



Women's Experiences of Continuous Fetal Monitoring – A Mixed-Methods Systematic Review

DOI:

[10.1111/aogs.13231](https://doi.org/10.1111/aogs.13231)

Document Version

Accepted author manuscript

[Link to publication record in Manchester Research Explorer](#)

Citation for published version (APA):

Crawford, A., Hayes, D., Johnstone, E., & Heazell, A. (2017). Women's Experiences of Continuous Fetal Monitoring – A Mixed-Methods Systematic Review. *Acta Obstetrica et Gynecologica Scandinavica*. <https://doi.org/10.1111/aogs.13231>

Published in:

Acta Obstetrica et Gynecologica Scandinavica

Citing this paper

Please note that where the full-text provided on Manchester Research Explorer is the Author Accepted Manuscript or Proof version this may differ from the final Published version. If citing, it is advised that you check and use the publisher's definitive version.

General rights

Copyright and moral rights for the publications made accessible in the Research Explorer are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Takedown policy

If you believe that this document breaches copyright please refer to the University of Manchester's Takedown Procedures [<http://man.ac.uk/04Y6Bo>] or contact uml.scholarlycommunications@manchester.ac.uk providing relevant details, so we can investigate your claim.





Women's Experiences of Continuous Fetal Monitoring – A Mixed-Methods Systematic Review

Journal:	<i>Acta Obstetrica et Gynecologica Scandinavica</i>
Manuscript ID	AOGS-17-0553.R1
Wiley - Manuscript type:	Systematic review
Date Submitted by the Author:	29-Aug-2017
Complete List of Authors:	<p>Crawford, Alexandra; University of Manchester, Maternal and Fetal Health Research Centre, Division of Developmental Biology and Medicine, School of Medical Sciences, Faculty of Biology, Medicine and Health Hayes, Dexter; University of Manchester, Maternal and Fetal Health Research Centre, Division of Developmental Biology and Medicine, School of Medical Sciences Johnstone, Edward; University of Manchester, Maternal and Fetal Health Research Centre, Division of Developmental Biology and Medicine, School of Medical Sciences, Faculty of Biology, Medicine and Health ; Central Manchester University Hospitals NHS Foundation Trust, St Mary's Hospital, Heazell, Alexander; University of Manchester, Maternal and Fetal Health Research Centre, Division of Developmental Biology and Medicine, School of Medical Sciences, Faculty of Biology, Medicine and Health ; Central Manchester University Hospitals NHS Foundation Trust, St Mary's Hospital</p>
Keywords:	CTG, Fetal Monitoring

SCHOLARONE™
Manuscripts

1
2
3 **Women's experiences of continuous fetal monitoring – a mixed-methods**
4 **systematic review**
5
6
7
8
9

10 Running Title – Women's experiences of fetal monitoring
11
12
13
14
15
16

17 Alexandra Crawford¹, Dexter Hayes¹, Edward D Johnstone^{1,2} & Alexander E.P Heazell^{1,2}
18
19

20 1. Maternal and Fetal Health Research Centre, Division of Developmental Biology and
21 Medicine, School of Medical Sciences, Faculty of Biology, Medicine and Health, University of
22 Manchester, St. Mary's Hospital, Manchester,
23
24

25 2. Central Manchester University Hospitals NHS Foundation Trust, St. Mary's Hospital,
26 Manchester, UK
27
28
29
30
31

32 **Corresponding Author**
33

34 Alexander Heazell
35

36 Maternal and Fetal Health Research Centre, 5th floor (Research), St Mary's Hospital, Oxford
37 Road, Manchester, M13 9WL, UK
38
39

40 Email – alexander.heazell@manchester.ac.uk
41
42
43
44
45
46
47

48 **Conflict of Interest Statement:**
49

50 There are no conflicts of interest associated with any of the authors involved in this work.
51
52
53
54
55
56
57
58
59
60

Abstract

Introduction: Antepartum stillbirth is often preceded by detectable signs of fetal compromise, including changes in fetal heart rate and movement. It is hypothesised that continuous fetal monitoring could detect these signs more accurately and objectively than current forms of fetal monitoring and allow for timely intervention. This systematic review aimed to explore available evidence on women's experiences of continuous fetal monitoring to investigate its acceptability prior to clinical implementation and to inform clinical studies. *Material and methods:* Systematic searching of four electronic databases (Embase, PsycINFO, MEDLINE and CINAHL), using key terms defined by initial scoping searches, identified a total of 35 studies. Following title and abstract screening by two independent researchers five studies met the inclusion criteria. Studies were not excluded based on language, methodology or quality assessment. An integrative methodology was used to synthesise qualitative and quantitative data together. *Results:* Forms of continuous fetal monitoring used included Monica AN24 monitors (n=4) and phonocardiography (n=1). Four main themes were identified: practical limitations of the device, negative emotions, positive perceptions and device implementation. Continuous fetal monitoring was reported to have high levels of participant satisfaction and was preferred by women to intermittent cardiotocography. *Conclusion:* This review suggests that continuous fetal monitoring is accepted by women. However, it has also highlighted both the paucity and heterogeneity of current studies and suggests further research should be conducted into women's experiences of continuous fetal monitoring before such devices can be used clinically.

Keywords

Continuous fetal monitoring; pregnancy; patient experience; maternal anxiety; cardiotocography.

Abbreviations

CFM continuous fetal monitoring;

CTG cardiotocography;

HIC high income countries;

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Key Message

Continuous fetal monitoring is associated with high levels of participant satisfaction and is preferable to intermittent CTG monitoring

For Peer Review

Introduction

Late stillbirth is defined by the WHO as a fetus which has died before birth and after the 28th week of gestation (1). In 2014, the incidence of stillbirth in high income countries (HICs) varied from 1.3 to 8.8 per 1,000 total births; the annual rate reduction from 2000-2015 varies from +0.5% to -6.8% (2). The variation in stillbirth rates and annual rate reductions which have been achieved by some HICs indicates that there remains room for improvement in stillbirth rates in some HICs (2). If HICs reduced stillbirth rates to 2.0 per 1,000 births, over 20,000 stillbirths could be avoided. Data from the UK in 2014 found that one third of reviewed stillbirths occurred in normally-formed, term, singleton babies (3). Given their gestational age, these babies would be expected to have a low risk of neonatal mortality and morbidity and therefore represent a missed opportunity to prevent fetal death if fetal compromise could be reliably detected.

Antepartum fetal monitoring aims to reduce perinatal mortality rates by detecting signs of fetal compromise which occur in response to the sub-optimal intrauterine environment and often precede stillbirth, such as changes in fetal heart rate or fetal movements (4). However, current forms of fetal monitoring do not significantly reduce perinatal mortality rate, especially in women who have a low risk of complications as they have poor predictive value. Hence, confirmatory testing is often required, resulting in additional testing requiring increased resources (5). Additionally, current fetal monitoring methods do not provide a longitudinal and objective view of fetal wellbeing and therefore may not be able to detect intermittent signs of fetal compromise (6).

Continuous fetal monitoring (CFM) describes technologies which can provide an objective view of fetal wellbeing and could reasonably be practically used over long periods of time without risk of injury to either the mother or fetus. Ultrasound-based technologies, such as cardiotocography (CTG) and Doppler velocimetry are not considered to have potential use in CFM due to the risk of ultrasonic heating of fetal tissue with prolonged use (7). Current forms of CFM can measure fetal heart rate or fetal movement to detect signs of fetal compromise before death and allow for timely delivery. Fetal electrocardiography has been subject to the most research and is most advanced in its development. One particular example of this technology is the Monica AN24 (Figure 1), which uses five adhesive trans-abdominal electrodes and an inbuilt accelerometer to non-invasively record maternal movement, uterine activity, maternal heart rate and fetal heart rate. This produces a fetal heart recording which can be interpreted by clinicians retrospectively, whereby data are

1
2
3 stored on the device and downloaded once the recording has finished, or in real-time which
4 requires the use of an additional Bluetooth device (8).
5
6

7 In a questionnaire study of 125 clinicians, 45% of respondents felt that CFM would be beneficial.
8 The majority of respondents would use such a device in high-risk pregnancies such as in cases of
9 fetal growth restriction, reduced fetal movements or previous stillbirth (9). Thus, CFM is
10 proposed as an alternative method of fetal monitoring to current intermittent fetal monitoring for
11 high-risk pregnancies performed in healthcare settings (6). However, the questionnaire study also
12 found that 64.3% of clinicians expressed concern that, if implemented into routine clinical care,
13 CFM could increase levels of maternal anxiety (9). Conversely, only 23.6% of clinicians felt that
14 CFM would provide pregnant women with a sense of reassurance (9). This is important as anxiety
15 in pregnancy has been associated with an increased risk of adverse outcome, including low
16 birthweight (relative risk 1.79) and preterm labour (relative risk 1.50), and would likely act as a
17 barrier to implementation (10). Despite these concerns the majority of surveyed clinicians
18 believed CFM would be beneficial to obstetric practice (9). It is therefore necessary to assess the
19 clinical benefit of CFM against the potential for negative psychological consequences.
20
21
22
23
24
25
26
27
28

29 Therefore, this systematic review was conducted which aimed to explore current knowledge about
30 women's experiences of CFM and whether it has a positive or negative effect on anxiety.
31
32
33
34
35

36 **Material and methods**

37
38
39

40 This systematic review and meta-analysis used a mixed-methods synthesis to combine the
41 paradigms of qualitative and quantitative research exploring a single research question, and thus
42 understand a phenomenon in its entirety (11). A mixed-methods approach also permitted the
43 scope of this review to be as wide as possible, which was important given the anticipated paucity
44 of literature concerning women's experiences of CFM. The primary outcome was to report
45 women's experiences of CFM.
46
47
48
49

50 A series of initial scoping searches were conducted by the primary researcher (A.C) prior to the
51 main search. This found that no previous systematic review had explored women's views of CFM.
52 Scoping searches served as an iterative process to identify relevant search terms for the review.
53 For instance, some studies of CFM were set in the context of home induction of labour so
54 ((induct* OR induce*) ADJ3 labour) was included in the search strategies.
55
56
57
58
59
60

1
2
3 Four electronic databases (MEDLINE, Embase, CINAHL and PsycINFO) were systematically
4 searched to identify full-text studies which investigated women's views of CFM. An example
5 search strategy is shown in Supporting Information Appendix S1. The Cochrane Database of
6 Clinical Trials, Google Scholar, Web of Knowledge, the Royal College of Obstetricians and
7 Gynecologists (RCOG) and the National Institute for Health and Care Excellence (NICE) were
8 also searched for further studies. The review was registered in PROSPERO (CRD42016035715).
9

10
11
12
13
14 Key search terms (fetal monitoring AND monitoring AND satisfaction) were mapped to the
15 thesaurus where possible. Synonyms of the key search terms were used to capture the maximal
16 amount of relevant literature. To maximise the scope of the review, there were no limits applied to
17 publication and non-English language papers were included. Following searches of the core
18 databases, key studies were subject to footnote and citation chasing. The titles and abstracts were
19 screened by two independent researchers (A.C & D.H) against the inclusion and exclusion
20 criteria. Studies were included if they reported women's experiences of CFM at any point in their
21 pregnancy using either quantitative or qualitative methodology to obtain data.
22
23
24
25
26

27
28 For the purpose of this review, fetal monitoring technologies considered to be continuous were
29 those that are non-invasive and could feasibly and safely be used over a sustained period of time
30 to obtain an objective view of fetal wellbeing. Examples of technology which fell under this
31 definition include; phonocardiography, accelerometry, vectorcardiography and fetal
32 electrocardiography. Ultrasound-based technologies, such as CTG and Doppler ultrasound, were
33 excluded due to the risk of ultrasonic heating of fetal tissue with long-term use (7). Invasive
34 technologies such as ST waveform analysis were also excluded.
35
36
37
38
39

40
41 Two researchers (A.C & D.H) independently assessed the quality of included studies using the
42 EPPI Centre criteria, adapted by McDermott et al. (12). Using these criteria each study was
43 graded from A-D based on the reliability and validity of the study (A – No or few flaws, B –
44 Some flaws, C – Significant flaws which may affect the validity of the findings, D –
45 Untrustworthy findings/conclusions). This quality assessment tool was chosen as it was deemed to
46 be sufficiently flexible to accommodate the heterogeneity of study design of included studies and
47 could be utilised for qualitative, quantitative and mixed-methods studies. No studies were
48 excluded based on their quality assessment, but the quality assessment was considered during data
49 analysis.
50
51
52
53
54

55
56 Data extraction was performed by A.C. All foreign language papers were translated into English
57 using a hospital-approved translation service. Authors were contacted to provide additional study
58
59
60

1
2
3 information where necessary or answer queries regarding study design. An integrated
4 methodology was used to extract and analyse data in this mixed-method synthesis, as
5 demonstrated in Figure 2.
6
7

8
9 Qualitative and quantitative data were extracted separately. Qualitative data were extracted
10 through iterative re-reading and inductive thematic analysis (13). Initially, data from each of the
11 five studies was coded manually. Codes were then compared across studies to identify major
12 themes and subthemes. Direct quotations were taken from studies to illustrate individual
13 subthemes. Quantitative data were exported into a Microsoft Excel (Microsoft, Washington, USA)
14 spreadsheet. Weighted mean averages were calculated using the formula:
15
16
17

$$18 \text{ Weighted mean average} = \frac{x_1w_1 + x_2w_2 + x_3w_3}{w_1 + w_2 + w_3}$$

19
20
21 *Where x = satisfaction score and w = sample number.*
22

23
24
25 To allow for comparison between studies all Likert-scale data were standardised to a 10-point
26 scale. All data extraction and calculations were conducted by two authors (A.C and A.H). Graphs
27 were constructed using GraphPad Prism 6.0 (GraphPad Software Inc., San Diego, USA).
28
29 Qualitative and quantitative data were synthesised together to assess for agreement or
30 disagreement.
31
32
33

34 35 **Results**

36
37
38
39 Thirty five studies were identified using the search strategy. Following review of titles and
40 abstracts five studies were included in this review. A PRISMA flow diagram summarising the
41 study selection process is shown in Figure 3. The summary characteristics of all studies included
42 in this systematic review and their quality assessment grade can be found in Table 1.
43
44
45

46
47 All studies included in this review were full text articles published in peer-reviewed medical
48 journals. The publication date of included studies ranged from 2008 to 2013. Studies originated
49 from Germany (15), Italy (16), France (17) and the UK (8, 18). Sample sizes ranged from 6 to 70
50 women, the total number of women included in this review was 105, accounting for the overlap in
51 participants used by Rauf et al. and O'Brien et al. (8, 18). The gestational age range of participants
52 was 32-42 weeks' gestation. Two studies included only women with low-risk pregnancies (8, 18)
53 and three did not report the risk status of participants (15-17).
54
55
56
57
58
59
60

1
2
3 Four studies used the Monica AN24 (8, 15, 17, 18) and one used phonocardiography (16) to
4 conduct CFM. No studies were found which examined at other forms of CFM, such as
5 accelerometry. Fetal monitoring was conducted in real-time in the participants' own home in two
6 studies (8, 18). In one study monitoring occurred in the participants home with retrospective
7 analysis in the hospital (16). In a further two studies monitoring was conducted in a hospital
8 setting with interpretation of recording occurring only after monitoring had finished (15,17).
9 Monitoring of the period during induction of labour was assessed in three studies (8, 17, 18)
10 whereas two studies concerned monitoring in the antepartum period (15, 16). The length of
11 individual recordings varied from 20 minutes to 22 hours.
12
13
14
15
16
17

18
19 Methods of data collection included semi-structured diary (8), semi-structured interview (18) and
20 questionnaire (15-17). Two studies compared women's views of CFM with CTG (15, 17).
21 Women's experience of CFM was the sole focus of only one study (18), with the remainder being
22 mixed-methods studies which also assessed other aspects of CFM recordings. No studies reported
23 assessment of maternal anxiety using a validated maternal anxiety score, thus the secondary
24 outcome measure of this synthesis could not be addressed. Regarding the primary outcome of
25 maternal experience four main themes and 11 subthemes were identified (Figure 4).
26
27
28
29
30
31

32 Practical Limitations

33 *Mobility*

34
35 Some participants described feeling that their mobility was reduced by the monitoring device,
36 particularly due to the presence of multiple cables with the Monica AN24, whilst others described
37 a relative increase in their mobility compared to other forms of monitoring. "*I also felt mobile and*
38 *non-restricted whilst I was wearing the device*" (8). The freedom to mobilise was particularly
39 important in studies of induction of labour as women felt that they experienced less pain and
40 gained a greater sense of control.
41
42
43
44
45

46 *Disturbed sleep*

47
48 The issue of disturbed sleep was noted in two of the five studies (15, 17). One study reported this
49 was due to an electrode repeatedly disconnecting (17) and in the other one participant requested
50 not to receive overnight recordings, but no reason was given for this (15). None of the studies
51 using real-time monitoring at home reported issues with sleep disturbance (8, 18). It is probable
52 that this was not due to the device itself but rather the location of monitoring as had these women
53 received standard induction of labour they would have had to be in hospital.
54
55
56
57
58
59
60

Positive Perceptions

Preference for CFM

In both comparative studies CFM was preferred by the majority of women when compared to CTG, as shown in Figure 5A. In both studies comparing CTG with CFM, women who preferred CTG stated that they found the audible fetal heart sounds reassuring (15, 17). The inability to hear fetal heart sounds whilst undergoing CFM was not mentioned by any of the other studies.

Satisfaction

All studies reported high levels of satisfaction during CFM. Scores from papers reporting Likert scales for satisfaction have been standardised and are shown in Figure 5B. The weighted mean average for satisfaction scores was 8.4/10.

Romano et al. found that quality of life was considered improved with phonocardiography and that satisfaction did not vary with the amount of time that the device was used for, although this study had the shortest period of use (16). Particular aspects of the experience which were identified to contribute to the high level of satisfaction were the freedom to mobilise, be comfortable and, for those receiving real-time monitoring, the ability to be at home.

Comfort

Both phonocardiography and the Monica AN24 were considered comfortable by participants in all studies. One study measured comfort quantitatively. Using a four-point Likert scale, with one being very uncomfortable and four being very comfortable, a mean score of 3.3 (Standard Deviation (SD) \pm 0.6) was calculated (8). When the Monica AN24 was used during induction of labour some women experienced discomfort during uterine activity.

Reassurance

For studies using devices that allowed real-time transfer of recordings, women described knowing that someone was watching their baby's wellbeing as reassuring. *"I found in the hospital you get monitored so many times throughout the day, whereas this I felt like I was being monitored constantly"* (18).

Device Implementation

Home monitoring

High levels of participant satisfaction were found when CFM was used remotely to generate real-time recordings whilst participants were at home. Monitoring at home allowed women a greater

1
2
3 degree of privacy, comfort and better access to support from friends and family. *“I could watch*
4 *the telly, I could you know, do washing or ironing and do whatever I wanted really...I could just*
5 *rest and take it easy...all in all it was a lot more comfortable being at home”* (18). Women also
6 liked being in a less clinical environment and felt that it allowed them to relax more than if they
7 were in hospital.
8
9

10 11 *Perceived relief on staff workload*

12 Women who were monitored remotely felt as though they were reducing staff workload and
13 hospital resources.
14
15

16 17 *Communication with the hospital*

18 One of the main themes to come from the work of O’Brien et al. was the *“virtual presence*
19 *required for remote reassurance”* (18). It was found that women who received regular contact
20 from the hospital were more satisfied with their experience of CFM. Those that did not receive
21 regular contact reported feeling anxious or worried. *“I think it would’ve been nice just to know*
22 *that when the handover happened...you know, that you were still being monitored, and maybe just*
23 *have a little bit more communication from the hospital.”*
24
25
26
27
28
29

30 31 *Need for confidence in staff*

32 The need for women to have confidence and trust in the staff responsible for interpreting
33 recordings was highlighted by Rauf et al. and O’Brien et al. *“If you’re confident in the staff who*
34 *are, kind of, responsible for you when you are going home, then it’s easier to go home”* (8, 18).
35
36
37

38 Negative Emotions

39 Some women reported feeling anxious whilst undergoing CFM. The semi-structured diaries
40 contained 34 comments regarding women’s worries (8). Again, worry and anxiety was found to
41 be increased in women who did not receive regular communication from the hospital as they
42 feared that their baby was not being properly monitored, *“Am I being monitored?”* (8). A degree
43 of anxiety was also noted towards the beginning of monitoring with the Monica AN24 as some
44 women were concerned about displacing electrodes.
45
46
47
48

49
50 However, when assessing how well participants coped with the experience of CFM Rauf et al.
51 found a mean coping score of 3.5 (SD ± 0.6), using a four-point Likert scale, with four indicating
52 that the women coped very well (8). Those who coped less well had experienced issues with
53 device error or a lack of hospital contact.
54
55
56
57
58
59
60

1
2
3 Furthermore, O'Brien et al. noted a greater need for communication amongst primiparous women
4 when compared to multiparous women whilst being monitored remotely (18). The different needs
5 for women who had not experienced pregnancy before was not explored in any of the other
6 included studies.
7
8
9

10 **Discussion**

11
12
13
14 This mixed-methods systematic review included five studies that explored women's experiences
15 of CFM in 105 participants. Synthesis of qualitative and quantitative data has shown that CFM is
16 associated with high levels of participant satisfaction and is preferable to standard CTG
17 monitoring. CFM allows women greater freedom to mobilise and, if used in combination with
18 wireless technology, the ability to be monitored away from hospital both of which were perceived
19 favourably. However, CFM may be associated with some degree of anxiety, although this appears
20 to be related to the implementation strategy used and the degree of communication with clinicians.
21
22
23
24
25
26
27
28

29
30 As both English and non-English language papers were included in this review it was possible to
31 take account of an additional three studies and a total of four countries. This systematic and mixed
32 methods approach allowed for increased scope of the review and eliminated the risk of language
33 bias.
34
35
36

37 This review is limited by the low number of included studies and consequently, the number of
38 participants. Although the included studies were generally of good quality, there were high levels
39 of heterogeneity (summarised in Table 1) in terms of their methodology, the duration of
40 monitoring, the context in which the research was conducted and the country in which the
41 research was undertaken all of which may have affected the results. For example, two included
42 studies used CFM during home induction of labour; these were the only studies to use CFM to
43 provide real-time and remote fetal monitoring (8, 18). Hence, these studies addressed similar, but
44 not identical issues to the other studies. It is likely that the experiences and concerns of women
45 receiving real-time monitoring at home are different to those of women being monitored in
46 hospital with standard CTG monitoring. Therefore, the high satisfaction levels found in studies
47 providing monitoring at home may be related to the location of monitoring rather than to the
48 device itself or the concept of CFM. Furthermore, it would also be expected that issues
49 surrounding antepartum monitoring are different to monitoring during induction of labour.
50
51
52
53
54
55
56
57
58
59
60

1
2
3 There was also a high degree of heterogeneity in the parameters used to assess the experiences of
4 participants following CFM. For instance, though both Rauf et al. and Reinhard et al. utilised
5 questionnaires, “*coping*” and “*wellbeing*” were assessed respectively and it cannot be assumed
6 that these parameters are comparable (8, 15). Only one of the included studies was wholly
7 qualitative in nature (18). Importantly, the small number of studies of the experiences of women
8 using CFM limits the generalisability of findings.
9

10
11
12
13
14 Issues with the design of the monitoring devices were raised in all studies. Practical limitations of
15 the device predominantly focussed on the number of cables though manufacturers of CFM devices
16 appear to be responding to these concerns as the most recent model of the Monica AN24, the
17 Monica Novii, has a cable-free design (19).
18
19

20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
Though some women stated that being able to hear fetal heart sounds would provide reassurance,
this appears to be a matter of individual preference and may serve to increase anxiety in others. A
similar level of reassurance may be gained from receiving regular contact from clinicians during
CFM.

Brown et al. found that 64.3% of clinicians expressed concern that CFM could increase women’s
levels of anxiety (9). This systematic review shows that these concerns may be overstated as none
of the included studies found maternal anxiety to be a significant issue. However, no studies to
date have conducted a formal assessment of anxiety. Hence, future studies exploring the
experiences of women undergoing CFM should use validated assessment tools for maternal
anxiety. However, a systematic review of anxiety scores in pregnancy has shown that none of the
available measures are wholly reliable (20). Therefore, it may be necessary to use a combination
of different measures.

The means by which CFM is implemented appears to play an important role in women’s
experiences. Contact with clinicians during monitoring provides reassurance and may reduce
anxiety. In the case of overnight monitoring which is associated with higher levels of recording
quality due to reduced maternal artefacts, regular contact could conflict with previously noted
issues of disturbed sleep (21). This highlights the need for effective communication to ascertain
individual women’s preferences and the trade-off between these preferences and obtaining high
quality recordings of fetal wellbeing.

In order for implementation of CFM to be successful it must be acceptable to clinicians as well as
women. Clinicians’ concerns must be understood and addressed so that they feel comfortable and

1
2
3 confident using the technology. Implementation also needs to account for adequate training of
4 staff to reduce inter-observer variability when interpreting recordings. There is very little literature
5 concerning clinicians' views of fetal monitoring and only one study has explored views of CFM
6 specifically (9). Future studies should address health care professionals' as well as mothers'
7 experiences of CFM.
8
9

10
11 CFM could be used adjunctively to or in place of intermittent CTG monitoring to detect signs of
12 fetal compromise, but further research is needed to ascertain the feasibility of CFM within a real-
13 world setting and to explore the factors that contribute to the acceptability of fetal monitoring
14 devices.
15
16
17

18
19 In conclusion, recently devised CFM technology could benefit obstetric practice and help to
20 reduce perinatal morbidity and mortality. Though these devices may have the ability to improve
21 pregnancy outcome, they may also significantly impact women's experience of pregnancy,
22 particularly if the device must be worn over a sustained period of time. This systematic review
23 explored women's experiences of CFM and, whilst high levels of patient satisfaction were found,
24 the paucity and heterogeneity of the available literature leaves the findings of this systematic
25 review inconclusive. Consequently, further studies of CFM are required before firm conclusions
26 can be drawn about its effects on women's experiences. Future studies should consider potential
27 sources of heterogeneity identified in this review, including the setting of monitoring (home vs.
28 hospital), timing of monitoring (real-time vs. retrospective analysis), context of monitoring
29 (antenatal vs. induction of labour) and the risk status of participants as these factors may all
30 impact upon women's experience of CFM. A greater number of studies would allow more
31 detailed exploration of the origins of study heterogeneity.
32
33
34
35
36
37
38
39
40
41

42 Ultimately studies are needed to assess the efficacy of CFM in comparison to current methods of
43 fetal monitoring before CFM can be incorporated into clinical practice. This review suggests that
44 CFM does not have a deleterious effect on maternal experience, so this should not be a barrier to
45 such studies. However, the paucity of evidence identified in this review indicates that such studies
46 should continue to assess how clinicians and women view this technology and how the technology
47 could best be employed. Thus, it is imperative that studies of the clinical effectiveness of CFM
48 robustly explore the impact on maternal experience especially during the antenatal period (22).
49
50
51
52
53
54

55 56 **Funding** 57 58 59 60

1
2
3 This project was funded by the Maternal and Fetal Health Research Centre at the University of
4 Manchester.
5
6
7

8 **References**

- 9
10
11 1. WHO. Stillbirths. Available online from:
12 www.who.int/maternal_child_adolescent/epidemiology/stillbirth/en/ (Accessed April 18, 2017).
13
14 2. Flenady V, Wojcieszek AM, Middleton P, Ellwood D, Erwich JJ, Coory M, et al. Stillbirths:
15 recall to action in high-income countries. *Lancet*. 2016;387(10019), 691-702.
16
17 3. Manktelow BN, Seaton SE, Hyman-Taylor P, Kurinczuk JJ, Field DJ, Smith PW, et al.
18 Perinatal Mortality Surveillance Report UK Perinatal Deaths for Births from January to December
19 2014. Leicester: University of Leicester, 2016.
20
21 4. Zalud I & Maulik D. Doppler ultrasound in obstetrics and gynecology. Berlin: Springer, 2006.
22
23 5. Haws RA, Yakoob MY, Soomro T, Menezes EV, Darmstadt GL, Bhutta ZA. Reducing
24 stillbirths: screening and monitoring during pregnancy and labour. *BMC Pregnancy Childbirth*.
25 2009;9(1), S5.
26
27 6. Brown R, Wijekoon JH, Fernando A, Johnstone ED, Heazell AE. Continuous objective
28 recording of fetal heart rate and fetal movements could reliably identify fetal compromise, which
29 could reduce stillbirth rates by facilitating timely management. *Med Hypotheses*. 2014;83(3), 410-
30 417.
31
32 7. Doppler in Obstetrics. Available online at: [www.fetalmedicine.org/var/uploads/Doppler-in-](http://www.fetalmedicine.org/var/uploads/Doppler-in-Obstetrics.pdf)
33 [Obstetrics.pdf](http://www.fetalmedicine.org/var/uploads/Doppler-in-Obstetrics.pdf) (Accessed April 18, 2017).
34
35 8. Rauf Z, O'Brien E, Stampalija T, Ilioniu FP, Lavender T, Alfirevic Z. Home labour induction
36 with retrievable prostaglandin pessary and continuous telemetric trans-abdominal fetal ECG
37 monitoring. *PLoS One*. 2011;6(11), e28129.
38
39 9. Brown R, Johnstone ED, Heazell AE. Professionals' views of fetal-monitoring support the
40 development of devices to provide objective longer-term assessment of fetal wellbeing. *J Matern*
41 *Fetal Neonatal Med*. 2016;29(10), 1680-1686.
42
43 10. Pimenta BS, Nomura RM, Nakamura MU, Moron AF. Maternal anxiety and fetal movement
44 patterns in late pregnancy. *J Matern Fetal Neonatal Med*. 2015;1-5.
45
46 11. Pearson A, White H, Bath-Hextall F, Salmond S, Apostolo J, Kirkpatrick P. A mixed-methods
47 approach to systematic reviews. *Int J Evid Based Healthc*. 2015;13(3), 121-131.
48
49 12. McDermott E, Graham H, Hamilton V. Experiences of being a teenage mother in the UK: a
50 report of a systematic review of qualitative studies. Lancaster: Lancaster University, 2004.
51
52
53
54
55
56
57
58
59
60

13. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006; 3(2), 77-101.
14. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4:1.
15. Reinhard J, Hatzmann H, Schiermeier S. Foetal electrocardiography (ECG) is an alternative to Doppler ultrasound cardiotocogram (CTG) for antenatal assessment of foetal well-being-- preliminary results. *Z Geburtshilfe Neonatol*. 2008; 212(6), 226-229.
16. Romano M, Cesarelli M, D'Addio G, Mazzoleni MC, Bifulco P, Ferrara N, et al. Telemedicine fetal phonocardiography surveillance: an Italian satisfactory experience. *Stud Health Technol Inform*. 2010; 155, 176-181.
17. Philippe A, Curinier S, Piquier-Perret G, Delabaere A, Acocebery M, Velemir L, et al. [Use of Monica AN24 for fetal monitoring during labour induction]. *J Gynecol Obstet Biol Reprod (Paris)*. 2012;41(2), 194-197.
18. O'Brien E, Rauf Z, Alfirevic Z, Lavender T. Women's experiences of outpatient induction of labour with remote continuous monitoring. *Midwifery*. 2013;29(4), 325-331.
19. Monica Healthcare. Novii Wireless Patch System. Available online at www.monicahealthcare.com/products/labour-and-delivery/monica-novii-wireless-patch-system (Accessed April 19, 2017).
20. Brunton RJ, Dryer R, Saliba A, Kohlhoff J. Pregnancy anxiety: A systematic review of current scales. *J Affect Disord*. 2015;176, 24-34.
21. Graatsma EM, Jacod BC, van Egmond LA, Mulder EJ, Visser GH. Fetal electrocardiography: feasibility of long-term fetal heart rate recordings. *BJOG*. 2009;116(2), 334-337.
22. Van Teijlingen ER, Hundley V, Rennie AM, Graham W, Fitzmaurice A. Maternity satisfaction studies and their limitations: "What is, must still be best". *Birth*. 2003;30(2), 75-82.

Supporting Information legend

Appendix S1. Example search strategy for Medline database.

Legends

Table 1 - Summary characteristics of included studies.

Figure 1: An example of a device for continuous fetal monitoring (MONICA AN24) showing adhesive electrodes applied to the maternal abdomen connected by wires to a storage device which produces a recording of the fetal heart rate trace and uterine activity. Photograph used with permission of Monica Healthcare Limited.

Figure 2: Diagram demonstrating the integrative approach to mixed-method systematic review. Adapted from Pearson A, White H, Bath-Hextall F, Salmond S, Apostolo J, Kirkpatrick P. A mixed-methods approach to systematic reviews. *Int J Evid Based Healthc.* 2015;13,121-131.

Figure 3: PRISMA flow diagram of study selection. CFM, continuous fetal monitoring. Adapted from Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev.* 2015;4:1.

Figure 4: Thematic diagram of the main themes and subthemes identified by the systematic review. Main themes are represented by ellipses and subthemes by squares. CFM, continuous fetal monitoring.

Figure 5: A) Proportions of preferences for continuous fetal monitoring versus CTG (15, 17) and B) Satisfaction scores standardised to a 10-point Likert scale, with 10 being completely satisfied

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

and 0 being completely unsatisfied. Error bars are provided where possible from the published data [Data extracted from References (8),(15) and (17)].

For Peer Review

Table 1 - Summary characteristics of included studies.

Authors	Sample Characteristics	Location of monitoring	Country of study	Timing of Monitoring	Data Collection	Key Findings	Quality Assessment
Reinhard et al. 2008 (15)	Ten pregnant women >32 weeks' gestation, received overnight monitoring with Monica AN24. All women had a previous hospital admission during pregnancy.	During inpatient admission.	Germany	Retrospective	Satisfaction and preference questionnaires.	All participants were outwardly happy with Monica AN24. Overall participants were satisfied with Monica AN24 and 80% preferred Monica AN24 to CTG. 20% of participants preferred CTG due to reduced mobility and lack of audible fetal heart sounds with Monica AN24.	B
Romano et al. 2010 (16)	Six pregnant women at 39-42 weeks' gestation received 20 minute phonocardiography recordings twice a week	Antenatal monitoring at home	Italy	Retrospective	Satisfaction questionnaire on a Likert scale of 1-4 completed before and after recordings.	Participants reported high levels of satisfaction and improved quality of life with phonocardiography. Satisfaction did not vary between participants who used the monitor for short or long periods of time.	B
Rauf et al.	Seventy low-risk women were monitored with	At home during	UK	Real-time	Semi-structured diaries assessed	Women predominantly coped well or very well and were	A

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

2011 (8)	Monica AN24	induction of labour.			coping, comfort, satisfaction and location preference on a 4-point Likert scale with free text space for comments.	overall satisfied or very satisfied. Satisfaction was influenced by the level of contact with hospital. Women mostly preferred being at home to in hospital and were generally comfortable.	
Philippe et al. 2011 (17)	Nineteen pregnant women 34-42 weeks' gestation received recordings with Monica AN24 and CTG.	In hospital during induction of labour	France	Retrospective	Satisfaction questionnaire.	Women generally preferred Monica AN24 over CTG and all would recommend Monica AN24 to a friend. Some participants reported discomfort, reduced mobility and disturbed sleep.	B
O'Brien et al. 2013 (18)	Fifteen low-risk pregnant women were monitored with Monica AN24.	At home during induction of labour.	UK	Real-time	Individual semi-structured interviews. Transcripts were subject to thematic coding and analysis.	Three main themes were identified: need for women to labour in their comfort zone, desire to achieve the next best thing to a normal labour and importance of a virtual presence to offer remote reassurance.	A

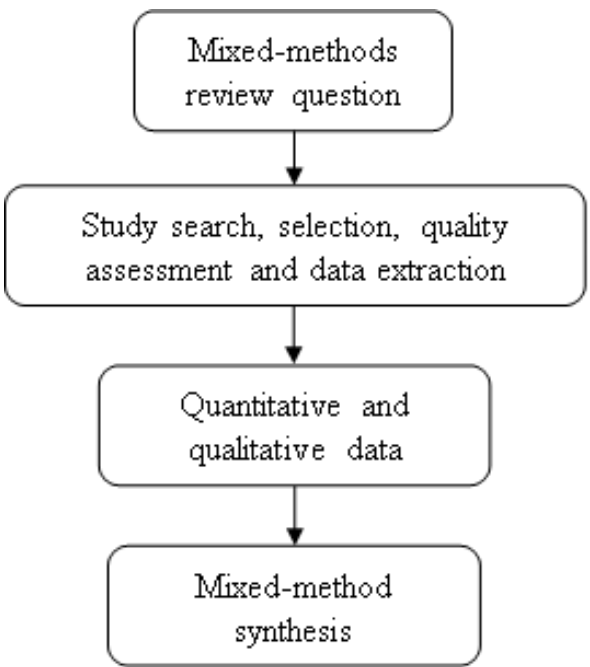


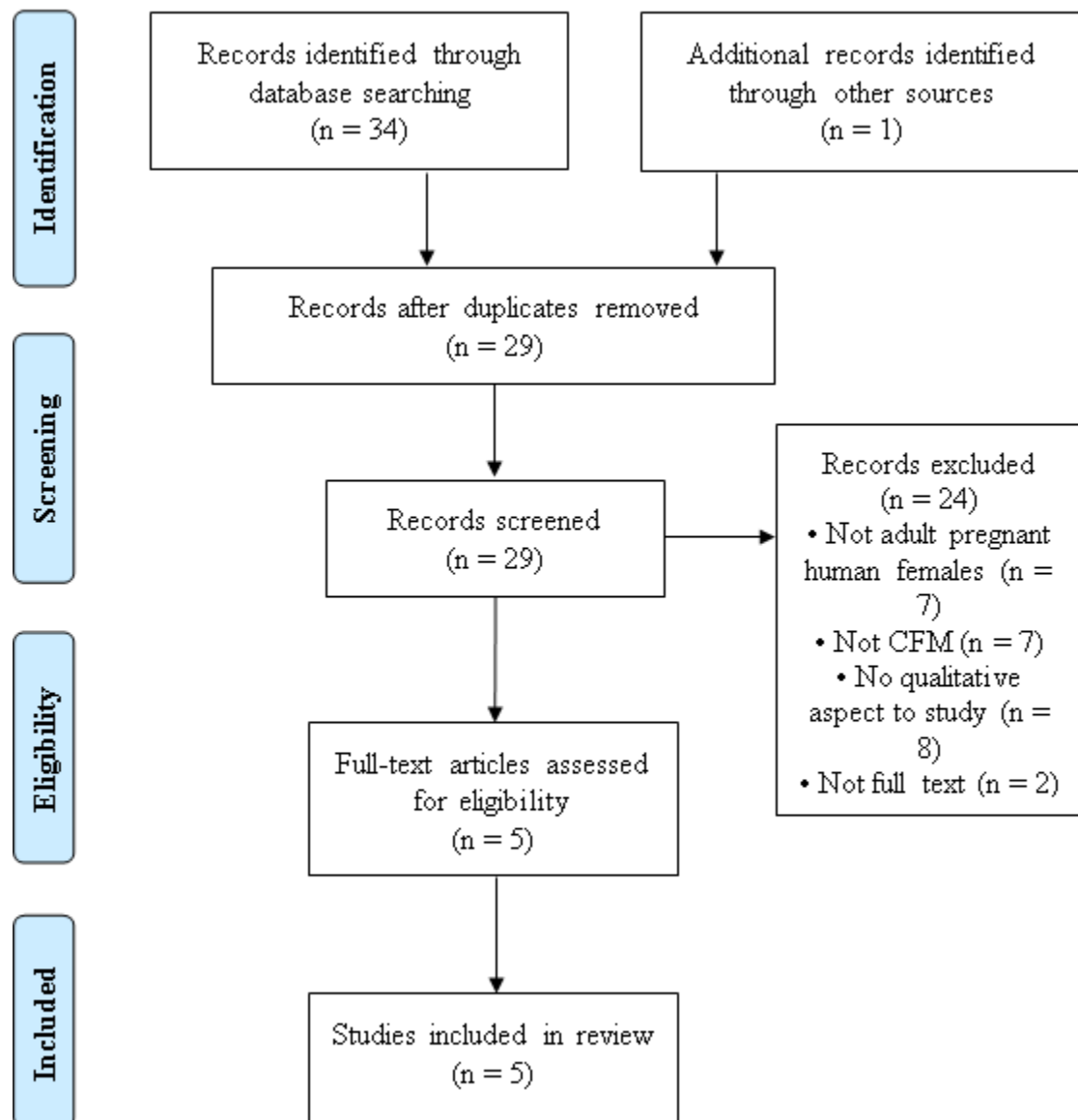
Figure 1: An example of a device for continuous fetal monitoring (MONICA AN24) showing adhesive electrodes applied to the maternal abdomen connected by wires to a storage device which produces a recording of the fetal heart rate trace and uterine activity. Photograph used with permission of Monica Healthcare Limited.

438x292mm (300 x 300 DPI)

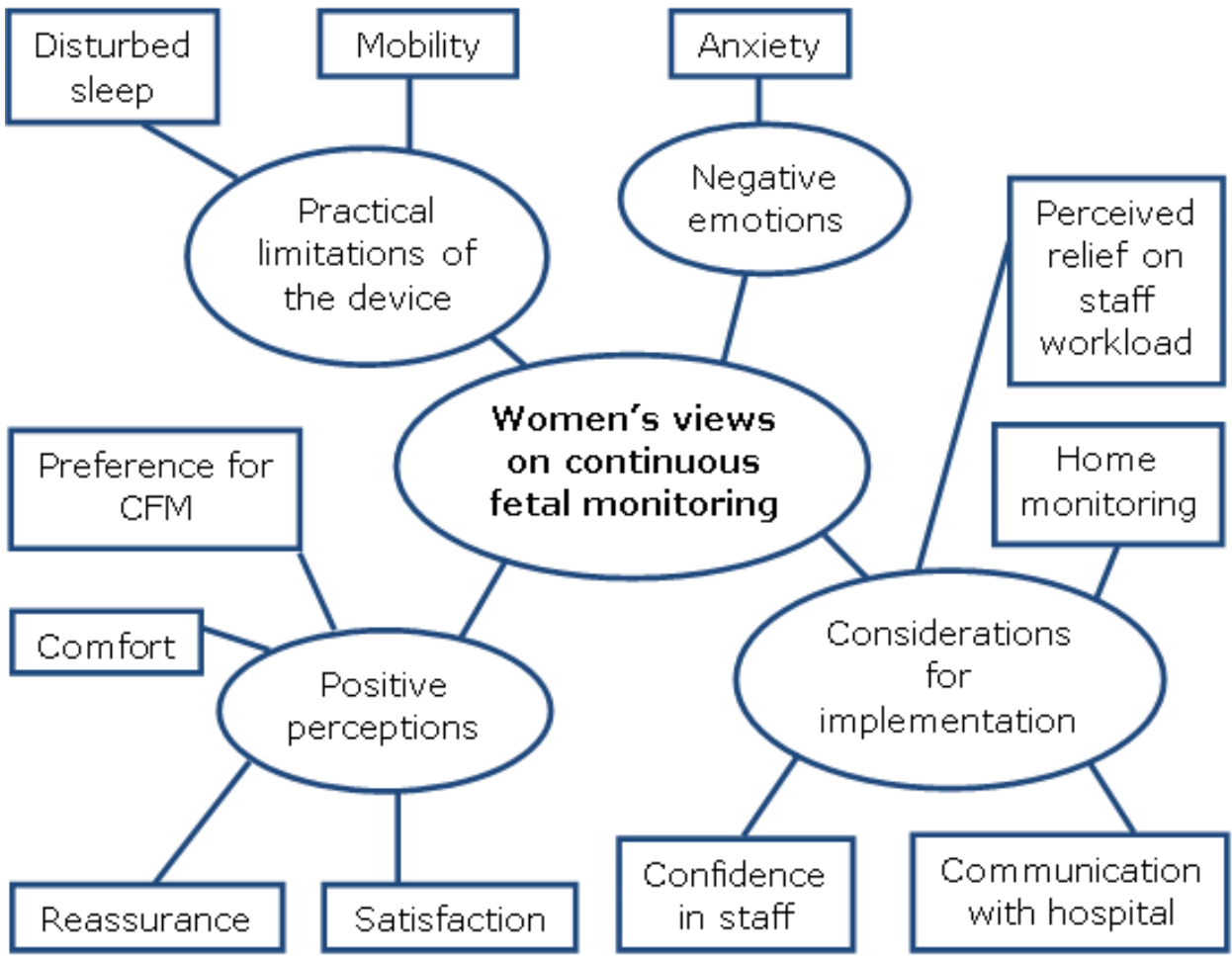
review

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60





1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



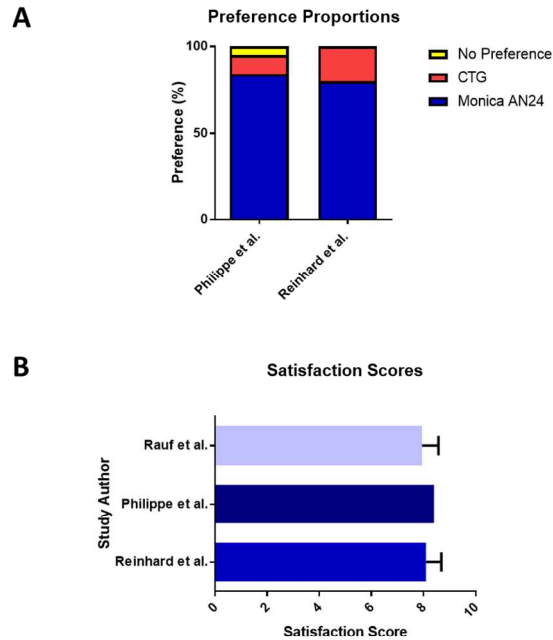


Figure 5: A) Proportions of preferences for CFM versus CTG (15, 17) and B) Satisfaction scores standardised to a 10-point Likert scale, with 10 being completely satisfied and 0 being completely unsatisfied. Error bars are provided where possible from the published data (8, 15, 17).

190x275mm (150 x 150 DPI)

Appendix S1.

1. Medline; exp FETUS/; 145072 results.
2. Medline; ((fetus OR foetus OR fetal OR foetal) ADJ3 monitor*).ti,ab; 348 results.
3. Medline; ((fetus OR foetus OR fetal OR foetal) ADJ3 movement*).ti,ab; 146 results.
4. Medline; ((fetus OR foetus OR fetal OR foetal) ADJ3 electrocardiogra*).ti,ab; 27 results.
5. Medline; ((fetus OR foetus OR fetal OR foetal) ADJ3 ecg).ti,ab; 12 results.
6. Medline; ((fetus OR foetus OR fetal OR foetal) ADJ3 "heart rate").ti,ab; 117 results.
7. Medline; electrocardiography.ti,ab; 11470 results.
8. Medline; exp ELECTROCARDIOGRAPHY/; 184388 results.
9. Medline; exp PHONOCARDIOGRAPHY/; 7602 results.
11. Medline; ((induce* OR induct*) ADJ3 labour).ti,ab; 7280 results.
12. Medline; 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 11; 166882 results.
13. Medline; "long term".ti,ab; 583838 results.
14. Medline; continuous*.ti,ab; 353270 results.
15. Medline; continual*.ti,ab; 15889 results.
16. Medline; 13 OR 14 OR 15; 930835 results.
17. Medline; exp TELEMEDICINE/; 17880 results.
18. Medline; remote*.ti,ab; 51226 results.
19. Medline; wireless*.ti,ab; 7880 results.
21. Medline; transabdominal*.ti,ab; 6262 results.
22. Medline; exp MONITORING, AMBULATORY/; 22985 results.
23. Medline; wearable.ti,ab; 3155 results.
24. Medline; exp TELEMETRY/; 10145 results.
25. Medline; "long distance".ti,ab; 9420 results.
26. Medline; telehealth.ti,ab; 2025 results.
27. Medline; 17 OR 18 OR 19 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26; 118647 results.
28. Medline; 12 AND 16 AND 27; 221 results.
29. Medline; exp CARDIOTOCOGRAPHY/; 1647 results.
30. Medline; ultrasound.ti,ab; 174896 results.
31. Medline; doppler.ti,ab; 86647 results.
32. Medline; ctg.ti,ab; 3082 results.
33. Medline; 29 OR 30 OR 31 OR 32; 246054 results.
34. Medline; 28 NOT 33; 199 results.
35. Medline; monica*.ti,ab; 1661 results.
36. Medline; 12 AND 35; 13 results.
37. Medline; 34 OR 36; 212 results.
38. Medline; exp PERSONAL SATISFACTION/; 12952 results.
39. Medline; acceptab*.ti,ab; 122767 results.
40. Medline; experience*.ti,ab; 772846 results.
41. Medline; satisf*.ti,ab; 239760 results.
42. Medline; 38 OR 39 OR 40 OR 41; 1086614 results.
43. Medline; 37 AND 42; 13 results.