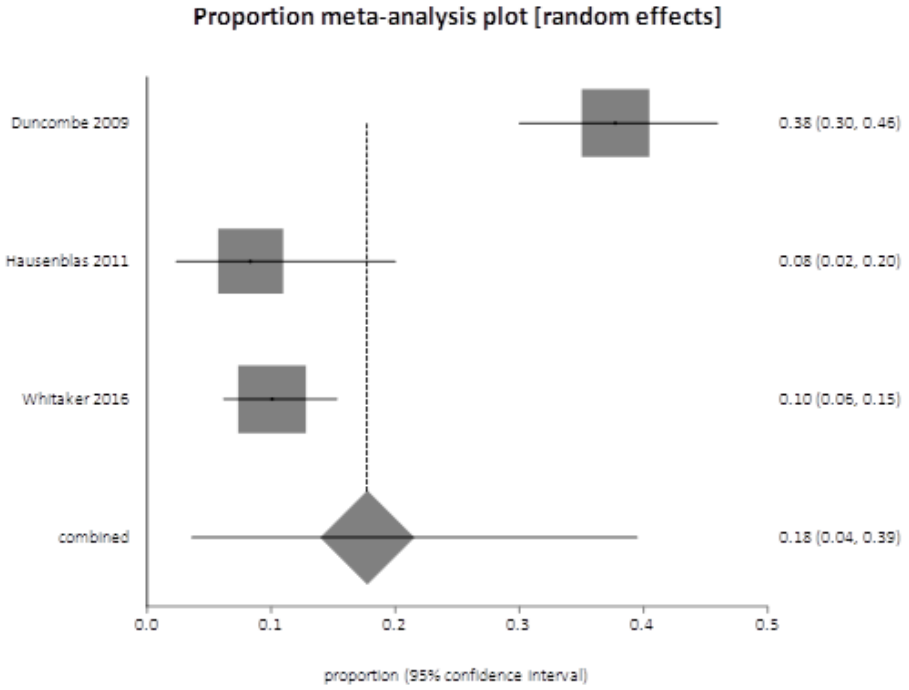
Haakstad et al (2009) 1/50
Kolt and Nicoll (1999) 102/131
Whitaker et al (2016) 16/189



The estimated population proportion is 0.24 (95% CI 0.00 to 0.78)

For meta-analysis of "Confidence to exercise and physical activity habit as a perceived enabler to physical activity in pregnancy"

Duncombe et al (2009) 57/151
Hausenblas et al (2011) 4/48
Whitaker et al (2016) 19/189

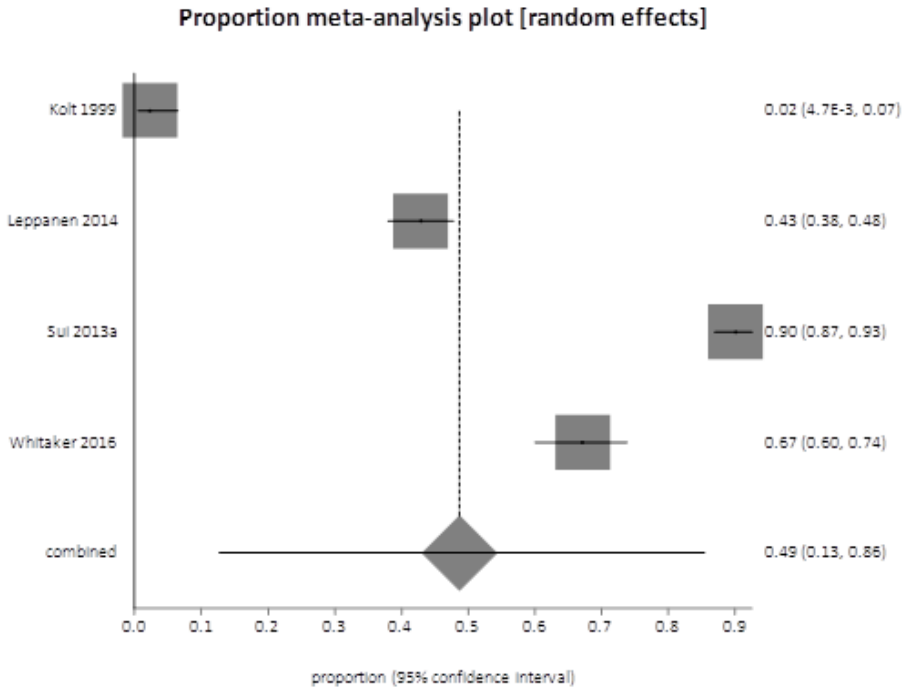


The estimated population proportion is 0.18 (95% CI 0.04 to 0.39)

Interpersonal enablers

For meta-analysis of "Social support from family/friends/company for walks as a perceived enabler to physical activity in pregnancy"

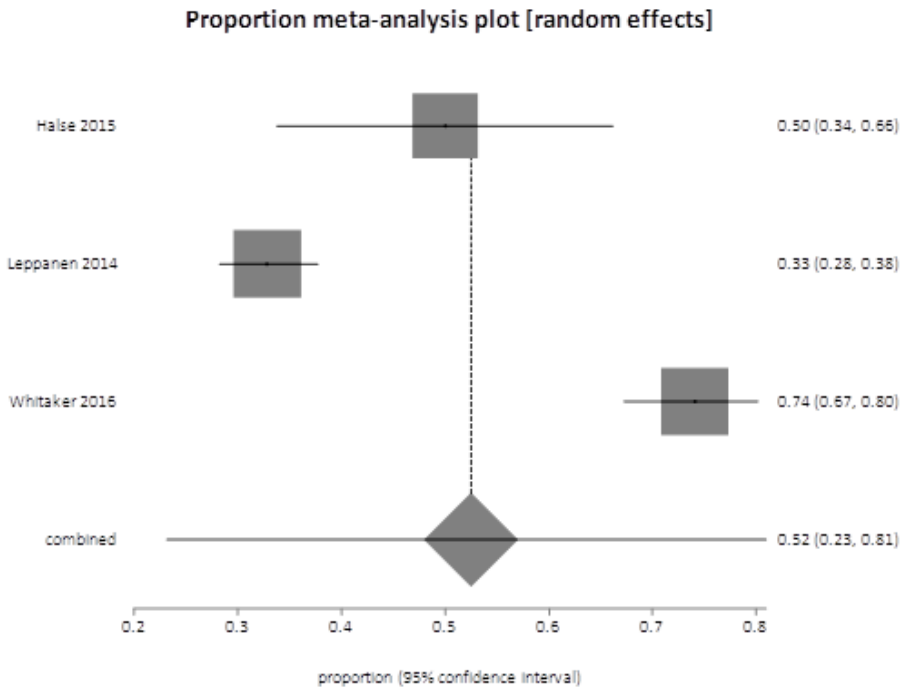
Kolt and Nicoll (1999)	3/131
Leppanen et al (2014)	171/399
Sui et al (2013a)	418/464
Whitaker et al (2016)	127/189



The estimated population proportion is 0.49 (95% CI 0.13 to 0.86)

For meta-analysis of "Social support from partner as a perceived enabler to physical activity in pregnancy"

Halse et al (2015)	20/40
Leppanen et al (2014)	131/399
Whitaker et al (2016)	140/189

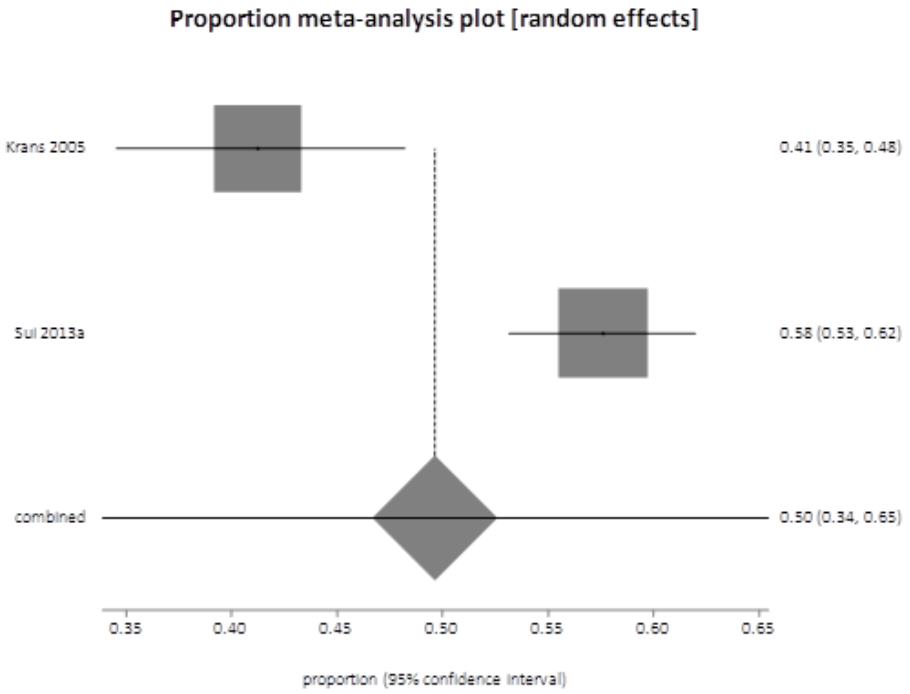


The estimated population proportion is 0.52 (95% CI 0.23 to 0.81)

For meta-analysis of "More information /advice as a perceived enabler to physical activity in pregnancy"

Krans et al (2005) 87/211

Sui et al (2013a) 288/500



The estimated population proportion is 0.50 (95% CI 0.34 to 0.65)

For meta-analysis of "Less responsibilities/more time as a perceived enabler to physical activity in pregnancy"

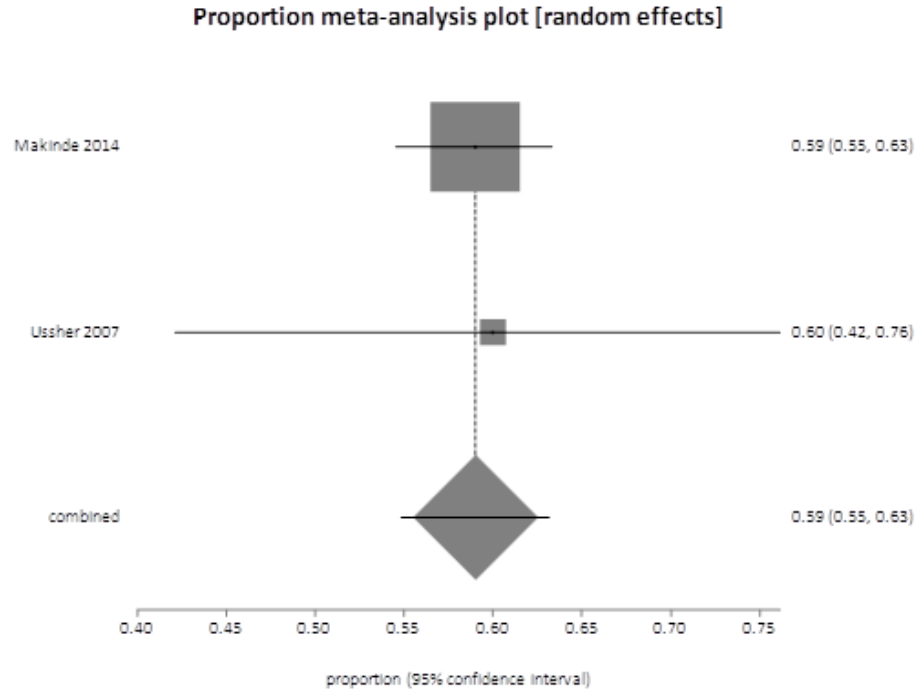
Whitaker et al (2016) 39/189

The estimated population proportion is 0.21 (95% CI 0.15 to 0.27)

Environmental/policy/programs enablers

For meta-analysis of "Pregnancy specific programs as a perceived enabler to physical activity in pregnancy"

Makinde et al (2014) 295/500
Ussher et al (2007) 21/35

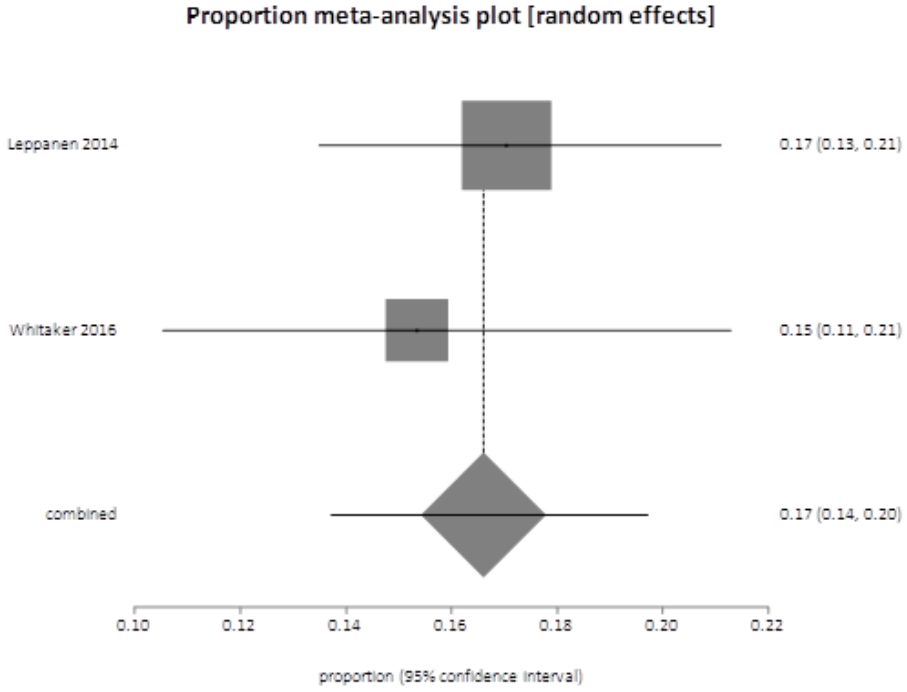


The estimated population proportion is 0.59 (95% CI 0.55 to 0.63)

For meta-analysis of "Access to (affordable) facilities as a perceived enabler to physical activity in pregnancy"

Leppanen et al (2014) 68/399

Whitaker et al (2016) 29/189

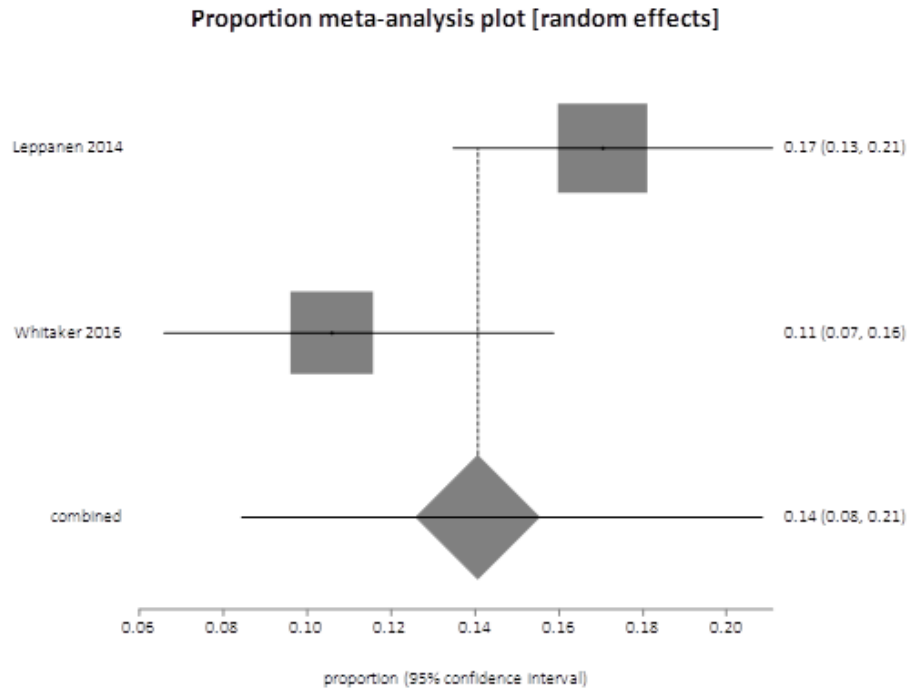


The estimated population proportion is 0.17 (95% CI 0.14 to 0.20)

For meta-analysis of "Good weather as a perceived enabler to physical activity in pregnancy"

Leppanen et al (2014) 68/399

Whitaker et al (2016) 20/189



The estimated population proportion is 0.14 (95% CI 0.08 to 0.21)

Chapter 4:
Women with gestational diabetes want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study

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4.1 Preface

The systematic review reported in Chapter 3 (Harrison et al., 2018) provided evidence pregnant women believe physical activity in pregnancy is important and beneficial. It also found data were lacking on attitudes, barriers and enablers to physical activity for the sub-group of pregnant women with gestational diabetes mellitus.

In Chapter 4, a qualitative study was completed to identify and explore the attitudes of women diagnosed with gestational diabetes mellitus toward physical activity during pregnancy and the perceived barriers to, and enablers of, physical activity during pregnancy for these women.

4.2 Study three

Chapter 4 is presented in its published format as (Harrison, Taylor, Frawley, & Shields, 2019):

Harrison, A. L., Taylor, N. F., Frawley, H. C., & Shields, N. (2019). Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study. *Journal of Physiotherapy*, *65*(1), 37–42.

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Research

Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study

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KEY WORDS

Physical activity
Gestational diabetes
Attitudes
Barriers
Enablers

ABSTRACT

Questions: What are the attitudes of women diagnosed with gestational diabetes mellitus (GDM) towards physical activity during pregnancy? What are the perceived barriers to and enablers of physical activity during pregnancy in women with GDM? **Design**: A qualitative study with phenomenology and interpretative description as theoretical frameworks. **Participants**: Pregnant women experiencing an uncomplicated singleton pregnancy, diagnosed with GDM, and aged 18 to 40 years were recruited using purposive sampling. **Method**: Semi-structured interviews were recorded, transcribed verbatim and returned to participants for member checking. Three researchers independently and thematically analysed the qualitative data using an inductive method. Data were coded and compared, and themes were developed, discussed and defined. Recruitment continued until data saturation. Emergent themes were sent to participants and peer reviewed for confirmation. **Results**: The participants were 27 women, with mean age 32 years (SD 3), mean gestation 30 weeks (SD 5), mean pre-pregnancy body mass index 26 kg/m^2 (SD 5), and born in 10 different countries. The process of communicating information about physical activity (messaging) was the main theme to emerge. Sub-themes included: wanting information about physical activity from credible sources; wanting clear, specific information about safe physical activity during a GDM pregnancy; receiving information at GDM diagnosis because this event triggered women's desire to be more physically active; understanding why physical activity is important to improving outcomes for themselves and their babies; and wanting information about flexible, convenient and practical physical activity options. **Conclusion**: To feel confident and safe about being physically active during pregnancy, women with GDM wanted clear, simple and GDM-specific messages from credible sources. Health professionals can support women with a GDM pregnancy with targeted physical activity messages. **[Harrison AL, Taylor NF, Frawley HC, Shields N (2019) Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study. *Journal of Physiotherapy* 65:37–42]**

Introduction

Physical activity (any movement produced by skeletal muscles that results in energy expenditure)[1] has substantial benefits and minimal risks for pregnant women,[2–16] including those diagnosed with gestational diabetes mellitus (GDM).[3,17–25] The benefits include a reduced risk of excessive weight gain,[6] premature birth,[7] low back pain,[8,9] anxiety and depressive symptoms,[10,11] and improved physical fitness,[3–5] sleep,[12] and health perception.[13] Physical activity also assists glycaemic control in pregnant women with GDM.[17,20] Given these substantial benefits, guidelines recommend that pregnant women, including those with GDM, participate in physical activity.[2,15,16,22]

GDM is defined as glucose intolerance of variable severity that occurs during pregnancy.[26,27] It is a common complication of pregnancy, with reports of its incidence ranging from 3.5 to 12%.[18,19] The risks associated with GDM include maternal hypertension and pre-eclampsia,[27] birth trauma from macrosomia for the baby,[18,28] and a longer-term risk of developing type 2 diabetes in both mother[27–29] and baby.[30,31] GDM is diagnosed through routine pregnancy oral glucose tolerance testing.[27] Usual management comprises diet therapy, self-monitoring of blood glucose levels, and insulin as required.[18,19,28]

Physical activity is recommended for women with GDM because it improves glycaemic control,[17,20] which is a critical factor in reducing the associated risks for the mother and her baby. When performed at a moderate intensity for 30 minutes on most days of the week, physical activity is a safe and effective adjunctive intervention for GDM.[16,19–25,32] However, more than 60% of women with GDM do not participate in physical activity as recommended.[33] Therefore, to help

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design appropriate interventions to improve engagement in physical activity, it is important to understand the factors influencing physical activity participation in these women.

A diagnosis of GDM introduces additional complexity to the pregnancy, due to the associated risks and requirement for active management. Experiencing complications during pregnancy, such as GDM, may influence women's attitudes to physical activity. It might present additional barriers to physical activity (eg, heightened perception of risk) or enablers to physical activity (eg, more frequent contact with health professionals providing advice about being physically active), compared with women experiencing an uncomplicated pregnancy. Few studies have explored the attitudes and perceptions of pregnant women with GDM to physical activity. A recent systematic review[34] found only three qualitative studies that explored[35–37] barriers and enablers to physical activity for pregnant women with GDM. None of these studies reported data about attitudes to physical activity in women with GDM. Safety, lack of time and pregnancy symptoms, including tiredness,[35–37] were reported as barriers; and benefits for the baby's health and social support were described as enablers to physical activity.[35,36] Two studies included women predominantly of Asian ethnicity[35,36] who were attending a clinic servicing a socially disadvantaged area.[36] The third study[37] had a very small sample size of five participants. These features suggest that the available data may have limited generalisability. To improve participation in physical activity in women with GDM, more data are needed to help clinicians better understand the attitudes of these women to physical activity during pregnancy, the reasons why they do not engage in physical activity, and enablers that could be harnessed. This information could be used to develop GDM-specific physical activity interventions that are relevant, realistic and acceptable to women with GDM and thereby help facilitate behaviour change and participation in this specific group.

Therefore, the research questions for this study were:

1. What are the attitudes of women diagnosed with GDM towards physical activity during pregnancy?
2. What are the perceived barriers to and enablers of physical activity during pregnancy in women with GDM?

Box 1. Eligibility criteria.

Inclusion criteria

- Women diagnosed with gestational diabetes mellitus
- Aged 18 to 40 years [a]
- Singleton pregnancy and a normal 18-week ultrasound scan [b]
- Able to express their thoughts in English

Exclusion criteria

- Women considered to have a high-risk pregnancy [c]
- Women with conditions affecting their ability to participate in physical activity

[a] Old enough to legally provide informed consent and because pregnant women aged > 40 years are generally considered as having higher risk pregnancies.[45]
[b] As considered to be lower risk, therefore able to exercise without restriction.
[c] Risk of premature labour, incompetent cervix, persistent bleeding, ruptured membranes, growth retardation, preeclampsia, severe anaemia, placenta previa after 26 weeks' gestation, haemodynamically significant heart disease or restrictive lung disease.[2,15]

Methods

Theoretical framework

Understanding women's attitudes and perceptions of barriers and enablers to physical activity in pregnancy is well suited to a qualitative method of enquiry. A phenomenological approach aims to explore lived experiences to help understand how people make sense of the world in which they live,[38] and provides a deeper understanding that may not be revealed through ranked responses.[39,40] An interpretative description theoretical framework[41] enables an understanding of the phenomena from a clinical perspective facilitating application of findings to clinical practice.[42] These frameworks were applied in the current study to gain a deeper understanding of the perceptions of women diagnosed with GDM about physical activity and to help facilitate translation of the findings into practice.

Participants were interviewed following screening to confirm eligibility and receipt of written informed consent. The study was reported according to the Consolidated Criteria for Reporting Qualitative studies (COREQ) checklist[43] and the Standards for Reporting Qualitative Research (SREQ).[44]

Participants

Pregnant women diagnosed with GDM, who met the eligibility criteria (Box 1), were recruited from antenatal clinics at two hospitals in Melbourne, Australia: one tertiary maternity hospital servicing north-east Melbourne and a general hospital in western Melbourne. Purposive sampling[46] was used to select participants from diverse backgrounds to improve transferability of findings. Guided by previous studies in similar populations,[47–50] in which saturation was achieved within 15 to 26 interviews, a sample of between 24 and 30 participants was expected to be sufficient to achieve data saturation. Data saturation occurs when no new data are obtained from subsequent interviews with new participants. In this study, sampling continued until data saturation.[51]

Data collection

Participant demographics

The following demographic details were obtained from each participant's hospital record: age, gestation, parity, body mass index, educational level completed, and country of birth. During the interview, information about each participant's pre-pregnancy physical activity levels was collected (see interview guide, Appendix 1 on the eAddenda).

Interviews

Semi-structured interviews were conducted face to face or by telephone, according to participant preference. The interviewer (AH) was a physiotherapist employed by the hospitals, with interview experience, and who was not involved in the clinical management of the participants. The other researchers (HF, NT, NS) were physiotherapists employed at universities with no connection to any participant. An interview guide (Appendix 1 on the eAddenda) of open-ended questions was used to cover key topics while encouraging women to share their experiences. Data collection and analysis were completed concurrently so findings from early interviews informed later interviews, enabling in-depth exploration of evolving themes.

Interviews were digitally audio-recorded and observations noted. Audio-recordings were transcribed verbatim, checked, and then sent to the participant to provide feedback. Each participant was assigned a pseudonym to ensure anonymity.

Data analysis

Data analysis followed an inductive thematic analysis method.[52,53] One researcher (AH) entered the transcripts into NVivo[a], a data management software program. Transcripts were independently analysed and coded by two researchers (AH and NS or HF) to improve reliability of the analysis. Initially, transcripts were read through in their entirety several times to gain a broad sense of the data. Transcripts were reviewed line by line, using an inductive approach. Each idea or concept emerging from the data was coded and descriptive memos written to explain and record the researchers' thoughts and interpretations. The coding phase was iterative, with several levels of analysis occurring as data were coded and constantly compared, and

themes and sub-themes were developed, discussed and defined. Three researchers (AH, NS and HF) then met to compare their independently identified codes, identify and discuss similarities and differences, and agree on the key emergent themes and sub-themes. To check accuracy, completeness and representativeness of the agreed themes, one researcher (AH) then re-read the transcripts and cross-checked with the data coded in NVivo[a]. Following this, a fourth researcher (NT) read transcripts and independently reviewed the coding and themes to ensure that data and nuances had been accurately interpreted and the context of the data was intact.

Participant demographic data were described using means and standard deviations (age, gestation, parity) or proportions (educational level, ethnicity). Pre-pregnancy activity level was determined according to whether the participant met physical activity recommendations of ≥150 minutes of at least moderate-intensity physical activity per week (active) or not (not very active).

As qualitative research involves immersion in the research process, it is recognised that completely avoiding personal bias is difficult. Therefore, information about the research team has been provided above to enhance reflexivity and credibility.[44,54]

To enhance methodological rigour, detailed patient demographic data were reported so that relevance to other situations could be considered (transferability) and the process of data collection and analysis was recorded in detail (dependability). Member checking of transcripts and key emergent themes was completed to ensure that they accurately reflected the participants' lived experiences,[39] which enhanced confirmability. Confirmability was also improved by having the themes generated by the data analysis peer reviewed by a diabetes educator and a dietitian to check the clinical applicability of the interpretation. Verbatim quotations from participants have also been reported, linking the data to generated themes (confirmability). To address trustworthiness,[55] an audit trail was kept, analysis was augmented by keeping interpretive memos, an iterative process was followed involving independent coding and inter-coder comparison and discussion, and checking by an independent researcher.

Results

Participants

Twenty-nine women consented to participate and 27 completed an interview (Table 1). One withdrew as she was too busy and another did not attend for interview nor respond to a reminder email. The women who participated were born in 10 different countries and represented a range of ages, parity, gestational stages, pre-pregnancy body mass index, and educational backgrounds (Table 2 on the eAddenda). The interviews were 30 to 45 minutes in duration. Data saturation was achieved by the 25th interview and was confirmed when two subsequent interviews found no new data.

Table 1
Characteristics of participants (n = 27).

Characteristic	Participants (n = 27)
Age *(years)*, mean (SD) range	32 (3) 26 to 38
Gestation *(weeks)*, mean (SD) range	30 (5) 20 to 37
Pre-pregnancy BMI *(kg/m²)*, mean (SD) range	26 (5) 19 to 38
Parity, n (%)	
primiparous	12 (44%)
multiparous	15 (56%)
GDM in previous pregnancy, n (%)	4 (15%)
Pre-pregnancy activity level, n (%) [a]	
active	16 (59%)
not very active	11 (41%)
Educational level, n (%)	
≤ high school	6 (22%)
> high school	21 (78%)
Country of birth, n (%)	
Australia	9 (33%)
Asia	17 (63%)
other	1 (4%)

BMI = body mass index, GDM = gestational diabetes mellitus.
[a] Women who met the physical activity guidelines were classified as active, whereas those who did less than the physical activity guidelines were classified as not very active.

Themes

The central theme that emerged was the process of communication of information (messaging) about physical activity specifically for a pregnancy complicated by GDM. The sub-themes that emerged related to practical aspects of messaging. The women reported that the shock of being diagnosed with GDM and their subsequent concerns for their health and pregnancy motivated them to 'be healthier', including being more physically active. They described needing information about physical activity from a credible source (such as a health professional) that was easy to understand, and clearly explained what type and how much physical activity was safe and relevant for their GDM pregnancy. Participants also described needing information to explain why physical activity was important for their pregnancy, especially for the baby, which was a strong motivator for them to be physically active. They talked about needing information that provided flexible, convenient, practical options to be physically active that could be tailored to meet their individual needs and fit in with their busy lifestyles (Box 2).

GDM diagnosis triggered women's desire to be more physically active

Women with GDM reported needing information about physical activity when they were first diagnosed. They described feeling 'shocked', 'upset' and 'guilty' when diagnosed with GDM. They reported that the diagnosis of GDM made them stop and think about the need to be healthier. Their sense of concern about their diagnosis and feelings of guilt that it might be their 'fault' that they developed GDM and that it might affect the health of the baby triggered in them the desire to be more active to help manage their blood sugar levels and improve the outcomes for themselves and particularly for their babies.

> *Shocked, disappointed, very disappointed, a bit worried about what it would mean for my baby and my birth. And pretty disappointed that I had a high risk of getting type 2 diabetes later on and my baby has the high risk as well.* (Participant 8)

Women wanted information from credible sources

Participants said they needed information about physical activity during a GDM pregnancy to come from a credible source such

Box 2. Central theme and sub-themes arising from the study.

Central theme	Sub-themes
Messaging to women with GDM about physical activity	The GDM diagnosis triggered women's desire to be more physically active.
	Women wanted information from credible sources.
	Women wanted clear, specific information about safe physical activity during a GDM pregnancy.
	Women wanted to understand why physical activity was important for improving outcomes for themselves and their babies.
	Women wanted information about flexible, convenient and practical physical activity options.

GDM = gestational diabetes mellitus.

as a health professional. Some women said there was 'lots of information out there' about physical activity in pregnancy and that they sourced this information from family, friends and the Internet. However, they expressed a lack of confidence in available information as it was often inconsistent and they were uncertain of its applicability to their GDM pregnancy, particularly in terms of safety. Women described experiencing negative cultural influences toward physical activity in pregnancy from family members but reported that they placed more emphasis on information provided by a health professional.

One says it's a great idea, someone else says it's not, which is why I'll often ask a doctor, a midwife, a physio, rather than a gym person who's done a six-month course. (Participant 12)

My aunties, they're very traditional, they go … and my mum, she goes you shouldn't be doing this, you shouldn't be doing that … For me I just follow what the doctor said. If it's fine, it's fine. I'll just do that. (Participant 11)

Women wanted clear, specific information about safe physical activity during a GDM pregnancy

Although all participants expressed the attitude that physical activity during pregnancy was important and beneficial, they felt uncertain about the specific details of what and how much physical activity was relevant and safe for them. The participants described how they learnt about reducing 'carbs' or 'sugary foods' to help control their blood sugar levels at a GDM group education session, but reported receiving little information about the role of physical activity in managing GDM, except 'to walk after meals' to help their blood sugar levels, or for general health and wellbeing. They talked about being unsure whether they needed to walk after every meal or just occasionally, how long they needed to walk for and at what intensity.

I think exercise is critical, it's so important. (Participant 4)

There's all these stuff about eating well and stuff but I don't think there's anything about exercise. I don't think it's stressed enough as eating … it's not as emphasised by everyone. (Participant 18)

Women with GDM said they wanted clear, 'simple' information about what type and how much physical activity was safe and beneficial for their pregnancy. In particular, they said they wanted information about improving outcomes for themselves and their babies.

I think that the information [about physical activity] just needs to be simpler and more black and white. Really simple … you need to do this minimum amount, you know, put down the minimum and make it really, really simple. (Participant 12)

Women wanted to understand why physical activity was important to improving outcomes for themselves and their babies

The women talked about why they wanted to know about the importance of physical activity. They wanted to understand the risks and complications (both short-term and long-term) for themselves and especially their babies if they did not exercise and/or did not manage their GDM. They said knowing the risks, which they felt concerned and 'scared' about, motivated them sufficiently to overcome their pregnancy tiredness and to find time to increase their physical activity.

I just think about the baby and try and work it out … I'll just suck it up and do what I have to do just to have a healthy baby. (Participant 11)

It was the baby that's the most motivating for me to be more active. (Participant 7)

Women wanted information about flexible, convenient and practical physical activity options

Participants described wanting physical activity options that were convenient and suited their individual preferences, such as physical activity that could be performed individually or with others, at home or at a specified location, and at a time to fit in with their lifestyle. Walking was the most common and preferred form of physical activity. They felt that walking was a 'very safe' and convenient exercise, and that it helped them to overcome their pregnancy fatigue and discomforts. Social support was a factor the women described as important in helping them to be active. This was either direct support, such as encouragement to do physical activity and/or company while doing exercise from someone (partner, family, child or friend) saying it made the exercise more 'enjoyable' and made the 'time pass more quickly', or indirect, such as support through minding other children so that they could go out and exercise.

I exercise in my house. I don't go out because sometimes it's too cold, sometimes wet. Being my son only 2 years old, I feel too hard, so after dinner I walk [inside]. (Participant 21)

Discussion

Women diagnosed with GDM believed that physical activity during pregnancy was beneficial and important, but they were concerned about safety. They expressed their need for clear, specific information about physical activity (messaging) relevant to their GDM pregnancy that was delivered by a credible source so they would feel confident being active. They wanted information that explained why physical activity was relevant and important to GDM pregnancy outcomes, especially for the baby, and about flexible physical activity options that could be tailored to fit in with their personal preferences and busy lifestyles. The women also identified the importance of social support as an enabler to participation. These findings are consistent with the findings from a recent systematic review about exercise in pregnancy generally,[34] and extend those findings by identifying the attitudes toward physical activity of women with GDM specifically. These findings also add to the understanding of the factors influencing physical activity participation in women with GDM, by identifying the need for specific messaging, including what information women require, and reinforcing the importance of the baby as a key motivator.

Our findings suggest that the general message about physical activity for health and wellbeing in uncomplicated pregnancies had been received because all participants expressed the attitude that physical activity during pregnancy was important and beneficial. This is important because attitude influences intention to action (physical activity).[56–59] However, the diagnosis of GDM also triggered concerns about the safety of physical activity. Combined with uncertainty about what type and how much physical activity was safe in a GDM pregnancy, this appeared to create a disconnection between the women's intentions and their actions (a knowledge-to-action gap).[60] As proposed by the Theory of Planned Behaviour,[61] factors additional to attitudes that hinder or enable behaviour may also influence intention and subsequent action.[61,62] Inconsistency in information, specifically about physical activity for a GDM pregnancy and the lack of confidence in sources such as the Internet, were barriers hindering the women's participation in physical activity. Translating this into practice, clinicians may direct their efforts into focusing on overcoming these barriers to physical activity by harnessing what women with GDM identified as enablers (eg, improving messaging to facilitate a shift from intention to action) to improve participation in physical activity for pregnant women with GDM.

Health professionals such as physiotherapists are well qualified to provide messaging about physical activity recommendations to

facilitate more effective transfer of information from guidelines into practice, thereby assisting in bridging the apparent evidence-to-practice gap.[60] Clinical guidelines for GDM management[22,28,32] recommend a moderate exercise program[28] aiming for 30 minutes of exercise at least 5 days a week,[22,32] for example walking for 30 minutes after a meal to improve glycaemic control.[22] High-level evidence from a systematic review[20] supports these guidelines, finding that exercise as an adjunct to standard GDM care is beneficial in glycaemic control in women diagnosed with GDM.[17,20–22] However, the women's uncertainty about what and how much exercise was safe specifically for their GDM pregnancy suggests that in practice the information from these guidelines is not reaching women with GDM. As primary GDM healthcare providers, doctors, midwives, diabetes educators and dietitians appropriately focus on medical care and diet therapy; health professionals such as physiotherapists are needed to provide the necessary focus on exercise. Physiotherapists can translate clinical guidelines about physical activity in GDM into information resources with clear, simple and GDM-specific physical activity messages appropriate to women's needs. This information about physical activity for GDM needs to include why women with GDM need to exercise, and the importance for glycaemic control, health and wellbeing. It also needs to provide specific details about safe and appropriate physical activity interventions suitable for GDM, including dosage and considerations for the stage of pregnancy, any co-existing musculoskeletal limitations, and physical activity preferences.

Consistent with two qualitative studies of women with GDM,[35,36] concern for the health and wellbeing of the baby was a powerful influencing factor and a key motivator. This knowledge could be applied by health professionals with skills in exercise prescription and behaviour change, to encourage women's participation in physical activity during pregnancy. Key drivers to be physically active were both positive and negative and related to health outcomes for the mother but particularly her concern for the baby. Drivers were: wanting to avoid a caesarean section, pregnancy complications and insulin injections; risk to the baby at birth from macrosomia; and the risk to both mother and baby of developing diabetes in the future. However, of all of these factors, the key motivating factor for these women during their GDM pregnancy was minimising risks to the baby's health now and in the future. This study focused on physical activity during a GDM pregnancy; however, the knowledge that the baby's health was the women's strong overriding motivator could be harnessed by clinicians in both pregnancy and postnatally. Women may be motivated to stay physically active for their own health and wellbeing in the longer-term if messaging also emphasises the importance of staying active and healthy to look after the baby throughout its childhood and adolescence.

As reported in other studies, the diagnosis of GDM shocks women[35,36,63] and appears to be a trigger that makes them re-prioritise their health and lifestyle. However, the role of physical activity was not explicit in the GDM education sessions they received. There is a potential window of opportunity at diagnosis for health professionals (credible sources) to provide the information women reported needing about physical activity for their GDM pregnancy. The time period immediately after diagnosis was 'a teachable moment' when health professionals could message the benefits of physical activity at a time when women with GDM are very receptive to hear and act on those messages. Providing targeted physical activity messages to women with GDM at this time may help bridge the physical activity knowledge-to-action gap.

Strengths of this study were the diversity and detailed accounts of participant demographics, continuation of recruitment until data saturation, and the rigour of the qualitative process. This enhances the confirmability, trustworthiness, and transferability of findings to similar populations. Recruitment of only English-speaking women may have influenced findings and was a limitation but, despite this eligibility criterion, a range of ethnicities were represented, as seen in the breadth of birth countries (Table 2 on the eAddenda). The ethnicity of participants did not, however, include participants from African-American or Hispanic backgrounds, which limits the generalisability of the findings to those populations.

Although clinical practice guidelines for physical activity in pregnancy are available, they are not explicitly conveyed to women with GDM at or soon after the time of diagnosis. Women with GDM described needing physical activity messages specific for their pregnancies complicated by GDM to be clear, simple, consistent information from a credible source, such as health professionals. They also wanted messages about physical activity to be explicit about what and how much they need to participate in specifically during their GDM pregnancy for their health and the health of the baby.

What is already known on this topic: Physical activity is recommended for women with uncomplicated pregnancies, including those with GDM. Despite recommendations to be active, many pregnant women with GDM are inactive. Data are lacking on attitudes, barriers and facilitators to physical activity for the group of pregnant women diagnosed with GDM who are at risk from inactivity.

What this study adds: Women with GDM want clear, simple, GDM-specific physical activity messages directly related to pregnancy outcomes that are delivered by a credible source with flexible options so physical activity can be tailored to fit in with their lifestyles. They also want messages to be explicit about what and how much physical activity they need to participate in during their GDM pregnancy for themselves and especially for the health of the baby, which is a strong motivator.

Footnotes: [a] NVivo 11. Version 11 2015. QSR International Pty Ltd.

eAddenda: Appendix 1 and Table 2 can be found online at DOI: https://doi.org/10.1016/j.jphys.2018.11.007.

Ethics approval: The study was approved by the Mercy Health and La Trobe University Human Ethics Committees. All participants provided written informed consent.

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4.3 Study three – Supplementary material included on Journal of Physiotherapy e-Addenda

Semi-structured interview question guide (appendix 1 on Journal of Physiotherapy e-Addenda).

Semi-structured interview question guide

Some questions were used to ensure coverage of the key aspects and enable comparability. However, there was also flexibility to encourage the woman to openly describe her perceptions, attitudes and to share her personal stories and experiences.

Question guide:

1. How are you feeling today?
   If needed prompt - How would you describe your mood? (This conveys the interviewer's interest in the participant. Also important as mood can influence the participant's responses and this should be noted.)
2. Tell me about how much you exercised before you became pregnant?
   If needed prompt – What type of exercise, how regularly?
3. How recently did you find out that you had gestational diabetes?
   If needed prompt - How do you feel about this?
4. Tell me what you think about women in general exercising during pregnancy?
   If needed prompt – Do you feel you have enough information or understand the information? Do you feel exercise for pregnant women generally is important? What do you think are the benefits? Do you feel exercising in pregnancy is safe for the baby?
5. Tell me what **you** think of exercising in pregnancy?
   If needed prompt - Has this changed since you found out you had GDM? If so, what do you think now? If not, why not?
6. Please tell me about things that have stopped you from exercising now that you know you have GDM?
   If needed prompt - Can you describe anything else that you feel makes it difficult for you to exercise at the moment? If needed, for example lack of time, feeling tired, pain, musculoskeletal problems, pelvic

floor/continence problems, being afraid, advice from others (and if so who?), cultural influences/beliefs.

7. I'm interested in hearing what you think are the things that make it easier for you to exercise?

   If needed prompt - Can you describe anything else that you feel would make it easier to exercise at the moment? If needed, prompt with examples such as: social support (and if so from whom), pregnancy specific groups, improving your health and well-being or your baby's health, low cost or convenience of time/place (eg, with clinic visits)?
8. What do you think is needed to help pregnant women who don't exercise to change their behaviour from not exercising to participating in exercise?
9. What message about exercise would you give other women with gestational diabetes?
10. Is there anything else that you would like to add?

Do you have any questions?

Table 2 Individual participant characteristics (as included on Journal of Physiotherapy e-Addenda).

Identifier	Age *(years)*	Gestation *(weeks)*	Parity	Pre-pregnancy BMI *(kg/m^2)*	Prior GDM	Pre-pregnancy activity level [a]	Highest level of education	Country of birth
P1	27	35	G1 P0	38	No	Active	Bachelors	Australia
P2	37	21	G1 P0	25	No	Active	Masters	India
P3	28	31	G2 P1	23	No	Active	Bachelors	Australia
P4	34	36	G4 P1	20	No	Not very active	Bachelors	China
P5	28	30	G2 P1	28	No	Active	Bachelors	Australia
P6	26	36	G1 P0	31	No	Active	Year 10	Thailand
P7	36	31	G3 P1	26	Yes	Not very active	High school	Vietnam
P8	32	32	G2 P1	19	No	Active	Bachelors	Australia
P9	30	28	G1 P0	20	No	Active	Bachelors	Pakistan
P10	31	32	G1 P0	24	No	Active	Bachelor	Philippines
P11	30	20	G2 P0	33	No	Not very active	TAFE	Australia
P12	35	37	G2 P0	24	No	Not very active	High school	Australia
P13	30	24	G4 P2	25	Yes	Not very active	Bachelors	China
P14	31	32	G4 P1	27	No	Not very active	Bachelors	Philippines
P15	31	31	G1 P0	19	No	Active	Bachelors	India
P16	35	22	G1 P0	24	No	Active	Bachelors	Australia
P17	28	31	G1 P0	19	No	Active	Masters	Australia

P18	36	31	G2 P1	26	No	Active	Bachelors	Egypt
P19	32	36	G2 P1	31	No	Not very active	Bachelors	Bangladesh
P20	29	31	G1 P0	30	No	Not very active	Masters	India
P21	33	35	G2 P1	24	No	Active	High school	Bangladesh
P22	36	37	G4 P2	25	Yes	Not very active	Masters	India
P23	38	25	G4 P3	26	Yes	Not very active	Year 10	Australia
P24	29	25	G1 P0	32	No	Not very active	Bachelors	India
P25	37	31	G1 P0	27	No	Active	Year 10	Vietnam
P26	33	34	G2 P1	21	No	Active	Bachelor	Taiwan
P27	31	25	G1 P0	27	No	Active	Bachelors	India

[a] Women who met the physical activity guidelines were classified as active, whereas those who did less than the physical activity guidelines were classified as not very active.

G = gravida (total number of pregnancies), GDM = gestational diabetes mellitus, P = parity (number of pregnancies carried to a viable age)

Chapter 5:
A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial.

5.1 Preface

The qualitative study reported in Chapter 4 (Harrison et al., 2019) found that although clinical practice guidelines for physical activity in pregnancy are available, it appears they are not explicitly conveyed to women with gestational diabetes mellitus at, or soon after, the time of diagnosis. To feel confident and safe about being physically active during pregnancy, women with gestational diabetes mellitus wanted clear, simple and gestational diabetes mellitus specific messages from credible sources such as health professionals. They also wanted this physical activity messaging to include and be explicit about what and how much they need to participate in specifically during their gestational diabetes mellitus pregnancy for their health and the health of the baby.

In Chapter 5 a randomised controlled trial was completed to evaluate if a consumer co-created infographic about physical activity, additional to usual-care gestational diabetes education, improves knowledge of physical activity and self-efficacy to exercise in women with gestational diabetes mellitus compared to gestational diabetes education alone.

5.2 Study four

Chapter 5 is presented in its published format as (Harrison, Taylor, Frawley & Shields, 2020):

Harrison, A. L., Taylor, N. F., Frawley, H. C., & Shields, N. (2020). A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial. *Journal of Physiotherapy*, *66*(4), 243–248.

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Research

A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial

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KEY WORDS

Physical activity
Gestational diabetes
Knowledge
Self-efficacy
Infographic

ABSTRACT

Question: In women with gestational diabetes mellitus, does the addition of a consumer co-created infographic to usual education about gestational diabetes mellitus improve knowledge about physical activity and self-efficacy to exercise? **Design**: A randomised trial with concealed allocation, a blinded assessor and intention-to-treat analysis. **Participants**: Sixty-nine women diagnosed with gestational diabetes mellitus. **Intervention**: In addition to gestational diabetes education, the experimental group received a paper copy of a consumer co-created infographic about physical activity during a gestational diabetes pregnancy. The control group received gestational diabetes education alone. **Outcome measures**: Participants completed outcome measures at baseline and again 1 week later. Knowledge of physical activity in a gestational diabetes mellitus pregnancy was assessed using a 19-item questionnaire modified to reflect current physical activity guidelines, with a total score from 0% (worst) to 100% (best). Self-efficacy was measured using the nine-item Self-Efficacy for Exercise Scale, with a total score from 0 (not confident) to 10 (very confident). **Results**: Provision of the infographic led to a clinically important between-group difference in knowledge (MD 12%, 95% CI 10 to 15) and self-efficacy (MD 2.5 units, 95% CI 1.9 to 3.0). **Conclusion**: In women with gestational diabetes mellitus, short-term knowledge about physical activity and self-efficacy to exercise were improved when usual education was supplemented with a consumer co-created infographic that provided specific and relevant information about physical activity during a gestational diabetes mellitus pregnancy. **Trial registration**: ACTRN12619001207101. **[Harrison AL, Taylor NF, Frawley HC, Shields N (2020) A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial. *Journal of Physiotherapy* 66:243–248]**

Introduction

Physical activity (any movement produced by skeletal muscles that results in energy expenditure)[1] has substantial benefits and minimal risks for pregnant women,[2–4] and is important for the health of women with gestational diabetes mellitus (GDM) and their babies.[5–7] Physical activity is recommended for women with GDM because it improves glycaemic control,[5,7] a critical factor in reducing adverse risks associated with GDM such as maternal hypertension, pre-eclampsia[8] and birth trauma from macrosomia.[9,10] GDM, a common complication of pregnancy[11] defined as glucose intolerance during pregnancy,[12] also has longer-term health implications including increased risks of recurrence in subsequent pregnancies[13] and the risk of developing type 2 diabetes mellitus later in life for both mother and child.[14] Physical activity performed at a moderate intensity for 30 minutes on most days of the week is a safe and effective adjunctive intervention for improving glycaemic control.[5,7] Given this, guidelines recommend that pregnant women with GDM participate in physical activity.[2,15] However, up to 60% of women with GDM do not participate in physical activity as recommended.[16]

A diagnosis of GDM introduces complexity to a pregnancy and can negatively impact a woman's confidence to be physically active, due to concerns about safety.[17] Inconsistency in information about physical activity during a GDM pregnancy, lack of confidence in knowledge sources such as the Internet and uncertainty about specific details of what type and how much physical activity is safe for a GDM pregnancy have been identified as barriers hindering women's participation in physical activity.[17] This suggests that information from guidelines is not reaching women with GDM or is not in a format that meets their needs.[17]

A recent qualitative study concluded that women with GDM wanted clear and simple messaging about physical activity from a

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credible source, such as health professionals, to feel confident and safe being physically active.[17] Self-efficacy theory[18] suggests a person's confidence in their ability to perform a specific behaviour is positively related to their ability to action and perform that behaviour.[19,20] Self-efficacy to undertake exercise in pregnant women and others has been shown to increase as a result of the provision of highly relevant messages[20,21] and when messages are from credible sources.[20,22] Therefore, it is important that health professionals such as physiotherapists find effective ways to satisfy women's information needs, in order to increase confidence and feeling of safety during physical activity.

One way to provide relevant and easy-to-understand physical activity information is by using an infographic. An infographic presents data and ideas visually with minimal use of text and can provide messaging that is engaging, clear and simple.[23] Information from an infographic is more likely to be remembered compared with text alone,[24] as visual inputs improve ability to process and retain information.[24] It has been reported that almost 60% of Australian adults are insufficiently health literate to understand healthcare information,[25] so it is important to find effective modes of messaging, like infographics, that are appropriate for the target audience.

Current literature also recommends consumer involvement in healthcare.[26] Engaging women with GDM to co-create messaging about physical activity in a GDM pregnancy is important for ensuring that information is relevant, appropriate and specific to their needs, including how messages are presented. Providing physical activity information to women in the form of a consumer co-created infographic may be an effective strategy to improve the knowledge and self-efficacy of women with GDM.

Therefore, the research question for this randomised trial was:

> In women with gestational diabetes mellitus, does the addition of a consumer co-created infographic to usual education about gestational diabetes mellitus improve knowledge about physical activity and self-efficacy to undertake physical activity?

Method

Design

A parallel-group, randomised controlled trial was conducted with women diagnosed with GDM who attended a metropolitan hospital in Melbourne, Australia. Recruitment was completed between September and November 2019. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry. The trial was approved by the hospital and university ethics committees, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) Statement[27] and the Template for Intervention Description and Replication (TIDieR) checklist.[28]

Participants

Pregnant women newly diagnosed with GDM, who met the eligibility criteria (Box 1) and consented, were recruited from antenatal clinics.

As per the usual clinic process, women were booked to attend the next available date for a GDM education class; this was done by an administrative officer with no involvement in the trial. Screening of women listed to attend a GDM education class for inclusion in the trial was completed by a member of the research team (AH). All class dates were randomised to either the experimental or control group by an independent, off-site person using a computer-generated randomisation sequence. Due to the potential for contamination within a class, all participants attending on the same class date received the individual intervention as randomly allocated for that class date. The holder of the allocation emailed the researcher the day before the class to reveal the allocation. All eligible women attending GDM education classes during the period of data collection were invited to participate. Written participant information statements were individually provided to interested women who met the eligibility criteria. Participants who volunteered completed a written consent form.

Box 1. Eligibility criteria

Inclusion criteria
- Women with a singleton pregnancy[a]
- Diagnosed with GDM
- Aged 18 to 40 years[b]
- Able to read and write in English

Exclusion criteria
- High-risk pregnancy[c]
- Conditions affecting ability to participate in physical activity

[a] Considered lower risk, therefore able to exercise without restriction.
[b] Minimum age to legally provide informed consent; maximum age because pregnant women aged > 40 years are generally considered as having higher-risk pregnancies.[29]
[c] Risk of premature labour, incompetent cervix, persistent bleeding, ruptured membranes, growth retardation, pre-eclampsia, severe anaemia, placenta previa after 26 weeks' gestation, haemodynamically significant heart disease or restrictive lung disease.[2,3]

GDM = gestational diabetes mellitus.

Intervention

Infographic development

An infographic about physical activity for women diagnosed with GDM was co-created in collaboration with consumers, prior to trial commencement. The Critical Appraisal Skills Programme's Patient and Public Involvement checklist was used to guide consumer engagement.[30] The consumers were 13 pregnant women with GDM who consented to participate in a 20-minute, face-to-face, group consultation meeting. Four group meetings were held, with two to five consumers participating per meeting. A question guide was used to facilitate the group meetings on key points about the infographic design, including ranking the priority of different pieces of information, and presentation features such as the amount of text versus graphics, graphic preferences, colours, readability, and text font and size. During the meetings the consumers were shown four examples of infographics about physical activity for other health conditions[31–34] to elicit responses about how they felt about different design features. They were also shown a draft document developed by the researchers, with information based on current evidence and physical activity guidelines for women with GDM[5–7,15] and which incorporated data from women with GDM about what physical activity messages were considered important.[17] During each meeting, information from the consumers was recorded on poster paper for them to view, add to and refine during the session. This information was read back at the end of the session and consumers were given the opportunity to add further information and confirm if it was a true and accurate representation of their contributions. This process of consumer consultation meetings continued until no new information emerged. Inductive thematic analysis of the information collected from the consumer meetings was completed to identify the key concepts to inform the design and development of a draft infographic about physical activity for pregnant women with GDM. A paper, colour copy of this draft infographic was then shown individually to a further five women with GDM who provided feedback. This additional round of consumer feedback assisted in refining the infographic and improving dependability of the findings and relevance for women with GDM.

Consumers prioritised information that they felt was important, such as listing the benefits of physical activity for a GDM pregnancy, among which blood sugar control, weight control, baby's health and physical activity (amount, frequency and type) were considered the most important. Consumers recommended stating that physical activity was safe for mother and baby in a GDM pregnancy and adding a hospital logo to reassure women that the information was from a credible source. In terms of physical activity prescription, all consumers reported that 10 minutes of walking three times per day after meals was more achievable and more encouraging than listing a daily or weekly amount. They said that this text should be bolded and placed centrally, as this information was a priority. All consumers reported that their preferred type of physical activity was walking, with three also including swimming. For design, they preferred less text and more icon-style graphics, which they felt were quick and easy to understand. They recommended blue and green colours because they felt that these were energising and they recommended including an image of a baby, as this was a key motivating factor for them. The final consumer co-created infographic (Appendix 1 on the eAddenda) included information about the benefits of physical activity during a GDM pregnancy, and the duration, frequency and types of suitable physical activities. It was used as the intervention for this trial.

Randomised trial

All participants received usual GDM education at the same clinic location and from the same staff, diabetes educators and dietitians, during a single 2.5-hour education class and then at follow-up appointments as required. This education class included information about: GDM; when and why it occurs; nutritional requirements in pregnancy; GDM dietary modifications and lifestyle changes; and regular monitoring of blood sugar levels and, if necessary, medication to reduce risks associated with poor glycaemic control during pregnancy.[7–10] In addition to usual GDM education, a researcher (AH) handed a paper, colour copy of the co-created infographic to each consenting participant attending on dates randomly allocated to the experimental group on that one occasion. This was accompanied by a simple verbal instruction of < 5 minutes to each participant, advising her to take the infographic home, read it and display it somewhere highly visible as a regular reminder to participate in physical activity during her GDM pregnancy.

Outcome measures

Two outcomes were assessed: knowledge about physical activity during a GDM pregnancy and self-efficacy to participate in physical activity. Participants completed these outcome measures at baseline (Week 0) on the day of attending the GDM class and again at follow-up 1 week later (Week 1). Participants completed follow-up questionnaires either via email or individually in person if attending a follow-up dietetic or ante-natal appointment, where they were given a paper copy of the questionnaires to complete and return in a sealed and addressed envelope.

The participants' knowledge about physical activity during a GDM pregnancy was assessed using questions that were based on a questionnaire about physical activity knowledge in adults[35] and modified to reflect current physical activity guidelines[36] and pregnancy guidelines,[2–4] including those specific to GDM.[7,15] Knowledge was assessed using 19 questions: seven true/false questions about physical activity prescription and 12 questions about which types of physical activity were safe or should be avoided during pregnancy. Correct responses were allocated a score of '1' and incorrect a '0'. The percentage of total correct responses was calculated.

Self-efficacy to undertake physical activity was measured using the Self-Efficacy for Exercise Scale, for which there is evidence of reliability and validity.[37,38] This nine-item measure, which was modified slightly to reflect current physical activity dosage guidelines,[36] asked participants to rate their level of confidence to participate in physical activity for 30 minutes, five times a week for each statement from '0' (not confident) to '10' (very confident) and the mean of these nine responses was calculated as the self-efficacy score.[37,38]

Data analysis

With an alpha of 0.05, this study would have exceeded 80% power to identify a 1.2-unit between-group difference in exercise self-efficacy on the 0-to-10 scale, given an initial cohort of 60 participants, a standard deviation of 1.6, and an allowance of loss to follow-up of two participants.[39]

Data were analysed according to the principle of intention to treat, with all available data used for analysis. Participant demographic data were described using means and standard deviations (age and gestation) or proportions (parity, body mass index, previous GDM, educational level and country of birth). The difference in mean values of knowledge and self-efficacy between the experimental and control groups at follow-up (Week 1) were analysed with analysis of covariance, using the baseline (Week 0) scores as covariates. A separate analysis of covariance was completed with the day of the week of the class added as an additional covariate in a sensitivity analysis to account for any effect from the day of class that women attended. Consistent with recommendations, the level of significance was not adjusted to account for multiplicity related to the two outcomes, since there was no universal hypothesis.[40,41] Any statistically significant differences were interpreted as being clinically worthwhile if the mean difference and the 95% confidence interval exceeded the minimum important difference. Half a standard deviation of the baseline control group score was nominated as the minimum important difference.[42]

Results

Flow of participants through the trial

Of the 123 women booked to attend a GDM education class, 69 were eligible and consented to participate (Figure 1). Sixty-eight participants completed the outcome measures at both time points. One participant in the control group was lost to follow-up and did not complete the outcome measures at Week 1.

The groups appeared well matched for demographic factors, as shown in Table 1. The groups were also well matched for their baseline values on the study's outcome measures, as shown in the first two columns of data in Table 2.

Compliance with the trial protocol

The number of participants who completed the study (n = 69) exceeded the sample size target of 60 because the final class from which participants were recruited was large and many women attending that class expressed an interest in the trial. Several participants were slow to complete and return the follow-up outcome measures (Week 1) due to changing their follow-up clinic appointment or delay in their return by email; however, all data were received within 2 weeks of baseline (Week 0).

Effect of intervention

The effect of the experimental intervention on knowledge about physical activity during a GDM pregnancy was estimated to be a greater increase in knowledge by 12%. A similar result was obtained when we accounted for the day of the week on which participants attended their education class (Table 2). The lower band of the 95% CI for the outcome of knowledge (ie, 10%) exceeded the clinically important difference of 6.5%.

The effect of the experimental intervention on self-efficacy to undertake physical activity during the pregnancy was estimated to be a 2.5-unit improvement in self-efficacy on the 0-to-10 scale. A similar result was obtained when we accounted for the day of the week on which participants attended their education class (Table 2). The lower

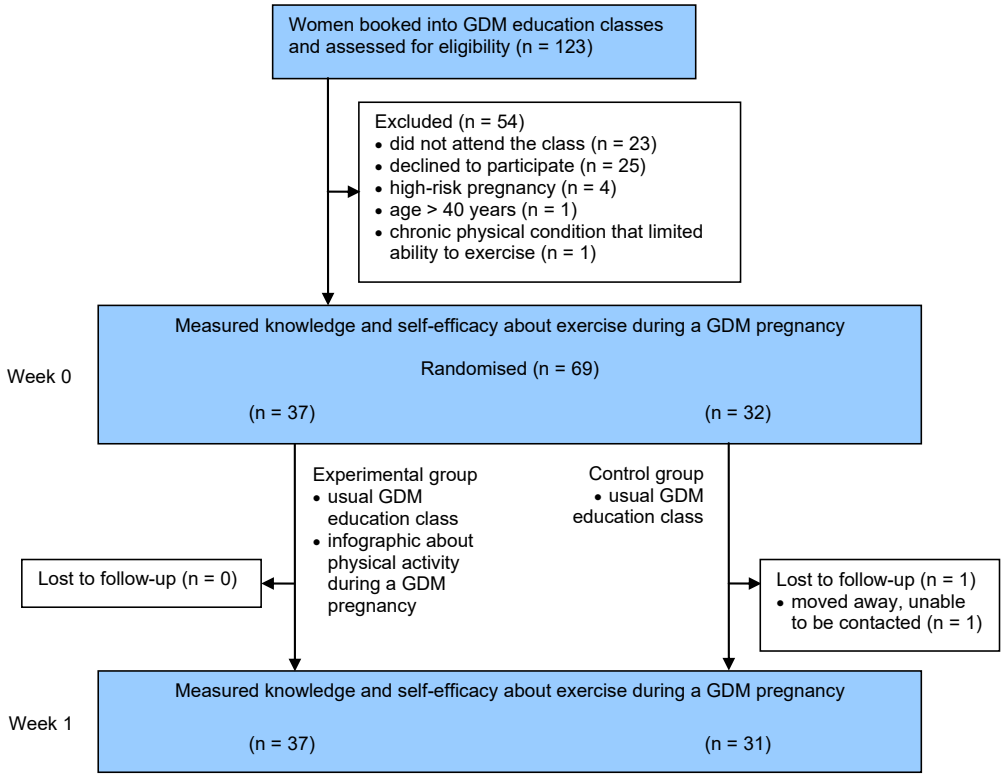

Figure 1. Design and flow of participants through the trial.
GDM = gestational diabetes mellitus.

band of the 95% CI for the outcome of knowledge (ie, 1.9 units) exceeded the clinically important difference of 1.2 units.

Discussion

A consumer co-created infographic with specific and relevant information about physical activity during a GDM pregnancy, provided in addition to standard GDM education, resulted in clinically important short-term improvements in women's knowledge and self-efficacy to participate in physical activity compared with standard education alone. This trial contributes to the existing literature on co-designed infographics about physical activity and their use as an intervention.

Table 1
Baseline characteristics of the participants.

Characteristic	Exp (n = 37)	Con (n = 32)
Age *(yr)*, mean (SD) range	31 (3) 24 to 38	32 (4) 23 to 39
Gestation *(weeks)*, mean (SD) range	27 (5) 17 to 33	27 (5) 15 to 34
Parity, n (%)		
nulliparous	14 (38)	13 (41)
multiparous	23 (62)	19 (59)
Pre-pregnancy BMI *(kg/m²)*, n (%)		
≤ 25	19 (51)	15 (47)
26 to 29	10 (27)	9 (28)
≥ 30	8 (22)	8 (25)
GDM in previous pregnancy, n (%)	8 (22)	5 (16)
Education, n (%)		
≤ high school	3 (8)	3 (9)
> high school	34 (92)	29 (91)
Country of birth, n (%)		
Australia	5 (14)	3 (9)
India	19 (51)	18 (56)
Asia (excluding India)	10 (27)	8 (25)
Africa	2 (5)	2 (6)
Oceania (excluding Australia)	1 (3)	1 (3)
Day of class, n (%)		
Tuesday	14 (38)	10 (31)
Thursday	23 (62)	22 (69)

BMI = body mass index, Con = control group, Exp = experimental group, GDM = gestational diabetes mellitus.

The diagnosis of GDM shocks women[17,43,44] and triggers concerns about the safety of physical activity.[17] Combined with a lack of certainty about what type and how much physical activity is safe in a GDM pregnancy, this may contribute to a disconnect (ie, a knowledge-action gap)[45] between a woman's intention and her action. As proposed by the Theory of Planned Behaviour,[46] factors additional to attitudes that hinder or enable behaviour may also influence intention and subsequent action.[46,47] Inconsistency in information about physical activity for a GDM pregnancy specifically and a lack of confidence in knowledge sources such as the Internet are known to be barriers that hinder women's participation in physical activity.[17] Women have described improved messaging about physical activity during a GDM pregnancy as a key enabler.[17] One enabling factor was the provision of specific information from credible sources (such as health professionals) that clearly and simply explains what and how much physical activity is safe during a GDM pregnancy, and why it was relevant and important to improving their GDM pregnancy outcomes. Another enabling factor was the provision of practical, convenient and flexible exercise options, such as walking, that could be tailored to fit in with women's busy lives.[17] Therefore, as diagnosis appears to be a trigger that makes women receptive to information about their health, findings from this trial suggest that providing targeted physical activity messages in an easy-to-read infographic format to women newly diagnosed with GDM is effective in improving their short-term knowledge and self-efficacy regarding physical activity during their pregnancy.

Co-designing the infographic about physical activity during a GDM pregnancy with consumers may have been an important factor contributing to its effectiveness. The consumer co-created infographic gave women the specific and relevant information about physical activity in a GDM pregnancy that women with GDM said they wanted, and in the easy-to-read and understandable format they recommended. Providing pregnant women with specific and relevant information about benefits of physical activity has previously been shown to influence their beliefs and intentions about physical activity participation.[21] Although providing a one-page information sheet about physical activity during a GDM pregnancy, in addition to standard GDM education, may seem a very simple intervention, it is

Table 2
Mean (SD) of groups, mean (SD) within-group difference and mean between-group difference (95% CI) using baseline scores as covariates.

Outcome	Groups				Difference within groups		Difference between groups	
	Week 0		Week 1		Week 1 minus Week 0		Week 1 with baseline scores as covariate[a]	Week 1 with baseline scores and day of the week as covariates
	Exp (n = 37)	Con (n = 32)	Exp (n = 37)	Con (n = 31)	Exp (n = 37)	Con (n = 31)	Exp minus Con	Exp minus Con
Knowledge *(0 to 100)*	82 (10)	83 (13)	96 (4)	85 (10)	14 (9)	2 (6)	12 (10 to 15)	12 (10 to 15)
Self-efficacy *(0 to 10)*	4.8 (1.6)	5.1 (2.4)	7.2 (1.3)	4.9 (2.0)	2.4 (1.5)	−0.2 (1.0)	2.5 (1.9 to 3.0)	2.5 (1.9 to 3.0)

For both outcome measures, higher scores are better.
Con = control group, Exp = experimental group.
[a] Derived from ANCOVA with dependent variable at baseline as covariate.

suggested that its effectiveness was increased because the infographic was co-created with women with GDM. Consistent with current recommendations for developing patient information,[25,26] this appeared to be because it made the messaging about physical activity highly relevant to these women's specific information needs at a time when they were concerned about their health and pregnancy and provided it in a format that met their needs.

Increasing women's knowledge and sense of confidence about safe physical activity in a GDM pregnancy, and the relevance to pregnancy and child outcomes, may provide the motivation and confidence to facilitate a shift from intention to action, thereby creating the behaviour change necessary to improve participation in physical activity. Higher self-efficacy has been reported to be positively associated with the adoption and participation in physical activity.[19,20,48] However, further research is needed to explore if providing a co-designed infographic translates into women with GDM actually being more physically activity during their pregnancy.

The participants in our study included a high proportion of women born in Asia. This is consistent with reported risk factors for developing GDM, which include specific race/ethnic backgrounds.[11] Women born in Southern and Central Asia are more than twice as likely, and women born in South-East Asia are 1.7 times more likely, to be diagnosed with GDM than Australian-born women;[11,49] therefore, a higher proportion of women presenting with GDM from these higher risk areas is expected. Therefore, the participants included in our trial appear representative of women diagnosed with GDM in terms of country of birth,[11,49] age[44,50] and gestation, as routine GDM screening occurs at between 24 to 26 weeks.[51] Recruitment of only English-speaking women may have influenced our findings and is a limitation. However, with the women's country of birth from 17 different countries, a range of ethnicities and cultural backgrounds was represented. The diversity and detailed descriptions of participant characteristics enhance the generalisability of findings to similar populations.

Although the intervention was conducted at an individual level, the process of randomisation by class rather than by individual, to account for the risk of contamination, could be considered a limitation. However, the randomisation process resulted in groups that were well balanced for the day of the week on which the class was conducted, and a sensitivity analysis that added day of the week as a covariate confirmed the main analysis. Due to the type of intervention, it was not possible to blind the participants or the therapist who provided the infographic to participants. However, it was possible for the knowledge tests to be scored by a blinded researcher; therefore, this primary outcome had a blinded assessor. Randomisation was performed by an independent, off-site person and the researcher was only notified of the intervention allocated to each class the day before the class occurred. By this time, the women were already booked into the class, so to this extent the allocation was concealed. Other strengths include: the use of intention-to-treat analysis, the use of estimation with 95% CI to report the effects of the intervention, comparison of these results against smallest worthwhile effect thresholds, and incorporation of consumer involvement into the study. Also, the extent of loss to follow-up was less than what was allowed for in the original sample size calculation, which assisted the study to achieve greater statistical power than anticipated. Although the use of infographics is becoming a popular means of providing health information, randomised trials evaluating the effectiveness of using infographics as an intervention are uncommon.[52] A strength of this trial is its contribution to those existing trials by studying a consumer co-designed infographic about physical activity.

In conclusion, this study estimated the effects of adding a consumer co-created infographic to the usual education class given to women with GDM. This simple intervention was estimated to cause worthwhile improvements in short-term knowledge about physical activity during a GDM pregnancy and self-efficacy to undertake physical activity.

What was already known on this topic: Physical activity is recommended for women with gestational diabetes mellitus, but most of these women are inactive during their pregnancy. These women want clear, simple and gestational diabetes-specific physical activity messages that are: directly related to pregnancy outcomes; explicit about what and how much physical activity they need to participate in during their pregnancy; and delivered by a credible source.

What this study adds: Consumers were involved in co-creating an infographic that provides clear, simple, specific and relevant information about physical activity and gestational diabetes. For women with gestational diabetes, provision of the infographic in addition to usual education about gestational diabetes led to worthwhile improvements in both knowledge and self-efficacy in relation to physical activity during their pregnancy.

eAddenda: Table 3 and Appendix 1 can be found online at https://doi.org/10.1016/j.jphys.2020.09.010.

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Competing interests: Nil.

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Provenance: Not invited. Peer reviewed.

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5.3 Study four - Supplementary material for *e*-Addenda,

Appendix 1 Consumer co-created infographic about physical activity in a GDM pregnancy

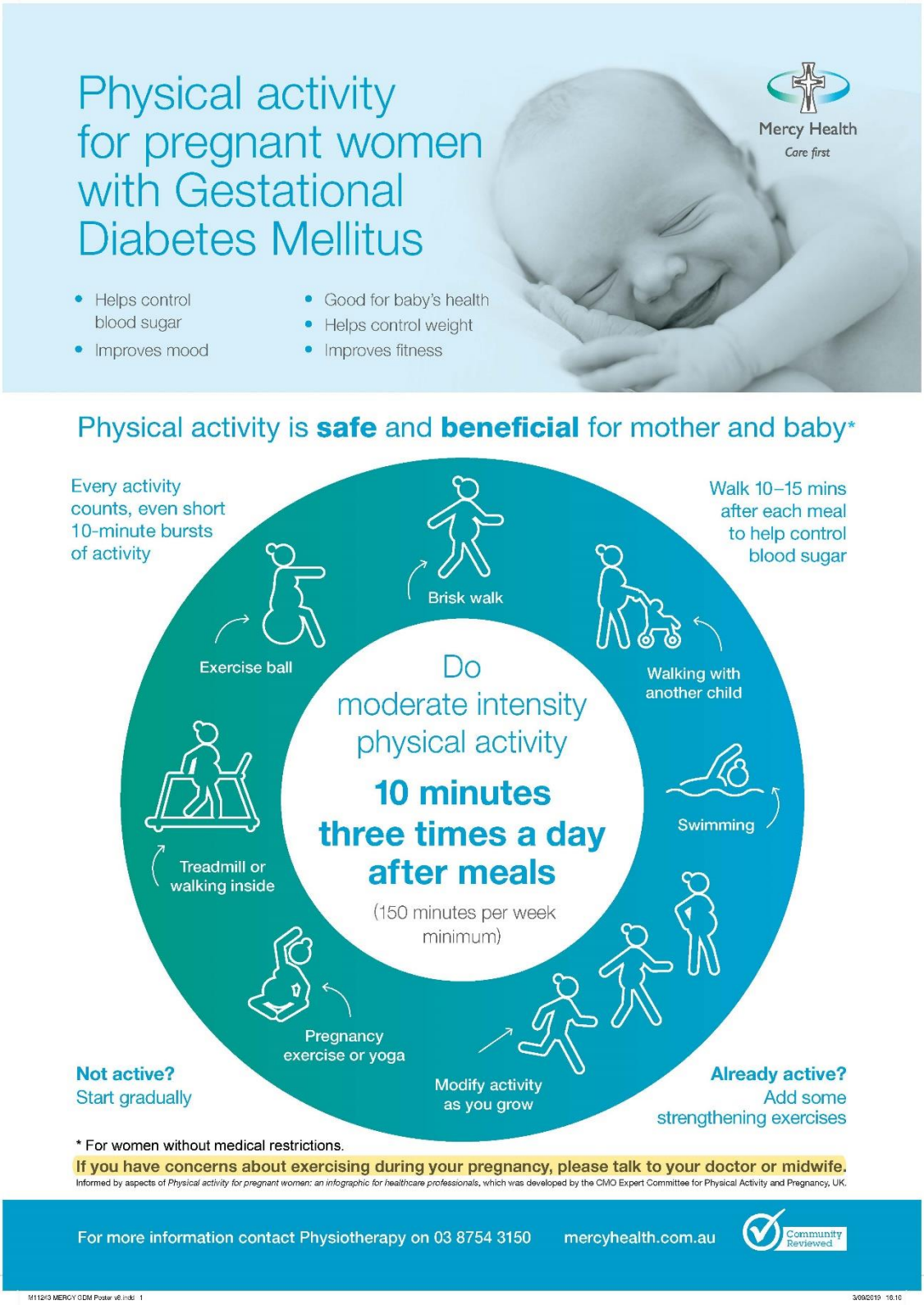

Table 3 Individual outcome data

eAddendum

Harrison AL, Taylor NF, Frawley HC, Shields N

A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial

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Table 3. Individual outcome data.

Subject no.	Group	Total knowledge of physical activity *(0 to 100)*		Self-efficacy for PA *(0 to 10)*	
		Week 0	Week 1	Week 0	Week 1
1	Exp	79	100	4.1	5.0
2	Exp	68	95	4.6	5.4
3	Exp	68	95	3.3	9.0
4	Exp	79	95	3.0	4.2
5	Exp	68	95	2.7	6.0
6	Exp	68	89	3.9	8.3
7	Exp	74	100	5.6	6.8
8	Exp	100	100	8.1	7.8
9	Exp	100	100	3.0	5.7
10	Exp	79	100	2.9	5.7
11	Exp	89	95	5.7	7.8
12	Exp	74	89	4.4	6.4
13	Exp	74	95	4.0	5.0
14	Exp	79	100	3.0	7.9
15	Exp	95	95	5.6	7.8
16	Exp	95	100	5.7	5.8
17	Exp	89	100	3.0	6.2
18	Exp	95	95	5.6	7.6
19	Exp	79	95	7.3	9.2
20	Exp	79	100	7.0	8.0
21	Exp	100	100	2.7	6.3
22	Exp	89	95	5.9	6.2
23	Exp	89	95	1.8	8.1
24	Exp	74	95	5.2	7.9
25	Exp	84	100	4.9	7.2
26	Exp	68	89	6.2	8.6
27	Exp	95	95	6.8	7.6
28	Exp	79	100	6.8	9.6
29	Exp	74	95	2.4	7.7
30	Exp	84	89	5.6	8.8
31	Exp	89	100	6.7	8.6
32	Exp	74	95	5.2	8.7
33	Exp	84	100	5.1	8.7
34	Exp	74	89	3.4	7.6
35	Exp	89	95	6.1	6.7
36	Exp	84	100	6.4	8.7
37	Exp	84	100	5.6	7.8

Subject no.	Group	Total knowledge of physical activity *(0 to 100)*		Self-efficacy for PA *(0 to 10)*	
		Week 0	Week 1	Week 0	Week 1
1	Con	100	100	4.4	4.3
2	Con	53	74	6.1	5.0
3	Con	95	95	6.7	7.0
4	Con	84	84	4.3	3.9
5	Con	95	95	7.6	6.9
6	Con	79	74	0.0	0.2
7	Con	100	100	2.4	3.0
8	Con	84	84	5.4	5.4
9	Con	100	100	9.4	8.1
10	Con	95	95	4.9	6.0
11	Con	100	100	6.2	4.9
12	Con	74		6.0	
13	Con	95	95	10.0	8.7
14	Con	79	79	5.0	5.2
15	Con	58	68	3.4	3.1
16	Con	74	68	4.8	3.0
17	Con	68	74	4.9	4.9
18	Con	79	79	6.1	6.0
19	Con	63	79	1.0	1.8
20	Con	79	79	1.9	2.4
21	Con	79	74	4.2	4.3
22	Con	74	74	9.3	7.8
23	Con	89	84	5.9	6.0
24	Con	95	89	4.0	6.3
25	Con	74	79	4.7	4.8
26	Con	68	74	3.6	4.2
27	Con	74	84	2.6	3.0
28	Con	95	95	6.4	3.4
29	Con	95	95	4.9	4.9
30	Con	74	74	2.9	3.1
31	Con	95	95	7.8	7.1
32	Con	79	84	9.3	8.8

Chapter 6: Discussion

6.1 Summary of Main Findings

Physical activity is recommended for women with gestational diabetes mellitus due to its ability to assist with glycaemic control - a critical factor in combatting the adverse effects of this condition. However, despite published recommendations, many pregnant women with gestational diabetes mellitus are inactive. Therefore, the aims of this thesis were to confirm the effect of exercise on glycaemic control in gestational diabetes mellitus, to explore attitudes, barriers and enablers to physical activity for women diagnosed with gestational diabetes mellitus and to trial an intervention that addressed the identified physical activity barriers and facilitated enabling factors. This chapter summarises the main findings from a series of four studies conducted as part of this thesis. Also discussed are the key issues arising from this body of work, clinical implications, strengths and limitations and directions for future research.

> Key finding 1 (Chapter 2): *Physical activity, adjuvant to standard gestational diabetes mellitus care, safely helps to control postprandial blood glucose levels and other measures of glycaemic control in women diagnosed with gestational diabetes mellitus.*

As there was an absence of high level evidence from a systematic review investigating the effect of physical activity on postprandial blood sugar levels in women diagnosed with gestational diabetes mellitus, the first step in this research was to investigate if physical activity was beneficial in improving blood sugar levels in these women. A systematic review of randomised, controlled trials (Chapter 2) was conducted. Following searching of 11 databases, eight randomised controlled trials involving 588 participants were included. Meta-analysis found exercise, as an adjuvant to standard care, significantly improved postprandial glycaemic control and lowered fasting blood glucose levels, compared to standard care alone, with no increase in adverse events. Programs of aerobic or resistance exercise appeared equally effective if performed at a moderate intensity or greater, for 20 to 30 minutes, three to four times a week. These findings confirmed, with greater certainty than before, that physical activity, adjuvant to standard gestational

diabetes mellitus care, safely helped to control postprandial blood glucose levels and other measures of glycaemic control in women diagnosed with gestational diabetes mellitus.

> Key finding 2 (Chapter 3): *Pregnant women believe physical activity in pregnancy is important and beneficial. Information on barriers and enablers to physical activity in women with gestational diabetes mellitus were lacking.*

Having confirmed physical activity was beneficial for women with gestational diabetes mellitus, the question remained as to why these women do or do not exercise as recommended. A second systematic review (Chapter 3) explored the factors influencing physical activity participation in pregnant women including those with gestational diabetes mellitus. Following searching of eight databases, 49 articles reporting data from 47 studies (7,655 participants) were included. Pregnant women had strong, positive attitudes toward physical activity during pregnancy. Intrapersonal factors – including maternal health and wellbeing, managing pregnancy symptoms, time and safety – were frequently cited as both barriers and enablers to physical activity during pregnancy. Barriers to physical activity were factors such as fatigue, lack of time and pregnancy discomforts. Maternal and foetal health benefits and social influences, particularly partner and family support, appeared to be important enablers. Few environmental factors were identified. Little information was available about attitudes, barriers and enablers of physical activity for pregnant women with gestational diabetes mellitus who are at risk from physical inactivity. These findings suggested person-centred strategies that increase the relevance of physical activity recommendations for the women could be used to address intrapersonal and social factors and translate pregnant women's positive attitudes into increased participation. It also identified further research is needed to extend our understanding of attitudes, barriers and facilitators to physical activity participation in women diagnosed with gestational diabetes mellitus.

> Key finding 3 (Chapter 4): *Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during their pregnancy*

To fill the gap in the literature identified by the previous systematic review (Chapter 3), a qualitative study to identify barriers and enablers to physical activity specifically for women with gestational diabetes mellitus was completed. Semi-structured interviews

were completed with 27 women diagnosed with gestational diabetes mellitus. The process of communicating information about physical activity ("messaging") was the main theme to emerge. Sub-themes included: wanting information about physical activity from credible sources; wanting clear, specific information about safe physical activity during a gestational diabetes mellitus pregnancy; receiving information at time of diagnosis because this event triggered women's desire to be more physically active; understanding why physical activity is important to improving outcomes for themselves and their babies; and wanting information about flexible, convenient and practical physical activity options. This study found that, although clinical practice guidelines for physical activity in pregnancy were available, it seemed they were not explicitly conveyed to women with gestational diabetes mellitus in a format these women needed and at the time they needed them. The key enabler identified by the women was better messaging about physical activity for a gestational diabetes mellitus pregnancy. To feel confident and safe about being physically active during pregnancy, women with gestational diabetes mellitus wanted clear, simple, gestational diabetes mellitus specific physical activity messages directly related to pregnancy outcomes and delivered by a credible source with flexible options so physical activity can be tailored to fit in with their lifestyles. They also wanted messages to be explicit about what and how much physical activity they need to participate in during their gestational diabetes mellitus pregnancy for them-selves and especially for the health of the baby, which was a strong motivator.

Key finding 4 (Chapter 5): *Providing a consumer co-created infographic about physical activity, additional to usual gestational diabetes mellitus education, improved short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus*

In response to the findings of the qualitative study (Chapter 4), a randomised controlled trial was completed to answer the question: does the addition of a consumer co-created infographic to a gestational diabetes education class improve knowledge and self-efficacy of physical activity for women with gestational diabetes mellitus compared to an education class alone? In this trial, 69 women diagnosed with gestational diabetes mellitus, were randomly allocated to either an experimental group that received a paper copy of a consumer co-created infographic about physical activity in addition to gestational diabetes education; or to a control group that received gestational diabetes education alone. This trial found a clinically important, between-group difference in

physical activity knowledge and self-efficacy at post-intervention favouring the experimental group. These results provide evidence that, the addition to usual education of a consumer co-created infographic, that provided simple, specific and relevant information, improved short-term knowledge and self-efficacy about physical activity during pregnancy in women with gestational diabetes mellitus. The involvement of consumers in the development of the infographic likely contributed to its effectiveness because it ensured the information was highly relevant to women's needs and presented in a format that made it easy to understand.

6.2 Key Issues and Clinical Implications

6.2.1 *Benefits of applying a theoretical approach to the problem of changing physical activity behaviour in women with gestational diabetes mellitus*

Health behaviour theory can assist in exploring the questions of 'why', 'what', and 'how' to help understand factors that influence behaviour (Glanz et al., 2002; Rimer & Glanz, 2005). Health behaviour theory, including those considered in the context of the work for this thesis, the social-ecological model (Bronfenbrenner, 1994; Stokols, 1996), Health Belief Model (Champion & Skinner, 2008; Rosenstock, 1974; Rosenstock et al., 1988), Theory of Planned Behaviour (Ajzen, 1991) and Social Cognitive theory (Bandura, 1986a, 1986b, 1997), provides a framework to assist in understanding the reasons why people do or do not engage in certain health behaviours. Health behaviour theory, models and frameworks are also helpful for informing appropriate strategies that help reach the target group and are therefore more likely to be effective.

As the majority of women with gestational diabetes mellitus do not participate in physical activity as recommended (Symons Downs & Ulbrecht, 2006; Anjana et al., 2016), from a health behaviour theory perspective, the qualitative study (Chapter 4) was an important first step for exploring 'why'. The social-ecological model (Bronfenbrenner, 1994; Stokols, 1996) applied in Chapter 4 provided a theoretical framework highlighting that multiple factors across several domains (intrapersonal, interpersonal, and environmental) influenced behaviour. Therefore, this model provided a framework to improve our understanding of the many factors that may influence attitudes of women with gestational diabetes mellitus to physical activity, the reasons why they do not engage in physical activity and enablers that could be harnessed. This was considered necessary to inform

planning and design of an effective intervention (the 'what' and 'how') to address these women's needs.

The findings from the systematic review (Chapter 3) and the qualitative study (Chapter 4) suggested the general, population health message about physical activity for health and wellbeing in pregnancy had been received because women expressed the attitude that physical activity during pregnancy was important and beneficial. This was an important finding because theorists suggest attitude influences intention to action – in this case physical activity participation (Fishbein & Ajzen, 1975; Godin, 1987; Godin & Shephard, 1986; Godin, Vezin & Leclerc, 1989). The Theory of Planned Behaviour also proposes that factors additional to attitudes, that hinder or enable behaviour, may also influence intention and subsequent action (Ajzen, 1991; Armitage & Conner, 2001).

The diagnosis of gestational diabetes mellitus triggered concerns about the safety of physical activity and combined with uncertainty about what type and how much physical activity was safe, this appeared to create a disconnect between the women's belief that physical activity was important and their action: a knowledge-to-action gap (Kitson & Strauss, 2010). From a theoretical perspective these findings are consistent with key constructs from Social Cognitive Theory (Bandura, 1986a, 1986b, 1997) and the Health Belief Model (Champion & Skinner, 2008; Rosenstock, 1974; Rosenstock et al., 1988). Building on Bandura's Social Cognitive Theory, which proposes there are continual, dynamic interactions occurring between a person, environmental factors and behaviour that influences a person's subsequent behaviour and introduces the construct of self-efficacy (Bandura, 1986a, 1986b, 1997), the Health Belief Model theorises that key factors influence and predict health-related behaviours. These include a person's perceived concern about their health and safety (susceptibility), perceived behavioural barriers and enablers, potential positive benefits of behaviour, exposure to factors that encourage the health behaviour (cue to action) and their confidence to successfully perform the health behaviour (self-efficacy) (Bandura 1986b, 1997; Champion & Skinner 2008; Rosenstock, 1974; Rosenstock et al., 1988). Therefore, Social Cognitive Theory and the Health Belief Model assist our understanding of how the diagnosis of gestational diabetes contributes to women's perceived physical activity barriers due to its potential to cause ill-health (susceptibility) and uncertainty causing lack of self-efficacy about physical activity during a gestational diabetes pregnancy which hinders action (physical activity participation).

Inconsistency in information, specifically about safe physical activity for a gestational diabetes mellitus pregnancy, and the lack of confidence in sources such as the internet, were also barriers hindering women's participation in physical activity. To feel confident (self-efficacy) and safe about being physically active during pregnancy, women said they wanted clear, simple and gestational diabetes-specific messages from credible sources (enablers) explaining what type and how much physical activity was safe. The subsequent intervention of a consumer co-created infographic (Chapter 5) provided the specific information for 'shaping of knowledge' and about 'health consequences', as described in the Behaviour Change Technique Taxonomy (Michie et al., 2013), that addressed their health concerns and provided the key, practical and gestational diabetes mellitus-specific messages the women said they needed in the simple, easy-to-read format they requested. Therefore, this infographic may have the potential to provide the 'cue to action' these women need to be more physically active. Addressing the health concerns of being diagnosed with gestational diabetes, providing gestational diabetes-specific information about benefits of physical activity and succinct, clear messages about what type and how much physical activity, the infographic addressed barriers, was enabling, and was shown to increase short-term knowledge and self-efficacy about being physically active.

The Health Belief Model (Champion & Skinner, 2008; Rosenstock et al., 1988) proposes self-efficacy as a key factor positively influencing health behaviours. Self-efficacy Theory proposes self-efficacy is an important factor in behaviour change, with a person's confidence in their ability to perform a specific behaviour positively related to their ability to action and perform it (Bandura, 1986b, 1997). Knowing what and how to perform the behaviour is also an important factor. Therefore, in keeping with theory and based on the findings from Chapters 3 and 4 of this thesis, the intervention of a consumer co-created infographic (Chapter 5) was an appropriate and effective strategy for improving short-term self-efficacy belief by providing clear and simple information for women with gestational diabetes about what types and how much physical activity to participate in and improving the knowledge necessary for behavioural capability. It also explained gestational diabetes mellitus-specific benefits including blood sugar control which was reinforced by the feedback from women's regular monitoring of blood sugar levels, which theory proposes increases a person's likelihood of repeating the behaviour. As such, from a theoretical perspective, the provision of a consumer co-created infographic with specific gestational diabetes mellitus-related information appears to be

an appropriate intervention for bridging the previously identified knowledge gap about physical activity in the women with gestational diabetes mellitus.

Therefore, the findings of this thesis suggest applying frameworks from health behaviour theory (social-ecological model, Theory of Planned Behaviour, Social Cognitive Theory and the Health Belief Model) can assist health professionals to apply a systematic, scientific approach to addressing the health issue of physical activity participation in women with gestational diabetes mellitus (Glanz et al., 2002; Rimer & Glanz, 2005). Theory is helpful in providing a lens through which to consider and better understand the way factors may influence behaviour (Chapter 3 and 4) and to inform planning, implementation and evaluation of health-promoting interventions that are relevant and meaningful in specific contexts and to specific populations.

6.2.2 *Importance of partnering with consumers* - '*doing it with us not for us*' *(Department of Health Victoria 2011; Turk et al. 2017)*

The development of a consumer co-created infographic (Chapter 5), was based on the principle that those for whom the intervention is intended have a right to provide input to ensure it meets their needs (NHMRC, 2016; Miller et al., 2017). Consumer and community involvement frameworks, or patient and public involvement as termed in the United Kingdom, are based on the principle of involving consumers (patients, potential patients, survivors, carers, or those with lived experience of a condition) as active participants in health care decisions, interventions or research to ensure relevance for those it aims to help (Cancer Australia, 2011; Cochrane Community, 2018; International Association for Public Participation, 2018; Jennings et al., 2018; Price et al. 2018). Involving participants representative of consumers in research and planning can improve quality and relevance (Hanney, Boaz, Jones & Soper, 2013) as outcomes are more likely to be useful and of benefit to them (National Institute for Health Research INVOLVE, 2012; Miller et al, 2017). There is also increasing acceptance that a person-centred approach and involving consumers as partners in healthcare and research can improve safety, patient experience and outcomes (Luxford & Newell, 2015, South et al., 2016). Involving consumers in research may also reduce research 'waste' and assist translation to practice because it ensures research is relevant (Chalmers et al., 2014). For these reasons, involvement of consumers in research is recommended in patient and public involvement frameworks (International Association for Public Participation, 2018; Price et al. 2018; South et al., 2016).

The level of consumer involvement in research can vary (Staley, 2015, Stacey et al., 2015). As outlined in frameworks, levels of consumer involvement can be summarised as informing, consulting, involving, collaborating or partnering, and empowering or consumer-led (Cancer Australia, 2011; International Association for Public Participation, 2018; Miller et al., 2017; National Institute for Health Research INVOLVE, 2012). The informing level involves providing information to assist the consumer to understand the problem and possible solutions and so may assist in improving health literacy. At the consulting level the researcher listens to the consumer and seeks information and feedback. The involving level builds consumer engagement to ensure issues are understood. The level of collaboration involves consumers working with researchers and health professionals at all levels and incorporates consumer recommendations in decision making. The final level is empowering of consumers to enable a consumer-led approach to setting priorities, policy and decision-making (Cancer Australia, 2011; International Association for Public Participation, 2018; Miller et al., 2017; National Institute for Health Research INVOLVE, 2012).

While the ideal of consumer and patient and public involvement frameworks is for consumers to participate at all levels, the challenge of realistically achieving this is recognised (Greenhalgh et al., 2019). A recent systematic review identified and synthesised 65 frameworks supporting consumer, patient and public involvement and described the tension between the academic ideal of a framework and the local context (Greenhalgh et al., 2019). It concluded that pragmatically, a single framework may not be as useful as reviewing various consumer involvement frameworks and harnessing the most appropriate tools to develop a locally relevant, co-design activity that realistically meets the needs of the local context (Ghate, 2018; Greenhalgh et al., 2019). So, although it is acknowledged that consumer involvement at all levels was not realised, consistent with the findings from Greenhalgh et al., (2019) relevant elements of the consumer involvement frameworks were used and participants who were representative of consumers were involved as appropriate to the clinical context and resource constraints.

The first systematic review (Chapter 2), with twenty citations, helped to inform and build public awareness about the benefits of physical activity in assisting glycaemic control in gestational diabetes mellitus. The second systematic review (Chapter 3) sought to understand the physical activity attitudes, context and experience of pregnant women

including those with gestational diabetes. This review highlighted a gap in information and understanding about the needs of a specific group, (women with gestational diabetes), which the qualitative study (Chapter 4) subsequently aimed to fill. The qualitative study (Chapter 4) involved semi-structured interviews with participants, who were representative of consumers diagnosed with gestational diabetes mellitus, to gather evidence to assist in better understanding the lived experience and needs of the women with gestational diabetes mellitus. A key barrier hindering women's participation in physical activity was inconsistent information and suggested information from guidelines (ACOG, 2020; NICE, 2015) may not be reaching women with gestational diabetes mellitus, or that information was not in a format that met their needs. This highlighted an evidence-knowledge gap. Women with gestational diabetes wanted improved physical activity messaging that was clear and easy to understand and specific for their gestational diabetes pregnancy. The evidence gathered in Chapter 4 informed, and provided direction for, the subsequent trial (Chapter 5) and highlighted the need to partner with these women to inform the intervention so that it was person-centred and satisfied their specific needs.

Participation of women with gestational diabetes mellitus as collaborators in the design of the study was a key focus of Chapter 5 and was important in informing the direction of the research and intervention to ensure it was safe, relevant and met the needs of the target group. Through group consultation meetings in the study (Chapter 5), women with gestational diabetes clearly communicated what they wanted in an intervention which was specific, clear and practical messaging about physical activity during their pregnancy that provided physical activity options that were realistic, achievable and flexible to fit in with their busy lifestyle. They wanted this information from a credible source at the time (or soon after) they were diagnosed. This was consistent with the findings of the qualitative study (Chapter 4). Co-designing the infographic intervention with the women with gestational diabetes mellitus values their knowledge and lived experience (Chapter 5). Although providing an infographic may seem simple, the fact it was co-created with women with gestational diabetes mellitus likely contributed to its effectiveness. Consistent with consumer/patient and public involvement framework benefits (Cancer Australia, 2011; International Association for Public Participation 2018; Miller et al., 2017) and recommendations for developing patient information (Miller et al. 2017; National Institute for Health Research INVOLVE, 2012), this appeared to be because the infographic intervention was derived from involvement of participants who were representative of the consumers it aimed to help. Therefore, the infographic's messaging

about physical activity was highly relevant to these women's specific needs and their preferred format; so consistent with the theoretical perspective, it contributed to their perceived behavioural control and self-efficacy.

The findings from the studies in Chapters 4 and 5, suggest understanding the context and specific needs of the target population are an important part of developing and disseminating health messaging. This appears especially relevant in an environment where, health funding and resources are scarce; patients are time-poor or where there are restrictions limiting face to face interventions. This ensures the intervention is relevant to the context and the consumers thereby potentially reducing waste (Chalmers et al., 2014). Involving participants, who are representative of consumers, to find new ways to provide health messaging is also important in bridging the evidence-to-action gap.

6.2.3 *Effective ways to promote health messages*

Finding effective modes of creating physical activity messaging that is appropriate for the target audience, such as women with gestational diabetes, is needed to bridge the evidence-to-action gap. Although clinical guidelines recommending physical activity for women with gestational diabetes exist (ACOG, 2020; NICE, 2015), they are often lengthy, targeted more at health professionals and so not easily accessible for patients. Therefore, it is important for health professionals to find better ways of transmitting this information to consumers in a format that is easy for them to access and understand.

Health professionals developing health messages can learn much from the field of social (public health) marketing. This historically draws on principles from commercial marketing which had long been considered an effective tool for selling products (Kotler & Zaltman, 1971; Wiebe, 1951). Commercial marketing's principles of researching the attitudes and behaviours of the target consumer group to inform design and promotion of products that consumers wanted was credited as contributing to its effectiveness and is consistent with the consulting level in patient and public involvement frameworks (International Association for Public Participation, 2018; Kotler & Zaltman, 1971; Wiebe, 1951). Therefore, the idea of social marketing was suggested in the early 1950s as a way to improve the effectiveness of messaging about social behaviour change programs (Wiebe, 1951). It was suggested social marketing provided a link between social scientists' behavioural theories and marketing frameworks for researching, planning, implementing, and communicating social behavioural change programs (Kotler &

Zaltman, 1971). Effective social/public health marketing campaigns have assisted health-promotion programs to become well known and influence people's behaviour. The '5 A Day' program of nutritional advice is a good example of an effective public health program targeting health behaviour (Andreasen, 1995; Alcalay & Bell, 2000; Glanz et al., 2002). The findings of this thesis suggest public health marketing principles of researching consumer attitudes, needs and involving consumers to better target audience needs, as used at a population level in large public health promotion campaigns and consistent with patient and public involvement frameworks, can be easily adopted and used by health professionals more locally. This increased understanding of consumer needs may increase the effectiveness of health professionals' health messaging for improving health behaviours of their patients such as improving physical activity participation.

Drawing on health behaviour theory, social marketing research is used to capture information about intrapersonal, interpersonal and environmental factors including attitudes, barriers, enablers and personal priorities, which may influence consumer's behaviour (French & Blair-Stevens, 2007; Glanz et al., 2002). This information is useful when health professionals are crafting and pitching the health message so that they ensure communication is highly relevant and attuned to the target group's social and behavioural profile. Health promotion is similar in that it aims to 'sell' health-promoting behaviours such as physical activity. So, adopting some of the key aspects of social marketing practices used in public health promotion may be helpful for health professionals in clinical settings for planning and design of messaging aimed at improving health behaviour. Supported by the findings from this thesis (Chapter 5) and by public health marketing principles (French, 2009; Glanz et al. 2002; Kotler & Zaltman, 1971), consumer input to inform and refine messages is important for success as it reinforces the principle of consumers as partners in development of health care information.

Social, or health promotion marketing, reconceptualises components of commercial marketing principles to fit the social or health context. The 'four Ps' (product, price, place, promotion) are key components of commercial marketing practice (McCarthy, 1960) that aim to highlight benefits, promote enablers, and combat barriers to 'product' uptake (French & Blair-Stevens 2007; Glanz et al. 2002). In terms of health promotion, the 'product' relates to the desired health behaviour and its benefits. 'Price' relates to the time, effort, or cost of participating in that health behaviour e.g. time and cost of

participation in physical activity. ‘Place’ is about accessibility and convenience and ‘Promotion’ refers to how the product (desired behaviour), including all its benefits, is communicated to the target group (Rimer & Glanz, 2005; French, 2009). Health professionals are experts in the health behaviour ‘product’ and so they often focus on providing clinical information. However, what the patient wants to know is how this relates to their life, practical options for what they need to do e.g. walking versus exercising at a gym, and practical ways to manage this change within their lifestyle.

Consistent with the fact that almost 60% of Australian adults are not sufficiently health literate to understand health care information (Australian Commission on Safety and Quality in Health Care, 2014), patients also wanted this information presented in a format that was easy to understand. Health literacy recommendations for developing consumer information include, use of simple, easily understood language (rather than medical jargon), short sentences and minimising text, and are helpful to facilitate understanding (Australian Commission on Safety and Quality in Health Care, 2014, 2020). The involvement of consumers ensures a person-centred approach and enables patients to be actively engaged with professionals in determining the priorities for their care. In this case, being active contributors to the development of health messages ensures those messages are relevant and appropriate to the needs of consumers in the specific context, such as for pregnant women diagnosed with gestational diabetes mellitus.

The findings from Chapter 5 also supports the concept of providing health information in a way that is engaging, suitable for the specific needs of the audience and limited to key information as prioritised by the target group. An infographic presents data and ideas visually with minimal use of text and so provides messaging that is engaging, clear and simple (Krum, 2013; Murray et al., 2017). Consistent with findings of the randomised controlled trial (Chapter 5), it has been reported that even three days after receiving information in an infographic format, the message is 6.5 times more likely to be remembered than from reading text alone (Krum, 2013). This is because visual inputs improve our ability to process and retain information (Smiciklas, 2012; Scott, Fawkner, Oliver & Murray, 2016) and are a faster and more effective way of delivering information than text alone (Reeve & Morris, 2016). As infographics are easily shared, when consumer informed, they can be a useful tool for health professionals for providing

engaging, effective messages for dissemination via various mediums thereby increasing audience reach and impact.

In summary, combining principles from theory, consumer involvement, and social/public health marketing may be useful for health professionals developing effective strategies to promote and communicate health messages. Using these principles appears to assist in translating evidence from guidelines into a format that improves transmission to the target audience and may assist in bridging evidence-to-action gaps necessary for improving health behaviour.

6.3 Strengths and Limitations

The mix, breadth and rigour of research methods used to explore and extend the current body of knowledge about physical activity for women with gestational diabetes mellitus are key strengths of this thesis. These methods included two systematic reviews (Chapters 2 and 3), the first confirming exercise has a beneficial effect on glycaemic control in women diagnosed with gestational diabetes mellitus. The second systematic review (Chapter 3) combined evidence from 47 quantitative and qualitative studies, providing a rich, deep understanding of perceptions of pregnant women toward physical activity. A qualitative study (Chapter 4) using semi-structured interviews with 27 women provided an in-depth insight into physical activity perceptions and lived experiences of women with gestational diabetes mellitus. Finally, a parallel group, randomised, controlled trial (Chapter 5) with concealed allocation and intention-to-treat analysis involving 69 participants (experimental group n=37; control group n=32) evaluated the effectiveness of the consumer co-designed intervention aimed at addressing the women's needs for improved messaging about physical activity.

The systematic reviews, qualitative study and randomised trial were reported using appropriate guidelines. Protocols for the two systematic reviews (Chapters 2 and 3) were prospectively registered with PROSPERO and the reviews reported according to the Preferred Reporting for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). The second review, which included qualitative as well as quantitative studies, additionally complied with the Enhancing Transparency in Reporting the Synthesis of Qualitative Research: ENTREQ statement (Tong, Fleming, McInnes, Oliver & Craig, 2012) and was also guided by information from the Cochrane Qualitative and Implementation Methods Group (Noyes et al., 2013).

The qualitative study (Chapter 4) was reported according to the Consolidated Criteria for Reporting Qualitative studies (COREQ) checklist (Tong, Sainsbury & Craig, 2007) and the Standards for reporting Qualitative Research (SREQ) (O'Brien, Harris, Beckman, Reed & Cook, 2014). The randomised controlled trial (Chapter 5) was prospectively registered with Australian New Zealand Clinical Trials Registry and reported according to the Consolidated Standards of Reporting Trials (CONSORT) Statement (Schultz, Altman, & Moher & CONSORT Group, 2010) and the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014).

Consistent with recommendations about the importance of involving patients in research (Cochrane Community, 2018; Miller et al., 2017), consumer participation was a major feature of this thesis (Chapter 5) to ensure relevance to those it aims to assist. The qualitative study (Chapter 4) used a phenomenological approach to understand the lived experience of women with gestational diabetes (Smith & Osborn, 2008) providing a deeper understanding than that which may have been revealed through quantitative data alone (Liamputtong, 2013; Lichtman, 2006). An interpretive description theoretical framework was applied to enable an understanding of the phenomena from a clinical perspective to help facilitate translation of findings into practice (Thorne, Kirkham, & MacDonald-Emes, 1997; Thorne, Reimer Kirkham, & O'Flynn-Magee, 2004). The randomised trial (Chapter 5) involved consultation and involvement with consumers to co-create an infographic about physical activity for women diagnosed with GDM prior to trial commencement. The Critical Appraisal Skills Programme (CASP) Patient and public involvement (PPI) checklist was used to guide the consumer engagement (Wright, Foster, Amir, Elliott, & Wilson, 2010).

In Chapter 3, similar themes emerged across both the qualitative and quantitative studies, contributing to the generalisability of the findings and could be considered a strength. The consistency of the women's narratives across studies (Chapters 4 and 5) confirmed the insights into their attitudes, barriers and enablers to physical activity during pregnancy gleaned from the second systematic review (Chapter 3). Given the representativeness of the participant samples across studies this improves the external validity of these findings and is a strength.

The diversity and detailed accounts of participant demographics, continuation of recruitment until data saturation and the rigour of the qualitative process enhanced the

confirmability, trustworthiness, and transferability of findings to similar populations are further strengths (Chapter 4). The trial sample was also representative of women diagnosed with gestational diabetes mellitus in terms of country of birth (Australian Institute of Health and Welfare, 2019; Yuen & Wong, 2015) age (Barakat et al. 2011; Carolan, Gill & Steele, 2012) and gestation (Nankervis et al., 2014). These detailed descriptions of participant characteristics enhance the generalisability of findings to similar populations.

A further strength of this trial is its contribution to the current body of knowledge about the use of a co-designed infographic about physical activity participation, as an intervention. Although the use of infographics is becoming a popular means of providing health information, randomised trials evaluating the effectiveness of using infographics as an intervention are limited (McCrorie, Chen, Weller, McGlade & Donnelly, 2018). Therefore, by applying the combined principles of consumer involvement frameworks, health marketing principles with infographic design for health messaging, the trial in this thesis contributes new evidence to the limited body of knowledge about the effectiveness of providing health information in a consumer co-designed infographic format for improving short-term knowledge and self-efficacy.

This thesis also has several limitations. The differing types of exercise among the included trials in the first systematic review (Chapter 2) could be considered a limitation. A previous systematic review (Umpierre et al., 2011) concluded aerobic and/or resistance exercises were similarly effective in improving glycaemic control in people with type 2 diabetes. Therefore, it was considered acceptable to combine trials using different types of exercise as long as they were similar in dosage. In the second review (Chapter 3) the large number of included studies (47 discrete studies with 7655 participants from a broad range of backgrounds) was a strength. The heterogeneity of data across quantitative studies was a potential limitation; however the quantitative findings were supported by the key themes arising from the qualitative studies which also provided context to the findings. In the qualitative study (Chapter 4) and the randomised controlled trial (Chapter 5), the recruitment of only English-speaking women may have influenced findings and is acknowledged as a limitation however the diversity and detailed descriptions of participant characteristics in both the study and the trial enhance the generalisability of findings to similar populations. In the trial (Chapter 5) although the intervention was conducted at an individual level, the process of randomisation occurred by the education

session attended rather than by individual to account for the risk of contamination and could be considered a limitation. However, the randomisation process resulted in the groups being well balanced for the day of the week on which the class was conducted, and a sensitivity analysis adding day of the week as a covariate was performed and confirmed the main analysis. Also, in the trial, blinding of participants was not possible due to the type of intervention.

A limitation of the thesis overall is that it is acknowledged that the problem, of women with gestational diabetes not participating in physical activity as recommended in clinical guidelines, is multi-factorial and therefore may require multiple strategies to address. For example, the findings in Chapter 2 suggested that the information from clinical guidelines appeared not to be reaching women however did not investigate other possible contributing factors such as how well the guidelines are disseminated and transferred to the target group. Therefore, it is recognised and acknowledged as a limitation, that the problem of inactivity in women with gestational diabetes mellitus is multi-factorial and may require several and further strategies to address this problem which were not explored in this thesis.

6.4 Directions for Future Research

The four studies that comprise this thesis pave the way for further research. A key question arising from the randomised trial (Chapter 5) is whether the positive changes in knowledge and self-efficacy, from consumer co-designed messaging about physical activity during a gestational diabetes pregnancy, translates into increased physical activity participation in women with gestational diabetes and maintenance of glycaemic control. Although self-efficacy has been positively correlated with improved physical activity participation in pregnant women (Gaston, Cramp, & Prapavessis, 2012); it is still unknown whether the short-term improvement in knowledge and self-efficacy translates into improved physical activity participation in women diagnosed with gestational diabetes mellitus. Chapter 2 of this thesis provided evidence that moderate intensity physical activity performed for at least 30 minutes three times weekly was beneficial for glycaemic control in gestational diabetes. Therefore, investigating if increased knowledge and self-efficacy about physical activity translates into improved physical activity participation is important.

The proposed next step in this program of research is a parallel, randomised controlled trial to investigate the effects of a consumer co-designed infographic about physical activity during a gestational diabetes pregnancy on physical activity participation levels and glycaemic control during the gestational diabetes pregnancy.

Therefore, the research questions for this the proposed trial would be:

1. Does a consumer co-created infographic, additional to usual-care gestational diabetes management, safely improve physical activity participation in women with gestational diabetes mellitus compared to gestational diabetes education alone?
2. Does a consumer co-created infographic, additional to usual-care gestational diabetes management, improve glycaemic control in women with gestational diabetes mellitus compared to gestational diabetes education alone?

Participants would be women aged 18 to 40 years with a healthy singleton pregnancy with no known reason precluding them from physical activity and diagnosed with gestational diabetes mellitus. Recruitment would be targeted at places of ante-natal care including ante-natal clinics and General Practitioner practices to ensure a broad sample. To facilitate diversity of participants, as key cultural groups such as women from Asia and South-East Asia are known to have higher rates of diabetes, non-English speaking women from Asian backgrounds would be included and catered for with use of translated written material.

Consenting participants would be randomised at the level of the individual by an independent researcher not involved in participant recruitment or evaluation. The randomisation of allocations would be through a concealed method, determined by computer-generated program and placed in a sequentially numbered, opaque envelope. The researcher administering the intervention would be informed of each participant's random allocation but would not be involved in the collection of outcome data or analysis.

Participants randomised to the experimental group would receive, by mail, email or text at week 1, a copy of the consumer co-created infographic about physical activity during a gestational diabetes pregnancy used in the trial (Chapter 5). This would be in addition to usual-care gestational diabetes management. The experimental group participants would

also receive weekly text or email reminders with the infographic. The participants allocated to the comparison group would receive usual-care gestational diabetes management. Usual care typically includes information about gestational diabetes mellitus, when and why it occurs, nutritional requirements in pregnancy, gestational diabetes mellitus dietary modifications and lifestyle changes, regular monitoring of blood sugar levels and if necessary medication, to reduce risks associated with poor glycaemic control during pregnancy.

The primary outcome measure would be self-reported physical activity at weeks eight and twelve. Secondary outcomes measures would be blood glucose levels and medically-reported birth outcomes. Daily self-reporting of type, frequency and duration of physical activity would be added to the usual-care blood sugar monitoring diary or recorded using their smart phone. This monitoring diary would be completed by participants several times daily before and after meals throughout their pregnancy and would also provide real-time feedback on the effect of physical activity on their blood sugar targets. To capture daily step count, participants would also be provided with a pedometer. Measures of physical activity and blood sugar levels would be compared at baseline (week 0), and at four-weekly intervals or in the week prior to onset of labour if this occurs before week 12. Birth outcomes would include measures of maternal and neonatal safety such as pregnancy induced-hypertension, caesarean sections, premature birth, neonatal hypoglycaemia, birth weight > 90^{th} percentile and shoulder dystocia as reported in the medical record. Participant demographic details would be collected at baseline and include age, gestation, parity, history of gestational diabetes mellitus, pre-pregnancy body mass index, educational level and country of birth.

An a priori sample size would be estimated to ensure the trial is fully powered to detect any effect of the intervention on the primary outcome of changes in the amount of moderate intensity, physical activity at weeks 8 and 12. The estimate of the sample size would be based on using a two-sided, 0.05 level of significance, 80% power and observational data reporting levels of moderate intensity physical activity in women with gestational diabetes mellitus at 7.5 min/day (± 49.5) (Galliano et al., 2019). Assuming a clinically meaningful difference of an increase of ≥15 minutes per day of moderate intensity physical activity (Wen et al., 2015) (or increase of 5000 steps per day), allowing for 10% attrition, it is estimated that a sample size of 384 participants (192 participants in each group) is needed. Data would be analysed according to the principle of intention-to-

treat with all available data used for analysis. Participant demographic data will be analysed using means and standard deviations (age, gestation, BMI) or proportions (parity, educational level and ethnicity). The difference in mean values of the outcomes between the intervention and control groups at four weekly intervals will be analysed with linear mixed models.

6.5 Conclusion

Physical activity is recommended for women with gestational diabetes mellitus. However, the majority of women with gestational diabetes mellitus are physically inactive, despite most having a positive attitude towards being active. This thesis demonstrated that involving women with gestational diabetes mellitus to inform and co-design an intervention to address their identified barriers to physical activity participation during pregnancy, can improve their knowledge and self-efficacy about physical activity. Given the important role that physical activity plays in glycaemic control, this body of work provides an impetus for further research to investigate if improving knowledge and self-efficacy can translate to increased participation in physical activity, and other improved health outcomes for women with gestational diabetes mellitus and their babies.

Appendix A: Ethics Approval Statements

Study 3 (Chapter 4)

Mercy Health
Care first

Mercy Health
Level 2, 12 Shelley Street
Richmond Vic 3121
Phone: +61 3 8416 7777
Fax: +61 3 8416 7888
mercyhealth.com.au

21 February 2017

Ms Anne Harrison
Physiotherapy Manager
Physiotherapy Department
Werribee Mercy Hospital
300 Princes Highway
Werribee
VIC 3030

Dear Ms Harrison

Re: 2017-001: A Qualitative exploratory study of attitudes, barriers and enablers to physical activity in women with gestational diabetes mellitus.

I am pleased to advise following receipt of the amendments as listed on the letter dated 15 February 2017, Mercy Health Human Research Ethics Committee agreed that this research can be ***approved*** as ***low risk research***.

Specifically, the following documentation is approved:

Module One	Dated 15 February 2017
1. Flyer	Version 7, Dated 29 November 2016
2. Participant Information Statement	Version 7, Dated 29 November 2016
3. Consent Form	Version 7, Dated 29 November 2016
4. Withdrawal of Consent Form	Version 7, Dated 29 November 2016
5. Semi-structure Interview schedule & Question guide	Dated 16 February 2017
6. Timeline of tasks	Version 7, Dated 29 November 2016
7. Risk Matrix	Version 7, Dated 29 November 2016
Project Proposal	Version 13, Dated 29 November 2016

The Human Research Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007- updated May 2015).

This approval by the Mercy Health Human Research Ethics Committee is valid from 21 February 2017 to 20 February 2019. That is, the project should be completed by the approval expiry date, of **20 February 2019**.

Should you require an extension of ethics approval, the HREC office must be contacted before the ethics approval runs out and your request must be accompanied with a current progress report. (Blank copy emailed with this letter)

Please note that the research project should have commenced within 6 months from the date of this letter.

1. Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, of any serious adverse effects on participants;

2. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
3. Notification and reasons for ceasing the project prior to its expected date of completion;
4. The completion of a progress report annually for the duration of the project;
5. Human Research Ethics Committee approval of any proposed modifications to the project;
6. The submission of a final report and papers published on completion of the project.

Please also note:
7. Consent Forms must be available for audit by the Human Research Ethics Committee and retained for the period required by law;
8. The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

If you have any queries, please do not hesitate to contact Ms Carole Branch, Administrative Officer, Mercy Health Human Research Ethics Committee on (03) 8458 4808.

Yours sincerely

Mr Tim O'Leary
Chair, Mercy Health Human Research Ethics Committee

LA TROBE UNIVERSITY

University Human Ethics Committee

RESEARCH OFFICE

MEMORANDUM

To: **Professor Nora Shields, School of Allied Health, College of SHE**

From: **Senior Human Ethics Officer, Ethics and Integrity**

Subject: **UHEC acceptance of Mercy Health HREC approved project - 2017-001**

Title: **A qualitative exploratory study of attitudes, barriers and enablers to physical activity in women with gestational diabetes mellitus**

Date: **2 March 2017**

Thank you for submitting the above protocol to the University Human Ethics Committee (UHEC). Your material was forwarded to the UHEC Chair for consideration. Following evidence of a full review and subsequent final approval by the **Mercy Health HREC**, the UHEC Chair agrees that the protocol complies with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and is in accordance with La Trobe University's *Human Research Ethics Guidelines*.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by **Mercy Health HREC.**

Limit of Approval. La Trobe UHEC endorsement is limited strictly to the research protocol as approved by **Mercy Health HREC**.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by **Mercy Health HREC** for the project should be notified formally to the UHEC.

Annual Progress Reports. Copies of all progress reports submitted to **Mercy Health HREC** must be forwarded to the UHEC. Failure to submit a progress report will mean that endorsement for your involvement this project will be rescinded. An audit related to your involvement in the study may be conducted by the UHEC at any time.

Final Report. A copy of the final report is to be forwarded to the UHEC within one month of it being submitted to **Mercy Health HREC.**

If you have any queries on the information above please e-mail: **humanethics@latrobe.edu.au** or contact me by phone.

On behalf of the La Trobe University Human Ethics Committee, best wishes with your research!

Kind regards,

Sara Paradowski
Senior Human Ethics Officer
Executive Officer – University Human Ethics Committee
Ethics and Integrity / Research Office
La Trobe University Bundoora, Victoria 3086
P: (03) 9479 – 1443 / F: (03) 9479 - 1464
http://www.latrobe.edu.au/researchers/ethics/human-ethics

Study 4 (Chapter 5)

Mercy Health
Care first

Mercy Hospitals Victoria Ltd
Level 2, 12 Shelley Street
Richmond Vic 3121
Phone: +61 3 8416 7777
Fax: +61 3 8416 7888
mercyhealth.com.au

18 February 2019

Ms Anne Harrison
Physiotherapy Manager
Werribee Mercy Hospital
300 Princes Highway
Werribee VIC 3030

Dear Ms Harrison,

Re: 2018-073: Does a consumer co-created infographic improve knowledge and self-efficacy about physical activity for women during a GDM pregnancy?

I am pleased to advise that the Mercy Health Human Research Ethics Committee meeting held on 11 December 2018 endorsed the approval of the above research proposal.

It was noted that the study had formerly received expedited approval from the Mercy Health HREC Expedited Review Working Party.

In particular, the following is approved:

Document	Version	Date
Expedited Review Application Form	1	Received 14 December 2018
Low Risk Checklist	1	Received 14 December 2018
Researchers' Declaration – Signed	1	Received 14 December 2018
Section E: Collection/Use/Disclosure of Information	1	Received 14 December 2018
CV – Anne Harrison	-	Received 14 December 2018

The Mercy Health Human Research Committee has granted approval of research until 29 January 2020.

Mercy Health
Care first

The Human Research Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007- updated 2018).

In accordance with the NHMRC Guidelines, approval is subject to:

1. Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, of any unforeseen events that may affect the continuing ethical acceptability of the project;
2. Notification and reasons for ceasing the project prior to its expected date of completion;
3. The completion of a progress report at 6 months and then annually for the duration of the project.
4. Human Research Ethics Committee approval of any proposed modifications to the project;
5. The submission of a final report and papers published on completion of the project.

Please also note:

6. The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

In future correspondence please quote the given project number: **2018-073.**

Extensions:

If an extension of ethics approval is required, the HREC office must be contacted before the ethics approval runs out. Your request must be accompanied with a current progress report.

Progress Report:

Progress reports are due on the anniversary of ethical approval. Continuation of ethics approval is contingent on submission of an annual progress report. Failure to comply with this requirement may result in suspension of this research.

Amendments:

Amendments to approved research can be made at any time. Amendments must be submitted with a Mercy Health Amendment Request Form and copies of any additional or amended documentation with tracked changes.

If you have any queries, please do not hesitate to contact Ms Natasha Rooney, Administrative Officer Mercy Health Human Research Ethics Committee on 8458 4808 or email ethics@mercy.com.au.

Mercy Health

Yours sincerely,

Mr Tim O'Leary

Chair, Mercy Health Human Research Ethics Committee

LA TROBE UNIVERSITY

4 February 2019

Research Office

To	Nora Shields
From	University Human Ethics Committee
Reference Number	MercyHealth2018-073
Project title	Does a consumer co-created infographic improve knowledge and self-efficacy about physical activity for women during a GDM pregnancy?
Subject	Externally Approved Project
Date	4 February 2019

The externally approved project submitted above was reviewed and noted by the University Human Ethics Committee Chair.

Please note that all requirements and conditions of the original ethical approval for this project still apply.

Should you require any further information, please contact the Human Research Ethics Team on:
T: +61 3 9479 1443 | E: humanethics@latrobe.edu.au.

Warm regards,

David Finlay
Chair, University Human Ethics Committee

Appendix B: Publication Statements

Study 1 (Chapter 2)

Statement from the authors confirming the authorship contribution of the Professional Doctoral Candidate:

"As co-authors of the paper, '**Harrison, A. L.,** Shields, N., Taylor, N. F., & Frawley, H. C. (2016). Exercise improves glycaemic control in women diagnosed with gestational diabetes mellitus: a systematic review. *Journal of Physiotherapy, 62*(4), 188–196.' we confirm that Anne Harrison made the following contributions:"

- Conception and design of the research
- Collection of data
- Analysis of data
- Interpretation of findings
- Writing the paper
- Critical appraisal of the content and
- Response to reviewers

Professor Nora Shields …… ……. Date: 28 / 08 / 2020

Professor Nicholas F Taylor …… …… Date: 28 / 08 / 2020

A/Professor Helena C Frawley …… …… Date: 28 / 08 / 2020

Study 2 (Chapter 3)

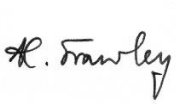
Statement from the authors confirming the authorship contribution of the Professional Doctoral Candidate:

"As co-authors of the paper, '**Harrison, A. L.,** Taylor, N. F., Shields, N., & Frawley, H. C. (2018). Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review. *Journal of Physiotherapy, 64*(1), 24–32.' we confirm that Anne Harrison made the following contributions:"

- Conception and design of the research
- Collection of data
- Analysis of data
- Interpretation of findings
- Writing the paper
- Critical appraisal of the content and
- Response to reviewers

Professor Nora Shields …… …… Date: 28 / 08 / 2020

Professor Nicholas F Taylor …… …..…….. Date: 28 / 08 / 2020



A/Professor Helena C Frawley …… …… Date: 28 / 08 / 2020

Study 3 (Chapter 4)

Statement from the authors confirming the authorship contribution of the Professional Doctoral Candidate:

"As co-authors of the paper, '**Harrison, A. L.,** Taylor, N. F., Frawley, H. C., & Shields, N. (2019). Women with gestational diabetes mellitus want clear and practical messages from credible sources about physical activity during pregnancy: a qualitative study. *Journal of Physiotherapy*, *65*(1), 37–42.' we confirm that Anne Harrison made the following contributions:"

- Conception and design of the research
- Collection of data
- Analysis of data
- Interpretation of findings
- Writing the paper
- Critical appraisal of the content and
- Response to reviewers

Nora Shields

Professor Nora Shields …… …… Date: 28 / 08 / 2020

Professor Nicholas F Taylor … ……..….. Date: 28 / 08 / 2020

H. Frawley

A/Professor Helena C Frawley …… …… Date: 28 / 08 / 2020

Study 4 (Chapter 5)

Statement from the authors confirming the authorship contribution of the Professional Doctoral Candidate:

"As co-authors of the paper, '**Harrison, A. L.**, Taylor, N. F., Frawley, H. C., & Shields, N. (2020). A consumer co-created infographic improves short-term knowledge about physical activity and self-efficacy to exercise in women with gestational diabetes mellitus: a randomised trial. *Journal of Physiotherapy, 66*(4), 243-248.' we confirm that Anne Harrison made the following contributions:"

- Conception and design of the research
- Collection of data
- Analysis of data
- Interpretation of findings
- Writing the paper
- Critical appraisal of the content and
- Response to reviewers

Professor Nora Shields …… …… Date: 28 / 08 / 2020

Professor Nicholas F Taylor …… …… ….….. Date: 28 / 08 / 2020

A/Professor Helena C Frawley … …….. Date: 28 / 08 / 2020

Appendix C: Copyright Permissions

Items subject to copyright:

Chapters 2, 3, 4 and 5 of this thesis were published in the Journal of Physiotherapy by Elsevier.
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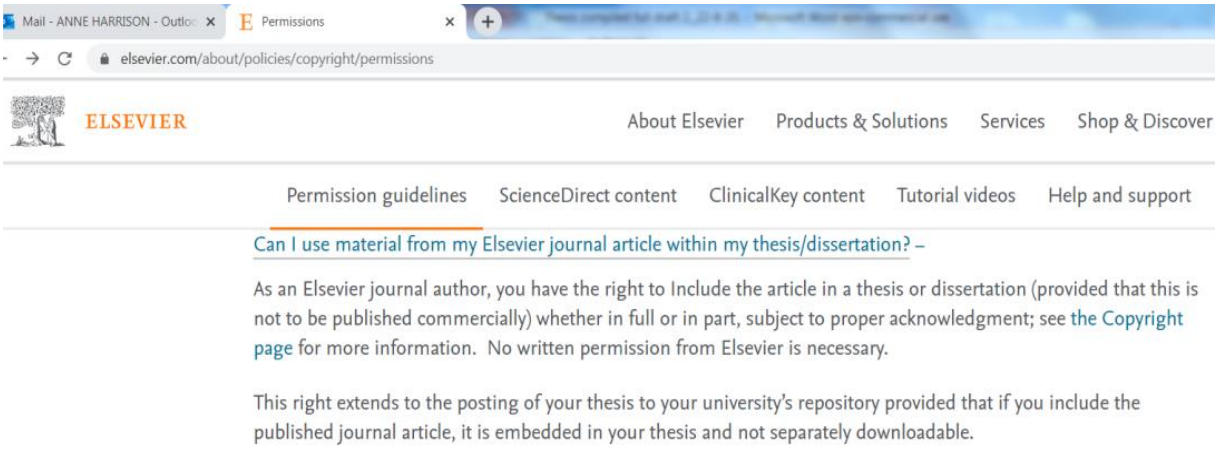

Appendix D: Completed Reporting Checklists

Study 1 (Chapter 2)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE		**Exercise for women diagnosed with gestational diabetes mellitus improves glycaemic control: a systematic review**	
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Pages 3 - 4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 2

Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 4 & Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Page 5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Pages 5 - 6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Pages 5 - 6

Study 2 (Chapter 3)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE		**Attitudes, barriers and enablers to physical activity in pregnant women: a systematic review**	
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Pages 4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 5 & 6 & Box 1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 5 & Appendix 1

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 6 & 7 & Box 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 7 & 8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Pages 6 & 7 & Table 1
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Pages 7 & 8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Pages 7 & 8

Study 2 (Chapter 3)

ENTREQ Checklist

No	Item	Guide and description	Response (Page No. in manuscript)
1	Aim	State the research question the synthesis addresses.	To identify the attitudes, barriers and enablers to physical activity perceived by pregnant women including women diagnosed with gestational diabetes mellitus. (Abstract, p.3; Introduction, p.5)
2	Synthesis methodology	Identify the synthesis methodology or theoretical framework which underpins the synthesis, and describe the rationale for choice of methodology *(e.g. meta-ethnography, thematic synthesis, critical interpretive synthesis, grounded theory synthesis, realist synthesis, meta-aggregation, meta-study, framework synthesis).*	Meta summary of qualitative and quantitative findings. (Introduction, p.4; Methods, p.7) Use of socio-ecological framework to group findings. (Abstract, p.3; Methods, p.8)
3	Approach to searching	Indicate whether the search was pre-planned (*comprehensive search strategies to seek all available studies)* or iterative (*to seek all available concepts until they theoretical saturation is achieved)*.	Pre-planned see Methods, p.5
4	Inclusion criteria	Specify the inclusion/exclusion criteria *(e.g. in terms of population, language, year limits, type of publication, study type).*	See Methods, pp. 5-6 & Box 1
5	Data sources	Describe the information sources used (e.g. *electronic databases (MEDLINE, EMBASE, CINAHL, psycINFO, Econlit), grey literature databases (digital thesis, policy reports), relevant organisational websites, experts, information specialists, generic web searches (Google Scholar) hand searching, reference lists)* and when the searches conducted; provide the rationale for using the data sources.	See Methods, Identification and selection of studies, p.5 and Appendix 1

No	Item	Guide and description	Response (Page No. in manuscript)
6	Electronic Search strategy	Describe the literature search *(e.g. provide electronic search strategies with population terms, clinical or health topic terms, experiential or social phenomena related terms, filters for qualitative research, and search limits).*	See Methods, Identification and selection of studies, p.5 and Appendix 1
7	Study screening methods	Describe the process of study screening and sifting *(e.g. title, abstract and full text review, number of independent reviewers who screened studies).*	See Methods, Identification and selection of studies, p.5
8	Study characteristics	Present the characteristics of the included studies *(e.g. year of publication, country, population, number of participants, data collection, methodology, analysis, research questions).*	Results (pp. 5-6) and Table 2
9	Study selection results	Identify the number of studies screened and provide reasons for study exclusion *(e,g, for comprehensive searching, provide numbers of studies screened and reasons for exclusion indicated in a figure/flowchart; for iterative searching describe reasons for study exclusion and inclusion based on modifications t the research question and/or contribution to theory development).*	Flow of studies through the review is summarised in Figure 1 and Results p. 8.
10	Rationale for appraisal	Describe the rationale and approach used to appraise the included studies or selected findings *(e.g. assessment of conduct (validity and robustness), assessment of reporting (transparency), assessment of content and utility of the findings).*	See Table 1, for Quality assessment criteria and page 7
11	Appraisal items	State the tools, frameworks and criteria used to appraise the studies or selected findings *(e.g. Existing tools: CASP, QARI, COREQ, Mays and Pope* [25]*; reviewer developed tools;*	Included studies were assessed for validity and rigor using the McMaster Critical Review Forms for qualitative and quantitative research. Adapted

No	Item	Guide and description	Response (Page No. in manuscript)
		describe the domains assessed: research team, study design, data analysis and interpretations, reporting).	from the McMaster Forms, the rating method for key criteria for quantitative and qualitative studies, as developed by Imms[33] was used (Table 1) and Methods p.6
12	Appraisal process	Indicate whether the appraisal was conducted independently by more than one reviewer and if consensus was required.	Appraisal was conducted by two reviewers independently and any disagreement discussed until consensus reached
13	Appraisal results	Present results of the quality assessment and indicate which articles, if any, were weighted/excluded based on the assessment and give the rationale.	See Table 2. No articles were excluded on the basis of quality assessment.
14	Data extraction	Indicate which sections of the primary studies were analysed and how were the data extracted from the primary studies? *(e.g. all text under the headings "results /conclusions" were extracted electronically and entered into a computer software).*	The whole manuscript was read and findings were extracted onto electronic versions of a data extraction form – Methods p.7 Data were extracted by one reviewer (AH), summarised into tables and independently checked by a second reviewer (HF/NT). Qualitative and quantitative data were analysed separately.
15	Software	State the computer software used, if any.	Word, Excel and EndNote
16	Number of reviewers	Identify who was involved in coding and analysis.	AH and NS - Methods p. 7
17	Coding	Describe the process for coding of data *(e.g. line by line coding to search for concepts).*	Methods pp. 7-8
18	Study comparison	Describe how were comparisons made within and across studies *(e.g. subsequent studies were coded into pre-existing concepts, and new concepts were created when deemed necessary).*	Methods pp. 7-8
19	Derivation of themes	Explain whether the process of deriving the themes or constructs was	Inductive - Methods pp. 7-8 An inductive approach was used to

No	Item	Guide and description	Response (Page No. in manuscript)
		inductive or deductive.	categorise the data into themes and sub-themes under this framework.
20	Quotations	Provide quotations from the primary studies to illustrate themes/constructs, and identify whether the quotations were participant quotations of the author's interpretation.	Page 8.
21	Synthesis output	Present rich, compelling and useful results that go beyond a summary of the primary studies (e.g. *new interpretation, models of evidence, conceptual models, analytical framework, development of a new theory or construct).*	Tables 3 & 4 inductively interpreted and organised within a social-ecological framework. Synthesis of qualitative findings to complement quantitative data to provide a powerful meta-summary that benefits from the advantages of each, improving generalisability, considered within theoretical constructs providing deeper insights into pregnant women's beliefs and perceptions about physical activity during pregnancy.

Study 3 (Chapter 4)

This study was reported according to the Consolidated Criteria for Reporting Qualitative studies (Tong et al., 2007) and the Standards for Reporting Qualitative Research (O'Brien et al., 2014). As these provide criteria and standards as a guide but not checklist tables for completion, checklists were not required for publications.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Pages 1 and 3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 4 - 5
	2b	Specific objectives or hypotheses	Page 5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Box 1
	4b	Settings and locations where the data were collected	Page 5 - 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 6 - 8

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 9

Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1 and 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 2
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Nil
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 10 - 12

Other information			
Registration	23	Registration number and name of trial registry	Page 3 (end of abstract)
Protocol	24	Where the full trial protocol can be accessed, if available	Page 3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 2

Study 4 (Chapter 5)

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	**Provide the name or a phrase that describes the intervention.** Consumer co-created infographic about physical activity for women with gestational diabetes mellitus	Pages 1 and 22	_____
	WHY		
2.	**Describe any rationale, theory, or goal of the elements essential to the intervention.** Physical activity is recommended for women with gestational diabetes mellitus (GDM), however many pregnant women with GDM are inactive. Women with GDM want clear, simple and GDM-specific, physical activity messages, delivered by a credible source. Providing physical activity information to women in the form of a consumer co-created, easy-to-read infographic with information that is highly relevant to their needs may meet their messaging needs and so be an effective strategy to improve the physical activity knowledge and self-efficacy of women with GDM. Therefore, the research question for this randomised trial was:	Pages 4 and 5	_____

	Does a consumer co-created infographic, additional to usual-care gestational diabetes education, improve knowledge and self-efficacy of physical activity for women with gestational diabetes mellitus compared to the gestational diabetes education alone?		
	WHAT		
3.	**Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).** A consumer co-created infographic about physical activity for women during a pregnancy complicated by gestational diabetes mellitus.	Page 7 and Appendix 1	_____
4.	**Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.** In addition to usual-care GDM education, consenting participants attending on dates allocated to the experimental group were individually given a paper, colour copy of the co-created infographic by the researcher on this one occasion. This was accompanied by a simple verbal instruction of less than five minutes to each participating individual advising to take the infographic home, read it, and display it somewhere highly visible as a regular reminder to participate in physical activity during their GDM pregnancy.	Pages 6 to 8	_____
	WHO PROVIDED		
5.	**For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise,**	Pages 7 to 8	_____

	background and any specific training given. All participants received usual-care GDM education at the same usual clinic location and from usual staff, Diabetes Educators and Dietitians, during a single 2.5-hour education class and then at follow-up appointments as required. This included information about GDM, when and why it occurs and the management of GDM with regular monitoring of blood sugar levels, dietary modifications, lifestyle changes and if necessary medication, important to reducing the risks associated with poor glycaemic control during pregnancy.[7,11,12] Dietitians provided education about nutritional requirements in pregnancy and dietary modification to assist in controlling blood sugar levels.		
	HOW		
6.	**Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.** Participants attending the ante-natal clinic for gestational diabetes education and were allocated to the experimental group were individually handed a paper, colour copy of the co-created infographic by the researcher on this one occasion.	Page 8	_____
	WHERE		
7.	**Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.** Women diagnosed with GDM who attended GDM education at ante-natal clinics at a metropolitan hospital in Melbourne, Australia.	Pages 5 to 8	_____

	WHEN and HOW MUCH		
8.	**Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.** Participants allocated to the experimental group were individually handed a paper, colour copy of the co-created infographic by the researcher when attending for their GDM education. This was accompanied by a simple verbal instruction of less than five minutes to each participating individual advising to take the infographic home, read it, and display it somewhere highly visible.	Page 8	_____
	TAILORING		
9.	**If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.**	N/A	_____
	MODIFICATIONS		
10.‡	**If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).**	Not modified	_____
	HOW WELL		
11.	**Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.**	N/A	_____
12.‡	**Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.**	N/A	_____

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