BJOG An International Journal of Obstetrics and Gynaecology

DOI: 10.1111/1471-0528.13802
www.bjog.org

Systematic review

Interventions to enhance maternal awareness of decreased fetal movement: a systematic review

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Accepted 11 October 2015. Published Online 2 December 2015.

Background Decreased fetal movement is associated with adverse pregnancy and birth outcomes; timely reporting and appropriate management may prevent stillbirth.

Objectives Determine effects of interventions to enhance maternal awareness of decreased fetal movement.

Search strategy Cinahl, The Cochrane Library, EMBASE, MEDLINE, PsycINFO and SCOPUS databases; without limitation on language or publication year.

Selection criteria Randomised or non-randomised studies evaluating interventions to enhance maternal awareness of decreased fetal movement.

Data collection and analysis Two authors independently extracted data and assessed quality.

Main results We included 23 publications from 16 studies of fair to poor quality. We were unable to pool results due to substantial heterogeneity between studies. Three randomised controlled trials (RCTs) and five non-randomised studies (NRSs), involving 72 888 and 115 435 pregnancies, respectively, assessed effects of interventions on stillbirth and perinatal death. One large cluster RCT (n = 68 654) reported no stillbirth reduction, one RCT (n = 3111) reported significant stillbirth reduction, and one RCT (n = 1123) was small with no deaths. All NRSs favoured intervention over standard care; three studies (n = 31 131) reported significant reduction, whereas two studies (n = 84 304) reported non-significant reductions in stillbirth or perinatal deaths. Promising results from NRSs warrant further research. We found no evidence of increased maternal concern following interventions. No cost-effectiveness data were available.

Conclusions We found no clear evidence of benefit or harm; indirect evidence suggests improved pregnancy and birth outcomes. The optimal approach to support women in monitoring their pregnancies needs to be established. Meanwhile, women need to be informed about the importance of fetal movement for fetal health.

Keywords Awareness, decreased fetal movement, fetal movement counting, maternal concern, maternal-fetal attachment, stillbirth.

Tweetable abstract The benefits and risks of interventions to increase pregnant women's awareness of fetal movement are unclear.

Linked article This article is commented on by AM Carnero, p. 899 in this issue. To view this mini commentary visit http://dx.doi.org/10.1111/1471-0528.13865.

Please cite this paper as: Winje BA, Wojcieszek AM, Gonzalez-Angulo LY, Teoh Z, Norman J, Frøen JF, Flenady V. Interventions to enhance maternal awareness of decreased fetal movement: a systematic review. BJOG 2016;123:886–898.

Introduction

Decreased fetal movement (DFM) is associated with a range of adverse pregnancy and birth outcomes, including fetal growth restriction[1–3] and stillbirth,[4–7] presumably linked through an underlying placental dysfunction.[8] Timely reporting of DFM may enable preventive management and reduce the risk of stillbirth, particularly when stillbirth is deemed avoidable.[5–7,9]

Maternal concern about DFM is a common reason for unscheduled antenatal visits.[10–13] Many of these pregnancies continue without complication, despite the increased risk of poor birth outcome.[1,7,12,14] However, failure to report DFM in a timely manner may place the fetus at greater risk.[5,15]

The need for pregnant women and clinicians to act on sudden or substantial changes in fetal activity is broadly recognised. Controversy remains regarding how women

should be informed about DFM, what constitutes clinically important DFM, and whether fetal movement counting (FMC) should be recommended. FMC is the systematic daily recording of a mother's perception of her baby's movement, with the aim of increasing maternal awareness about fetal movement as a sign of fetal health.

Several reviews and expert commentaries have discussed the usefulness of interventions to raise maternal awareness of fetal movement. Only two Cochrane reviews meet formal quality requirements; one measured the effect of FMC on birth outcomes[16] and the other assessed the effects of clinical management strategies in pregnancies affected by DFM.[17] Both reviews included only randomised controlled trials (RCTs). However, RCTs may underestimate the effects of large public health interventions, as vigilance may increase throughout the population following broad interventions. In such settings, non-randomised studies (NRSs) may be useful.[18] NRSs may also be suitable in studying rare outcomes, complementing knowledge when few RCTs are available, and guiding the design of future studies.[18] For these reasons, we included NRSs.

Although many promote maternal fetal movement awareness to prevent stillbirth and perinatal death, others argue that this may cause maternal concern, overuse of health care resources, and iatrogenic pregnancy and birth complications. We aimed to review comprehensively the effects of any interventions to enhance maternal awareness of DFM in reducing perinatal morbidity and mortality, including effects on maternal concern, maternal-fetal attachment (MFA), resource use, safety, and costs. We also assessed compliance with interventions.

Methods

This study was conducted in accordance with the PRISMA statement. The protocol was registered in PROSPERO (no. CRD42014009651; http://www.crd.york.ac.uk/PROSPERO/) on 7 May 2014 (updated 12 September 2014).

Search strategy

We searched the Cinahl, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Database of Systematic Reviews (CDSR), the Cochrane NHS Economic Evaluation Database (NHSEED), EMBASE, MEDLINE, PsycINFO and SCOPUS databases with no limitation on language or year of publication. The search was last updated August 2015. Search terms included 'fetal/fetus activity', 'fetal movement(s)', 'fetal movement count(s)', 'fetal movement chart(s)', 'kick count(s)', and 'kick chart(s)' using American and British spellings. The search was restricted to human studies. We hand-searched personal files and bibliographies of included studies to identify additional non-indexed publications. Complete electronic search strategies are presented in Table S1.

Two authors (BAW, VF) independently screened records to determine their eligibility for inclusion in the review. Disagreements were resolved by consensus or consultation with a third author (AMW).

Inclusion criteria

We included randomised or non-randomised studies evaluating interventions to enhance maternal awareness of DFM through provision of standardised information to women and care providers, with or without FMC. The population comprised women with third trimester singleton pregnancies. Eligible comparators were standard care, information only or FMC in selected pregnancies. Standard care was defined as care provided with no standardised information or FMC. We included different FMC method as an eligible comparator in studies assessing acceptability of different FMC methods.

Primary outcomes were perinatal death, stillbirth, early or late neonatal death, preterm birth, small-for-gestational-age (<10th percentile or <2.5th percentile/>2 SD below mean), Apgar scores (<4 and $<7_{5\,min}$), low birthweight (<2500 g), number of induced deliveries, emergency caesarean sections, or number of infants transferred to neonatal care unit (NCU). Secondary outcomes were maternal concern (as measured by validated inventories), maternal fetal attachment (as measured by validated inventories), use of resources (number of DFM consultations, ultrasound scans, cardiotocograms and hospital admissions), safety (maternal delay in seeking care >48 hours in DFM and >24 hours in absence of FM) and costs (crude costs), and compliance with and acceptability of intervention (number of days recorded of number of days eligible).

Exclusion criteria

Studies reporting other comparators than those listed were excluded.

Planned comparisons

Analyses were designed to compare (1) FMC versus standard care, (2) FMC versus information only, (3) FMC for all versus selected pregnancies, (4) awareness with optional FMC versus standard care, (5) awareness without FMC versus standard care, and (6) acceptability of and compliance with FMC versus alternate counting method.

We present studies separately according to applied counting method and thresholds for DFM (full-day versus focused FMC). Full-day counting was defined as a protocol consisting of >2-hour counting periods or subsequent shorter counting sessions, with alarm limits for DFM based on 12- or 24-hour counts. Focused counting was defined as a protocol consisting of <2-hour counting periods and with

generally sensitive DFM limits, developed to identify risk rather than death.

Data extraction and quality assessment

Two authors independently extracted outcome (BAW, ZT) and quality (BAW, LYGA) data using predefined formats. Disagreements were resolved by consensus or consultation with review team members (AMW, VF). We contacted trial authors to obtain additional study information. In the case of duplicate reports, we extracted data from the most recent publication.

We used The Cochrane Collaboration's tool to assess risk of bias in RCTs.[19] Non-randomised studies lack the experimental element of random allocation to intervention or control groups and are more susceptible to bias. For quality assessment of NRSs we used the checklists provided by Wells et al.,[20] which are based on publications from the Ottawa Non-Randomised Studies Workshop.[18,21–23] For risk of bias we assessed whether there was a relevant comparator, how groups were formed, which parts of the study were prospective and on which variables comparability was assessed.[18] For confounding we assessed how researchers considered potential confounders and to what extent these were controlled for in the design- or analyses in the primary studies.[23] Lastly we assessed directness of evidence; whether the studies provided answers that were relevant to the population, intervention, comparison and outcome(s) defined in the review protocol.[22,24]

Data management and analyses

We planned to undertake meta-analyses using random effects models and to explore reasons for statistical heterogeneity ($I^2 > 30\%$) through subgroup analyses and examination of study characteristics. We analysed NRSs and RCTs separately, and presented data that may not be combined in descriptive, qualitative synthesis.

In Grant et al.[9] the design effect for the cluster trial was calculated as $1 + (M - 1)$ ICC, where M is the average cluster size and ICC is the intra-cluster correlation coefficient.[25] As no ICC was presented in the study, we used the external ICC estimate for stillbirth (0.003) obtained from the 2005 World Health Organization Global Survey on Maternal and Perinatal Health.[26] The numbers of stillbirths and participants were divided by the calculated design effect (estimated to be 4) before analysis.

Results

Search results

Of 3124 identified publications, 2909 were excluded based on screening of titles and abstracts; 192 of the remaining 215 publications were excluded after full text reviews. Reasons for exclusion are provided in Figure S1. The review thus comprised 23 publications describing 16 studies. Four studies[13,27–29] reported different outcomes in separate publications,[27,30–34] one study used an extended follow-up period in a second publication[35] and one published an erratum to the original study.[36] We identified two ongoing fetal movement trials (NCT 01777022, ACTRN12614000291684).

Eight studies, five NRSs[29,35,37–39] (n = 118 435) and three RCTs[9,13,40] (n = 73 141), reported effects of interventions on stillbirth or perinatal death, four RCTs (n = 2063) reported effects of interventions on maternal psychological health,[27,34,41,42] three RCTs (n = 1468) reported the effect on maternal-fetal attachment[28,32,43] and four RCTs (n = 1650) assessed acceptability of methods by comparing different FMC methods.[31,44–46] Two RCTs, Gibby[41] and Smith et al.,[46] provided insufficient numerical detail to tabulate data by allocation group, and results are not presented. Table S2 presents detailed characteristics of all included studies.

Study characteristics

Table 1 presents the designs, interventions, comparators, and primary outcomes for included studies. FMC was the core intervention in most studies. No intervention comprised information provision or awareness promotion alone. All NRSs reported perinatal mortality.

In studies on pregnancy and birth outcomes, four studies applied full-day counting with DFM defined as absence of FM for 12 hours or <10 FMs for 2 days.[13,29,35,40] Four studies applied focused counting, with DFM defined as <4 FMs/2 days,[40] <10 FMs/2 hours,[35] or a maternal subjective complaint.[13,29] The number of participants ranged from 1155 to 68 654 and the studies were published over a 30-year period. Improvements in pregnancy care over this time-period may have affected outcomes under study. Stillbirth rates ranged from 2.4 to 13 per 1000 prior to study implementation (Table 2). With the substantial variation across studies, we were unable to pool test results.

Studies on secondary outcomes were mainly RCTs, one was a cluster RCT[43] and two were cross-over RCTs.[44,46] The number of participants ranged from 33 to 1400. All studies used validated inventories, although methods of measurement differed for similar outcomes.

Methodological quality

Quality assessment results are presented in Figure 1. Several studies were published prior to 2000 and study quality ranged from very low to fair.

RCTs

For the 11 RCTs assessed, many quality indicators were classified with unclear or high risk of bias (Figure 1). Random sequence generation was judged as low risk of selection bias in five studies[13,27,28,42,44] and risk for allocation

Table 1. Overview of included studies

Study (year) references	Population at entry	Risk profile	Gestation	Intervention	Focus of investigation	Outcome measure
Non-randomised studies						
Lobb et al. (1985)[38]	20 302	Mixed high/low risk	From 28 weeks	FMC for all versus FMC in selected pregnancies	Birth outcome	Stillbirth
Westgate & Jamieson (1986)[39]	16 290	Total population	From 26/30 weeks high/low risk	FMC versus standard care	Birth outcome	Stillbirth
Czapla et al. (1987)[37]	6564	Mixed high/low risk	From 35 weeks	FMC versus standard care	Birth outcome	Perinatal death
Moore & Piacquadio (1989)[35,47]	8277***	Total population	From 28 weeks	FMC versus standard care	Birth outcome	Stillbirth
Tveit et al. (2009)[29,36]	64 002****	Total population	From 28 weeks	Awareness with optional FMC versus standard care	Birth outcome	Stillbirth >28 weeks or 1000 g
Randomised controlled trials						
Grant et al. (1989)[9]	68 654*	Total population	From 28 to 32 weeks	FMC for all versus FMC in selected pregnancies	Birth outcome	Normally formed stillbirths
Neldam (1983)[40]	3332	Mixed high/low risk	From 28 to 32 weeks	FMC versus standard care	Birth outcome	Stillbirth >1500 g
Saastad et al. (2011)[13]	1155	Total population	From > 28 weeks 22 and 35 weeks 22 and 35 weeks	FMC versus standard care	Birth outcome Maternal concern MFA	Composite outcome ******** CWSPAI
Abasi et al. (2010)[43]	100*	Low risk	(4 weeks) Range: 28–32 weeks	FMC versus standard care	MFA	Cranley
Mikhail et al. (1991)[28]	213	Low risk	(4 weeks) Range: 28–32 weeks	FMC versus standard care	MFA Acceptability******, *******	Cranley Failure to comply
Liston et al. (1994)[42]	633	Low risk	28 and 37 weeks	FMC versus standard care	Maternal concern	MAPI, STAI, Rotter
Delaram et al. (2015)[30]	242	Total population	28 and 37 weeks	FMC versus standard care	Maternal concern	GHQ-28 STAI
Gibby (1988)[41]	33	Low risk	Range: 33–37 weeks	FMC versus standard care	Maternal concern	STAI
Gomez et al. (2007)[45]	1400	High-risk	From 30 weeks	FMC versus alternate FMC method	Acceptability******	Failure to comply
Christensen et al. (2003)[44]	40**	High-risk	(2 weeks) Range: 28–34 weeks	FMC versus alternate FMC method	Acceptability******	Failure to comply
Smith et al. (1992)[46]	85**	Unknown	(3 weeks) Range: 32–40 weeks	FMC versus alternate FMC method	Acceptability******	Failure to comply

Cranley, Cranley maternal-fetal attachment inventory; CWS, Cambridge Worry Scale; FMC, fetal movement counting; GHQ-28, General Health Questionnaire; MAPI, Maternal Attitude to Pregnancy Instrument; MFA, maternal-fetal attachment; PAI, Prenatal Attachment Inventory; Rotter, Internal and external locus of control scale; STAI, State and Trait Anxiety Inventory.
*Cluster randomised controlled trial.
**Randomised controlled cross-over trial.
***Updated publication reporting from an extended follow-up period.
****Correction of Tveit et al.[29]
******Acceptability refers to women's preferences of different FMC methods.
*******Reported on two of three trial arms from Mikhail et al. (n = 125).
********Composite outcome, fetal growth restriction <2.5th percentile; emergency caesarean section on fetal indication; oligohydramnios; pathological blood flow in arteria umbilicalis; maternal perception of absent fetal movements for more than 24 hours before admission to hospital, or perinatal death. The study also reported outcomes separately.

Table 2. Effect of interventions on stillbirth/perinatal death, by counting method and comparator

Study (year) references	Counting method	Stillbirth			Perinatal death			Primary outcome	Stillbirths per 1000 before study*	Stillbirths per 1000 during study**
		I *n/N*	C *n/N*	Effect RR (95% CI, *P*-value)	I *n/N*	C *n/N*	Effect RR (95% CI, *P*-value)			
(a) Fetal movement counting for all women versus standard care										
Saastad et al. (2011)[13,***]	FC	0/544	0/532	–	0/544	0/532	–	Composite outcome	–	–
Neldam (1983)[40,****]	FC	3/1583	12/1569	0.25 (0.1, 0.9, *P* = 0.03)	14/1583	21/1569	0.66 (0.3, 1.3, *P* = 0.23)	Stillbirth >1500 g	6.1	4.8
Moore & Piacquadio (1989)[35,*****]	FC	21/5758	22/2519	0.42 (0.2, 0.8, *P* = 0.01)	–	–	–	Stillbirth	8.7	3.6
Westgate & Jamieson (1986)[39,******]	FDC	67/8163	88/8127	0.76 (0.6, 1.1, *P* = 0.09)	119/8163	163/8127	0.73 (0.6, 0.9, *P* = 0.01)	Stillbirth	10.8	8.2
Czapla et al. (1987)[37,*******]	FDC	–	–	–	20/3258	57/3280	0.35 (0.2, 0.6, *P* = 0.01)	Perinatal death	–	–
(b) Awareness with optional fetal movement counting for all women versus standard care										
Tveit et al. (2009)[14,********]	FC	102/44 967	55/19 035	0.79 (0.6, 1.1, *P* = 0.15)	–	–	–	Stillbirth >28 weeks or 1000 g	2.4	1.7
(c) Fetal movement counting for all women versus fetal movement counting in selected pregnancies										
Lobb et al. (1985)[38,*********]	FDC	39/6597	93/13 705	0.87 (0.6, 1.3, *P* = 0.47)	–	–	–	Stillbirth	13.0	6.5

Table 2. (Continued)

Study (year) references	Counting method	Stillbirth			Perinatal death			Primary outcome	Stillbirths per 1000 before study*	Stillbirths per 1000 during study**
		I *n/N*	C *n/N*	Effect RR (95% CI, *P*-value)	I *n/N*	C *n/N*	Effect RR (95% CI, *P*-value)			
Grant et al. (1989)[9,] **********	FDC	99/31 648	100/36 231	1.14 (0.7, 2.0, $P = 0.63$)	–	–	–	Normally formed stillbirths	4.0	2.8

C, control group; CI, confidence interval; cRCT, cluster randomised controlled trial; FC, focused counting (counting period <2 hours); FDC, full-day counting (counting period ≥2 hours or subsequent shorter counting sessions, with alarm limits for DFM based on 12- or 24-hour count); I, intervention group; NRS, non-randomised study; RCT, randomised controlled trial; RR, risk ratio.

*Total stillbirth rate in the period prior to study implementation.

**Total stillbirth rate in the intervention period.

***RCT, Norway, total population, no fetal deaths were reported in this trial.

****RCT, Denmark, single-site hospital study, mixed high-low risk pregnancies.

*****NRS, USA, historically controlled. study, single site hospital study, total population. Update with an extended 30-month follow-up period ($n = 5758$). Numbers taken from update.

******NRS, New Zealand, retrospective historically controlled study, single site hospital study, total population.

*******NRS, Poland, historically controlled study, single-site hospital population, mixed high-low risk pregnancies.

********NRS, Norway, historically controlled quality improvement intervention (awareness with optional FC), total population. Numbers taken from published erratum.

*********NRS, UK, single-site hospital study (included women from two separate hospital units with competing protocols), mixed high-low risk pregnancies.

**********cRCT, Multi-country (UK, Belgium, Sweden, Ireland, USA) cluster randomised controlled trial, 33 intervention and 33 control clusters, total population. Effect estimate corrected for the design effect (number of stillbirths and participants were divided by an estimated design effect of 4, see manuscript for details).

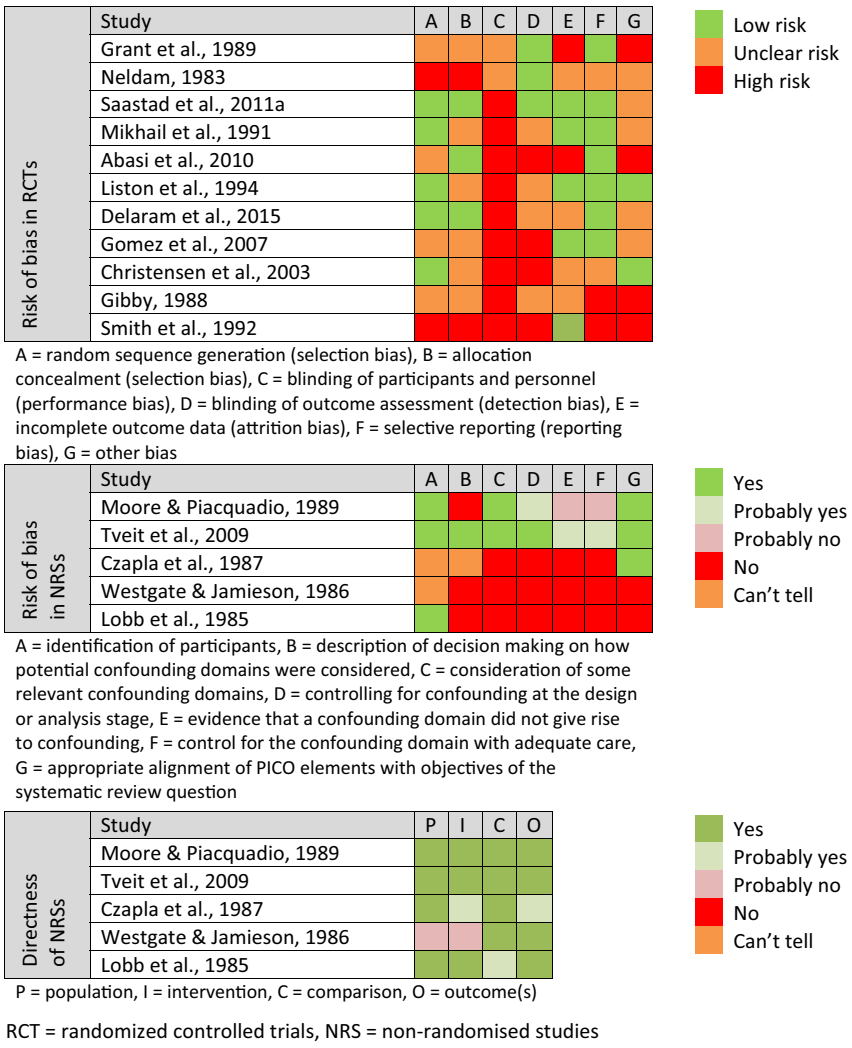

Figure 1. Quality assessment of included studies.

concealment was low in three studies.[13,27,43] Blinding of participants and personnel is not feasible in FMC studies; the risk of performance bias was high in most studies, as women's active participation are required and should be guided by health care personnel. Risk of detection bias attributable to inadequate blinding of outcome assessors was unclear in four studies[27,28,41,42] and high in four studies[43–46] because of open-label methodologies. Blinding of outcome assessors was judged as adequate in three studies[9,13,40] given the use of objective outcomes such as fetal death, which are unlikely to be influenced by assessors' knowledge of treatment groups. Risk of attrition bias was judged to be low in five studies[13,28,42,45,46] and risk of reporting bias low in seven studies.[9,13,27,28,42,43,45]

NRSs

Five NRSs, all with relevant comparisons, were included. In four studies, groups were formed by time difference (historically controlled studies)[29,35,37,39] and in one study by location difference (two hospital units using competing protocols).[38] For one study it was unclear which components of the study were prospective,[37] and for another it was unclear whether assessment of outcomes occurred before or after the intervention[39] (Table S3). Only two studies assessed comparability between groups based on potential confounders.[29,35]

The earliest NRSs[37–39] provided little evidence of adequate control for confounding and were judged as having high risk of bias (Figure 1). These studies were nevertheless included in the review. While their characteristics may guide future research, results need to be interpreted carefully. Two NRSs[29,35] documented adequate measures to account for confounding domains; both considered potential confounders at the design stage and one described how potential confounding domains were considered and adjusted for these in the analyses.[29] Directness of evidence to the review question was acceptable across studies, with

Table 3. Effect of fetal movement counting versus standard care on attachment and maternal concern

Study (year) references	Number analysed		Inventory	Measure	Sub-scale	Mean score (SD) Post-intervention		Mean difference I/C post-intervention (95% CI)	*P* value
	I	C				I	C		
Maternal concern									
Saastad et al. (2012)[13,*]	503	510	Cambridge Worry Scale	16-item inventory measuring content and degree of pregnant women's worries. Item scores 0–5		0.77 (0.55)	0.90 (0.62)	−0.13 (0.06–0.21)	<0.001
Delaram et al. (2015)[30,*]	100	108	General Health Questionnaire	28-item inventory measuring psychiatric stress related to general medical illness. Item scores 0–3		21.09 (10.1)	23.88 (8.6)	−2.79	0.022
			State–Trait Anxiety Inventory	Self-report scales measuring state and trait levels of anxiety. Item score 0–4. Scale scores 20–80	State anxiety	35.34 (9.98)	38.25 (9.63)	−2.91	<0.001
					Trait anxiety	35.88 (8.19)	39.15 (9.25)	−3.27	0.008
Liston et al. (1994)[42,*,***]	178	382	State–Trait Anxiety Inventory	Self-report scales measuring state and trait levels of anxiety. Item score 0–4. Scale scores 20–80	State anxiety	32.3	32.2	0.1	ns****
					Trait anxiety	34.1	34.0	0.1	
			Internal and external locus of control scale	23 paired statements of sources of personal control. Item score contributes one point to total score.	Locus of control	9.0	9.3	−0.3	
			Maternal Attitude to Pregnancy Instrument	48 questions, four scales. Item scores 1–4	Well–being	59.2	59.3	−0.1	
					Pride	25.8	25.6	0.2	
					Concern for delivery	10.4	10.5	−0.1	
					Attitude to infant	29.3	29.4	−0.1	
Maternal–fetal attachment									
Saastad et al. (2011)[13,*******,*]	478	473	Prenatal Attachment Inventory	21-item inventory indicating how often mother has affectionate thoughts or behaves affectionately toward fetus. Item scores 1–4		59.34 (9.75)	59.54 (9.39)	0.20 (−1.42 to 1.02)	0.747
Abasi et al. (2010)[43,**]	40	43	Cranley maternal–fetal attachment inventory	24-item inventory describing expectant mothers' baby-related thoughts and actions Item scores 1–5		3.96 (0.38)	3.42 (0.41)	0.54 (0.38–0.70)	<0.001
Mikhail et al. (1991)[28,*]	125	88				3.80 (0.39)	2.97 (0.83)	0.83 (0.64–1.02)	<0.001

C, control group; CI, confidence interval; I, intervention group; SD, standard deviation.
*RCT, randomised controlled trial.
**cRCT, cluster randomised controlled trial.
***Women were allocated to fetal movement counting, sleep recording, or standard care; results from fetal movement counting and standard care groups reported here. No overall measure or SD was reported.
****No *P*-value reported for individual items; all results non-significant (State-Trait Anxiety Inventory, $P = 0.299–0.907$; Maternal Attitude to Pregnancy Instrument, $P = 0.127–0.99$).

the exception of one retrospective study[39] and one study where FMC was introduced at >35 weeks of pregnancy, which may be considered too late for screening.[37]

Effects of interventions

Primary outcomes

Table 2 presents results by comparator, counting method, and outcome for eight studies reporting on pregnancy and birth outcome. Details of counting method and DFM definitions are presented in Table S4.

FMC versus standard care for prevention of death: Five studies involving 35 618 women evaluated the effect of FMC for all versus standard care for prevention of stillbirth/perinatal death; two were RCTs (4487 women) and three were historically controlled studies (31 131 women). One study reported only stillbirths,[35,47] one only perinatal deaths,[37] and one study reported no death.[13]

All studies favoured interventions over standard care and effects were generally substantial (range: 24–75% reduction in stillbirth/perinatal deaths) (Table 2). Studies with focused counting (n = 11 609) yielded statistically significant reductions in stillbirths. One was a single-site hospital RCT, in which approximately 40% were risk pregnancies,[40] whereas the other was a total population NRS.[35] The two NRSs applying full-day counting yielded significant reduction in perinatal deaths,[37,39] and one reported a non-significant reduction in stillbirth.[39] Both studies have substantial methodological weaknesses.

Awareness with optional FMC versus standard care for prevention of death: One intervention aimed to improve quality of care with information about DFM to women with optional FMC alongside clinical management guidelines for care providers.[29,36] Approximately 9% of women reported that they used an FMC once or more per week. The intervention reduced stillbirths (28 weeks or 1000 g) by 21%, which was not significant.[36] However, stillbirths were reduced substantially in the intervention compared with the baseline period in the subset of women with DFM, 50/1215 and 73/3038, respectively [odds ration (OR) 0.58, 95% confidence interval (CI) 0.41–0.84, P = 0.004].

FMC for all versus selected pregnancies for prevention of stillbirth: One large cluster RCT[9] (n = 68 654) and one NRS[38] (n = 20 302) compared counting for all women with counting for selected women. Effect sizes were low, and neither approach resulted in a significant reduction in stillbirth rate (Table 2). In the large multi-country cluster RCT, the risk profile is unknown for 9% of women in the control clusters who were provided with fetal movement charts (at doctors' discretion). The NRS compared stillbirths in two hospital units with competing protocols and a few women (number not specified) with high-risk pregnancies in the control unit were asked to count FM.[41] Exclusion criteria differed; women with Rhesus iso-immunisation were excluded in one unit and not in the other.

Other birth outcomes

Two RCTs involving 3332 and 1155 women, respectively, reported on pregnancy and birth outcomes other than death.[13,40] One of the studies[13] included mostly healthy pregnancies, whereas in the other[40] up to 40% of pregnancies were high risk. The studies were published 27 years apart and definitions of outcomes were inconsistent. For this reason, results were not pooled. None of the studies reported significant difference between the intervention and control groups for small-for-gestational-age or emergency caesarean section. One reported on additional outcomes; small-for-gestational-age <2.5th percentile, Apgar score $<4_{5\ min}$, preterm birth, induced delivery and number of neonates transferred to neonatal care.[13] Effect estimates varied, range risk ratio (RR) 0.20–1.71, with wide confidence intervals. Both trials were small for outcomes measured, and were likely to be underpowered for detecting true differences. Data are presented in detail in Table S5.

Secondary outcomes

Table 3 presents outcome measurements and effect of interventions on maternal concern and maternal-fetal attachment.

Maternal concern: We report results from three RCTs,[27,30,34,42] involving 2030 women that compared effects of FMC and standard care on maternal concern and anxiety in overall healthy pregnant women. The studies used validated inventories and self-report scales to measure the effect of FMC on maternal concern and anxiety (Table 3). The studies used one,[34] two,[27,30] and three[42] inventories respectively. Maternal psychological health was similar at baseline (week 22[34] or 28[27,30,42]) and was reassessed post-intervention (week 35[34] or 37[27,30,42]). Irrespective of inventory used, we found no evidence of increased maternal concern or anxiety caused by FMC. Two trials[27,30,34] reported significantly lower mean scores among women who were counting FM than among women who did not count when measured by the Cambridge Worry Scale,[13]or the State-Trait Anxiety Inventory and the General Health Questionnaire.[27,30] One trial[42] reported no difference between groups when measured by the State-Trait Anxiety Inventory, Rotter internal and external locus of control inventory or the Maternal Attitude to Pregnancy Inventory.

MFA: We report results from three studies, two RCTS[28,32] and one cluster RCT[43], involving 1468 women, which reported on the effect of FMC on MFA in overall healthy women (Table 3). The studies were published 20 years apart. Two studies[28,43] (n = 313) used the Cranley MFA inventory to assess expectant women's baby-related thoughts and actions. Women started to count FM at 28–32 weeks of pregnancy and

MFA was measured after 4 weeks of counting (week 37). Higher scores indicated greater MFA. Both studies reported significantly higher mean MFA scores in women who had counted FM than women who received standard care.[28,43] One RCT (n = 1155) used the Prenatal Attachment Inventory to assess how often women had reported affectionate thoughts or behaviours towards their infant. The study reported no overall difference in post-intervention mean MFA score between the intervention and control groups, after 8 weeks of counting (week 35).[32] In all studies, the groups were similar at baseline.

Compliance: Three trials,[31,44,45] one with a cross-over design,[44] measured failure to comply by comparing different FMC methods (Table S6). All studies included a version of the count-to-ten method. Trials differed in alternate counting method, number of participants (range 40–1400 women) and intervention period (range 2 to ~10 weeks). Failure to comply was significantly lower with the count-to-ten method than the alternate FMC method in two studies,[44,45] whereas one study reported no difference between the groups.[31] Detailed results on compliance are presented as Table S6.

Use of resources: Four of the studies,[9,13,29,35] involving 142 088 women reported on effect of interventions on the number of DFM consultations. Although the intervention resulted in an increased number of pregnancies with reported DFM in some studies,[9,35] this change was not consistent among studies (Table S7). One NRS[35] reported a 13% increase in testing requirements following the intervention and a three-fold increase in interventions for fetal distress (OR 2.6, 95% CI 0.98–7.2, P = 0.04). The quality improvement NRS[29] recommended use of cardiotocography and ultrasound in consensus-based management guidelines, which explains increased use of these tests. The numbers of additional follow-up consultations and admissions for induction were reduced, and number of emergency caesarean sections remained unchanged.

Safety: One NRS[33] reported a significant reduction in maternal delay in seeking health care for DFM; compared with baseline, fewer women waited >48 hours after DFM (49/897 versus 54/415, RR 0.83, 95% CI 0.70–0.98) or >24 hours in the absence of fetal movement (18/201 versus 24/99, RR 0.70, 95% CI 0.53–0.92; Table S7).

Costs: We identified no studies reporting costs of intervention related to outcomes.

Discussion

Main findings

We found insufficient evidence to recommend interventions to enhance maternal awareness of DFM as a means to assess fetal well-being. Few high-quality trials were available. However, less-rigorously designed studies have provided indirect evidence of beneficial effects on morbidity and mortality, and must be confirmed in large-scale RCTs.

We found no evidence of increased maternal concern or anxiety following interventions. Studies yielded conflicting results on MFA. Finally, several studies reported increased use of resources with the introduction of FMC, but no study reporting on costs or cost-effectiveness confirmed any economic impact.

Strengths and limitations

Among the strengths of this review are the inclusion of many relevant outcomes for fetal movement interventions, including the search for studies related to costs, the comprehensive literature search with no language restriction, the inclusion of NRSs, and the rigorous methods employed to limit bias.

Limitations include the small number of studies, the poor quality of the earliest NRSs, and the limited data from high-quality RCTs. For birth outcomes, few studies reported outcomes other than death.

Quality of evidence

Many studies were conducted more than 20 years ago and reported insufficient information for us accurately to assess methodological quality. Study results were inconsistent and there was little evidence for effects of interventions on stillbirth/perinatal death. Three of the NRSs[37–39] showed substantial risk of confounding and the quality of the RCTs was limited by insufficient randomisation,[40] precision,[13] and the risk of spill-over effect.[9,13] The two NRSs[29,35] with focused counting show promising results with high directness. Nonetheless, residual confounding cannot be ruled out in NRSs.

Stillbirth was only defined in three studies.[13,29,40] Several reported on 'avoidable' stillbirths,[9,35,38–40] implying that FMC may only improve outcomes in viable fetuses. However, the definition of 'avoidable' was neither transparent nor comparable across studies. Publication bias is possible, although both small and large studies, yielding negative and positive effects, were identified and included.

The quality of evidence for intervention effects on maternal concern and anxiety were of fair quality, due to lack of blinding and variation in outcome measures. Quality was fair to poor for remaining outcomes.

Interpretation

While our findings for primary outcomes concur with the conclusions of the Cochrane review that evidence is still insufficient to guide practice,[16] we identified NRSs showing promising results in stillbirth reduction,[29,35] warranting further research. The NRS quality improvement intervention[29] included guidance for women and care providers, emphasising the need to look beyond fetal movement counting as a single intervention in improving pregnancy care.

Concern for DFM is a substantial everyday challenge in obstetric care, yet evidence to guide practice remains

scarce. The negative findings from the large cluster RCT (Grant et al.)[9] has had a profound impact and almost ended fetal movement research.[10] As discussed, limitations of the trial undermine its results. Use of FMC is widespread, despite uncertain effects. Substantial benefits to patients and healthcare providers would likely accrue from a better understanding of how best to inform women about fetal movement as a sign of fetal well-being.

This review has highlighted several features worthy of attention. First, results appeared to be independent of counting method and DFM limit used, indicating that increased vigilance is important in stillbirth prevention. This observation has been corroborated by studies designed specifically to validate FMC data.[48–50] Given the prominent role of awareness, the value of other interventions in raising maternal awareness warrants further study.

Secondly, being vigilant concerning fetal movement may increase throughout the population following large public health interventions. In the study by Grant et al.,[9] stillbirth rates declined from a fairly low pre-intervention estimate to a remarkably low rate in the intervention period, which may illustrate such an effect. In historically controlled studies, study groups were not randomised or contemporaneous, rendering conclusions less certain. However, promising results from Moore and Piacquadio[35] and Tveit et al.[29] are sufficiently valid to recommend further research. Both studies involved care providers as a key component of the interventions. Future studies must emphasise careful planning to address methodical shortcomings of previous RCTs.

Thirdly, interventions to raise awareness among women do not have an impact unless supplemented with well-designed management protocols. Grant et al.[9] reported that fetuses were alive at first hospital presentation in several pregnancies ending in late stillbirth, predominantly in the intervention group, and that these fetuses died as a consequence of clinical error and false reassurance from fetal assessments. Thus, the intervention did not have the expected beneficial effect in reducing mortality. Research is called for to establish optimal clinical management of DFM; a recent Cochrane review found no RCT examining such management.[17]

Fourthly, the success of any DFM intervention should reside in its ability to identify fetuses at risk. Few studies reported on outcomes other than death. A broader set of outcomes could help to disentangle whether interventions should be regarded as favourable or unfavourable. Antenatal detection of growth restriction may facilitate early intervention and optimal management before, during, and after delivery.

Moreover, we found no evidence of an increase in maternal concern due to FMC, despite concerns that such negative side effects could arise. FMC seems to be acceptable to women, with few negative psychological implications. However, irrespective of FMC, concern about DFM was common in third-trimester pregnancies.[34] This is consistent with previous findings that unguided self-screening may cause concern among pregnant women.[51]

Studies reporting on MFA yielded discordant results. This could be explained by differences in participants' socio-economic backgrounds, inventories used, and observation periods in pregnancy. Further research may identify factors moderating the relationship between fetal movement awareness and MFA.

Lastly, direct comparison showed that women preferred the count-to-ten method over other methods, due to shorter counting times and simplicity. However, when participants were asked to count fetal movement throughout pregnancy, compliance rates varied substantially, and health professionals' attitudes are reported to be a key factor,[35,40] which implies that interventions must also be acceptable to care providers.

Conclusion

This review found insufficient evidence to recommend introduction of FMC or any other fetal movement intervention to a select or total population. However, indirect evidence suggests that fetal movement interventions improve perinatal outcomes. Until more rigorous evidence becomes available, clinicians should inform women about the importance of FM awareness and the need to report to antenatal care in case of perceived DFM.

Future research should establish the optimal approach to support women in monitoring their pregnancies, including the added value of FMC over other interventions. Such trials must be adequately powered to detect reductions in stillbirth. The two ongoing trials identified in this review have adopted a stepped-wedge cluster randomisation design. These trials may provide high-level evidence to guide universal self-screening, diagnostic measures, and subsequent DFM interventions. Further research is required to identify obstacles to the uptake of fetal movement interventions in a total population. Although we found no evidence of negative effects on maternal concern or anxiety, cost-effectiveness studies are necessary to assess whether the increased use of resources and iatrogenic complications reported in some settings are outweighed by reductions in morbidity and mortality.

Acknowledgements

We would like to acknowledge Wenche Jacobsen, Head Librarian at the Norwegian Institute of Public Health, and Kirsty Rickett, Clinical Librarian, UQ Mater McAuley Library, for their support with the literature searches.

Disclosure of interests

Full disclosure of interests available to view online as supporting information.

Contribution to authorship

BAW initiated the study, screened studies, extracted and analysed data, and wrote the manuscript. VF contributed to the study design and concept, screened studies for eligibility, and critically revised the manuscript. AMW contributed to the study design and concept, developed tools, served as the third reviewer in case of disagreement, and critically revised the manuscript. TZ and LYG-A extracted data and critically revised the manuscript. JN contributed to the interpretation of results and critically revised the manuscript. JFF contributed to the study design and critically revised the manuscript.

Details of ethics approval

This review of published literature required no ethical approval.

Funding

Nil.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. PRISMA flow diagram.

Table S1. Complete description of electronic search strategies.

Table S2. Characteristics of the studies included in the review.

Table S3. Risk of bias assessment of non-randomised studies.

Table S4. Details of fetal movement counting methods and limits for decreased fetal movement.

Table S5. Effect of interventions on pregnancy and birth outcomes (other than death).

Table S6. Failure to comply with different methods of fetal movement counting.

Table S7. Use of resources and maternal behaviour related to decreased fetal movement. ■

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