Title: A systematic review of supportive interventions for women during induction of labour to promote comfort and wellbeing

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Conflict of Interest

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Ethical Approval

Not applicable

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ABSTRACT

Aims: To evaluate the effectiveness of non-pharmacological non-invasive supportive interventions for impacts on women's comfort and wellbeing during induction of labour.

Design: A quantitative systematic review without meta-analysis.

Data Sources: Databases were searched for primary research published in English between 2000-2019: AMED, CINAHL, Medline, Maternity and Infant Care database, PsycINFO, and ProQuest. The quality of studies was evaluated using JBI levels of evidence and established critical appraisal tools. Studies describing measures of comfort, coping and wellbeing for women during induction of labour were included.

Results: Two articles met the criteria for inclusion. There is limited evidence to suggest that women having out-patient cervical priming were more satisfied with their experience than women having in-patient cervical priming and that outpatient cervical priming did not increase women's anxiety. A specifically designed information brochure explaining the induction process improved women's knowledge and understanding.

Review methods: The quantitative systematic review followed the Centre for Reviews and Dissemination guidelines and Cochrane Effective Practice and Organisation of Care guidance. Quality appraisal was conducted using JBI levels of evidence, Cochrane Risk of Bias and other established tools. A narrative description of the quantitative data was undertaken. There was insufficient evidence to perform a narrative synthesis or meta-analysis due to the nature of the study designs and insufficient outcome data.

Conclusions: Globally, the number of women having an induction of labour is increasing and there is a lack of evidence on the effectiveness of supportive interventions. Components of supportive care for women having induction of labour require urgent evaluation. Measurement tools which capture the complexity of supportive care for women having induction of labour need to be developed and validated.

Impact: This is the first review to evaluate non-pharmacological, non-invasive supportive interventions for women having induction of labour. The findings of this review identify the urgent need to develop an evidence base for effective supportive.

Keywords

Supportive care; induction of labour; systematic review; non-pharmacological; nursing; midwifery

INTRODUCTION

The numbers of women experiencing induction of labour (IOL) has increased over recent decades. Around one in four women in many high-income countries and some low and middle income countries experience IOL (WHO 2018). In England IOL rates have increased from 20% in 2007-08 to 33% in 2018-19 (NHS digital 2019). The rise in IOL has been attributed to a rise in women with high BMI and diabetes, increased maternal age and clinical management policies (Walker et al. 2014, Ferrazzi et al. 2019). IOL is usually performed by administering oxytocin or prostaglandins to the pregnant woman or by manually rupturing the amniotic membranes (WHO 2018). Recommended IOL process includes cervical assessment (Bishop score) and electronic fetal monitoring prior to administration of vaginal prostaglandin E2 (PGE2) where appropriate. Depending on the method of PGE2 administration, the Bishop score is reassessed 6 - 24 hours after vaginal PGE2 insertion. If labour is not induced, women may be offered further PGE2 administration or amniotomy followed by oxytocin infusion (National Institute for Health and Care Excellence, NICE 2008). Other methods of IOL include mechanical induction with a balloon to stretch the cervix. This method has been reported to be as effective as PGE2 however further evidence is required is on safety outcomes and maternal satisfaction (de Vaan 2019). Current clinical guidance reflects review level evidence indicating that IOL at, or beyond, term is associated with fewer perinatal deaths in comparison to expectant management (National Institute for Health and Care Excellence 2008, Middleton et al. 2018). However, the optimal timing of offering IOL in low-risk pregnancies is still not clear, sub-group analysis comparing IOL at less than 41 weeks and IOL at or above 41 weeks revealed no clear differences in neonatal outcomes (Middleton et al. 2018, Royal College of Midwives 2019).

BACKGROUND

Induction of labour has been associated with increased intervention, pain and operative vaginal birth (Middleton et al. 2018, Coates et al. 2018). Women's experience of IOL can affect their satisfaction with labour and birth and have a lasting effect on their relationship with their baby (Brown & Furber, 2015, Akuamoah-Boateng and Spencer, 2018). Women have reported negative experiences of maternity care during IOL, expressing feelings of anxiety and being fearful about the impact on themselves and their baby (Hildingsson et al. 2011, Wier et al. 2018). Existing systematic reviews have focused on the optimal timing of IOL, supporting decision-making, induction techniques and pharmacological methods for IOL (Middleton et al. 2018, Coates at al. 2019, de Vaan et al. 2019). There are no existing reviews which have evaluated non-pharmacological and non-invasive supportive interventions to improve women's comfort and coping during cervical ripening and

induction procedures with the intention therefore of reducing peri and postnatal distress and trauma. Supportive care for women having an induction of labour should include information about the reasons and process of IOL, pain relief options and emotional support, discussing the risks, benefits and alternative options and supporting decision making (NICE 2008). Qualitative studies have reported women's experiences during IOL, highlighting areas to focus improvements in care provision and guide further research, for example:

- Informational support: receiving clear information to support the woman's decision-making, managing women's expectations and providing timely midwifery support and advice throughout the induction process (Gatward et al. 2010, Jay et al. 2018, Wier et al. 2018, Akuamoah-Boateng and Spencer 2018, Oster et al. 2011, Brown & Furber 2015, Coates et al. 2019, Henderson & Redshaw 2013)
- Esteem support: being actively involved in the decision making and fostering a sense of control and choice about having an induction and the series of interventions involved in the induction process (Henderson & Redshaw 2014, Akuamoah-Boateng et al. 2018, Coates et al. 2019)
- Emotional support: discussing women's concerns and feelings about IOL (e.g. potential cascade of intervention and sense of disappointment) and accommodating partners to remain with women throughout the process (Akuamoah-Boateng et al. 2018, Coates at al. 2019, Henderson & Redshaw 2014, Brown & Furber 2015, Jay et al. 2018).
- Practical support: providing areas for women to mobilise with access to refreshments for themselves and partners; having peaceful, private spaces to relax and sleep (Brown & Furber 2015, Jay et al. 2018, Coates et al. 2019, Oster et al. 2011, Howard et al. 2014).

This systematic review was informed by consultations with maternity service users who were asked to identify aspects of the induction process important to women and to identify areas requiring improvement. Feedback from service users resonated with many of the issues reported in the qualitative studies exploring women's experiences of IOL (Oster 2011, Brown & Furber 2015, Cotes et al. 2019, Akuamoah-Boateng et al. 2018, Henderson & Redshaw 2014, Jay et al. 2018). Research programs that involve women from local communities and are co-designed with women and other stakeholders will help to ask new kinds of research questions which encompass the "biological, psychological, emotional, social, economic, cultural, and life course aspects of the childbearing continuum" (page 229 Kennedy et al. 2018). In addition to helping to identify problems in maternity care contexts, the involvement of service users in maternity can provide vital insights to increase the

likelihood that future policy decisions will be relevant and appropriate for large-scale implementation (Kennedy at al. 2018).

THE REVIEW

Aim

This review aimed to locate and evaluate the available evidence to answer the question 'What non-pharmacological non-invasive supportive interventions are effective, valued and acceptable in promoting women's comfort and well-being during induction of labour?'. The framework for the review was developed to present an overarching evaluation of concepts associated with women's comfort and wellbeing. Service user involvement helped identify aspects of comfort and wellbeing that were important to women and their families. It was also important to identify aspects of supportive care during IOL which are not currently measured or reported in order to inform further research and highlight gaps in knowledge.

Design

A quantitative systematic review was conducted according to the Centre for Reviews and Dissemination guidelines (CRD 2009). The Cochrane Effective Practice and Organisation of Care (EPOC, 2017) guidance assisted further informed the systematic review methods with reference to data extraction, quality screening, analysis and presentation of the data. The report follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement reporting guidelines (Moher et al. 2009). The review protocol was registered on the PROSPERO database at the CRD (CRD42019127728).

Search methods

An initial scoping search was conducted (Arksey and O'Malley, 2007, Peters et al., 2015) to map the current evidence base, identify gaps in the current literature, focus the research question and identify relevant search terms. The Cochrane Library, The CRD database, The Joanna Briggs Institute Library (JBI) and the National Institute for Health and Care Excellence databases were searched for existing or in progress systematic reviews or clinical trials of induction of labour interventions published in the last five years.

The systematic literature search was then developed for AMED (Allied and Complementary Medicine Database), CINAHL (Cumulative Index to Nursing and Allied Health Literature), EMBASE (Excerpta Medica Database), Medline (Medical Literature Analysis and Retrieval System Online), Maternity and Infant Care database from MIDIRS (Midwives Information and Resource Service), PsycINFO, and ProQuest databases. Two reviewers completed the literature search in March 2019. A summary of

the search terms is included in Table 1 and a supplementary file 1 provides details of the full Medline search strategy.

Table 1: Search terms

(Labour) Induced / Induction	and	Coping methods	and	Comfort
(Pre) Induction / Labour		Relaxation / sleep		Pain
Cervical ripening / priming		Exercise / ambulation		Satisfaction
		Mobilisation / position		Benefit / effectiveness
		Birthing centres / hospitals / unit		Improve / reduce
		Delivery / labour rooms / wards		Achieve
		Home		Coping
		Facilities		Support
		Design / layout		Care
		Space / environment		Knowledge
		Music / quite / noise		Psychological / anxiety
		Equipment / ball		Self-efficacy
		Freedom / autonomy		Consent
		Privacy / dignity		Behaviour
		Personal / individual		Social support
		Information / choice / decision		Preference
		Consent / rights		Experience
		Nutrition / hydration		Emotion / mood
		Promote / encourage		Fear / distress
		Enable / assist / help		
		Foster / stimulate / increase		
		Partner / companion / supporter		

Papers were included in the review if they met the following criteria: (i) published in English, (ii) based in an OECD country (to enable greater comparability between health systems and socio-economic contexts), (iii) reporting quantitative primary research including randomised controlled trials, quasi-experimental studies and cohort studies (iv), were published between January 2000 to March 2019, (v) include pregnant women who have completed 36 weeks of pregnancy whose labour was being induced by mechanical, surgical or pharmacological methods (vii) reporting non-pharmacological, non-invasive interventions designed to support women's coping, comfort, knowledge and wellbeing (vii) report quantitative measures of comfort, coping and wellbeing (e.g. locus of control; self-efficacy, satisfaction, anxiety, pain perception, quality of care). Exclusion criteria were (i) papers reporting outcomes and/or experiences of women having augmentation of labour, (ii) surveys, qualitative studies, secondary data analysis and literature reviews, (iii) pharmacological interventions or invasive procedures (e.g. epidural, acupuncture).

The review team considered that the inclusion of a broad range of intervention designs would present an opportunity to compare the effectiveness of different intervention options (Higgins et al. 2019). A similar breadth was adopted to considering the supportive interventions delivered to women during IOL. These may include single or multi component interventions that reflect aspects of supportive care (Mander 2008):

- emotional support from care providers or companions

- instrumental support including physical spaces and environments
- informational and education support
- esteem support, which may include supporting women's decision making, sense of choice and control

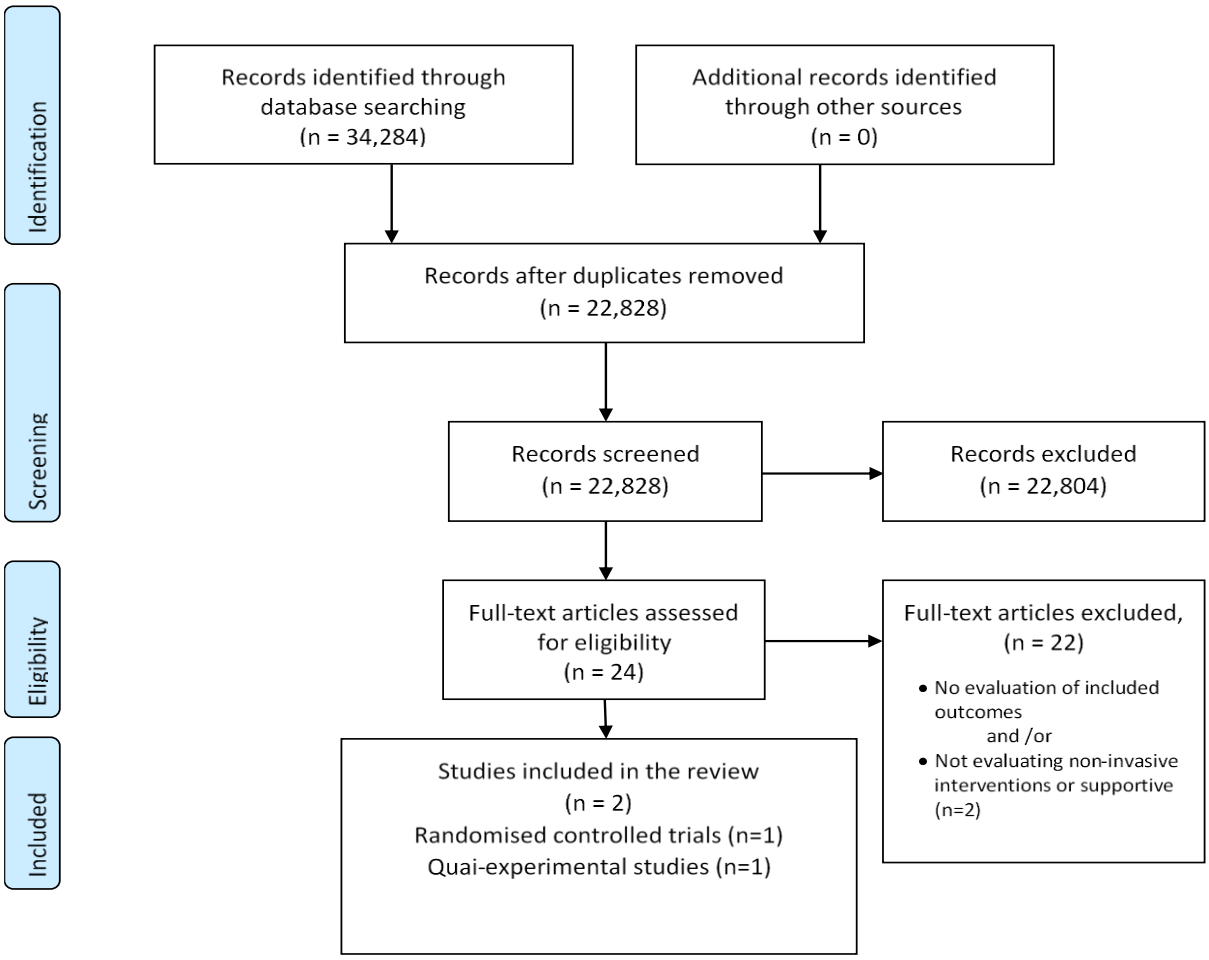
A broader focus that also included non-randomised studies was adopted to cover the scope of women-centred outcomes which may be measured more reliably through observational studies (Gartlehner & Flamm 2013).

Potential papers retrieved from the databases were imported to an EndNote library, and duplicate records were identified. Two researchers independently screened the titles and abstracts against the review inclusion and exclusion criteria. Full text papers of the remaining citations were then retrieved and independently assessed by two researchers. A third researcher moderated any discrepancies until the final selection of papers was agreed. Data were extracted using a pre-piloted form and was completed independently by two researchers.

Search outcome

The search identified 34,284 potentially eligible papers which were assessed on the information provided in the abstract using the review eligibility criteria. Duplicate papers were removed (n=11,456). Potentially eligible papers (n=24) were retrieved for full text assessment. Excluded papers (n=22) did not include relevant outcome measures or did not report non-pharmacological, non-invasive supportive interventions. The literature search and inclusion process are detailed in the PRISMA Flow diagram (Moher et al. 2009) (Figure 1).

Figure 1: PRISMA flow diagram: Supportive interventions for women having an induction of labour



Quality appraisal

The quality of studies included in the review was evaluated using Joanna Briggs Institute (JBI) levels of evidence (JBI 2013) and established critical appraisal tools selected for the study design: JBI tools for quasi-experimental studies (JBI 2017); The Cochrane Effective Practice and Organisation of Care (EPOC) Risk of Bias tool (2017) (supplementary file 2); and the CASP tool for cohort studies (2019).

Two independent researchers assessed study quality and banded studies as low, medium or high quality based on the quality assessment scores. There was consensus of opinion between the two researchers. Although no studies were excluded on the basis of quality, the quality assessment was used to identify the strengths and limitations of the review (Aromataris & Munn 2017).

Data extraction

Data extraction forms were designed and piloted. Extraction was completed by two independent researchers. Data extraction tables consisting of numerical and textual data were produced to present the study characteristics, results and quality assessments.

Data analysis and synthesis

There was insufficient evidence to perform a meta-analysis or synthesis without meta-analysis (Campbell et al. 2020) due to the nature of the study designs and insufficient outcome data. A narrative description of the quantitative findings was reported alongside the numerical data. A GRADE assessment (Schunemann et al. 2013, Cochrane EPOC 2018) of the review findings was planned, however, this was not conducted due to the paucity of studies and data.

RESULTS

Included studies

Two studies were included which were conducted in 2011 and 2013 in Australia. The study designs were a quasi-experimental study (Cooper & Warland 2011) and a randomised controlled trial (Turnbull et al. 2013) (Table 2). Both papers were assessed as being of high to medium quality. The intervention components are presented in Table 3 (TIDieR checklist, Hoffmann et al. 2014)

Women's anxiety and satisfaction of care was reported in one study (Turnbull et al 2013) which evaluated outpatient and inpatient cervical priming for post-maturity IOL. A questionnaire to assess outcomes and experiences was adapted from a previous study (Turnbull et al. 1996) and anxiety measures were collected via the Hospital Anxiety and Depression Scale the anxiety component of a Multiple Affect Adjective Check-List, and a 100 mm linear analog anxiety scale (Bjelland et al, 2002, Lubin et al. 2001, Elliott 1993). One study reported women's knowledge scores to evaluate the effectiveness of an information brochure (Cooper & Warland 2011). A questionnaire was developed by the authors based on evidence-based literature, expert input from obstetric and midwifery practitioners and a subsequent peer review. Outcomes including women's locus of control, self-efficacy or pain perception were not reported in any of the included studies.

Table 2. Characteristics of studies included in the review

First author Country Year	*Objectives*	*Included participants*	*Method / data collection*	*Data collection timepoint*	*Numbers eligible/ consented / included*	**Key results of interest**	**Quality / Risk of Bias assessment**
Quasi-experimental studies							
Cooper Australia 2011	To gain a better understanding of women's baseline level of knowledge of induction of labour (IOL) and determine whether giving written information at the time IOL is decided, results in significant differences in knowledge and understanding of the process	Women greater than or equal to 37 weeks of pregnancy who were undergoing induction of labour	Questionnaire	Antenatal admission for induction of labour	50 / 50	Statistically significant increases in knowledge reported in the intervention group for knowledge about action ($p = 0.002$) and timing of prostaglandins ($p = 0.03$), the number of side effects known ($p < 0.0001$) as well as time to birth ($p = 0.001$) indicating an increased understanding of the process as a result of reading an information brochure. Women in the non-intervention group lacked knowledge pertinent to IOL, even though they have consented to the IOL procedure. The most significant disparity noted between the intervention and non-intervention groups was women's knowledge of side effects of prostaglandin. Many women in the non-intervention group had unrealistic expectations of both the time for drug action and likely time from prostaglandin administration to birth. In contrast women in the intervention group knew about the common side effects of prostaglandin and possessed a more realistic understanding of the likely time to birth following this procedure. The results indicate that a specifically designed information brochure explaining the process of IOL has the effect of enhancing women's knowledge.	Medium - high
Randomised controlled trials							
Turnbull Australia 2013	To compare clinical, economic, and psychosocial outcomes of inpatient and outpatient cervical priming before induction of labour. (this paper presents the psychosocial outcomes)	Women with a low risk of obstetric complications, being induced for postdate pregnancy or social reasons	Questionnaire 7 weeks after birth	Postnatal data collection	821	No statistically significant or clinically relevant differences were found in immediate anxiety, depression, or infant feeding. Small, statistically significant differences favouring outpatient priming were found in seven of the nine subscales in the 7-week postpartum questionnaire. The direction of the effect was maintained, mostly with a larger effect size in women who received the intervention. Conclusion: Women allocated to outpatient priming were more satisfied with their priming experience than women allocated to inpatient priming. Being informed that they could go home after cervical priming did not increase women's anxiety	Medium to low risk of bias

Table 3: Summary table describing the interventions included in the systematic review.											
Author Year	Brief name	Recipient	Why	What (materials)	What (procedures)	Who provided	How	When and how much	Tailoring	Modifications	Fidelity
Cooper 2011	Induction of labour information brochure	Women greater than or equal to 37 weeks of pregnancy who were undergoing induction of labour	Written information is associated with increased knowledge and understanding of interventions, supports shared decision making, the patient-caregiver interaction and ensures informed consent. There has not been a formal evaluation of written IOL information	An information brochure including IOL process information at the study setting. Plain language. Included the definition and usual indications for IOL, methods and actions. The likelihood of possible events (e.g. vaginal examination, onset of labour, monitoring, repeat doses, artificial rupture of membranes, syntocinon, pain relief and instrumental or surgical birth). Side effects, risks and the time for drug. Information about when, where and how the woman would be induced and her current Bishop Score.	The brochure was given to the intervention group at the time of IOL decision. Women were given opportunity to read and discuss this additional information. Data collection occurred as soon as possible after hospital admission for IOL.	Midwife or doctor	Face-to-face	Participants were approached to participate by the midwife or doctor at the time their IOL was decided (a day or two before admission) and the information was provided to the intervention group.	Tailored to the IOL process at the study setting. The authors did not consider existing IOL written information suitable because they all omitted specific information relevant to the participating hospital's procedure for IOL.	Not described	Not described
Turnbull 2013	Inpatient and outpatient cervical priming	Women with a low risk of obstetric complications being induced for postdate pregnancy or social reasons	Limited evidence to support the merits of outpatient priming with little information on psychosocial impact. Studies are required to assess the safety, clinical effectiveness, and cost effectiveness of outpatient and inpatient priming taking into account women's views.	For women assigned to outpatient priming, cervical priming was followed by at least 40 minutes of electronic monitoring. If the monitoring was reassuring and uterine activity absent, the woman went home with written instructions from the midwife. Women presented to hospital the following morning or overnight if labour ensued. Women could telephone or return to hospital at any time. Recruitment via hospital clinics when induction was scheduled, this included completion of the randomisation process and recruitment interview with baseline data collection. Follow-up data collection occurred at 7 weeks postnatal.		Clinicians referred women to a designated research midwife who assessed eligibility. Midwives conducted the assessment and prostaglandin insertion.	Face-to-face	Recruitment an allocation during antenatal clinic appointment to discuss IOL. Outpatient cervical priming on admission for IOL process.	Not described (usual IOL process is described in the paper)	Not described	Not described Single process cervical priming

Turnbull et al (2013) evaluated outpatient and inpatient cervical priming for post-maturity IOL. The paper met the criteria for inclusion as the research aimed to explore women's anxiety and satisfaction with the cervical priming and induction process. From a total sample of 1,084 women, 827 women were eligible and willing to participate. Women who did not complete the intervention a) went into spontaneous labour, b) had medical risk factors or c) declined IOL (n=396). The inpatient cervical priming group received usual care which involved cervical priming with prostaglandin E2 gel with amniotomy and oxytocin infusion the following morning unless labour had commenced, or further prostaglandin application was indicated. In the outpatient group, women returned home following cervical priming if fetal monitoring was reassuring and uterine activity absent. Women returned to hospital the following morning or overnight if labour ensued.

Postpartum questionnaires were sent to 819 women seven weeks after birth with a 76% response rate in both groups. The questionnaire was developed following interviews with women who had experienced IOL and contained nine topic areas (Table 4) focused on women's satisfaction and experiences with care, current feeding practices and the Edinburgh Postnatal Depression Scale (Affonso et al. 2000). The authors reported that no significant differences were found in immediate anxiety, depression or infant feeding between the two groups. The authors reported small statistically significant differences between the two groups for seven of the nine subscales in the 7 week postnatal questionnaire (social support, self-efficacy, readiness, stress, control, information, safety), with more favourable scores for women allocated to outpatient priming than for those allocated to inpatient priming . No statistically significant differences were found for the subscales measuring 'Environment' and 'General Satisfaction' (Turnbull et al. 2013).

Table 4: Postnatal questionnaire subscales reported in the study by Turnbull et al. (2013)

Results	**Inpatient**			**Outpatient**			
(ITT)	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants	Mean difference (95% CI)
Social support	3.92	0.8	313	4.17	0.66	305	-0.25 (-0.13 to -0.37)
Environment	4.18	0.73	312	4.24	0.75	304	-0.06 (-0.18 to 0.06)
Self-efficacy	3.6	0.84	312	3.77	0.85	305	-0.17 (-0.03 to -0.30)
Readiness	3	0.89	310	3.18	0.97	304	-0.22 (-0.07 to -0.37)
Stress	3.16	0.92	310	3.37	0.93	304	-0.22 (-0.07 to -0.36)
Control	3.5	0.8	311	3.63	0.81	304	-0.13 (-0.003 to -0.26)
Information	3.63	0.74	311	3.8	0.76	304	-0.18 (-0.06 to -0.29)

Safety Satisfied	3.55 3.67	0.8 0.88	311 202	3.72 3.83	0.83 0.94	305 197	-0.16 (-0.03 to -0.29) -0.16 (-0.33 to 0.02)

Cooper & Warland (2011) conducted a quasi-experimental study to evaluate the effectiveness of an information brochure presented to women at the time of the IOL decision. The comparison group had access to traditional sources of information. The comparison group reported that their main source of information about IOL was their midwife. The brochure was developed by the authors following a review of the literature and guidelines for IOL and covered the induction process, the definition and usual indications for induction, types of prostaglandin (pessary or gel) and the usual action of the drug. The likelihood of possible events such as vaginal examination, onset of labour, fetal monitoring, repeat doses, no action, artificial rupture of membranes, syntocinon, pain relief and instrumental or surgical birth were included. Side effects, risks and the time for drug action and birth were also described. Outcome data were collected from the fifty participants via a postnatal questionnaire. Statistically significant increases in knowledge and understanding were reported for the intervention group for knowledge about action ($p = 0.002$) and timing of prostaglandins ($p = 0.03$), the number of side effects known ($p < 0.0001$) as well as time to birth ($p = 0.001$). The authors reported that prior to the study, the midwives and doctors may have initiated a greater emphasis on information facilitation, impacting on baseline knowledge and therefore the extent of change in understanding.

The two papers included in the review reported that written information explaining the process of IOL in plain language enhanced women's knowledge of the induction process. Outpatient cervical priming for IOL did not increase women's anxiety and women were more satisfied with their experience when compared to women receiving to inpatient cervical priming.

DISCUSSION

This review demonstrates that there is very limited evidence which has evaluated non-pharmacological, non-invasive supportive interventions for women specifically related to having an IOL. This is concerning in the context that IOL is widely used in many settings internationally, affecting the experiences of significant numbers of childbearing women (WHO 2018). Despite the broad range of candidate interventions derived from the conceptual framework, only two studies were located for inclusion in the review. These evaluated different interventions using different outcome measures relating to broad concepts of supportive care. The current evidence base is

insufficient to inform the design and implementation of supportive interventions to improve the quality of care for women having an IOL. There may be other supportive interventions which have been evaluated in clinical practice as part of service developments, however most service improvement projects are unpublished which is a serious barrier to the development of improvement in maternity care (Davidoff et al. 2008).

Kennedy et al (2018) identified that across all areas of midwifery care there is a serious imbalance in the current evidence base surrounding the provision of high-quality care. The authors identify the majority of existing maternity care research focuses on the treatment of complications, with very little attention paid to supportive care, an area in which most gains can be made. Supportive care for women in labour has been evidenced in numerous systematic reviews focused on early labour and continuous care during labour and birth (Kobayashi et al. 2017, Bohren et al. 2017) however these reviews have not included IOL.

Supportive care aims to enhance women's satisfaction, choice and control, reduce stress and anxiety and improve the quality of maternity care (Mander 2008). Kobayashi et al. (2017) define supportive interventions for women in early labour as non-pharmacological interventions that support pregnant women including relaxation or stress management training and education; professional or lay visits at home, telephone-based peer support; educational counselling; non-directive counselling and comfort measures. Women have reported receiving too little information about IOL, with the information provided tending to focus on the methods of IOL. Information relating to how women may feel during cervical priming for IOL, identifying ways to cope or women's options for the management of post-term pregnancies are often neglected (Jay et al. 2018, Akuamoah-Boateng and Spencer 2018). Several studies have reported that women felt poorly informed about the amount of time the induction process would take which caused them to worry about other children at home, unsure if partners were able to be present throughout, apprehensive about the level of pain they may experience and the type and level of care they would receive (Oster et al. 2011, Brown & Furber 2015, Coates et al. 2019).

The ways in which IOL is discussed can result in women feeling they have no choice and do not contribute to the decision-making process. While some women are happy to receive direction from care providers, some women feel powerless to challenge medical advice, especially if they feel pressured from family members concerned about the risks of a prolonged pregnancy (Henderson & Redshaw 2014, Akuamoah-Boateng & Spencer 2018, Coates et al. 2019). Often, women's feelings or fears are not discussed with their care providers and women have reported feeling concerned about

the potential cascade of intervention following an IOL and may feel disappointment that labour will not occur in the way they envisaged (Akuamoah-Boateng et al. 2018, Coates et al. 2019). It can be particularly distressing for women when IOL is strongly recommended by care providers to reduce the risks to their baby and then induction is delayed due to staffing concerns or lack of capacity in busy maternity units (Henderson & Redshaw 2014, Jay et al. 2018, Coates et al. 2019). In light of the extensive qualitative studies highlighting women's experience of IOL, interventional studies need to be developed which utilise the qualitative evidence base to generate theory, develop woman-centered outcome measures and ensure the acceptability of behavioural interventions (Meissner 2011, Lewin et al. 2009).

Research focused on cervical priming has evaluated the location of cervical priming on the efficiency of maternity units, women's safety, increasing the number of normal vaginal births and improving women's satisfaction (Kelly et al. 2013). Little attention has been paid to identifying and evaluating supportive interventions which aim to enhance women's comfort, coping and wellbeing in the different settings in which women undergo cervical priming. Women who experience cervical ripening for IOL in hospital settings described feeling distressed that partners were unable to be with them on maternity wards due to hospital rules and regulations (Henderson & Redshaw 2014, Brown & Furber 2015, Jay et al. 2018). Although some women reported feeling safe in the hospital setting, many reported feeling unsupported and isolated, reluctant to mobilise as they did not want to disturb other women or leave the ward setting without their partners to support them. Women have also reported being distracted by the noisy environment and lacking privacy or comforting distractions (Brown & Furber 2015, Jay et al. 2018, Coates et al. 2019). Midwifery support at this time has been described as reassuring minimal in some cases resulting in women feeling neglected by their midwives (Henderson & Redshaw 2014, Jay et al. 2018, Brown & Furber 2015). Women who felt distressed and experiencing pain have reported feeling that their needs and concerns were undermined and minimised by care providers (Henderson & Redshaw 2014, Brown & Furber 2015). Oster et al. (2011) suggest that care provision during IOL can be improved by making the hospital a more comfortable environment for women by the provision of facilities for partners to stay overnight and giving women the opportunity to be induced in more home-like environments such as birthing centres. Women have suggested they are prepared to travel to access facilities with private rooms and bathrooms and may welcome the opportunity to return home following cervical priming procedures (Howard et al. 2014). Women who experienced cervical ripening for IOL at home have reported feeling satisfied with the experience. More detailed information about the induction

procedure and ways to access professional support can enhance women's feeling of safety (Oster 2011, Brown & Furber 2015).

Measuring the outcomes of supportive intervention for IOL requires further consideration. Outcome measures solely focused on reporting rates of induction, length and timing of the induction process and birth outcomes will not sufficiently capture concepts of supportive care which are important to women. While there are numerous scales designed to measure women's childbirth experiences (Nilver et al. 2017), none exist specifically for IOL. Measures to evaluate women's experience of maternity care have mainly focused on labour and birth, with little attention paid to measuring women's experiences during other aspects of pregnancy and postnatal care (Redshaw et al. 2019). When selecting outcome measures for supportive IOL interventions, researchers should consider measurement properties which capture aspects of supportive care (Mander 2008) which are appropriate for the study objectives, setting and population. Locus of control, knowledge, attitudes, satisfaction and environment scales with psycho-social measures are used widely in maternity care research and need to be validated in the context of IOL. Early engagement of service users in the research process can assist to identify outcomes that matter most to women and families (Gartlehner & Flamm 2013, Hayes et al. 2012).

Researchers have suggested that women having an IOL in inpatient settings should, wherever possible, have provision for partners to stay with women throughout the induction process (Henderson & Redshaw 2014). Midwives should ask women about their needs during the induction process, provide women with the opportunity to ask questions, understand the benefits and possible risks and enable them to make informed decisions about their care (WHO 2018). Supportive aids and spaces should be available which are tailored to women's needs, for example spaces to mobilise, birthing balls, peaceful settings for women to relax and sleep and access to food and drink. Women experiencing IOL in all settings need to have easy and timely access to midwifery advice and support and enable women to discuss their plan of care throughout the process. Supportive interventions for women having an IOL could maximise the benefits of the continuity of carer models (NHS England 2016, Sandall et al. 2016). Promoting personalised care, ensuring women's physical, psychological and emotional needs are met, developing collaborative relationships to improve the co-ordination of care can enhance women's satisfaction throughout pregnancy, labour and the postnatal period. Many maternity units now provide dedicated induction suites, provide options for partners to stay overnight and out-patient induction care pathways. An IOL pathway, quality improvement project reported by Wier et al. (2018) implemented a dedicated midwifery induction team, developed enhanced information provision and provided education and training for clinicians.

The authors reported increased women's satisfaction with the service, whilst also enabling women to participate more fully in the decision-making process.

Limitations

Conclusions are limited as the review process resulted in only two included paper and should be interpreted with caution. Selection criteria may have limited the scope of the review including the restriction to English language and the exclusion of grey literature. These exclusions were made due to the time constraints of the review.

CONCLUSION

This is the first review to evaluate non-pharmacological, non-invasive supportive interventions for women having an IOL. The findings from this review provide some limited evidence to suggest that women having out-patient cervical priming were more satisfied with their experience than women having in-patient cervical priming and that outpatient cervical priming did not increase women's anxiety. This finding has also been reported in a systematic review comparing outpatient to inpatient IOL (Kelly et al. 2013) which concluded the overall evidence to evaluate outpatient induction are limited. A specifically designed information brochure explaining the induction process in plain language, including the actions and side effects of prostaglandin and the time involved in the process can improve women's knowledge and understanding. Other components of supportive care require urgent evaluation in the different contexts in which women undergo IOL. It is critical that measurement tools capture the complexity of supportive care for women having an IOL are developed and validated to enable a rigorous evaluation of new interventions within a research framework. Intervention components and outcome measures should be developed which build on the findings of existing literature and the theoretical base. In order to improve the experiences and outcomes for women in all IOL settings, further evidence is required to identify ways to facilitate and support women's decision making and develop useful and effective methods to support women and their families.

CONFLICT OF INTEREST

Conflicts of interest: none.

REFERENCES

AKUAMOAH-BOATENG, J. & SPENCER, R. (2018) Woman-centered care: Women's experiences and perceptions of induction of labor for uncomplicated post-term pregnancy: A systematic review of qualitative evidence. *Midwifery,* 67**,** 46-56.

AROMATARIS, E., & MUNN, Z. (Editors) (2017) *Joanna Briggs Institute Reviewer's Manual*. The Joanna Briggs Institute. Available from https://reviewersmanual.joannabriggs.org/

BJELLAND, I., DAHL, A., HAUG, T., NECKELMANN, D. (2002) The validity of the Hospital Anxiety and Depression Scale: an updated literature review. *Journal of Psychosomatic Research*, 52:69–77.

BOHREN, M. A., HOFMEYR, G. J., SAKALA, C., FUKUZAWA, R. K. & CUTHBERT, A. (2017) Continuous support for women during childbirth. *Cochrane Database Syst Rev,* 7**,** Cd003766.

BROWN, S. & FURBER, C. (2015) Women's experiences of cervical ripening as inpatients on an antenatal ward. *Sexual & reproductive healthcare : official journal of the Swedish Association of Midwives,* 6**,** 219-25.

CAMPBELL, M., MCKENZIE, J., SOWDEN, A., KATIKIREDDI, S., BRENNAN, S., ELLIS, S., HARTMANN-BOYCE, J., RYAN, R., SHEPPERD, S., THOMAS, J., WELCH, V., THOMSON, H. (2020) Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline. *BMJ.* 16;368:l6890. doi: 10.1136/bmj.l6890. PMID: 31948937; PMCID: PMC7190266.

CRITICAL APPRAISAL SKILLS PROGRAMME (2019). CASP Cohort Studies Checklist. [online] Available at: https://casp-uk.net/casp-tools-checklists/ Accessed: July 2019

COATES, R., CUPPLES, G., SCAMELL, A. & MCCOURT, C. (2019) Women's experiences of induction of labour: Qualitative systematic review and thematic synthesis. *Midwifery,* 69**,** 17-28.

COOPER, M. & WARLAND, J. (2011) Improving women's knowledge of prostaglandin induction of labour through the use of information brochures: A quasi-experimental study. *Women and birth : journal of the Australian College of Midwives,* 24**,** 156-64.

COCHRANE EFFECTIVE PRACTICE AND ORGANISATION OF CARE (EPOC) (2018) Reporting the effects of an ntervention in EPOC reviews. EPOC Resources for review authors. epoc.cochrane.org/resources/epoc-resourcesreview-authors (accessed 22/10/20) Reporting the effects of an intervention in EPOC reviews (Version: 1 December 2016)

COCHRANE EFFECTIVE PRACTICE AND ORGANISATION OF CARE (EPOC) domains (Cochrane Effective Practice and Organisation of Care (EPOC). EPOC Resources for review authors, 2017. epoc.cochrane.org/resources/epoc-resources-review-authors (accessed 24/10/2020)

CENTRE FOR REVIEWS AND DISSEMINATION (CRD) (2009) Systematic Reviews: CRD's Guidance for Undertaking Reviews in Healthcare. Published by CRD, University of York

DAVIDOFF, F., BATALDEN, P., STEVENS, D., OGRINC, G. & MOONEY, S. (2008) Publication guidelines for quality improvement in health care: evolution of the SQUIRE project. *Quality and Safety in Health Care,* 17**,** i3.

DE VAAN, MDT., TEN EIKELDER, MLG., JOZWIAK., M., PALMER, K., DAVIES-TUCK, M., BLOEMENKAMP, K., MOL, B., BOULVAIN, M. (2019) Mechanical methods for induction of labour. Cochrane Database of Systematic Reviews, Issue 10. Art. No.: CD001233. DOI: 10.1002/14651858.CD001233.pub3

Elliott, D. (1993) Comparison of the three instruments for measuring patient anxiety in a coronary care unit. *Intensive Crit Care Nurs*, 9:195–100.

FERRAZZI, E., BREMBILLA, G., CIPRIANI, S., LIVIO, S., PAGANELLI, A., PARAZZINI, F (2019) Maternal age and body mass index at term: Risk factors for requiring an induced labour for a late-term pregnancy. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 233, 151-157.

GARTLEHNER., G, FLAMM., M. (2013) Is The Cochrane Collaboration prepared for the era of patient-centred outcomes research?. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: ED000054. DOI: 10.1002/14651858.ED000054.

GATWARD, H., SIMPSON, M., WOODHART, L. & et al. (2010) Women's experiences of being induced for post-date pregnancy. *Women and Birth: the Journal of the Australian College of Midwives,* 23**,** 3-9.

HAYES H, BUCKLAND S, TARPEY M. (2012) INVOLVE Briefing Notes for Researchers: Involving the Public in NHS. Public Health and Social Care Research. Eastleigh: INVOLVE Available from: https://www.invo.org.uk/wp-content/uploads/2014/11/9938_INVOLVE_Briefing_Notes_WEB.pdf

HENDERSON, J. & REDSHAW, M. (2014) Women's experience of induction of labor: a mixed methods study. *Acta Obstetricia et Gynecologica Scandinavica,* 92**,** 1159-67.

HIGGINS, J. , ALTMAN, D. , GØTZSCHE, P. , JÜNI, P., MOHER, D., OXMAN, A. D., SAVOVIĆ, J., SCHULZ, K. F., WEEKS, L. & STERNE, J. A. C. (2011) The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ,* 343**,** d5928.

HIGGINS, J., THOMAS, J., CHANDLER, J., CUMPSTON, M., LI, T., PAGE, M., WELCH, V (editors) (2019) *Cochrane Handbook for Systematic Reviews of Interventions* version 6.0 (updated July 2019). Cochrane, 2019. Available from www.training.cochrane.org/handbook.

HILDINGSSON, I., KARLSTROM, A. & NYSTEDT, A. (2011) Women's experiences of induction of labour--findings from a Swedish regional study. *The Australian & New Zealand journal of obstetrics & gynaecology,* 51**,** 151-7.

HOFFMANN, C., GLASZIOU, P., BOUTRON, I. (2014) Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*;348:g1687.

HOWARD, K., GERARD, K., ADELSON, P., BRYCE, R., WILKINSON, C. & TURNBULL, D. (2014) Women's preferences for inpatient and outpatient priming for labour induction: a discrete choice experiment. *BMC health services research,* 14**,** 330.

JAY, A., THOMAS, H. & BROOKS, F. (2018) In labor or in limbo? The experiences of women undergoing induction of labor in hospital: Findings of a qualitative study. *Birth: Issues in Perinatal Care***,** 45, 64-70.

JBI. 2013. *New JBI Levels of Evidence*. University of Adelaide, Australia: Joanna Briggs Institute.

JBI. 2017. *Checklist for Quasi-experimental studies*. The Joanna Briggs Institute.

KELLY, A., ALFIREVIC, Z. & DOWSWELL, T. (2013. Outpatient versus inpatient induction of labour for improving birth outcomes. *Cochrane Database of Systematic Reviews.*

KENNEDY, H., CHEYNEY ,M., DAHLEN, H., DOWNE, S., FOUREUR, M., HOMER, C., JEFFORD, E., MCFADDEN, A., MICHEL-SCHULDT, M., SANDALL, J., SOLTANI, H., SPECIALE, A., STEVENS, J., VEDAM, S., RENFREW, M. (2018) Asking different questions: A call to action for research to improve the quality of care for every woman, every child. Birth, 45 (3), 222-231.

KOBAYASHI, S., HANADA, N., MATSUZAKI, M., TAKEHARA, K., OTA, E., SASAKI, H., NAGATA, C. & MORI, R. (2017) Assessment and support during early labour for improving birth outcomes. *The Cochrane database of systematic reviews,* 4**,** CD011516-CD011516.

LEWIN, S., GLENTON, C. & OXMAN, A. (2009) Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ,* 339**,** b3496.

LUBIN, B., Van Whitlock, R., Reddy, D., Petren, S (2001) A comparison of the short and long forms of the Multiple Affect Adjective Check List-Revised (MAACL-R). *J Clin Psychol*, 57:411–416.

MANDER, R. (2008) *Supportive Care and Midwifery*, Wiley.

MEISSNER, H. (2011) Use of qualitative methods to ensure acceptability of interventions. *J Public Health Dent,* 71 Suppl 1**,** S83.

MIDDLETON, P., SHEPHERD, E., CROWTHER, C. (2018) Induction of labour for improving birth outcomes for women at or beyond term. *Cochrane Database of Systematic Reviews*, Issue 5. Art. No.: CD004945. DOI: 10.1002/14651858.CD004945.pub4.

MOHER, D., LIBERATI, A., TETZLAFF, J., ALTMAN, D. (2009) Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 6(7), e1000097.

NILVÉR, H., BEGLEY, C., BERG, M. (2017) Measuring women's childbirth experiences: a systematic review for identification and analysis of validated instruments. *BMC Pregnancy Childbirth,* 17**,** 203.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (2008) Inducing Labour CG70. National Institute for Health and Care Excellence. London. Avaolable from: https://www.nice.org.uk/guidance/CG70

NHS DIGITAL (2019) NHS Maternity Statistics, England 2018-19 [PAS]. NHS Digital, London. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2018-19

NHS ENGLAND (2016) National Maternity Review: Better Births – Improving outcomes of maternity services in England – A Five Year Forward View for maternity care. NHS England, London.

OSTER, C., ADELSON, P., WILKINSON, C. & TURNBULL, D. (2011) Inpatient versus outpatient cervical priming for induction of labour: therapeutic landscapes and women's preferences. *Health & place,* 17**,** 379-85.

REDSHAW, M., MARTIN. C., SAVAGE-MCGLYNN, E., HARRISON, S. (2019) Women's experiences of maternity care in England: preliminary development of a standard measure. *BMC Pregnancy Childbirth* 19, 167. https://doi.org/10.1186/s12884-019-2284-9

ROYAL COLLEGE OF MIDWIVES (2019) Midwifery Care for Induction of Labour. RCM Midwifery Blue Top Guidance. Royal College of Midwives, London. Available from: https://www.rcm.org.uk/media/3552/midwifery-care-for-induction-of-labour-a4-2019-16pp_2.pdf

SANDALL , J., SOLTANI, H., GATES, S., SHENNAN,A., DEVANE, D. (2016) Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5.

SCHUNEMANN, H., BRIGNARDELLO-PETERSEN, R., CHAN, W., ALONSO-COELLO, P., KOSTER, M. & ROBBINS, C. (2013) 064WS How to Use the GRADE "Evidence-to-Recommendations Framework" to Develop Guideline Recommendations for Therapeutic Interventions. *BMJ Quality & Safety,* 22**,** A9.

TURNBULL, D., HOLMES, A., SHIELDS, N., ET AL. (1996) Randomised, controlled trial of efficacy of midwife-managed care. *Lancet*, 348:213–218.

TURNBULL, D., ADELSON, P., OSTER, C., BRYCE, R., FEREDAY, J. & WILKINSON, C. (2013) Psychosocial outcomes of a randomized controlled trial of outpatient cervical priming for induction of labor. *Birth (Berkeley, Calif.),* 40**,** 75-80.

DE VAAN, MDT., TEN EIKELDER, M., JOZWIAK, M., PALMER. K., DAVIES-TUCK, M., BLOEMENKAMP, K., MOL, B., BOULVAIN, M. (2019) Mechanical methods for induction of labour. *Cochrane Database of Systematic Reviews,* Issue 10. Art. No.: CD001233. DOI: 10.1002/14651858.CD001233.pub3.

WALKER, S., VAN RIJN, B., MACKLON, N., HOWE, D (2014) The rising rate of labour induction: what is causing the trend? Poster presentations, BMFMS: Labour and Delivery

WIER, J., HINCHEY-BEER, S. & WALKER, L. (2018) Improving induction of labour for women through the development of a new pathway. *British Journal of Midwifery,* 26**,** 585-590.

WHO recommendations (2018) induction of labour at or beyond term. Geneva: World Health Organization; Licence: CC BY-NC-SA 3.0 IGO

Supplementary material: Risk of Bias assessment for the included studies based on Cochrane EPOC domains (Cochrane Effective Practice and Organisation of Care (EPOC). EPOC Resources for review authors, 2017. epoc.cochrane.org/resources/epoc-resources-review-authors (accessed 24/10/2020)