# Effect of encouraging awareness of reduced fetal movement and subsequent clinical management on pregnancy outcome: a systematic review and meta-analysis



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#### Introduction

#### Reduced fetal movement

R educed fetal movements (RFMS) are defined as a decrease or change

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**OBJECTIVE:** Reduced fetal movement, defined as a decrease in the frequency or strength of fetal movements as perceived by the mother, is a common reason for presentation to maternity care. Observational studies have demonstrated an association between reduced fetal movement and still-birth and fetal growth restriction related to placental insufficiency. However, individual intervention studies have described varying results. This systematic review and meta-analysis aimed to determine whether interventions aimed at encouraging awareness of reduced fetal movement and/or improving its subsequent clinical management reduce the frequency of stillbirth or other important secondary outcomes.

**DATA SOURCES:** Searches were conducted in MEDLINE, Embase, CINAHL, The Cochrane Library, Web of Science, and Google Scholar. Guidelines, trial registries, and gray literature were also searched. Databases were searched from inception to January 20, 2022.

**STUDY ELIGIBILITY CRITERIA:** Randomized controlled trials and controlled nonrandomized studies were eligible if they assessed interventions aimed at encouraging awareness of fetal movement or fetal movement counting and/or improving the subsequent clinical management of reduced fetal movement. Eligible populations were singleton pregnancies after 24 completed weeks of gestation. The primary review outcome was stillbirth; a number of secondary maternal and neonatal outcomes were specified in the review.

**METHODS:** Risk of bias was assessed using the Cochrane Risk of Bias 2 and Risk of Bias in Non-Randomized Studies I tools for randomized controlled trials and nonrandomized studies, respectively. Variation caused by heterogeneity was assessed using  $\hat{F}$ . Data from studies employing similar interventions were combined using random effects meta-analysis.

**RESULTS:** A total of 1609 citations were identified; 190 full-text articles were evaluated against the inclusion criteria, 18 studies (16 randomized controlled trials and 2 nonrandomized studies) were included. The evidence is uncertain about the effect of encouraging awareness of fetal movement on stillbirth when compared with standard care (2 studies, n=330,084) with a pooled adjusted odds ratio of 1.19 (95% confidence interval, 0.96—1.47). Interventions for encouraging awareness of fetal movement may be associated with a reduction in neonatal intensive care unit admissions and Apgar scores of <7 at 5 minutes of age and may not be associated with increases in cesarean deliveries or induction of labor. The evidence is uncertain about the effect of encouraging fetal movement counting on stillbirth when compared with standard care with a pooled odds ratio of 0.69 (95% confidence interval, 0.18 —2.65) based on data from 3 randomized controlled trials (n=70,584). Counting fetal movements may increase maternal-fetal attachment and decrease anxiety when compared with standard care. When comparing combined interventions of fetal movement awareness and subsequent clinical management with standard care (1 study, n=393,857), the evidence is uncertain about the effect on stillbirth (adjusted odds ratio, 0.86; 95% confidence interval, 0.70—1.05).

**CONCLUSION:** The effect of interventions for encouraging awareness of reduced fetal movement alone or in combination with subsequent clinical management on stillbirth is uncertain. Encouraging awareness of fetal movement may be associated with reduced adverse neonatal outcomes without an increase in interventions in labor. The meta-analysis was hampered by variations in interventions, outcome reporting, and definitions. Individual studies are frequently underpowered to detect a reduction in severe, rare outcomes and no studies were included from high-burden settings. Studies from such settings are needed to determine whether interventions can reduce stillbirth.

Key words: kick counting, perinatal death, stillbirth, ultrasound

#### AJOG MFM at a Glance

#### Why was this study conducted?

This study aimed to determine whether interventions aimed at encouraging awareness of reduced fetal movement and/or improving its subsequent clinical management reduce the frequency of stillbirth or other adverse pregnancy outcomes.

#### **Key findings**

The evidence is uncertain about the effect of encouraging awareness of fetal movement or fetal movement counting on stillbirth when compared with standard care. Encouraging awareness of fetal movement may reduce neonatal intensive care unit admissions and Apgar scores of <7 at 5 minutes of age and may increase maternal-fetal attachment and decrease maternal anxiety when compared with standard care.

#### What does this add to what is known?

Encouraging awareness of fetal movement may be associated with reduced adverse neonatal outcomes without increased interventions in labor. The meta-analysis was hampered by variation in the outcome reporting, and individual studies are frequently underpowered to detect reductions in rare outcomes; studies from high-burden settings are needed.

in a baby's normal pattern of movements in utero as perceived by the mother.1 Concerns about RFM are a frequent reason for presentation to a hospital, occurring in up 15% of pregnancies.<sup>2</sup> Around 70% of pregnancies for which RFM has been reported have a normal outcome, but maternal perception of RFM is associated with adverse outcomes such as stillbirth and fetal growth restriction.<sup>3-6</sup> An individual participant data meta-analysis with data from 5 studies (n=3108) reported an adjusted odds ratio (aOR) of 2.33 (95% confidence interval [CI], 1.73 -3.14) for stillbirth in pregnancies with a decreased frequency of fetal movement in the last 2 weeks of gestation.<sup>7</sup> have demonstrated Studies between RFM and placental pathology, particularly those relating to maternal vascular malperfusion.<sup>8–10</sup> Thus, the association between RFM and fetal growth restriction and stillbirth is thought to represent fetal compensation for placental insufficiency (in which case the placenta cannot meet the metabolic demands of the fetus) or other fetal stressors, in an attempt to conserve energy and oxygen consumption. 11,12

## Interventions for reduced fetal movement

Interventions for RFM can be split into 2 categories, namely (1) those that aim to encourage awareness of fetal movement and/or fetal movement counting among clinicians, other healthcare professionals, or among people who are pregnant and (2) those that employ subsequent clinical management when there is concern about RFM to identify fetal compromise. Studies may employ 1 or the other approach or a combination of the 2. A diagram demonstrating how interventions might work in clinical practice is shown in Supplemental File S1.

Several large randomized trials have shown insufficient evidence for an effect of interventions on stillbirth in high-income settings. Two systematic reviews from 2015 and 2016 reported no clear evidence of harms or benefits associated with formal fetal movement counting or encouraging maternal awareness of RFM, respectively. A 2020 systematic review and meta-analysis of 5 randomized trials of fetal movement counting reported a relative risk (RR) of 0.92 (95% CI, 0.85–1.00) for

perinatal death and 0.94 (95% CI, 0.71 –1.25) for stillbirth. 19

## Current guidance and management strategies for reduced fetal movement

Current guidance is to contact a health professional or the maternity unit if a baby is moving less than usual or not at all.20-22 Guidance with respect to formal fetal movement counting and clinical management is variable, as is the quality of clinical practice guidelines, leading to variation in care. 23,24 Uncertainties persist despite recent publication of randomized controlled trials (RCTs) measuring the effects of interventions for RFM. 14,25 Conducting a systematic review with inclusion of both randomized and nonrandomized studies (NRS) will provide an updated view of the available evidence and also maximize the pool of evidence that has so far been synthesized.

#### Objectives

The primary objective was to determine whether encouraging awareness of fetal movement and/or the subsequent clinical management of pregnancies with RFM affects adverse maternal or perinatal outcomes when compared with other management strategies or no management.

The secondary objectives were as follows:

- to determine whether there is an optimal management strategy for RFM pregnancies.
- to determine if some management strategies were more effective than others.
- to describe the state of current evidence and to identify gaps in the literature.

#### **Materials and Methods**

The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on October 16, 2020, under identifier CRD 42018088635). Reporting followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement. 27

## Eligibility criteria, information sources, search strategy

Studies of interventions that aimed to encourage clinician or maternal awareness of the pattern, strength, and/or frequency of RFM in pregnancy and/or interventions for the subsequent clinical management of RFM were included if these interventions were investigated alone or in combination.

Studies were included if they reported data from singleton pregnancies after 24 completed weeks' gestation that presented to a hospital setting at least once. Included definitions of RFM were those based on maternal perception of a subjective decrease in fetal activity and/or a confirmed decrease by clinical assessment of fetal activity such as auscultation of the fetal heart, cardiotocography (CTG) monitoring, and/or ultrasound scanning. The gestational age threshold was set at 24 completed weeks because this is consistent with the current definition of still-birth in the United Kingdom.

Study types that were considered for inclusion were RCTs, quasi-RCTs, and some NRS. To be eligible, an NRS needed to have a clearly reported mechanism of group formation, clearly defined inclusion criteria, and clearly described methods of ascertainment of eligible patients and their recruitment. Cross-sectional studies, case control studies, and cohort studies without clearly defined comparator groups were not included because their internal validity was considered to be too poor for any exploration of intervention effectiveness.

Searches were performed in MED-LINE, Embase, CINAHL, The Cochrane Library, Web of Science, and Google Scholar (described in Supplemental File S2). Guidelines, trial registries, and gray literature were also searched. Studies were included irrespective of publication status and language of publication; the last search was on January 20, 2022.

#### **Outcomes of interest**

The primary outcome was stillbirth, defined as the death of a baby before birth and after 24 weeks' gestation or as described by the authors (because definitions may vary between study

populations and over time). Secondary outcomes were divided into maternal and neonatal outcomes. Maternal outcomes were proportion of induced labors, mode of birth, postpartum hemorrhage, measures of maternal-fetal attachment and maternal anxiety using any standardized scale, time taken to present to hospital after perceiving RFM, and measures of delayed presentation with RFM. Neonatal outcomes were neonatal death (death of a baby during the first 28 days of life), perinatal death (stillbirth or death within 7 days of birth), small for gestational age (SGA) infant (birthweight <10th percentile or the threshold used in the study if different), Apgar score (<7 at 5 minutes of age), preterm birth (<37 weeks of pregnancy), neonatal intensive care unit (NICU) admission, umbilical artery pH <7.05, or base excess more than -12 (indicating neonatal asphyxia).

#### Study selection and data extraction

The titles and abstracts of studies retrieved using our search strategy were screened by 2 authors independently (D.J.L.H. and A.E.P.H.). Disagreements between the 2 authors were resolved by consulting a third author (J.C.D. or T. W.). Full texts of the included studies were obtained when possible, and a standardized, prepiloted form was used to extract the data. Data were extracted by 2 authors independently (combinations of D.J.L.H., M.W., L.E.H., and A. E.P.H.) and discrepancies were amended through discussion.

When possible, study protocols were obtained for more information on the study design and to determine whether data for all prespecified outcomes were reported. Attempts were made to contact study authors if no protocol was available, if any characteristics of the intervention were unclear, or to enquire about unpublished data. Template for Intervention Description and Replication (TIDieR) checklists<sup>29</sup> were used to extract information from each study about the nature of the intervention.

#### Assessment of risk of bias

Risk of bias was assessed for RCTs using the Cochrane Risk of Bias 2 tool<sup>30</sup>; for NRSs, the Risk of Bias in Non-Randomized Studies I tool was used.<sup>31</sup> Two authors independently assessed the risk of bias and consultations took place in the case of any disagreements.

## Assessment of heterogeneity and sensitivity analyses

Clinical and methodologic heterogeneity was assessed using extracted information from the studies. Heterogeneity was also quantitatively assessed using the chi-squared statistic and the  $I^2$  measure.<sup>32</sup> Variation owing to heterogeneity was classified as low  $(I^2=0\%-40\%)$ , moderate  $(I^2=41\%-60\%)$ , substantial  $(I^2=61\%-80\%),$ or considerable  $(I^2=81\%-100\%)$ . Sensitivity analyses were planned to determine whether effect sizes were influenced by risk of bias or study inclusion criteria, described in the review protocol.

#### Data synthesis

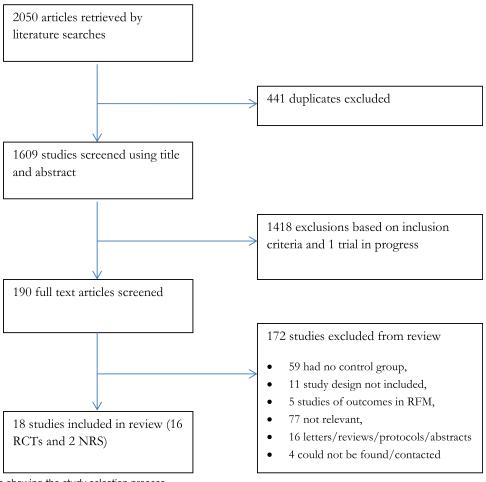
Interventions were broadly classified using the categories in the review protocol,<sup>26</sup> and these categories were used to group studies for analyses (Supplemental File S3).

Adjusted effect estimates were presented for the included studies when possible. When adjusted values were unavailable, ORs and their corresponding 95% CIs were calculated for binary outcomes. When adjusted and unadjusted estimates were provided for the same outcome and intervention groups, these were displayed as subgroups on the forest plot.<sup>34</sup>

Data were only combined after careful assessment of clinical and methodologic features of studies to ensure that pooled estimates would be meaningful. Binary data were combined using the random effects method (DerSimonian and Laird inverse variance<sup>35</sup>). For continuous outcomes, the standardized mean difference (SMD) was calculated along with corresponding 95% CIs. Effect estimates for RCTs and NRSs were calculated separately.

When studies had zero events for an outcome in both the intervention and comparator group, they were not included in analyses. A correction of 0.5 was added if there was one group with

## FIGURE 1 PRISMA flow diagram



PRISMA flow diagram showing the study selection process.

NRS, nonrandomized studies; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCTs, randomized controlled trials.

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zero events. When synthesis was not possible, data from individual studies were reported. Data from secondary outcomes were only reported when available.

#### Assessment of certainty of evidence

GRADE<sup>36,37</sup> was used to determine the certainty of the body of evidence by assessing the study design, inconsistency of results, indirectness of evidence, imprecision, and publication bias. This assessment reflects the extent of confidence that the estimate is certain for any given finding and was carried out for all comparisons for the outcomes of stillbirth, perinatal death, and

neonatal death. Evidence from RCTs starts out as high certainty and evidence from NRSs starts out as low certainty<sup>38</sup>; this was then upgraded or downgraded after assessing the characteristics of the included studies.<sup>39</sup>

#### **Results**

## Study selection and characteristics of included studies

The literature search identified 1609 citations. These were screened based on their titles and abstracts, leading to 18 included studies (Figure 1). These studies are described in Table 1. Additional data, study protocols, and/or further

details about the study were obtained from 5 authors. 13,25,42,57,58

In total, 16 RCTs and 2 NRSs were included. Of the RCTs, 12 focused on interventions aimed at encouraging fetal movement counting and/or awareness of the frequency, strength, or pattern of fetal movement among healthcare professionals and/or people who are pregnant, 3 focused on the subsequent clinical management of RFM after identification, and 1 employed a combination of these. Of the NRSs, 1 compared an intervention to encourage maternal awareness of RFM with standard care and the other compared 2 interventions for the subsequent clinical management

TABLE 1

Study	Study design	Population	RFM management in intervention group	RFM management in control group	Outcomes
Randomized studies					
Abasi et al, <sup>40</sup> 2013	RCT	Gestation: 28–32 wk RFM: kick chart Risk: low n=83	Mothers given training on fetal movement recording, asked to count FM for 1 mo daily after breakfast for half an hour	Standard care	Maternal-fetal attachment
Akselsson et al, <sup>14</sup> 2020	Cluster RCT	Gestation: >24 wk RFM: maternal perception Risk: mixed n=39,865	Leaflet about fetal movements given to women at 24 weeks' gestation and a lecture held for midwives. Women were asked to practice Mindfetalness from week 28 until birth.	Routine care at obstetrical clinics	Stillbirth (after 32 weeks' gestation). 5 min Apgar <7, 5 min Apgar <4, BW <10th centile, CD, NND <27 d, NICU admission, PTB <37 wk, SGA <10th percentile
Armstrong-Buisseret et al, <sup>41</sup> 2020	RCT	Gestation: 36–41 wk RFM: maternal perception Risk: mixed n=216	CTG and ultrasound at presentation. Women with abnormal CTG were not recruited. All women had blood samples taken and were offered expedited birth at 37+0 wk if their sFlt-1:PIGF ratio was above 38.	CTG and ultrasound at presentation as part of standard care. Women with abnormal CTG were not recruited.	Stillbirth (fetal death recorded after 36 wk 5 min Apgar <7, CD, EmCD, IoL, NICU admission, NND, perinatal death, SGA, UA pH <7.05.
Delaram and Jafarzadeh, 42 2016/Delaram and Shams, 43 2016	RCT	Gestation: after 28 wk RFM: kick chart Risk: mixed n=208	Daily fetal movement counting from 28 wk' gestation; kick charts were shown to care providers at weekly visits up to 37 wk.	Standard care	Stillbirth (fetal death after 28 weeks) Apgar score (mean), BW, FGR, maternal anxiety, PTB
Flenady et al, <sup>25</sup> 2022	Stepped wedge cluster RCT	Gestation: ≥28 wk RFM: maternal perception Risk: mixed n=290,219	Education package provided to clinical site teams to raise RFM awareness and management, materials such as posters and pens provided as well as an e-learning program. Mobile phone application for women.	Standard care, women were given a brochure about RFM and managed according to recommended guidelines	Stillbirth (from 28 wk' gestation) 5 min Apgar <7, BW <2500 g, CD, loL. NICU admission, SGA
Gibby, <sup>44</sup> 1988	RCT	Gestation: >33 wk RFM: kick chart Risk: low n=33	Cardiff count to 10 chart used, if 10 movements were not perceived in 10 hours then women were asked to call the hospital	Standard care, no formal fetal movement counting	Maternal anxiety
Gómez et al, <sup>45</sup> 2007	RCT	Gestation: >30 wk RFM: kick chart Risk: all high risk n=1400	Daily fetal movement counting using Latin American Center for Perinatology (CLAP) fetal movement chart	Count-to-10 method of fetal movement counting, record the elapsed time from the first to the tenth movement each day.	Intrauterine fetal death after 28 wk, NND
Grant et al, <sup>13</sup> 1989	Cluster RCT	Gestation: >28 wk RFM: kick chart Risk: mixed n=68,654	Fetal movement counting using a modified Cardiff "count-to-ten" chart. Women were instructed to contact hospital if movements were reduced.	Standard care. Women could raise concerns about RFM and kick charts could be given when indicated.	Stillbirth (antepartum fetal death after 28 wk)
Güney and Uçar, <sup>46</sup> 2019	RCT	Gestation: 28–32 wk RFM: kick chart Risk: low (high risk excluded) n=100	Fetal movement counting using the Cardiff count-to-10 method	Standard antenatal care, no fetal movement counting training given	Maternal-fetal attachment

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## Characteristics of included studies (continued)

Study	Study design	Population	RFM management in intervention group	RFM management in control group	Outcomes
Heazell et al, <sup>47</sup> 2013	RCT	Gestation: ≥36 wk RFM: maternal perception Risk: mixed n=120	CTG and ultrasound in all women. hPL measured, <0.8 MoM considered low. Abnormal results led to expedited birth by the most appropriate method.	CTG in all women. EFW, liquor volume, UA Doppler if the criteria for ultrasound were met (2+ attendances with RFM, >37 wk gestation, SFH <10th percentile)	Stillbirths after 36 weeks' gestation BW ≤10th percentile, CD, IoL, NICU admission, UA pH ≤7.1
Liston et al, <sup>48</sup> 1994	RCT	Gestation: >28 wk RFM: kick chart Risk: low n=613	Daily use of a modified Cardiff count-to-ten chart. Biophysical profile would be carried out if 10 movements not perceived.	Standard care, women were given charts and instructed to record sleep times	Stillbirth after 28 wk. Maternal anxiety
Mikhail et al, <sup>49</sup> 1991	RCT	Gestation: 28–32 wk RFM: fetal movement counting Risk: low n=213	Two fetal movement counting groups using Sadovsky and Cardiff charts	No fetal movement counting	Maternal-fetal attachment
Neldam, <sup>50</sup> 1980	RCT	Gestation: no information RFM: maternal perception and fetal movement counting Risk: no information n=2250	Fetal movement counting. In cases with fewer than 3 movements per hour, CTG and ultrasound were performed, blood was taken for estriol and hPL testing. Testing could be an indication for expedited birth.	Standard care. No instruction to count fetal movements but women were always asked whether they felt movements. Perception of RFM led to CTG and blood tests, treatment decided by the obstetrician in charge.	Stillbirth, defined as intrauterine death in fetuses weighing >1500 g without congenital malformations. All occurred after 32 wk.
Norman et al, <sup>16</sup> 2018	Stepped wedge cluster RCT	Gestation: >24 wk RFM: maternal perception Risk: mixed n=385,552	e-learning package for all clinical staff, leaflet given to women at 20 wk' gestation. CTG and ultrasound after 24 weeks' gestation, UA Doppler encouraged if available. Testing could lead to expedited birth >37 wk.	No RFM information given. Standard care; data from 33 hospitals and thus no information on clinical management protocols.	Stillbirth after 24 wk gestation (or >500 g if gestation unknown) 5 min Apgar <7, BW <2500 g, CD, EmCD, IoL, NICU admission, NND, perinatal mortality, PTB, SGA
Saastad et al, <sup>51,52</sup> 2011	Multicenter RCT	Gestation: after 28 wk RFM: kick chart Risk: mixed n=1076	Information given on how to use a fetal movement chart, instruction to count fetal movements from 28 wk of gestation using a modified count-to-ten method.	Standard care according to Norwegian guidelines	Perinatal death Apgar score <4 at 1 and 5 min, BW, EmCD, maternal anxiety, NICU admission, SGA <10th percentile, PTB
Thomsen et al, <sup>53</sup> 1990	RCT	Gestation: from 29 wk RFM: modified Cardiff count-to- 10 chart Risk: low n=1112	Fetal movement counted daily using modified Cardiff count-to-10 chart. Admission to hospital if fewer than 10 movements recorded in 5 hours, could lead to expedited birth or CTG testing, further examination.	Estriol and hPL measured at 33, 36, 39, 41 wk and then twice weekly. CTG, physical examination, repeat analyses if results were below the 2.5% reference limit.	Stillbirth, not defined Apgar score <7 at 1 and 5 minutes, FGR <5th percentile, UA pH <7.15
Non-randomized studies					
Awad et al, <sup>54</sup> 2018	Retrospective observational study	Gestation: >26 wk RFM: maternal perception Risk: mixed n=579	CTG on admission, biophysical profile for all patients before discharge	CTG on admission, biophysical profile if CTG was no-reactive and/or oligohydramnios or IUGR.	Stillbirths after 26 wk (8 on arrival excluded) CD
Wackers et al, <sup>55</sup> 2019	Prospective cohort study	Gestation: >24 wk RFM: maternal perception Risk: mixed n=140	Information booklet regarding fetal movements given to women at 24 wk gestation	Information booklet regarding fetal movements given to women at 28 wk gestation	Time to present with RFM

(continued)

TABLE 1 Characteristics of included studies (continued)	icluded studies (cont	inued)			
Study	Study design	Population	RFM management in intervention group	RFM management in control group	Outcomes
Randomized studies in progress					
Damhuis et al, <sup>s6</sup> 2021	Multicenter cluster RCT	Gestation: 37 <sup>+0</sup> to 46 <sup>+1</sup> wk RFM: maternal perception Risk: low	Cerebroplacental ratio measured, expedited birth recommended if ratio is low	Standard care. Cerebroplacental ratio measured but results not revealed.	Stillbirth, neonatal mortality, Apgar score <7 at 5 min, UA pH <7.10, ennergency birth will be measured as part of a composite adverse outcome.
BW, birthweight, CD, cesarean de sive care unit; NVD, neonatal dea umbilical artery.	<i>BW</i> , birthweight; <i>CD</i> , cesarean delivery; <i>CTG</i> , cardiotocography; <i>FPW</i> , estimated fetal weigive care unit; <i>AMD</i> , neonatal death; <i>PTB</i> , preterm birth; <i>RCT</i> , randomized controlled trial; mibilical artery.	FW, estimated fetal weight; EmCD, emerge indomized controlled trial; RFM, reduced fet	BW, birthweight; CD, cesarean delivery; CTG, cardiotocography, EHV, estimated fetal weight; EmCD, emergency cesarean delivery; FM, fetal movement; hPL, human placental lactogen; bL, induction of labor; HDG, intrauterine growth restriction; NICU, neonatal interpretational age; sFI-1:PIGF, soluble fms-like tyrosine kinase 1;placental growth factor ratio; LA, umblilical artery.	placental lactogen; <i>IOL</i> , induction of labor; IU <i>GR</i> , ir Il for gestational age; <i>SRt-1:PIGF</i> , soluble fms-like	trauterine growth restriction, <i>NICU</i> , neonatal inten- yrosine kinase 1:placental growth factor ratio; <i>UA</i> ,

of RFM. One ongoing trial was identified. 56

#### Risk of bias of included studies

Of the 16 included RCTs, 9 were rated as being at low risk of bias; the other 7 RCTs were rated as being at high risk (Table 2). Concerns were mainly for deviations intended from the intervention, 14,16,25,42,45 low intervention fidelity, or adequacy of the randomization process. 14,40,44,50,53 Of the 2 NRSs, 1 study was rated as being at moderate risk of bias<sup>55</sup> and the other as being at critical risk<sup>54</sup> (Table 3). All NRSs were judged to be of at least moderate risk of bias for confounding.

#### Synthesis of results

Interventions for encouraging awareness of fetal movement (group 1). Encouraging awareness of fetal movement compared with standard care (2 randomized controlled trials; 330,084 participants). Data were available from 2 RCTs. Akselsson et al<sup>13</sup> (n=39,865) compared the Mindfetalness intervention, aimed at encouraging maternal awareness of the pattern of fetal movements, with standard care. Flenady et al<sup>25</sup> (n=290,219) compared an intervention that encourages awareness of fetal movement (using a mobile phone application for pregnant women and an educational program for clinicians) with standard care.

#### **Primary outcome**

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Stillbirth. The evidence was uncertain about the effect of encouraging awareness of fetal movement on stillbirth when compared with standard care; pooling aORs from both studies gave an aOR of 1.19 (95% CI, 0.96–1.47; I<sup>2</sup>, 0.0; P=.929). Evidence was of very low certainty, downgraded once for imprecision because the confidence interval failed to exclude important benefits and harms and no effect, once because of risk of bias (1 study contributing most of the weight of the analysis was rated as being at high risk of bias<sup>25</sup>), and once for indirectness because evidence was from high-income countries (Figure 2).

#### Secondary outcomes

Neonatal death. The evidence was uncertain about the effect of encouraging awareness of fetal movement on neonatal death when compared with standard care; pooling aORs from both studies gave an aOR of 0.80 (95% CI, 0.54–1.20; I², 0.0; *P*=.780). Evidence was of very low certainty, downgraded once for imprecision because the confidence interval included benefits of both the intervention and standard care, once for risk of bias as explained previously, and once for indirectness as explained previously (Figure 3).

Perinatal death. Currently, there is insufficient evidence for a difference in the effectiveness of encouraging awareness of fetal movement when compared with standard care; pooling ORs, calculated using the raw data from both studies, gave an OR of 0.88 (95% CI, 0.77 –0.99). Flenady et al<sup>25</sup> also reported an aOR of 1.07 (95% CI, 0.86–1.31) for perinatal death (Figure 4).

Evidence was of low certainty, downgraded once because 1 study contributed 94% of the weight of the analysis and was rated as being at high risk of bias and once because of the indirectness of the evidence (included studies were from high-income countries only).

#### Other secondary outcomes

Interventions for encouraging awareness of fetal movement may be associated with a reduction in NICU admissions; there may also be reductions in Apgar scores of <7 at 5 minutes of age, cesarean deliveries, and induction of labor (Figure 5).

Encouraging maternal awareness of reduced fetal movement in comparison with standard care (1 nonrandomized studies; 140 participants). Data for this comparison were available from 1 study, and stillbirth data were not reported;<sup>55</sup> the results of this study can be seen in Supplemental File S4.

Encouraging fetal movement counting in comparison with standard care (8 randomized controlled trials; 72,212

TABLE 2 Overall risk of bias for randomized studies using Risk of Bias 2 tool

	Risk of bias judgment categories							
Study	Randomization process	Deviations from the intended intervention	Missing outcome data	Measurement of outcomes	Selection of reported results	Overal		
Abasi et al, <sup>40</sup> 2013	High	Some concerns	High	Low	Low	High		
Akselsson et al, <sup>14</sup> 2020	Low	Some concerns	Some concerns	Low	Low	Low		
Armstrong-Buisseret et al,41 2020	Low	Some concerns	Low	Low	Low	Low		
Delaram and Jafarzadeh, 42 2016	Low	High	Low	Low	Low	High		
Flenady et al, <sup>25</sup> 2022	Low	High	Low	Low	Low	High		
Gibby, 44 1988	High	Some concerns	Some concerns	Low	Low	High		
Gómez et al, <sup>45</sup> 2007	Some concerns	High	Low	Low	Some concerns	High		
Grant et al, 13 1989	High	High	Some concerns	Low	Low	High		
Güney and Uçar, <sup>46</sup> 2019	Low	Low	Low	Low	Low	Low		
Heazell et al, <sup>47</sup> 2013	Some concerns	Some concerns	Low	Low	Low	Low		
Liston et al, <sup>48</sup> 1994	Low	Low	Low	Low	Low	Low		
Mikhail et al, <sup>49</sup> 1991	Some concerns	Low	Low	Low	Low	Low		
Neldam, <sup>50</sup> 1980	High	Some concerns	Low	Low	Low	High		
Norman et al, <sup>16</sup> 2018	Low	High	Low	Low	Low	High		
Saastad et al, <sup>51,52</sup> 2011	Low	Some concerns	Low	Low	Low	Low		
Thomsen et al, <sup>53</sup> 1990	High	Low	Low	Low	Low	High		
Hayes. Effect of reduced fetal movement av	wareness and clinical m	anagement on pregnancy outc	omes. Am J Obstet Gynec	ol MFM 2022.				

TABLE 3
Overall risk of bias for nonrandomized studies using the Risk of Bias in Non-Randomized Studies I tool

			Ri	sk of bias judgm	ent categories			
Study	Confounding		Classification of interventions	Deviations from intended interventions	Missing data	Measurement of outcomes	Selection of reported result	Overall
Awad et al, <sup>54</sup> 2018	Critical	Low	Low	Moderate	N/I	Low	Low	Critical
Wackers et al, <sup>55</sup> 2019	Moderate	Low	Low	Moderate	Low	Low	Low	Moderate

participants). A total of 8 RCTs compared encouraging fetal movement counting with standard care (as defined by each study); 4 of these were rated as being at low risk of bias, 46,48,49,51 the other 4 were rated as being at high risk. 13,40,43,50

Further details of these studies can be seen in Table 1. None of these studies presented adjusted effect estimates.

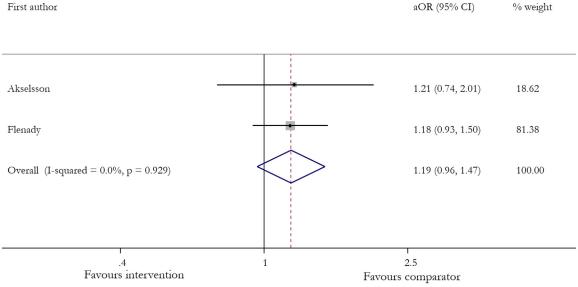
#### Stillbirth

The evidence was uncertain about the effect of encouraging fetal movement counting on the proportion of stillbirths when compared with standard care; pooling unadjusted data of 3 RCTs  $(n=70,584)^{13,48,50}$  gave an OR of 0.69 (95% CI, 0.18–2.65; I<sup>2</sup>, 53.1%) (Figure 6). The evidence was of very low certainty and was downgraded 3 times: once for imprecision (the 95% CI failed to exclude important benefit or harm), once for the inconsistency of the evidence because of clinical heterogeneity (study populations and definitions of standard care across these populations were likely to differ), and once because 2 studies (contributing more than 70% of the weight of the analysis) were at high risk of bias.

#### Secondary outcomes

Three randomized studies (n=406) presented data for maternal-fetal attachment; 2 studies<sup>40,49</sup> used the Cranley Maternal-Fetal Attachment Scale and the third<sup>46</sup> used the Condon Maternal Antenatal Attachment Scale. Maternal-fetal attachment scores may be higher, indicating greater attachment, in fetal movement counting groups when compared with standard care; the metaanalysis produced a pooled SMD of 1.22 (95% CI, 1.01–1.43;  $I^2$ , 48.0%; *P*=.146) (Figure 7).

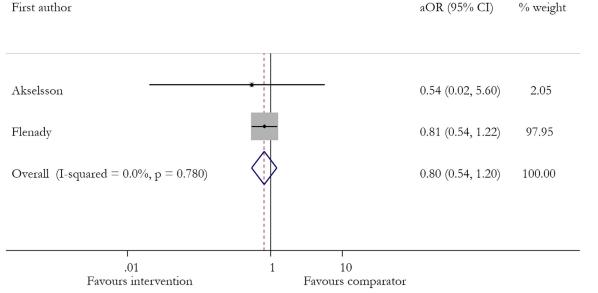




Forest plot showing the effect estimates for stillbirth from studies aimed at encouraging awareness of fetal movement. *aOR*, adjusted odds ratio; *CI*, confidence interval.

Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

## FIGURE 3 Effect of encouraging awareness of fetal movement on neonatal death



Forest plot showing the effect estimates for neonatal death from studies aimed at encouraging awareness of fetal movement. *aOR*, adjusted odds ratio; *CI*, confidence interval.

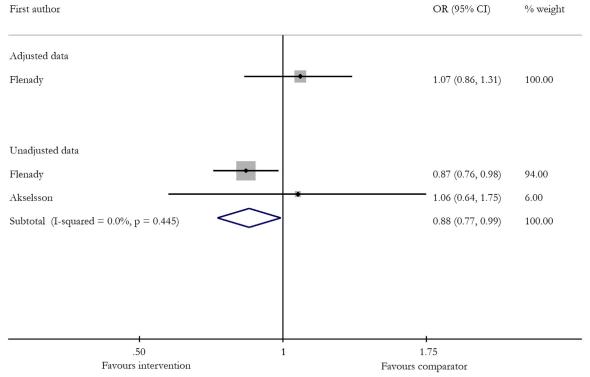
Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

Three randomized studies (n=281) presented data on maternal anxiety measured using the Spielberger State-Trait Anxiety Inventory, trait

scores, 43,59 or the Cambridge Worry Scale. 52 Another RCT could not be included in this analysis because it presented only *P* values and no data. 44

Pooling data from 3 studies suggested that maternal anxiety scores, and therefore anxiety itself, during pregnancy may be lower among those offered fetal

FIGURE 4
Effect of encouraging awareness of fetal movement on perinatal death



Forest plot showing the effect estimates for perinatal death from studies aimed at encouraging awareness of fetal movement.

CI, confidence interval; OR, odds ratio

Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

movement counting with a pooled SMD of -0.16 (95% CI, -0.24 to -0.08;  $I^2$ , 66.2%; P=.052) (Figure 7).

Data for other secondary outcomes are shown in Supplemental File S4. It was only possible to calculate effect sizes from 1 study<sup>52</sup>; there was insufficient evidence for any effects on other secondary outcomes because the CIs were wide and overlapped with zero.

Fetal movement counting compared with hormone analysis (1 study; 1112 participants). One RCT in a low-risk obstetrical population compared fetal movement counting from 29 weeks' gestation with blood tests for estriol and human placental lactogen (hPL) starting at 33 weeks' gestation. 53

#### Stillbirth

The evidence was uncertain about the effect of fetal movement counting on stillbirth when compared with hormone

analysis (OR, 3.67; 95% CI, 0.15 –90.17). Evidence was of very low certainty; findings were downgraded once for imprecision (data from 1 study with one stillbirth; confidence intervals failed to exclude important benefit or harm), once because the study was at high risk of bias because of concerns about the randomization process, and once for indirectness because the study was carried out in a low-risk population.

#### Secondary outcomes

Data for secondary outcomes can be seen in the Supplemental File; currently, there is no evidence for any effects because the CIs are wide and include both benefits and harms.

## Other fetal movement counting comparisons (1 study; 1400 participants)

One RCT compared 2 fetal movement counting methods <sup>45</sup>; this study reported

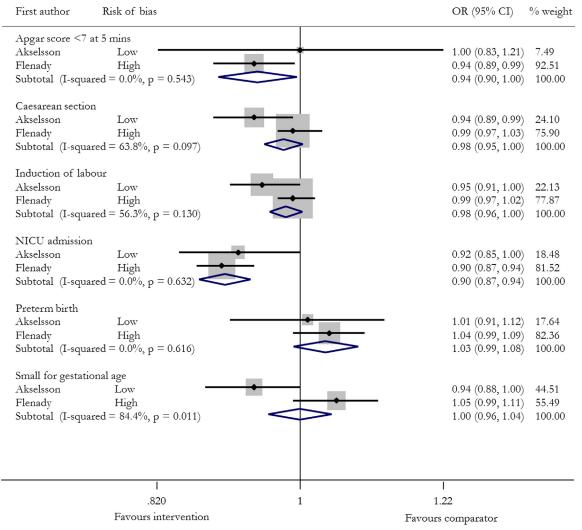
no relevant outcome data (Supplemental File S4).

Interventions for the subsequent clinical management of reduced fetal movement (group 2). Universal ultrasound screening for reduced fetal movement compared with ultrasound when indicated (1 nonrandomized study; 579 participants). One NRS compared universal CTG and ultrasound screening with universal CTG and targeted ultrasound (for biophysical profile) only if indicated.<sup>54</sup> This was a retrospective observational study with 579 participants who all self-reported RFM after 26 weeks of gestation.

#### Stillbirth

The evidence was uncertain about the effect of universal ultrasound screening on the proportion of stillbirths in RFM pregnancies when compared with targeted ultrasound (OR, 0.53; 95% CI, 0.05–5.86). Evidence was of very low

FIGURE 5 Effect of encouraging awareness of fetal movement on secondary outcomes



Forest plot showing the effect estimates for secondary outcomes from studies aimed at encouraging awareness of fetal movement. Cl, confidence interval; NICU, neonatal intensive care unit; OR, odds ratio.

Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

certainty, downgraded once because of serious and critical risk of bias in the study and once for imprecision (95% CIs failed to exclude important benefits or harms). No further outcomes relevant to the review were reported.

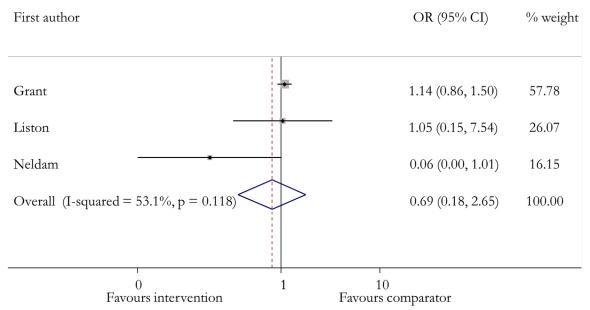
Universal ultrasound screening plus blood tests in comparison with standard care (2 randomized controlled trials; 336 participants). One RCT compared intensive management (ultrasound scan, serum hPL, expedited birth if indicated by these tests) with standard care

for presentation with RFM after 36 weeks' gestation (n=120).<sup>47</sup> A second RCT (n=216) compared standard care and a biomarker blood test (ratio of soluble fms-like tyrosine kinase-1 to placental growth factor), with the result of the blood test indicating whether expedited birth was offered, with standard care alone in presentations with RFM after 36 weeks' gestation.<sup>41</sup> No data for our primary outcome of stillbirth were reported; we did not pool data for secondary analyses because of differences in the interventions. Effect sizes for

secondary outcomes can be seen in Supplemental File S4.

Combined interventions for encouraging awareness of fetal movement and its subsequent clinical management (group 3). Encouraging maternal awareness of reduced fetal movement and subsequent clinical management in comparison with standard care (1 randomized controlled trial, n=393,857). Norman et al<sup>16</sup> conducted a stepped wedge RCT in 33 hospitals in which the education of pregnant women and clinicians, along with a clinical management plan

FIGURE 6
Effect of encouraging fetal movement counting on stillbirth



Forest plot showing the effect estimates for stillbirth from studies aimed at encouraging awareness of fetal movement.

CI, confidence interval; OR, odds ratio.

Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

including CTG and ultrasound for all presentations with RFM, was compared with standard care.

#### Stillbirth

The evidence was uncertain about the effect on stillbirth after 24 weeks' gestation when comparing this combination intervention with standard care (aOR, 0.86; 95% CI, 0.70–1.05). Evidence was of very low certainty, downgraded once because the study was rated as being at high risk of bias, once because the CI failed to exclude important benefits or harms and no effect, and once for indirectness because this was a single study in a high-income setting.

#### Perinatal death

The evidence was uncertain about the effect on perinatal death for the intervention compared with standard care; the study presented an aOR of 0.95 (95% CI, 0.81–1.12). The evidence was of very low certainty, downgraded once because of study limitations (rated as being at high risk of bias), once for imprecision, and once because of indirectness described previously.

#### Secondary outcomes

In the intervention group, the study reported statistically significant increases in the number of Apgar scores <7 at 5 minutes, cesarean deliveries, emergency cesarean deliveries, and NICU admission and statistically significant reductions in induction of labor and the proportion of SGA babies (Supplemental File S4). However, conclusions that can be drawn from these results are limited by the high risk of bias. Data were used from a corrected version of the online supplementary appendix.60

## Other planned analyses and changes from the protocol

We planned on presenting data as RRs, however, because of the nature of the data that were available (adjusted estimates were available as ORs only), we presented all data as ORs to minimize confusion. Most studies did not present adjusted effect estimates, although these were used when available. Planned sensitivity analyses were not possible because of the number of studies that were at an overall low risk of bias and

low number of included studies in each comparison. Comparisons between RCTs and NRSs were not possible. Other intervention comparison groups, such as hormone analyses, were added after extracting data from all studies.

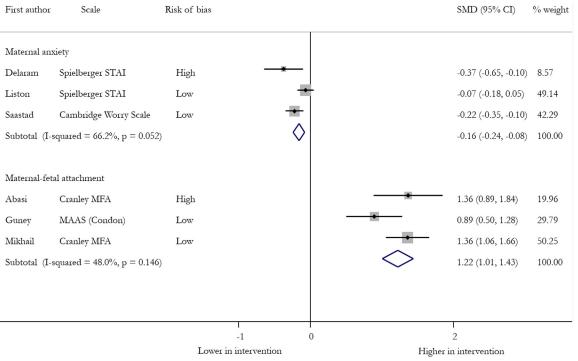
#### Comment

#### Main findings

The current evidence is insufficient for understanding the effects of interventions aimed at encouraging awareness of fetal movement or fetal movement counting on stillbirth, neonatal death, or perinatal death when compared with standard care. This may, in part, be a consequence of the relative rarity of these severe outcomes in high-resource settings and the size of the trials that have evaluated the outcomes instead of the interventions themselves.

A meta-analysis indicated that interventions encouraging awareness of fetal movement may lower NICU admissions. NICU admission is a more common outcome than perinatal death, and so it may be that the sample size allowed for the detection of an effect on this outcome. From a clinical standpoint, lower

FIGURE 7
Effect of encouraging fetal movement counting on secondary outcomes



Forest plot showing the effect estimates for maternal-fetal attachment and maternal anxiety from studies aimed at encouraging awareness of fetal movement.

Cl, confidence interval; MAAS, Maternal Antenatal Attachment Scale; MFA, maternal-fetal attachment; SMD, standardized mean difference; STAI, State-Trait Anxiety Inventory. Hayes. Effect of reduced fetal movement awareness and clinical management on pregnancy outcomes. Am J Obstet Gynecol MFM 2022.

NICU admission rates, a lower frequency of Apgar scores <7 at 5 minutes, and no increases in other outcomes, such as cesarean deliveries or induction of labor, indicates that the effects of these interventions are all acting in the same direction along the proposed clinical pathway. Thus, acting when presenting with RFMs reduces the number of babies that end up in NICU (ie, those that are unwell but not at immediate risk of death) but cannot always save those babies who are at immediate risk for death because in some cases, RFM may be too late of an indicator.

Our analyses also showed that interventions aimed at encouraging fetal movement counting may lead to higher maternal-fetal attachment and lower maternal anxiety when compared with standard care, although the risk of bias of the included studies must be considered, as well as whether the degrees of difference seen in the

standardized measures are clinically significant.

Importantly, there have been few studies on the subsequent clinical management of RFM, and no conclusions can be drawn about whether ultrasound screening or blood tests of placental markers are likely to be of benefit. The link between RFMs, placental insufficiency, and stillbirth is well established; the challenge is whether this link can be modified and demonstrated by trials.

#### Strengths and limitations

This was a comprehensive systematic review and meta-analysis of interventions for RFM, including both RCTs and the most appropriate NRSs while still employing strict inclusion criteria, and was conducted in accordance with a published protocol. This review builds on earlier work by widening the inclusion criteria for both study design and the types of interventions that were

included and by extracting data for a larger range of outcomes. <sup>17,19</sup> Validity has been maintained by only including robust study designs, only comparing interventions that we judged to be similar using the TIDieR checklist and applying GRADE to our findings. We were also able to obtain unpublished data from study authors to conduct analyses that would otherwise not have been possible.

Importantly, many included studies were not adequately powered to measure the effects of interventions on still-birth. We were only able to pool data from 5 studies (n=400,668) containing 962 stillbirths, leading to potential fragility of the meta-analyses. This review did not look at outcomes related to the psychological well-being of parents with previous stillbirths, which may be an avenue for future studies. Several uncontrolled before and after studies have been conducted to measure the

effect of guideline implementation for RFM on adverse outcomes. <sup>15,58,61</sup> However, this study design meant that it was not possible to attribute any differences in outcomes to the intervention. Our analyses were also limited by drawing evidence from high-income countries only; consequently, all analyses were downgraded.

#### Implications for future research

Interventions. Interventions for RFM should be multifaceted; encouraging awareness of RFM can only prevent adverse outcomes if combined with effective clinical management. Likewise, clinical management can only prevent fetal death in the event of timely presentation with RFM. Studies should consider the prognostic accuracy of clinical tests such as an ultrasound, which has been shown to lack the accuracy to predict a stillbirth. 62

In addition to this, the expected adherence to and acceptability of interventions needs to be considered and whether these will reach the people who need them the most; for example, those at higher risk for adverse outcomes because of socioeconomic factors who are often less able and/or more reluctant to go to hospital if they suspect something is wrong. <sup>63</sup>

#### Study design and sample size

A 2015 confidential enquiry showed that there was suboptimal management of RFM in 25% of antepartum stillbirths.<sup>64</sup> An intervention that is 50% effective would reduce antepartum stillbirth in these pregnancies by 12.5%. Using these numbers and a stillbirth rate of 4 in 1000 (a conservative estimate based on the population stillbirth rates of recent studies in high-income countries shown in Table S5 and the current United Kingdom stillbirth rate),<sup>65</sup> a trial would require more than 230,000 participants in each arm. NRSs may be an easier way to achieve the necessary sample sizes, and retrospective designs may also give more accurate reflections of standard care; however, these designs must be adequately controlled (such as controlled before-after

studies) in order for any differences in outcomes to be attributed to the intervention. Trials across multiple centers would allow for larger sample sizes and detection of potential variation in the effectiveness by country and income setting. Crucially, this would also allow the effects of interventions in lowresource settings, where incidences of severe outcomes are normally higher (and the link between RFM and stillbirth may be stronger<sup>66</sup>), to be examined. Current evidence suggests that interventions are unlikely to cause harm, although this has yet to be tested in lower-resource settings. Interventions for awareness and kick counting are easiest to implement and come with fewer associated costs.

#### Stillbirth rates

Study stillbirth rates varied because of the study settings and years in which they took place (Supplemental File S5). Notably, in several large trials, stillbirth rates in both the control and intervention groups were lower than the population stillbirth rates during the study period<sup>13,14</sup>; this may be a consequence of trial effects,<sup>67</sup> variation in the quality of guidelines in individual maternity units,<sup>24</sup> or underrepresentation of minority ethnic groups.<sup>68</sup> Changes in population stillbirth rates over the course of the trial, as was seen in some of our included studies, 16,25 also need to be accounted for because this could mean that any decreases in stillbirth rate associated with the interventions themselves would be difficult to detect.

#### Outcome measurement

There was wide variation in the measured outcomes of the included studies, which impeded a meta-analysis. A core outcome set to be used in studies of encouraging awareness and/or evaluating the clinical management of RFM is currently being developed to ensure that future studies measure the most important outcomes and to reduce the need for review authors to obtain unpublished data.<sup>69</sup>

#### Conclusion

Using evidence from both RCTs and NRSs, it is uncertain whether interventions aimed at encouraging maternal awareness of fetal movement over and above standard care affect the rate of stillbirth or perinatal death. Included studies varied in population stillbirth rates and adherence to the interventions, which may affect whether the true effect of the intervention is measurable. Further research is necessary because people who are pregnant are likely to present with concerns about their babies' movements, which need to be investigated and responded to appropriately. Thus, high-quality, controlled studies including those from lowresource settings are needed to provide evidence of, or refute, the effectiveness of common and novel clinical management strategies for presentations for RFM. Future studies also need to ensure that they measure the most important outcomes; core outcome sets for studies of RFM are being developed to improve future research evidence synthesis.69

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#### **Supplementary materials**

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2022. 100821.

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