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Maternally perceived fetal movement patterns: The influence of body mass index



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ARTICLE INFO	A B S T R A C T		
Keywords: Fetal movements Obesity Stillbirth Pregnancy Hunger	<i>Background:</i> Maternal reports of decreased fetal movements are associated with adverse pregnancy outcome, but there are conflicting data about perception of fetal movements in women with obesity. <i>Aim:</i> To compare perceived fetal movements in women with obesity (body mass index [BMI] ≥ 30 kg/m ²) and women with normal BMI (< 25 kg/m ²). <i>Material and methods:</i> Data from two separate pregnancy studies were used for this analysis; the Healthy Mums and Babies (HUMBA) trial, which recruited women with obesity and the Multicentre Stillbirth Study (MCSS), which recruited women from a general obstetric population. Fetal movement data were collected using identical interviewer-administered questionnaire in each study. We compared fetal movement strength, frequency and pattern between HUMBA and MCSS women with obesity and MCSS women with normal BMI. <i>Results:</i> Participants were 233 women with obesity and 149 with normal BMI. Mean (SD) gestation at interview was similar between groups (36.9 [2.2] vs 36.6 [0.9], <i>P</i> = 0.06). Perceived fetal movement strength and frequency did not differ between groups. In both women with obesity and normal BMI, a diurnal fetal movement pattern was present, with the majority reporting strong or moderate movements in the evening (88.7% vs 99.3%) and at night-time (92.1% vs 93.1%). Women with obesity, were more likely to report strong fetal movements when hungry (29.1% vs 17.7%, <i>P</i> = 0.001) and quiet fetal movements after eating (47.4% vs 32.0%, <i>P</i> = 0.001). <i>Conclusions:</i> In women with obesity compared to normal BMI, strength and frequency of fetal movements were similar, although patterns were altered in relation to maternal meals.		

1. Introduction

Obesity amongst pregnant women is increasing as prevalence of obesity climbs worldwide [1]. Maternal body mass index (BMI) above the normal range ($\geq 25 \text{ kg/m}^2$) is associated with increased poor perinatal outcomes across the spectrum, ranging from lower rates of conception and increased miscarriage through to increased risk of stillbirth and reduced infant survival [1,2]. Beyond the perinatal period, maternal obesity (BMI $\geq 30 \text{ kg/m}^2$) is associated with adverse outcomes for offspring such as increased infant language delay [3], lower schoolage IQ [4], autistic spectrum disorder [5], and attention deficit and hyperactivity disorder [6]. In high-income countries maternal obesity is the leading modifiable risk-factor for stillbirth, surpassing even maternal smoking in terms of the population attributable fraction [7].

A common strategy used in clinical practice to prevent stillbirth is monitoring of maternally perceived fetal movements [8]. In approximately half of stillbirth cases maternal perception of decreased fetal movements (DFM) precedes diagnosis of fetal death [9]. Reducing delayed (> 48 h) presentation with DFM has been shown to reduce stillbirths in Norway [10]. However, the large AFFIRM trial in the United Kingdom reported that a programme of encouraging presentation for DFM, coupled with low-threshold for induction of labour led to increased intervention with no significant reduction in stillbirths. Thus, the optimal approach to screening and management of women with DFM has yet to be determined. Despite this, maternal concern about reduced fetal movements remains an important indicator of possible fetal compromise and maternity providers are encouraged to review such cases [11]. One group of particular interest in relation to DFM is

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Abbreviations: BMI, body mass index; DFM, decreased fetal movements

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women with raised BMI.

Presentations for DFM are noted to be higher amongst women with raised BMI [12,13]. It has been suggested that DFM in women with obesity is due to a dampening effect of abdominal fat on fetal movement sensations and therefore more likely to be benign [12]. However, maternal obesity is also associated with pregnancy conditions such as gestational diabetes and preeclampsia which are also associated with fetal and infant death [1,14]. Further, it is been shown that women with DFM and raised BMI $\ge 25 \text{ kg/m}^2$ have increased risk of stillbirth and of small for gestational age infants when compared to women with DFM and normal BMI [15]. The question of whether fetal movement perception is altered in pregnant women with obesity is an important practical question for maternity providers given the increasing prevalence of obesity amongst pregnant women, and the conflicting reports about the significance of DFM in women with obesity.

A systematic review of the limited available data on maternal obesity and fetal movements found no evidence for reduced perception of fetal movements amongst women with raised BMI and only a small increase in the incidence of DFM presentations [16]. Studies investigating perceived fetal movements in women with obesity are scant and questions remain as to any potential differences in fetal behaviour, perception of fetal movements, and clinical significance of DFM in women with obesity [16]. In this study we therefore aimed to describe maternally reported fetal movement strength, frequency, and pattern in women with obesity compared to women with normal BMI in early pregnancy.

2. Material and methods

Participants were recruited from two studies conducted during pregnancy in New Zealand. The first study, the Healthy Mums and Babies (HUMBA) trial was a two-by-two factorial randomised controlled trial of dietary intervention and/or probiotics that aimed to reduce excessive gestational weight gain and infant birthweight [17]. Eligible participants for HUMBA had a BMI $\geq 30 \text{ kg/m}^2$, no diabetes at the time of enrolment and were residing in Counties Manukau, an urban locality in South Auckland, New Zealand with a multi-ethnic population and high rates of deprivation and obesity. Ethical approval for the HUMBA study was obtained from the Southern Health and Disabilities Ethics Committee (14/STH/205). Recruitment occurred between April 2015 and June 2017.

The Multicentre Stillbirth Study (MCSS) was a case-control study conducted across seven healthcare regions in New Zealand exploring modifiable risk factors for late (\geq 28 weeks') stillbirth [18]. Recruitment occurred between February 2012 and December 2015 and the main findings have been reported elsewhere [18]. Ethical approval for this study was obtained from the Northern "X" Regional Ethics Committee: NTX/06/05/054. For the present study, we used data from control women (ongoing pregnancies with a singleton, non-anomalous fetus randomly selected from hospital booking lists).

Demographic data were collected during interview and birth outcome data from medical records. A single prioritised ethnicity was established as recommended by the New Zealand Ministry of Health [19]. Social deprivation was derived from the address where the woman lived during pregnancy [20]. For both studies, we used customised birthweight centiles to define birth weight, taking into account maternal characteristics (height, earliest available pregnancy weight, ethnicity and parity), as well as gestation at birth and infant sex [21]. Small for gestational age (SGA) was defined as birthweight < 10th customised centile and large for gestational age (LGA) was defined as birthweight \geq 90th customised centile. Maternal BMI was calculated using the earliest available pregnancy weight, and height measured at interview.

2.1. Fetal movement questionnaire

Women from the HUMBA trial or the MCSS control group were

questionnaire at \geq 32 weeks' gestation. Women from HUMBA and MCSS with BMI $\geq 30 \text{ kg/m}^2$ (obese) were compared to MCSS women with $BMI < 25 \text{ kg/m}^2$ (normal). Data on maternally perceived fetal movement strength, frequency and pattern was collected using a structured questionnaire that was administered face-to-face by trained research midwives in the setting of the woman's choosing, usually the home. Fetal movement questions pertained to perceived fetal movements in the two weeks prior to interview and included strength, frequency, busy times, patterns of movement in relation to time of day, maternal position, maternal meals, and fetal stimuli. Maternal perception of strength and frequency of fetal movement was categorised as increased, decreased, staved the same or unsure. Busy times were defined for participants as 'a period where there is a group of movements, rather than single isolated movements, which might be short (15-45 seconds) or prolonged and involving many movements for up to 20 minutes'. Fetal movement responses in relation to time of day, maternal position, maternal meals, and fetal stimuli were categorised as 'notably quiet', 'subtle or light movement', 'moderate movement', 'jumps or startles' and 'unsure/don't notice'.

eligible for the present study if they had completed the fetal movement

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2.2. Statistical analysis

Data were analysed using SAS v9.4 (SAS Institute, Cary, NC, USA). The frequency of categorial fetal movement variables was compared between women with obesity and women with normal BMI, using chi square, with a P value < 0.05 regarded as statistically significant.

3. Results

The obesity group comprised 233 women with a mean early pregnancy BMI of 38.9 (SD 6.3). Of these 233 women, 163 had been recruited through HUMBA and 70 through MCSS. The normal BMI group comprised 149 women, all recruited through MCSS. Mean (SD) gestation at interview was similar for women included from both studies (36.9 [2.2] vs 36.6 [0.9], P = 0.06). All women gave birth to liveborn infants without major congenital abnormality. There were significant differences in demographic characteristics between groups, with women in the obese group more likely to be living in areas of high social deprivation, smoking and single marital status (Table 1). The rate of small-for-gestational age infants was similar in obese and normal BMI groups (Table 1). There were twice as many large-for-gestational infants in the obese group, but this difference was of borderline significance (11.2% vs 5.4%, P = 0.05) (Table 1).

3.1. Fetal movement strength, frequency and busy times

The majority of women reported that fetal movement strength had increased in the two weeks prior to interview and that frequency had either stayed the same or increased, with no significant differences between women with obesity and women with normal BMI (Table 2). In both groups, the majority of women reported between 3 and 7 fetal busy times per day, although overall, women with obesity reported more fetal busy times (Table 2, P = 0.02). The length of busy times was not different between women with obesity and women with normal BMI (Table 2, P = 0.79).

3.2. Fetal movement strength and time of day

In both women with obesity and women with normal BMI, there was a clear diurnal pattern of fetal movements with increasing frequency of strong fetal movements later in the day (Table 3). However, significant differences were seen between the two groups in reported fetal movement strength in the afternoon (P = 0.01) and evening (P = 0.003) (Table 3). In the afternoon, more women with obesity than normal BMI reported strong fetal movements (44.1% vs 31.7%) and in

Table 1

Participant characteristics.

Characteristics	Normal BMI N = 149	Obese N = 233	Р
Age (years)			
< 20	0 (0.00)	4 (1.7)	0.10
20–39	146 (98.0)	218 (93.6)	
≥40	3 (2.0)	11 (4.7)	
Ethnicity			
Māori	9 (6.0)	41 (17.7)	< 0.05
Pacific	6 (4.0)	107 (45.9)	
Indian	34 (22.8)	14 (6.0)	
Other Asian	21 (14.1)	6 (4.3)	
European	78 (52.4)	60 (25.8)	
Other	1 (0.7)	5 (2.2)	
Parity			
0	73 (49.0)	80 (34.3)	< 0.001
1–3	75 (50.3)	130 (55.8)	
≥4	1 (0.7)	23 (9.9)	
BMI at booking (kg/m ²)	21.95 (1.9)	37.70 (6.0)	< 0.05
Smoker	8 (5.4)	41 (17.6)	< 0.001
Marital status (married)	117 (78.5)	139 (59.7)	< 0.001
In paid work (last month)	99 (66.5)	125 (53.7)	0.01
Socioeconomic deprivation (highest quintile)	20 (13.4)	140 (60.1)	< 0.001
Gestation at interview (weeks)	36.9 (2.2)	36.6 (0.9)	0.06
Gestation at birth (weeks)	39.6 (1.1)	39.4 (1.3)	0.05
Infant birthweight (g)	3482 (449)	3657 (525)	< 0.001
Customised birthweight centile	49 (29)	49 (29)	0.96
Small-for-gestational-age infant	16 (10.7)	25 (10.7)	1.0
Large-for-gestational-age infant	8 (5.4)	26 (11.2)	0.05

Data are number (percent), or mean (standard deviation).

Table 2

Fetal movement strength, frequency and busy times.

Interview question	Normal BMI N = 149	Obese N = 233	Chi-square (P)				
In the last two weeks did the strength of your baby's movements?							
Increase	81 (54.4)	140 (60.1)	6.80 (0.08)				
Decrease	7 (4.7)	23 (9.9)					
Stay the same	57 (38.3)	66 (28.3)					
Unsure	4 (2.7)	4 (1.7)					
In the last two weeks did th	e frequency of you	r baby's movemei	nts?				
Increase	60 (40.3)	103 (44.2)	2.57 (0.46)				
Decrease	25 (16.8)	26 (11.2)					
Stay the same	63 (42.3)	102 (43.8)					
Unsure	1 (0.7)	2 (0.9)					
In the last two weeks, how	In the last two weeks, how many busy times did your baby have in a day?						
0–2	36 (24.3)	31 (13.4)	7.48 (0.02)				
3–7	77 (52.0)	138 (59.5)					
8+	35 (23.7)	63 (27.1)					
In the last two weeks, on average, how long did these busy times last?							
Longer than before	52 (35.6)	86 (36.9)	0.48 (0.79)				
About as long as before	85 (58.2)	129 (55.4)					
Shorter than before	9 (6.2)	18 (7.7)					

Data are number (percent), Chi-square and P value is for comparison between normal BMI and obese groups.

the evening more women with obesity (9.3%) reported that their fetus was quiet than women with normal BMI (0.7%) (Table 3). At night time, including bedtime, the majority reported strong fetal movements and this was not different between women with obesity and women with normal BMI (Table 3).

3.3. Fetal movements in relation to maternal position, maternal meals and purported fetal stimuli

There was no difference in perceived strength of fetal movements between women with obesity and women with normal BMI in relation

Table 3					
Fetal movement s	strength	and	time	of	day.

	Normal BMI N = 149	Obese N = 233	Chi-square (P)
On waking (mi	ssing $= 2$)		
Quiet	63 (43.5)	111 (49.6)	3.80 (0.15)
Moderate	52 (35.9)	59 (26.3)	
Strong	30 (20.7)	54 (24.1)	
Unsure	3	8	
During morning	g (missing = 4)		
Quiet	56 (38.6)	71 (31.4)	2.93 (0.23)
Moderate	60 (41.4)	95 (42.0)	
Strong	29 (20.0)	60 (26.5)	
Unsure	3	4	
During afternoo	on (missing = 3)		
Quiet	29 (20.0)	51 (22.5)	8.61 (0.01)
Moderate	70 (48.3)	76 (33.5)	
Strong	46 (31.7)	100 (44.1)	
Unsure	2	4	
During evening	(missing = 4)		
Quiet	1 (0.7)	21 (9.3)	11.83 (0.003)
Moderate	37 (25.3)	51 (22.6)	
Strong	108 (74.0)	154 (68.1)	
Unsure	2	4	
Night time incl	uding bedtime (missing =	= 5)	
Quiet	10 (6.9)	18 (7.9)	0.16 (0.93)
Moderate	26 (17.9)	42 (18.4)	
Strong	109 (75.2)	168 (73.7)	
Unsure	1	3	

Data are number (percent), Chi-square and P value is for comparison between normal weight and obese groups of quiet, moderate and strong fetal movements.

Table 4

Fetal movement strength and maternal position.

	Normal BMI N = 149	Obese N = 233	Chi-square (P)
Walking around	(missing = 3)		
Quiet	82 (59.4)	111 (50.7)	2.61 (0.27)
Moderate	41 (29.7)	80 (36.5)	
Strong	15 (10.9)	28 (12.8)	
Unsure	10	12	
Standing in one	spot (missing = 2)		
Quiet	80 (57.6)	104 (47.3)	3.64 (0.16)
Moderate	39 (28.1)	75 (34.1)	
Strong	20 (14.4)	41 (18.6)	
Unsure	9	12	
Sitting quietly (missing = 7)		
Quiet	29 (20.1)	38 (16.7)	0.83 (0.66)
Moderate	50 (34.7)	78 (34.4)	
Strong	65 (45.1)	111 (48.9)	
Unsure	1	3	
Lie on side (mis	sing = 2)		
Quiet	35 (24.5)	50 (22.2)	0.41 (0.82)
Moderate	56 (39.2)	95 (42.2)	
Strong	52 (36.4)	80 (35.6)	
Unsure	5	7	

Data are number (percent), Chi-square and P value is for comparison between normal weight and obese groups of quiet, moderate and strong fetal movements.

to maternal position (Table 4). In both groups, women were most likely to perceive quiet fetal movements when standing or walking around and strong movements when sitting quietly (Table 4).

There were significant differences between women with obesity and women with normal BMI in reported fetal movement strength around maternal meals and hunger (Table 5). When hungry, 29.1% of obese women reported strong fetal movements compared to 17.7% of women

Table 5

Fetal movement strength and maternal meals.

-square (P) 0 (0.03) 66 (0.001)
56 (0.001)
56 (0.001)
56 (0.001)
56 (0.001)
56 (0.001)
7 (0.05)
1 (0.86)
49 (0.001)

Data are number (percent), Chi square and P value is for comparison between normal weight and obese groups of quiet, moderate and strong fetal movements.

Table 6

Fetal movement strength and physical stimuli.

	Normal BMI N = 149	Obese N = 233	Chi square (P)
Cold drink (missin	g = 3)		
Quiet	40 (31.8)	68 (34.0)	1.40 (0.50)
Moderate	41 (32.5)	73 (36.5)	
Strong	45 (35.7)	59 (29.5)	
Unsure	22	29	
Rub or prod abdor	nen (missing = 2)		
Quiet	43 (30.5)	61 (26.6)	3.36 (0.19)
Moderate	41 (29.1)	88 (38.4)	
Strong	57 (40.4)	80 (34.9)	
Unsure	7	3	
Loud noise (missin	g = 4)		
Quiet	39 (38.6)	93 (49.5)	3.13 (0.21)
Moderate	27 (26.7)	42 (22.3)	
Strong	35 (34.7)	53 (28.2)	
Unsure	47	45	
Sit in cramped pos	ition (missing = 2)		
Quiet	46 (35.9)	66 (31.1)	3.19 (0.20)
Moderate	43 (33.6)	61 (28.8)	
Strong	39 (30.5)	85 (40.1)	
Unsure	20	20	

Data are number (percent), Chi square and P value is for comparison between normal weight and obese groups of quiet, moderate and strong fetal movements.

with normal BMI. One hour after eating, 47.4% of women with obesity reported that the fetus was 'quiet', compared to 32.0% of women with normal BMI. (Table 5). There were no significant differences in perceived fetal movement strength between women with obesity and women with normal BMI in relation to purported physical stimuli such as cold drinks, loud noises, touching the abdomen or sitting in a cramped position (Table 6).

4. Discussion

We compared maternally perceived fetal movements in a group of women with obesity to a group with normal BMI. Our data demonstrate that maternally reported fetal movement; strength, frequency, length of busy times, and strength of fetal movements in response to maternal position and purported fetal stimuli, are very similar in women with obesity and women with normal BMI. In both groups, there was a diurnal pattern of perceived fetal movements involving an increase in frequency of strong movements later in the day. However, there were some differences between groups in reported fetal movement strength around mealtimes, and in the afternoon and evening.

Contrary to our hypothesis, fetal movement strength and frequency was not substantially different in women with obesity compared to women with normal BMI. Although it is widely believed that women with high BMI are less able to perceive fetal movements, a number of studies have explored maternal perception of fetal movements using ultrasound and reported no difference in rates of accurate movement perception attributable to maternal weight, BMI or thickness of skinfolds [22–25]. Our data support no significant reduction in sensitivity to fetal movement sensations in women with obesity compared to normal BMI.

Differences in fetal behaviour around maternal meals reported by women with obesity in this study are supported by existing literature. Increased fetal activity has been demonstrated in association with hypoglycaemia in diabetic women and a decrease or slowing of fetal movements following administration of glucose or when the mother is hyperglycaemic [26,27]. A small qualitative descriptive study of maternal perception of fetal movements in the third trimester reported that some women described increased fetal movement when they were hungry which they interpreted as a fetal demand for food. Participants also reported fetal quiescence following meals, which some interpreted as fetal satiation [28].

Behaviours commensurate with hunger and satiety are known to be hormonally controlled [29,30]. Maternal obesity is thought to have a causative role in development of offspring obesity due to programming of fetal metabolism in response to the altered endocrine milieu of pregnancy in women with obesity [31]. Animal studies have demonstrated that maternal obesity is also associated with altered neural pathways in offspring that regulate appetite and feeding behaviour [31,32]. Further, in a study of women undergoing oral glucose tolerance testing, fetal brain reactivity to stimulus one hour after oral glucose ingestion was inversely correlated with maternal glucose and insulin concentrations [33]. It is plausible, therefore, that the differences in fetal behaviour around meals reported by women with obesity in this study reflect longer term programming of metabolism and appetitive traits.

A diurnal fetal movement pattern characterised by increased likelihood of perception of strong movements in the evening and at nighttime was apparent in both women with obesity and women with normal weight. This is in keeping with other studies that show an increase in fetal movements during the evening by both maternal report [34] and objective observation by ultrasound [35,36]. In a separate study, maternal perception of quiet fetal movement in the evening was associated with an almost four-fold increased odds of late stillbirth, including after adjustment for maternal BMI [37]. One possible explanation for the small differences in fetal movement strength in the afternoon and evening seen in this study is confounding by the differences in fetal movement strength reported around maternal meals. Increased strength of fetal movements in the afternoon in women with obesity may reflect the fetal response to maternal hunger or anticipation of the evening meal, and likewise, increased quiet fetal movements reported by women with obesity in the evening may be related to postprandial quiescence. Although, the differences in fetal movement strength in the afternoon and evening in this study were statistically significant, very few women in either group reported quiet fetal movements in the

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evening or at night-time, including bedtime, suggesting that increased fetal movement in the evening is normal regardless of maternal body size.

A strength of our study is that it includes fetal movement data derived from maternal report by a sizable group of women with obesity and comparison to women with normal BMI using the same data collection tool. Accuracy of maternal perception of fetal movements in women with obesity is often questioned based on the observation of increased clinical presentation for DFM amongst these women. However, very few studies have directly investigated perception of fetal movements or reported fetal movements in women with high BMI. Maternal perception of fetal movement is generally considered to be reliable, with studies reporting that more than a third of fetal movements observed on ultrasound are detected by mothers [16,38]. Small fetal movements such as subtle movements of the hands and fetal movements that do not contact maternal structures such as the fetus touching their own face or contacting the placenta are unlikely to be detected by mothers [24]. However, stronger, more complex, and longer lasting bouts of movement are more accurately detected by pregnant women [39]. Importantly, subjective perception of decreased fetal movements by pregnant women is a known indicator of adverse pregnancy outcome and considered clinically important.

An acknowledged limitation of our study is that we were not able to consider possible differences in actual fetal behaviour, as opposed to reported fetal behaviour, between women with obesity and women with normal BMI. Maternal perception, though surprisingly accurate at times, varies widely between individuals and is subject to limitations. However, to the best of our knowledge, no gold-standard method of objective fetal movement observation currently exists. A further limitation of this study is that we were unable to compare fetal movement variables and pregnancy conditions or outcomes between groups, as detailed pregnancy outcome data were not available for the normal BMI group. There were significant differences between groups in demographic factors that may impact on fetal movements, such as maternal smoking and social deprivation. However, it seems unlikely that the finding of similar strength and frequency of fetal movements between women with obesity and women with normal BMI is due to confounding. The normal BMI group also included more primigravidae, but a number of ultrasound studies have shown that maternal sensitivity to fetal movement is not related to parity [22,25]. Thus, it is unlikely that the differences in fetal movement patterns reported in this study are explained by parity.

Pregnant women with concerns about DFM are commonly advised to drink cold water or eat sugary foods to increase fetal movements, despite this approach not being supported by evidence [11]. Our data suggest that such advice may be particularly unhelpful for women with obesity, as almost half reported fetal quiescence an hour after eating. For women wishing to observe moderate or strong fetal movements, the optimal approach appears to be observation when sitting quietly, especially during the evening or at night-time, regardless of maternal body size. Although strength and frequency were similar between women with obesity and women with normal weight we found a difference in perceived fetal movement strength in the afternoon and evening and some alteration in fetal movement patterns around maternal meals. These differences warrant further investigation as potential indicators of fetal programming effects.

5. Conclusion

This study adds important information on perceived fetal movements in women with high BMI. We found maternally reported fetal movement strength, frequency and busy times were similar between women with obesity and women with normal BMI. Our data do not support the view that perception of fetal movements in women with obesity is impaired. Therefore, presentation with concerns about decreased fetal movements in women with obesity should not be assumed to be a benign variation attributable to maternal body size and assessment of fetal wellbeing is required.

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Data availability statement

Due to ethical restrictions data cannot be shared publicly. Published data are available to approved researchers under the data sharing arrangements provided by the Maternal and Perinatal Central Coordinating Research Hub (CCRH), based at the Liggins Institute, University of Auckland (https://wiki.auckland.ac.nz/researchhub). Metadata, along with instructions for data access, are available at the University of Auckland's research data repository, Figshare (https://auckland.figshare.com). Data access requests are to be submitted to Data Access Committee via researchhub@auckland.ac.nz.

De-identified data will be shared with researchers who provide a methodologically sound proposal and have appropriate institutional approval. Due to ethical restrictions, provision of data will be subject to receiving appropriate New Zealand ethical approval. Researchers must sign and adhere to the Data Access Agreement that includes a commitment to using the data only for the specified proposal, to refrain from any attempt to identify individual participants, to store data securely and to destroy or return the data after completion of the project. The CCRH reserves the right to charge a fee to cover the costs of making data available, if required.

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Declaration of competing interest

None declared.

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