Effectiveness of birth ball exercise and structured antenatal counseling on labor pain, anxiety, and maternal satisfaction among primigravida women: A quasi-experimental study

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Abstract:

Background: Labour pain, anticipatory anxiety, and maternal satisfaction are linked but distinct dimensions of the childbirth experience. Primigravida women may have limited experiential knowledge of labour and may enter childbirth with uncertainty about contractions, coping strategies, clinical procedures, and the choices available to them. A birth ball offers a practical aid for supported movement and upright positioning, while structured antenatal counseling can address knowledge gaps, fear, coping confidence, communication, and informed decision-making. Their combined effectiveness, however, should not be assumed from the evidence for either component alone. Aim: This review synthesizes evidence on birth ball exercise and structured antenatal counseling for labour pain, anxiety or fear of childbirth, and maternal satisfaction among primigravida women. It also outlines a feasible quasi-experimental framework for evaluating the combined intervention in a maternity-care setting. Approach: The narrative synthesis draws on guidelines, systematic reviews, randomized trials, psychometric literature, and selected observational studies relevant to pregnancy exercise, labour mobility, birth-ball use, prenatal education, psychological preparation, respectful maternity care, and outcome measurement. The discussion distinguishes direct evidence for each intervention from the plausible but not yet established added effect of combining them. The proposed methods are a protocol framework and do not represent completed research. Synthesis: Trials and reviews generally suggest that birth-ball use may reduce reported pain during labour and can support movement and comfort, although study quality, intervention protocols, outcome timing, and participant characteristics vary. Structured psychoeducation may reduce fear in some pregnant populations, particularly when counseling is tailored to a woman's concerns and includes midwife support. Maternal satisfaction depends on more than pain intensity: communication, support, expectations, autonomy, consent, and perceived control are influential. Evidence for an integrated birth-ball-plus-counseling package among primigravida women remains less direct than evidence for the individual components. Conclusion: A supervised, preference-sensitive birth-ball programme combined with structured antenatal counseling is a reasonable intervention to evaluate as part of respectful maternity care for eligible low-risk primigravida women. A well-designed quasi-experimental study should measure outcomes with validated instruments, document co-interventions and safety, protect access to pharmacological analgesia, and avoid interpreting observational group differences as definitive causal proof.

Keywords:

Birth ball; antenatal counseling; primigravida; labour pain; childbirth anxiety; fear of childbirth; maternal satisfaction; quasi-experimental study; midwifery care.

1. Introduction:

Childbirth is simultaneously a physiological process, a major life transition, and a health-care experience shaped by social expectations, previous information, family relationships, clinical communication, and the woman's sense of agency. The experience of labour is not adequately represented by a single pain score. Two women with similar contraction intensity may report very different levels of fear, control, confidence, and satisfaction because they enter labour with different expectations and receive different forms of support. A comprehensive approach therefore considers physical comfort and psychological preparation together, rather than treating them as competing priorities.

Primigravida women are a particularly relevant population for antenatal preparation because the first pregnancy often involves learning the meaning of labour sensations and discovering which coping strategies are personally useful. Lack of direct experience can amplify uncertainty, although first-time pregnancy does not automatically imply high anxiety or poor coping. Some women approach childbirth with confidence, while others may have frightening stories from relatives, exposure to dramatic birth narratives, limited access to reliable information, previous traumatic health-care encounters, or concerns about pain, safety, infant well-being, and loss of control. Antenatal support should explore these differences instead of assuming that all primigravida women have the same needs.

The World Health Organization emphasizes a positive childbirth experience through respectful, evidence-based care that supports dignity, communication, companionship, mobility, and informed choice (WHO, 2018). Its antenatal-care recommendations similarly frame routine pregnancy visits as opportunities for health promotion, person-centred communication, and preparation, not merely the completion of clinical checks (WHO, 2016). NICE recommends helping women move and adopt comfortable positions during labour, and encouraging support from companions chosen by the woman (NICE, 2023). These principles create a strong service-level rationale for examining feasible approaches that improve both physical coping and confidence.

Birth balls, also called birthing balls or stability balls, are large inflatable balls that permit supported sitting, pelvic rocking, leaning, and position changes. They can be used in antenatal exercise sessions and, when appropriate, during labour. Structured antenatal counseling is a planned series of conversations or sessions that explain labour physiology, pain-relief options, coping methods, warning signs, likely procedures, consent, birth preferences, and postnatal care. Its value depends on more than the quantity of information: counseling should be understandable, non-coercive, responsive to anxiety, and practical enough for women to apply under the pressure of labour.

Evidence exists for birth-ball approaches and for psychoeducation, but the studies differ in how interventions are delivered and how outcomes are measured. Results from a randomised trial of a birth-ball exercise programme cannot automatically prove the effectiveness of a combined antenatal counseling package. Likewise, a counseling trial focused on fear of childbirth does not establish that an exercise component further reduces labour pain. The title of the proposed study therefore describes an evaluative question rather than a result. This article reviews the relevant evidence and outlines a design that can test the combined programme without presenting hypothetical findings as observed outcomes.

The central proposition is that supervised movement and structured preparation may complement one another. Ball-based movement may increase comfort, allow position changes, and support active coping during contractions. Counseling may improve understanding, normalize a range of pain responses, strengthen confidence, support shared decisions, and reduce uncertainty about hospital procedures. If both elements are acceptable and safely delivered, they may influence labour pain, anxiety, and satisfaction through overlapping yet distinguishable pathways. These potential benefits should be examined empirically, with a clear comparison group and adequate attention to clinical context.

2. Purpose and review questions:

The purpose of this review is to explain why birth-ball exercise and structured antenatal counseling may be relevant to pain, anxiety, and satisfaction among primigravida women; summarize the available evidence for each component; identify uncertainties in the combined evidence; and translate those findings into a reproducible quasi-experimental framework. The paper is designed as a narrative review with a proposed research protocol, rather than as a completed systematic review or an original report of patient-level data.

The review addresses five linked questions. First, what does the literature suggest about birth-ball use for pain, comfort, labour progress, and related maternal outcomes? Second, what evidence supports structured antenatal education or psychoeducation for fear, anxiety, coping confidence, and preparation for labour? Third, which features of care are associated with maternal satisfaction independently of pain intensity? Fourth, how should an integrated intervention be delivered while protecting informed choice and clinical safety? Finally, how can a quasi-experimental study estimate the effects of the programme while reducing bias arising from non-random allocation, baseline differences, variation in usual care, and missing outcomes?

The analysis prioritizes outcomes that can change within a clinically relevant period. Pain is considered as a subjective intensity and coping experience rather than a purely objective sign. Anxiety is distinguished from fear of childbirth, since state anxiety may fluctuate during labour whereas childbirth fear may be measured antenatally as an expectation or appraisal. Maternal satisfaction is treated as a multidimensional appraisal influenced by communication, respect, involvement in decisions, support, expectations, and perceived control. These constructs should be measured separately to avoid a composite score obscuring a meaningful effect on one outcome but not another.

3. Review approach and scope:

This is a narrative evidence review, not a registered systematic review. Evidence was located through targeted searches of bibliographic and guideline sources using combinations of terms such as birth ball, birthing ball, Swiss ball, labour pain, childbirth anxiety, fear of childbirth, antenatal education, psychoeducation, childbirth self-efficacy, birth satisfaction, primigravida, randomized trial, systematic review, World Health Organization, and intrapartum care. Priority was given to clinical guidelines, Cochrane reviews, systematic reviews or meta-analyses, controlled trials, and foundational measurement studies. Reference lists from key sources were also considered to identify relevant instruments and primary trials.

The synthesis is organized around the intervention components, proposed mechanisms, outcome definitions, implementation and safety, and implications for a quasi-experimental design. It does not claim an exhaustive search, formal duplicate screening, an independent risk-of-bias assessment of every included study, or pooled re-analysis of the individual trials. Because the methods are narrative, the evidence should be read as a structured overview rather than as a definitive estimate of effect. The date of the newest evidence included is October 2026, including a prenatal-education meta-analysis published in February 2026 (Karaçam et al., 2026).

Studies focused on low-risk pregnancies and uncomplicated labour are most directly applicable to a routine programme. The conclusions should not be extended to women with complications, women who cannot safely use a ball, or contexts where surveillance requirements and mobility restrictions differ. Evidence about mobility and upright positions in labour supports offering options within an appropriate clinical plan, not prescribing a particular posture to every woman. The intervention should therefore remain conditional on maternal preference, clinical eligibility, available staff, and fetal and maternal assessment (WHO, 2018; NICE, 2023).

The proposed framework is informed by the CONSORT and STROBE traditions of transparent reporting, while recognizing that a quasi-experimental design is not randomized. A final research team should pre-register the protocol where possible, publish a dated search strategy if the article is intended for journal submission, and specify its reporting checklist before enrolment. No sample results, p-values, effect sizes, or participant counts are reported in this review unless they belong to a cited published source. All proposed study procedures below are suggestions to be adapted to local policy and approved by an ethics committee.

4. Primigravida women and the transition to childbirth:

Primigravida refers to a woman who is pregnant for the first time. In research, the term should be operationally defined and distinguished from nulliparous, which generally describes a woman who has not previously given birth beyond a specified gestational threshold. Studies sometimes use these labels interchangeably, but they are not perfectly equivalent: a woman may have experienced a previous pregnancy loss without a previous birth. Eligibility criteria should identify whether the target population is first-pregnancy women specifically or women without a previous birth, and the protocol should use the same definition consistently.

First-time mothers may have more questions about the sequence of labour, the meanings of cervical dilatation, what contraction pain can feel like, when to come to hospital, what monitoring may be needed, and how pain relief choices are made. Their expectations can be influenced by family members, community norms, online content, previous encounters with health services, and the availability of skilled antenatal teaching. In settings where childbirth information is fragmented, antenatal visits may be the main opportunity to correct myths and explain how a woman can ask questions, request clarification, or change her preferences as labour unfolds.

A respectful programme avoids framing fear as a deficit or a failure of confidence. Fear can reflect reasonable uncertainty, concerns about previous health-care experiences, fear of injury or death, worries about the baby, or anticipated loss of privacy and autonomy. Counseling should create space for these concerns and should not make promises that labour will be painless or that a specific position guarantees vaginal birth. Instead, preparation should distinguish what is predictable from what is uncertain, discuss how the team monitors safety, and explain which decisions can be shared and revisited.

Women differ in language, literacy, disability, family participation preferences, prior trauma, cultural values, and access to transport or continuous care. A standard class can provide consistency, but individualized discussion is needed to make the content useful. For example, a woman who primarily fears the intensity of contractions may benefit from practicing breathing and positioning; a woman concerned about emergency interventions may need clear explanations of indications, consent, and communication; and a woman with marked anxiety may need further assessment or referral. A birth-ball programme should not be used as a substitute for mental-health support when anxiety is severe or persistent.

A key ethical point is that primigravida status is not an indication for a particular intervention. The intervention should be offered as an option, with the woman's own goals guiding whether she practices on the ball, prefers walking or side-lying, requests pharmacological analgesia, or chooses another strategy. The intended outcome is greater comfort, knowledge, and agency, not compliance with a prescribed style of labour.

5. Understanding labour pain:

Labour pain is a complex sensory and emotional experience arising from physiological processes and interpreted in a psychological and social context. During the first stage, pain is associated with uterine contractions, cervical change, and reduced perfusion of uterine muscle during contraction. As labour advances, distension and pressure of pelvic structures and the pelvic floor contribute additional sensations. Pain intensity can change over time and may be affected by contraction frequency, fetal position, fatigue, hydration, anxiety, expectations, previous experiences, support, and the woman's sense of safety.

The gate-control theory proposed by Melzack and Wall (1965) helped establish that pain experience is modulated by more than peripheral input alone. Attention, context, competing sensory information, interpretation, and descending influences can alter perceived intensity. This does not mean labour pain is imaginary or simply psychological. Rather, it recognizes that physical sensation and the nervous system's processing of it interact with emotions, beliefs, and the environment. Gentle rhythmic movement, upright posture, breathing, reassuring communication, and support may alter how a woman experiences contractions, even when they do not eliminate the underlying physiological stimulus.

Pain scales should be selected to reflect the immediate research question. A 0-to-10 numerical rating scale or a 10-cm visual analogue scale can describe reported intensity at defined time points, but neither captures the whole experience. A single score recorded shortly after an intervention may be sensitive to timing, contraction pattern, analgesic medication, cervical dilatation, and the wording of the question. Repeated measures at comparable points in labour are more informative than one isolated rating, and researchers should document the time of assessment and relevant co-interventions.

A clinically responsible non-pharmacological programme acknowledges that some women will request or need pharmacological pain relief. Offering a birth ball must never be used to delay analgesia, minimize a woman's report of pain, or imply that medication indicates poor coping. WHO and NICE recommendations emphasize mobility and individual comfort while retaining clinically appropriate monitoring and care (WHO, 2018; NICE, 2023). A good programme increases the range of options and helps women make informed choices; it does not narrow those choices.

A Cochrane review by Smith and colleagues (2018) examined relaxation methods for labour pain and concluded that relaxation, yoga, and music may have a role in pain reduction or satisfaction with pain relief, but the certainty of evidence varied and was generally low or very low. This review supports offering coping methods as preference-sensitive options while avoiding claims that any single technique reliably removes labour pain.

Pain intensity should also be interpreted alongside coping and satisfaction. A participant may report high pain but feel informed, supported, and satisfied with the care received. Another may report a lower pain score but remain distressed by inadequate explanation or lack of consent. Hodnett (2002) found that expectations, support, caregiver relationships, and involvement in decisions were important influences on women's evaluations of childbirth, sometimes more influential than pain or pain relief alone. This is a key reason the present title includes pain, anxiety, and maternal satisfaction as separate outcomes.

6. Anxiety and fear of childbirth:

Anxiety and fear of childbirth are related but conceptually distinct. State anxiety describes a temporary emotional condition that can rise during a stressful event and fall when the perceived threat changes. Trait anxiety refers to a more stable tendency to interpret situations as threatening. Fear of childbirth is more specifically focused on anticipated labour, birth, pain, loss of control, harm, or medical intervention. Instruments designed for general anxiety may not detect all childbirth-specific fears, while a childbirth-fear scale may not describe anxiety that arises in the active phase of labour.

The Spielberger State-Trait Anxiety Inventory is a widely used measure for separating state and trait anxiety, although licensing, language validation, and instrument-specific instructions should be checked before use (Spielberger, 1983). The Wijma Delivery Expectancy/Experience Questionnaire was developed to assess childbirth-related fear in pregnancy and after birth, with early psychometric work showing good internal consistency in the original samples (Wijma et al., 1998). A study should use a validated local-language version when available and should not casually substitute a locally invented translation without documentation.

Anxiety may intensify attention to threatening sensations, reduce confidence in coping, interfere with information processing, and create a feedback loop in which pain increases fear and fear makes pain feel more overwhelming. This is not a universal or deterministic response. Support, previous coping success, trust in staff, and access to clear information can buffer the cycle. A structured programme can target modifiable contributors by explaining the physiology of labour, practicing breathing or grounding techniques, discussing realistic expectations, and creating a plan for how to communicate distress and ask for help.

Antenatal psychoeducation studies provide a relevant evidence base. Toohill and colleagues (2014) evaluated a midwife-led psychoeducation intervention for pregnant women with high childbirth fear in the BELIEF trial. Fenwick and colleagues (2015) examined women's birth outcomes and postpartum psychological well-being following the intervention. These studies support the importance of addressing childbirth fear in a tailored manner, but their intervention content and target population are not identical to a class that combines counseling with birth-ball exercise. Any expected benefit of the combined package should therefore be stated as a hypothesis rather than a certainty.

A recent systematic review and meta-analysis by Karaçam and colleagues (2026) examined prenatal education and fear of childbirth. The publication adds contemporary support for examining antenatal education as a psychological intervention, while heterogeneity in education formats, comparison groups, participant risk, and scales remains important when translating pooled evidence into practice. The relevant practical message is not that every antenatal course reduces anxiety by the same amount, but that structured, relevant preparation deserves direct evaluation and should be adapted to women's expressed needs.

Severe anxiety, panic symptoms, intrusive trauma memories, or marked avoidance should trigger a more individualized assessment. A nurse or midwife can listen, offer basic emotional support, and arrange timely referral according to local pathways. Exercise on a birth ball alone is not a mental-health treatment and should not be presented as one. A well-designed intervention includes clear escalation criteria and does not force women to recount traumatic experiences in a group setting.

7. Maternal satisfaction and positive birth experience:

Maternal satisfaction is not a simple proxy for clinical outcome. It reflects how women interpret the overall experience in relation to their expectations, values, preferences, treatment, perceived safety, communication, dignity, and participation. A satisfying experience does not require a particular mode of birth or absence of pain. Similarly, an uncomplicated birth does not guarantee satisfaction if a woman felt ignored, uninformed, or unable to influence decisions. Research should make the construct explicit and select a measure that matches the intended dimension of satisfaction.

The Birth Satisfaction Scale was developed to capture women's perceptions of the birth experience, and the Birth Satisfaction Scale-Revised was later evaluated as a shorter instrument with psychometric testing in postpartum women (Hollins Martin and Fleming, 2011; Hollins Martin and Martin, 2014). Before selecting either version, investigators should examine language validation, permitted use, timing of administration, scoring instructions, and any applicable licence. A locally adapted scale may be appropriate when validated, but the adaptation process should be described.

Hodnett's systematic review of childbirth satisfaction suggested that personal expectations, the amount of caregiver support, the quality of the caregiver-woman relationship, and involvement in decision-making strongly influence evaluations of birth (Hodnett, 2002). Green and Baston (2003) similarly explored control during labour, distinguishing control over one's own behaviour, control during contractions, and control over what staff do. These findings help explain why counselling and birth-ball exercise may have benefits beyond measured pain intensity: both may give women a wider range of coping actions, but only if staff respect their preferences and explain care clearly.

Satisfaction must be measured without implying that a woman ought to be pleased with her care. Researchers should provide a private opportunity for feedback, ideally separate from the clinicians responsible for immediate treatment, and reassure participants that their responses will not affect access to services. Data collection should avoid leading questions such as whether the ball 'helped' and should instead ask neutral questions about comfort, communication, involvement, and overall experience.

Respectful care is a minimum standard rather than an optional study ingredient. The literature on mistreatment during childbirth describes categories including physical or verbal abuse, stigma or discrimination, failure to meet professional standards, poor rapport, and limitations on autonomy (Bohren et al., 2015). An intervention cannot be considered successful merely because women assigned to it report somewhat lower pain if they experienced pressure to comply, unsafe positioning, or restricted access to analgesia. Safety, dignity, and choice should therefore be treated as essential implementation outcomes alongside satisfaction.

Continuous support is another relevant part of the care environment. Bohren and colleagues (2017) concluded that continuous one-to-one support may improve several maternal and newborn outcomes, including women's evaluations of their birth experience, although effects vary by setting and support provider. Counseling and birth-ball practice should therefore fit within a wider model of supportive maternity care rather than be treated as isolated techniques.

8. Birth ball exercise: description and rationale:

A birth ball is an appropriately sized, inflatable exercise ball used to facilitate supported sitting, gentle pelvic tilting, rhythmic rocking, and leaning forward, and selected supported positions. Unlike a rigid chair, the ball allows small movements in multiple directions while the woman maintains contact with the floor through her feet. The ball can be used for short periods during antenatal sessions to familiarize the woman with the equipment and during labour if clinically appropriate. It is an aid to movement rather than a treatment that directly modifies uterine contractions or guarantees cervical dilatation.

Potential mechanisms include the opportunity to change position, reduced static loading through the lower back, gentle pelvic mobility, improved comfort when leaning forward, and a sense of active participation. Movement may also provide an alternative focus during contractions. The woman's response is likely to depend on ball size, stability, room layout, stage of labour, individual musculoskeletal comfort, fetal position, fatigue, staff support, and whether the intervention is welcomed. A ball that is too large or too small can make positioning difficult and may increase the risk of slipping or loss of balance.

Evidence from early randomized trials has evaluated birth-ball use in labour. Taavoni and colleagues (2011) reported lower pain scores in the birth-ball group than in the control group among 60 primiparous women, while the study did not find significant differences in active-phase duration or the interval between contractions. Gau and colleagues (2011) evaluated birth-ball exercise in relation to pain and childbirth self-efficacy in a randomized trial; only a subset of recruited participants completed the trial, a reminder that recruitment and attrition can affect precision and generalizability. Leung and colleagues (2013) reported before-after changes in pain, back pain, stress and anxiety, and high self-reported satisfaction in a programme using physiotherapist-taught exercises, but the case-series design limits causal inference.

Makvandi and colleagues (2015) reviewed the evidence for birth-ball use and labour pain relief. Their systematic review included a small number of trials and concluded that evidence was promising but limited. A more recent meta-analysis of randomized controlled trials by Terres and colleagues (2025) reported improvements in reported pain and several labour outcomes among low-risk women assigned to birthing-ball exercises. Meta-analysis can improve precision by combining studies, but pooled estimates still inherit the limitations of the underlying trials, including small samples, differences in the ball protocol, allocation methods, co-interventions, and outcome timing. These results justify further evaluation rather than an unconditional claim of efficacy in every setting.

The programme should separate antenatal familiarity from intrapartum use. During pregnancy, the focus is on basic safety, learning to mount and dismount with assistance, posture, movement, breathing, and identifying discomfort. During labour, any use should be guided by current clinical assessment and maternal preference. Some women may find side-lying, walking, kneeling, a chair, or standing more comfortable. The ball is one option among several, and its continuation should be reassessed whenever the woman's condition, fetal status, fatigue, or clinical plan changes.



Figure. 1: Supervised antenatal familiarization with a birth ball: stable seating, grounded feet, and professional guidance

9. Antenatal counseling: content and delivery:

Structured antenatal counseling differs from an unplanned conversation because the content, sequence, learning objectives, and opportunities for questions are agreed in advance. A strong programme uses a consistent core curriculum but adapts its delivery to the woman's language, literacy, values, and concerns. It can be delivered individually or in a small group, with private time available for personal matters. The objective is not to persuade women to use a specific method or to achieve a 'natural' birth. It is to provide understandable information, practice coping skills, describe clinical contingencies, and support autonomous decision-making.

Core content should include the stages and expected variability of labour; the difference between contractions and warning signs that require assessment; when and how to contact the maternity unit; positions and movement; breathing, relaxation, and focal-attention techniques; non-pharmacological and pharmacological pain-relief options; the possible need for monitoring or intervention; consent and the right to ask for explanations; companion preferences; and early postnatal needs. Information should be balanced: birth balls may be helpful for comfort, but they do not replace analgesia, clinical monitoring, or emergency treatment when required.

Counseling is more likely to be usable when women practice rather than only listen. A brief rehearsal can include slow breathing during a simulated contraction interval, supported forward-leaning, pelvic rocking, a request for assistance, and a phrase for asking staff to explain a procedure. Teach-back asks the woman to explain the main points in her own words. This method can reveal misconceptions without shaming the learner. Written or visual materials may reinforce learning but should not replace interpersonal dialogue, particularly when internet information is confusing or when reading comfort is limited.

A woman-centred session begins with assessment of prior knowledge and concerns. Open prompts such as 'What worries you most about labour?' or 'What would help you feel supported if pain becomes intense?' help identify priorities. The clinician then responds to the actual concern, checks understanding, and agrees on practical coping options. If the woman expresses a strong preference for epidural analgesia, the counselor should explain access and timing rather than imply that she must first attempt the ball. If she prefers minimal intervention, the counselor should affirm her preference while explaining that recommendations may change when safety requires it.

The psychological content should normalize a range of feelings without trivializing distress. Statements such as 'everyone is frightened' can silence women who need more help, while assurances that labour is always manageable may be unrealistic. Better counseling acknowledges uncertainty,

identifies available support, and explains how decisions will be made. The programme should not promise that birth-ball exercise will shorten labour or prevent operative birth. It can instead present the method as one possible tool for movement and comfort, noting that the evidence is evolving and individual responses vary.

Antenatal education has been examined in trials and syntheses, but the word 'education' includes many different interventions: brief leaflets, group classes, one-to-one psychoeducation, childbirth preparation courses, digital modules, and programmes for women with high fear. Toohill and colleagues (2014) tested a midwife-delivered psychoeducation intervention in a population selected for high childbirth fear; Fenwick and colleagues (2015) followed outcomes related to birth and postpartum well-being. Miquelutti and colleagues (2013) evaluated a birth-preparation programme for pregnancy-related health outcomes in a randomized trial. Their specific methods and outcomes should guide program design, while differences in delivery prevent a simple one-size-fits-all conclusion.

Counseling should include a safety net. If a woman reports persistent severe anxiety, depression symptoms, self-harm thoughts, trauma-related symptoms, domestic violence, or inability to function, the service should follow local safeguarding and mental-health referral policies. Group education should protect confidentiality and avoid requiring disclosure of private histories. Where a partner or family member attends, the woman must be offered the opportunity to speak privately and choose who is present. These safeguards are part of quality antenatal care and should be documented in implementation protocols.

10. Why combine birth ball exercise and counseling?

An integrated programme combines a physical coping option with the knowledge and confidence required to use it safely and voluntarily. Birth-ball exercise alone may be unfamiliar, technically awkward, or misunderstood as a device that guarantees a specific labour outcome. Counseling alone may improve knowledge but leave a woman without practice in movement or body-based coping. When combined, the woman can learn the purpose and limits of the ball, try it before labour, discuss when it might be useful, and identify alternatives if it does not suit her. This is a plausible complementarity mechanism, not proof that the combined intervention is superior to either component alone.

The programme can be described through a simple pathway. Structured counseling may improve understanding, reduce uncertainty, support realistic expectations, and increase confidence in seeking help. Supervised ball practice may improve familiarity, movement options, and perceived ability to respond during contractions. During labour, access to these skills may influence pain intensity, pain coping, anxiety, perceived control, and satisfaction. These relationships are affected by the care environment, staff attitude, companion availability, analgesia access, obstetric circumstances, and maternal preference. Outcomes should therefore be evaluated in context rather than attributed solely to the intervention.

An integrated package also creates a risk of intervention dilution if its components are poorly standardized. One facilitator may deliver a 45-minute interactive session with practical rehearsal, while another may give a short lecture and briefly show a ball. If actual exposure differs widely, a null result may reflect implementation variation rather than an ineffective concept. A manual, staff training, session checklist, attendance log, and fidelity audit can improve consistency while preserving a participant's right to decline specific exercises.

To test whether the combination has incremental benefit, a two-group quasi-experimental design can compare usual antenatal care with usual care plus the structured combined programme. This design estimates the effect of offering the package as a whole. It cannot separate the effect of counseling from the effect of ball practice, because both are delivered together. A three-arm design that compares counseling alone, combined counseling plus birth-ball practice, and usual care would help examine the added contribution of ball exercise, but it would require a larger sample and stronger protection against contamination. A factorial or randomized design could be considered if resources and ethics permit.

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Maternal satisfaction may be particularly responsive to the intervention if counseling changes expectations and the labour team follows through with respectful communication. However, satisfaction can be influenced by circumstances that the programme cannot control, including emergency operative birth, unexpected complications, lack of privacy, or long delays in access to pain relief. Researchers should not treat such contextual influences as participant failure. Instead, they should record major clinical events and care processes so that results can be interpreted fairly.



Figure. 2: Conceptual care pathway linking structured counseling, coping practice, supported movement, and person-centred intrapartum support. This illustration is conceptual and does not imply a guaranteed clinical effect

11. Summary of the evidence on birth-ball use:

The available birth-ball literature is encouraging but heterogeneous. Trials have often enrolled low-risk women in labour and have focused on pain intensity, comfort, labour duration, or childbirth self-efficacy. The studies vary in intervention timing, frequency, duration, exercise selection, comparison care, use of analgesia, and the time at which pain scores are collected. Small sample sizes and lack of participant blinding are common practical limitations for behavioural or positioning interventions. Pain reports are necessarily subjective, but this does not make them invalid; it makes careful outcome timing and transparent measurement especially important.

Taavoni and colleagues (2011) provide direct evidence from primiparous women and measured pain in the active phase. The reported reduction in pain supports further testing, but the small sample and the absence of significant differences in some labour measures caution against claiming broad obstetric benefits. Gau and colleagues (2011) considered pain and childbirth self-efficacy together, an important choice because confidence may be part of the pathway between exercise and experience. The incomplete follow-up from the initially recruited participants should be considered when appraising precision and feasibility.

Leung and colleagues (2013) described a 30-minute physiotherapist-taught programme and reported before-after reductions in several self-reported symptoms, alongside high satisfaction. Since participants served as their own pre-intervention comparison and there was no randomized concurrent control, change could reflect natural variation in labour, regression to the mean, attention from staff, or other care received during the observation period. The study nevertheless offers practical information about feasibility, participant response, and the potential role of interdisciplinary staff in teaching movement strategies.

The systematic review by Makvandi and colleagues (2015) and the updated meta-analysis by Terres and colleagues (2025) broaden the evidence beyond individual trials. The newer meta-analysis included ten randomized trials with 1,008 participants and reported lower pain ratings at selected cervical dilatations and potential effects on caesarean rates and first-stage duration. The review authors' statistical methods and pooled outcomes are useful, but pooled findings should be interpreted against the clinical and methodological diversity of the included trials. The results do not prove that

every ball protocol will produce the same effect or that differences necessarily arise from the ball itself rather than linked mobility, attention, and usual-care variations.

A critical gap is the limited direct evidence on the combination of a standardized antenatal counseling protocol and an antenatal familiarization-plus-intrapartum birth-ball approach specifically among primigravida women. Existing trials may include women of different parity or test a ball programme delivered during labour rather than a combined intervention beginning in pregnancy. This gap supports the proposed quasi-experimental evaluation, particularly if it separates antenatal outcomes from labour outcomes and measures the actual dose of intervention received.

The safest conclusion is that birth-ball use can be offered as a potential comfort and mobility option to appropriately assessed women who wish to try it. It should not be framed as proven prevention for caesarean birth, as a replacement for medication, or as an intervention whose benefits outweigh all other considerations. Shared decision-making and appropriate monitoring remain essential.

12. Summary of evidence on antenatal preparation and anxiety:

Antenatal education is not a single standardized treatment. Its effects depend on whether it provides general information or targeted psychoeducation, how much contact is delivered, who leads it, whether women can practice skills, and whether it addresses the specific fears that matter to participants. A leaflet may increase factual knowledge without strongly changing anxiety. A counseling intervention that supports reframing, coping confidence, question-asking, and discussion of birth preferences may address more of the psychological processes that maintain fear. The evaluation must describe these content differences clearly.

The randomized BELIEF trial reported by Toohill and colleagues (2014) studied midwife-led psychoeducation among pregnant women who identified high fear of childbirth, with a decision-aid resource forming part of the intervention context. This targeted approach is relevant because it does not assume all pregnant women require the same psychological content. Fenwick and colleagues (2015) examined related birth and postpartum outcomes, emphasizing that preparation may influence more than a single antenatal score. These studies provide support for counseling as a meaningful intervention domain while underscoring the need to tailor programmes to the population and local health system.

Karaçam and colleagues (2026) provide a newer systematic synthesis of prenatal education and fear of childbirth. The review indicates that prenatal education remains an active evidence area, with a growing need to distinguish programme content and population rather than treat all classes as equivalent. When the article is prepared for formal publication, the researchers should examine the full review's inclusion criteria, risk-of-bias assessment, pooled effect estimates, heterogeneity, and publication date directly, and should update their search before submission. A citation to a recent meta-analysis should not be used to imply that the combined intervention has already been tested.

Psychological outcomes can be affected by selection. Women who agree to attend education may differ from women who do not attend in motivation, transport access, family support, work commitments, literacy, health status, and baseline anxiety. A quasi-experimental study should record relevant baseline variables and explain how women entered the intervention group. If the intervention is introduced at one hospital and control observations are collected at another, institutional differences may confound the comparison. If participants are recruited during different calendar periods, changes in staff or analgesia policy may also affect results.

A practical program should build in assessment and referral. Counseling can reduce uncertainty for many women, but a high fear score may call for an extended conversation, additional appointments, or specialist support. The facilitator should avoid pathologizing normal concern and also avoid minimizing severe distress. The aim is to make help available according to need, not to force every participant toward the same anxiety score.

13. Clinical implementation and safety of birth-ball practice:

Clinical eligibility must be checked before beginning an exercise programme. ACOG advises that obstetric care professionals evaluate pregnant women before recommending exercise and assess

medical or obstetric complications that may alter recommendations (ACOG, 2020). The appropriate checklist depends on gestational age, the reason for the visit, current symptoms, pregnancy risk, prior advice, and local policy. The protocol should be approved by obstetric and midwifery leaders and specify when exercise should be deferred pending clinical review.

The birth ball should be sized so that the woman's feet are flat on the floor with knees comfortably flexed and hips level with or slightly higher than the knees when seated, depending on body proportions and ball characteristics. The ball should be intact, clean, correctly inflated, and placed on a non-slip surface. A stable chair, bed, wall bar, or trained staff member can provide support during mounting and dismounting. The woman should not be asked to balance on the ball without appropriate footing or to perform movements that exceed her comfort or ability. Loose clothing, cluttered floors, and inadequate space increase the risk of slipping.

Antenatal familiarization can begin with a short orientation: checking comfort while seated, feet apart for a stable base, shoulders relaxed, breathing normally, and making small pelvic tilts. The woman can explore gentle side-to-side or circular movement only if it feels comfortable. The facilitator should explain that not every movement is suitable for every woman and that a simple supported position may be preferable to active bouncing. Forceful, rapid, or high-amplitude bouncing is unnecessary. Practice should stop if symptoms arise or the woman wishes to stop.

During labour, ball use requires contemporaneous assessment, sufficient staff capacity, and an environment where help is readily available. Maternal dizziness, faintness, breathlessness beyond expected exertion, chest pain, vaginal bleeding, fluid leakage, severe headache, calf pain or swelling, unusual weakness, marked abdominal pain unrelated to normal contractions, or any concern about fetal well-being requires stopping the activity and following the maternity unit's assessment procedure. This list is not a substitute for local obstetric guidance, and the protocol should use the red flags approved for the specific clinical setting.

Monitoring requirements should determine which positions are feasible. Some women may use the ball while intermittent auscultation is performed according to the care plan; others may need a different position to support continuous monitoring, an examination, an urgent intervention, or maternal stabilization. The clinical team should explain the reason for any change and offer an alternative that preserves comfort where possible. WHO guidance encourages mobility and upright positioning for women at low risk while making clear that a woman's position should not be forced and fetal well-being must be appropriately monitored (WHO, 2018).

A birth ball is a comfort measure, not a guarantee of safety in every circumstance. It does not replace assessment of labour progress, maternal observations, fetal heart-rate monitoring when indicated, or the option of pharmacological analgesia. The nurse or midwife should ask periodically whether the position remains comfortable and whether the woman wants to continue. The intervention should be stopped without judgment if she prefers another strategy.

Table. 1: Core intervention elements, implementation focus, and safeguards

Component	Core activities	Quality and safety considerations
Antenatal counseling	Labour physiology, pain-relief options, warning signs, consent, coping choices, questions and teach-back.	Use plain language; individualize for anxiety and culture; offer privacy; refer when distress is severe.
Birth-ball familiarization	Stable sitting, feet placement, gentle pelvic tilts, supported forward leaning, safe stopping and dismounting.	Check clinical eligibility, ball size and condition, non-slip floor, support nearby, and participant comfort.
Intrapartum offer	Reassess eligibility, explain option, record choice, provide supported use and periodic review.	Do not delay analgesia or required monitoring; stop when requested or when symptoms or clinical changes arise.
Companionship and communication	Invite the woman's chosen support person when permitted; explain changes in plan;	Protect privacy, respect refusal, avoid coercion, and maintain respectful maternity care.

	ask permission before touch or procedures.	
Fidelity and process data	Record attendance, session content, actual use, duration where feasible, reasons for non-use and staff training.	Distinguish refusal or clinically appropriate discontinuation from implementation failure; document contamination.

14. Intervention fidelity and reproducibility:

A reproducible intervention manual should define the core elements of counseling and exercise without eliminating the flexibility needed for individual care. The manual can specify the number of counseling sessions, expected duration, topics, facilitator qualifications, materials, safety checklist, practical exercise sequence, opportunities for questions, and criteria for referral. It should also identify which elements are essential and which are optional. A clear manual helps other units reproduce the programme and enables a reviewer to determine whether a null finding reflects an intervention that was delivered as intended.

A feasible example is two structured antenatal sessions of approximately 35 to 50 minutes, with one practical birth-ball familiarization segment and one follow-up opportunity. The first session could assess concerns, explain labour, introduce coping strategies, review safety and pain-relief options, and demonstrate stable ball positioning. The second could revisit the participant's questions, rehearse movement and communication, and develop a flexible coping plan. This is a suggested template rather than a validated optimal dose; local pilot work should assess session length, comprehension, attendance, and burden before the main evaluation.

The intervention should record actual exposure. Attendance logs can show whether a participant received one or both sessions; a fidelity checklist can record whether essential topics were covered; and brief teach-back questions can assess comprehension. During labour, a clinical record can indicate whether the ball was offered, accepted, used, and stopped, as well as approximate duration and reason for discontinuation. Non-use should not automatically be treated as protocol failure: refusal, fatigue, clinical contraindication, discomfort, or a change in the clinical plan may be appropriate.

Staff preparation is as important as the equipment. Nurses and midwives who deliver the sessions need a shared understanding of the intervention's aims, safety boundaries, and limitations. A short training workshop can include demonstration, observation of technique, language for neutral counseling, scenario-based responses to anxiety, and escalation procedures. Periodic supervision can help avoid drift toward a rigid script or unrealistic promises. Team members should also understand that providing usual care consistently to the comparison group is part of ethical research, not an inferior-care condition.

Contamination can occur when staff trained for the programme also provide the same counseling materials to participants in the comparison group. Some contamination is unavoidable in a clinical setting because good communication and mobility support should be offered to all women. Investigators should define the intervention as the additional structured package, not claim exclusive ownership of routine respectful care. They can document whether comparison participants received similar education or used a ball on their own. The resulting effect estimate is then interpreted as the additional value of the structured programme under real service conditions.

15. Outcome definitions and measurement strategy:

The primary outcome should be specified before enrolment. If labour pain is the primary endpoint, the protocol must define whether the main comparison concerns pain during the active phase at a specified cervical dilatation, average pain across multiple measurements, worst reported pain, or pain shortly after a ball session. A single post-intervention score is easy to collect but can be biased by timing and by the woman's progression through labour. Repeated measurement at clinically meaningful and comparable times is preferable, provided assessments do not interfere with care or burden women during severe pain.

A numerical rating scale from zero to ten can be used to record current pain intensity, with standardized anchors and a consistent question. A visual analogue scale is another established method; Huskisson (1974) described its application in pain measurement. The team should select one primary pain measure and use it consistently. Recording stage of labour, analgesia received, position, contraction timing, and whether the participant used a ball nearby will help explain variation. Pain scores obtained before an epidural should not be compared uncritically with scores taken after analgesia, and a request for analgesia is an outcome of care, not a failure of the intervention.

Anxiety should be measured at a prespecified antenatal time and, if justified, during labour using an instrument suitable for the setting. The State-Trait Anxiety Inventory can separate state and trait elements (Spielberger, 1983), whereas the W-DEQ targets childbirth-related fear (Wijma et al., 1998). A study should avoid administering long questionnaires during intense contractions. Antenatal baseline assessment and postpartum recollection measure different constructs and should not be treated as interchangeable. The final protocol must define the chosen version, language, timing, scoring direction, and threshold for any secondary analysis.

Maternal satisfaction can be measured during the early postpartum period when the participant is clinically stable and able to respond. The Birth Satisfaction Scale or its revised version offers a structured method for capturing multiple dimensions (Hollins Martin and Fleming, 2011; Hollins Martin and Martin, 2014). A short supplemental questionnaire may ask about usefulness, perceived choice, communication, comfort, and willingness to use the strategy again, but these items should be clearly labelled as study-specific rather than presented as a validated scale. Anonymous or independent data collection may reduce social desirability bias.

Important secondary outcomes include childbirth self-efficacy, perceived control, use of pharmacological analgesia, mobility, duration of labour stages, mode of birth, perineal trauma, maternal or neonatal adverse events, intervention acceptability, attendance, and implementation fidelity. Childbirth Self-Efficacy Inventory concepts developed by Lowe (1993) may help explain whether confidence changes, but the team should not overload participants with every available measure. A concise outcome set that addresses the research questions is more likely to produce complete data than an extensive questionnaire battery administered at inconvenient times.

Measurement should distinguish outcome data from process data. Outcome data concern pain, anxiety, satisfaction, and clinical events. Process data concern whether counseling was delivered, which parts were completed, whether the woman practiced, staff training, fidelity, contamination, and participant preferences. Process data help explain why the programme did or did not work. They are especially important in quasi-experimental evaluations, where the intervention may be implemented differently across wards or groups.

Table. 2: Suggested outcome framework for the proposed quasi-experimental evaluation

Outcome domain	**Candidate operational measure**	**Suggested timing**	**Important interpretation notes**
Labour pain	0–10 numerical rating scale or 10-cm visual analogue scale.	Prespecified labour points.	Log stage, position and analgesia; compare similar conditions.
Anxiety or childbirth fear	Validated local-language STAI or W-DEQ.	Baseline and planned follow-up.	State anxiety differs from childbirth fear; avoid surveys during intense contractions.
Maternal satisfaction	Birth Satisfaction Scale or BSS-R, if suitable and validated.	Postpartum when clinically stable.	Collect privately; include all birth modes; avoid leading questions.
Self-efficacy / perceived control	Validated childbirth self-efficacy measure.	Baseline and after counseling.	May be a mediator; do not automatically adjust it out of the total-effect model.

Clinical and implementation outcomes	Analgesia, mode of birth, labour duration, adverse events, attendance and fidelity.	Clinical record and session log.	Predefine outcomes; document co-interventions, missing data and adverse events.

16. Proposed quasi-experimental study framework:

Study design: A prospective, two-group, pre-test/post-test quasi-experimental design is proposed. Eligible primigravida women receiving routine antenatal care would be allocated to an intervention group receiving usual care plus a structured counseling-and-birth-ball programme or a comparison group receiving usual antenatal care. Random allocation is not assumed in this framework. If one clinic or ward delivers the programme and another serves as the comparison site, the research team must acknowledge that site effects may be inseparable from the intervention effect unless multiple sites or strong adjustment strategies are used. A before-after comparison within a single group would be weaker because time trends and natural changes could explain observed differences.

Setting: The project could be conducted in an antenatal clinic linked to a hospital with labour and delivery services, provided staff can support antenatal sessions and document intrapartum outcomes. The clinical unit should have a policy for exercise eligibility, a suitable ball and space, access to obstetric assessment, and clear escalation procedures. If the study is planned in a resource-limited setting, the design should be workable under normal staffing conditions rather than depend on continuous research staff attendance that would be unavailable during routine service delivery.

Population: The target population is first-time pregnant women approaching term and expected to receive care at the study facility. Inclusion criteria might include a singleton pregnancy, gestation within a defined antenatal recruitment window, intention to give birth at the study facility, capacity to provide informed consent, and clinical eligibility for gentle supported ball exercises following obstetric assessment. The protocol must choose a clear definition of primigravida and avoid using parity terms inconsistently. Women who are not clinically eligible for ball use should not be pressured to participate in that component; depending on the research question, they may be excluded from the intervention evaluation while continuing to receive usual care.

Exclusion and deferral criteria: Conditions that make exercise or ball use unsuitable must be determined by the responsible obstetric service based on current guidance, not copied from an unreviewed template. Examples that may require clinical review include active bleeding, suspected ruptured membranes before assessment, severe maternal symptoms, significant mobility or balance limitations, obstetric complications requiring restricted activity, or a clinical plan that makes the proposed exercise inappropriate. Anxiety itself should not be an automatic exclusion. A participant with marked fear may need more support and referral, and the protocol should state how such care will be provided alongside or instead of the study sessions.

Sampling and sample size: Consecutive or systematic recruitment can be used depending on clinic flow, but the method should be the same in both groups where possible. Sample size should be calculated from a prespecified primary outcome and a clinically meaningful difference informed by pilot data or relevant literature, the expected standard deviation, type I error, desired power, attrition, and any clustering by clinic or provider. It is inappropriate to select a sample size merely because it is convenient or to claim that a fixed number guarantees adequate power. If multiple sites are used, the calculation should consider intracluster correlation or otherwise justify the analysis. A small pilot can estimate recruitment, attendance, outcome completion, and variability without being described as a definitive effectiveness trial.

Recruitment and allocation: Potential participants should receive a plain-language explanation that distinguishes routine maternity care from research activities. A neutral staff member should obtain written informed consent before research questionnaires are completed. If allocation follows clinic day, unit, or phased implementation, the mechanism must be specified in advance and the risk of selection bias discussed. Baseline characteristics should be collected before the intervention begins, including age, gestational age, education, language, employment or socioeconomic indicators where appropriate, planned birth setting, baseline anxiety or childbirth fear, childbirth information

previously received, and relevant obstetric factors. Only variables justified by the research question should be collected, and unnecessary sensitive data should be avoided.

Intervention group: Usual care plus structured antenatal counseling and supervised birth-ball familiarization should be delivered using a manual. A possible schedule comprises two antenatal sessions at a gestational window agreed with the clinical team. The opening segment assesses knowledge and concerns. The educational segment covers labour stages, signs requiring assessment, comfort options, pain relief, mobility, consent, companion preferences, and realistic expectations. The practical segment demonstrates stable sitting, feet placement, gentle pelvic tilts, forward leaning with support, breathing, and safe dismounting. The final segment uses teach-back and a written or pictorial plan that lists personal coping preferences and questions for the maternity team. The participant may decline any exercise without loss of standard care.

Control group: Participants continue to receive the unit's usual antenatal and intrapartum care, including all clinical education, respectful communication, movement options, and pain relief that would ordinarily be available. Researchers should not withhold standard information or supportive care to create a contrast. The study records what usual care includes, whether birth balls are already routinely available, and whether comparison participants receive relevant counseling. The estimand is the additional effect of offering the structured programme over actual local usual care, not a comparison with an artificially impoverished control.

Follow-up: Baseline anxiety or fear can be measured at enrolment. A brief knowledge or self-efficacy measure may be repeated after the counseling sessions to assess immediate change. Labour pain can be assessed at prespecified clinical points when the participant is able to respond, with analgesia timing and labour stage documented. Satisfaction should be collected postpartum, ideally before discharge or within a specified follow-up period, when the woman is clinically stable and has privacy. If a participant has an operative birth, emergency intervention, or a change in clinical status, the outcome assessment should adapt to her circumstances rather than interfere with treatment.

Blinding: Participants and intervention staff cannot realistically be blinded to ball use or counseling. Outcome assessors who collect postpartum satisfaction or enter data may be kept unaware of group allocation where feasible. Automated scoring, standardized scripts, and clear definitions can reduce assessor influence. Statistical analysts can receive group labels coded as A and B until the primary analysis plan is finalized. The report should openly describe which staff knew the allocation and how potential measurement bias was addressed.

Primary and secondary outcomes: The protocol should choose one primary outcome such as labour pain score at a specified stage or a prespecified anxiety score. Maternal satisfaction can be an important key secondary outcome, but selecting several co-primary outcomes without adjusting for multiplicity can increase the chance of a false-positive conclusion. Secondary outcomes may include anxiety or fear, self-efficacy, satisfaction, analgesia use, duration of labour, mode of birth, mobility, adverse events, intervention acceptability, and attendance. The study should define the direction of benefit in advance and describe how missing measurements will be handled.

Ethics and registration: Approval from a recognized institutional ethics committee is required before recruitment. The protocol should identify foreseeable risks, explain voluntary participation, protect confidentiality, specify referral pathways, and clarify that withdrawal will not affect care. Clinical staff must be able to discontinue ball use at any time for safety. Written materials should explain that participation does not guarantee less pain or a particular birth outcome. Data should be de-identified, stored securely, and accessed only by authorized research staff. Trial registration is appropriate when required by the applicable registry or journal policy, and protocol publication can improve transparency.

Protocol limitation: The proposed framework does not report recruitment, data collection, statistical findings, or observed outcomes. Those elements can only be added after an approved study is conducted and records are analyzed. The design is presented to support planning and reproducibility, not as evidence that the combined intervention has already been proven effective.

17. Suggested delivery schedule for the combined intervention:

The antenatal phase should start with a brief individualized needs assessment. The facilitator asks about prior information, current concerns, physical comfort, previous exercise experience, language preference, accessibility needs, support-person preferences, and any advice from the obstetric team that limits activity. The woman is told that the session is educational and that she may decline an activity, ask for a break, or change the subject if it becomes uncomfortable. For women with substantial fear, private counseling time is preferable to relying on a group discussion alone.

During the first session, the facilitator explains labour physiology using plain language and a visual sequence. Contractions are described as intervals that vary in intensity and frequency; the woman is encouraged to focus on patterns rather than anticipate a fixed timetable. The session reviews when to seek assessment, how the maternity unit communicates findings, and what factors may change the plan. The facilitator then introduces movement, breathing, touch or massage when welcomed, hydrotherapy if available, pharmacological analgesia, and other options used locally. No option should be presented as morally superior.

The practical demonstration starts with equipment and space checks. The facilitator ensures the ball is suitable for the woman's height, that the floor is dry and clear, and that a stable support is within reach. The woman sits slowly with feet planted apart, breathes normally, and confirms comfort. Gentle pelvic rocking can then be demonstrated. If tolerated, small forward-backward or circular movements may be tried. The educator asks the woman to identify signs that she is losing balance or becoming uncomfortable and practices a safe way to stop and stand with support. A woman who does not wish to sit on the ball can observe the demonstration and practice an alternative comfortable position.

The second session revisits the woman's questions, uses teach-back, and rehearses a labour communication plan. For example, a participant might decide to try the ball when she wants upright movement, ask a companion to remind her to relax her shoulders, and tell the midwife if the posture increases discomfort. The plan includes alternatives: walking, leaning over a raised bed, side-lying, kneeling with support, or requesting pain relief. It should be explicitly flexible rather than a contract to follow a birth plan regardless of circumstances.

Intrapartum use is offered after a fresh assessment and explanation. The nurse or midwife confirms that the woman wishes to try the ball and that the care plan allows it. The clinician checks stability, observes tolerance, and asks the woman to report dizziness, new symptoms, or discomfort. Use may be episodic, with reassessment after each interval. The ball can be stopped when the woman wishes, monitoring needs change, fatigue occurs, or staff identify a clinical reason. The birth companion may offer encouragement if the woman wants that support and if their presence is consistent with privacy and unit policy.

The postnatal conversation should not overstate success or assume that use of the intervention was the reason for any outcome. A brief debrief can invite the woman to describe which strategies were helpful, whether she felt informed and listened to, and what could have improved the experience. The study questionnaire should be administered separately from clinical decision-making and without coaching toward positive answers. This feedback can identify changes needed for future sessions and can provide useful implementation data even if the main outcomes do not differ.

18. Data analysis plan for the proposed study:

The analysis plan should be written before the data are examined. Baseline characteristics should be summarized by group using means and standard deviations for approximately normally distributed continuous variables, medians and interquartile ranges for skewed data, and counts with percentages for categorical data. Balance should be described transparently. A non-significant baseline p-value does not prove that groups are equivalent, especially in small samples; the magnitude and clinical relevance of differences should also be considered.

The primary comparison should estimate the between-group difference in change from baseline or the adjusted difference at follow-up, depending on the outcome and measurement schedule. Analysis of covariance can adjust a post-intervention score for the baseline value and prespecified confounders. Repeated pain assessments may be analyzed with an appropriate mixed-effects model that accounts for within-person correlation and differing measurement times, if sample size and data quality support

that approach. The model should avoid assuming that every woman has the same labour course or the same number of recorded observations.

Potential confounders should be chosen on clinical and causal grounds before analysis. Candidate variables may include baseline anxiety or fear, age, gestational age, educational level, planned birth setting, labour stage at pain assessment, induction or augmentation, analgesia, companion availability, and relevant obstetric risk. It is not appropriate to adjust automatically for every variable available, because some variables may be mediators or consequences of the intervention. For example, increased confidence may mediate the effect of counseling on anxiety; adjusting for it in the primary total-effect model could remove part of the effect the study aims to estimate. Mediation analysis should be prespecified and treated cautiously in small samples.

Effect estimates should be reported with confidence intervals and exact p-values where appropriate, alongside clinically interpretable measures. A statistically significant difference may be too small to matter to women, while a clinically relevant estimate may remain uncertain because a study is underpowered. The discussion should describe both magnitude and precision. The analysis should not focus selectively on outcomes that reach a conventional threshold while ignoring null or adverse results.

Missing data require explicit description. The authors should report the number missing for each measure and compare, where possible, the baseline profiles of participants with complete and incomplete follow-up. Complete-case analysis can be biased when missingness is related to anxiety, labour intensity, emergency intervention, or satisfaction. Multiple imputation may be considered if the assumptions are plausible and the sample size adequate. Sensitivity analyses can test whether the main conclusions change under reasonable assumptions. The reason for missing pain scores, including inability to respond during urgent care, should be documented where possible.

For a quasi-experimental study with non-random assignment, propensity-score methods, inverse probability weighting, or difference-in-differences may be useful in some settings, but they do not remove bias from unmeasured confounding. Difference-in-differences requires credible parallel trends, and propensity-score methods require measured confounders and adequate overlap. These methods should not be added merely to make the analysis look sophisticated. The simplest justified adjustment is often preferable, with the remaining limitations stated plainly.

Subgroup analyses by baseline childbirth fear, maternal age, education, or actual ball use may be clinically interesting but should be limited and ideally prespecified. Small subgroup comparisons can generate unstable results and false-positive findings. An exploratory pattern can suggest questions for a future trial, but it should not be presented as definitive evidence that the intervention works only for a particular subgroup. The main analysis should retain the originally specified group comparison.

The final report should describe the intervention, usual care, participant flow, exclusions, adherence, co-interventions, adverse events, and all prespecified outcomes. The design limitation should be prominent: without randomization, differences may reflect selection, site or time effects, or unmeasured characteristics. Reporting confidence intervals and sensitivity analyses will support a more balanced interpretation than a simple statement that the intervention was 'effective' or 'ineffective'.

19. Potential sources of bias and how to reduce them:

Selection bias is a central concern when women or clinics are not randomly assigned. Participants who are more motivated, less anxious, more physically comfortable, or better supported may be more likely to enrol or complete the intervention. A comparison group recruited from a different ward or time period may differ in staffing, referral patterns, analgesia policy, or case mix. Consecutive recruitment, a shared eligibility screen, baseline measurement before intervention, and careful documentation of recruitment can reduce but not eliminate this risk.

Performance bias occurs because staff and participants know whether the programme is delivered. Intervention participants may receive more attention, reassurance, or time from a clinician than controls. If the research question concerns the full package as implemented, some additional attention is part of the intervention. However, the report should be honest that effects cannot be attributed uniquely to ball movement or counseling content. A future three-arm trial could compare counseling

alone with counseling plus ball practice, and an attention-control group could help distinguish specific effects from added contact if ethically and practically feasible.

Detection bias may arise if an assessor expects the intervention to be beneficial or if participants feel pressure to provide positive responses. Blinding postpartum assessors where possible, using validated measures, adopting neutral questions, and collecting satisfaction data privately can help. The fact that a measure is self-reported is not a flaw when the outcome is subjective experience; the issue is whether the process of measurement is standardized and free from coercion.

Attrition bias can occur if women who experience severe pain, emergency intervention, anxiety, or dissatisfaction are less likely to complete questionnaires. A protocol should ensure that follow-up is not conditional on vaginal birth or uncomplicated recovery. It should also not burden women during emergencies. A flexible, respectful process can collect outcomes when clinically appropriate and record when it is impossible. Reporting only the women who used the ball or completed all sessions can overestimate acceptability or benefit; the primary analysis should follow the prespecified approach to all eligible participants with the required data.

Contamination, temporal changes, and co-interventions should be anticipated. Nurses may use techniques learned in training with all women; analgesia availability or staff mix may change during the recruitment period; and labour management may differ because of individual clinical needs. Standard clinical care should not be frozen in a way that denies needed care. Instead, changes should be documented, and the analysis should account for major differences where feasible. The report should distinguish the intervention as offered from the strategies each participant actually used.

Publication and selective-reporting bias are reduced when the study is registered and the statistical analysis plan is available before results are known. Authors should report adverse events and null findings, and should avoid changing the primary outcome after inspecting the data. A protocol that defines the primary outcome and secondary outcomes in advance improves credibility and helps subsequent reviews combine results across studies.

20. Equity, culture, and person-centred care:

Interventions that rely on attending multiple sessions can unintentionally exclude women who have limited transport, inflexible work, caregiving responsibilities, disability, language barriers, or restricted access to antenatal services. An implementation plan should consider alternative session times, brief catch-up options, accessible print and visual resources, interpretation, and opportunities for one-to-one counseling. These are not peripheral administrative details; they influence who receives the intervention and whether the evidence applies to the whole maternity population.

Birth preferences are culturally shaped but should not be stereotyped. Some women may welcome family involvement; others may want privacy or may be concerned about discussing pain and pregnancy decisions in front of relatives. The facilitator should ask the woman who she wants to involve rather than assume a partner or elder should lead decisions. Counseling materials should represent a range of acceptable coping options and should avoid messages that blame women for requesting analgesia or for needing operative birth.

Language and health literacy affect how women interpret the intervention. Terms such as 'active phase', 'cervical dilatation', 'fetal monitoring', and 'informed consent' need explanation in everyday language. Teach-back is a practical way to check understanding. A short video or illustration can supplement the conversation, but the educator should invite questions and make clear that a visual example is not a prediction of the individual's labour. The resources should be reviewed with women from the target community before implementation to identify confusing language or culturally inappropriate assumptions.

Respectful maternity care includes attention to confidentiality, dignity, consent, and freedom from mistreatment. Bohren and colleagues (2015) documented a broad evidence base on mistreatment during facility childbirth, reminding researchers that a programme should be assessed within the care environment in which it operates. A birth ball cannot compensate for disrespectful interaction, and counseling that teaches women to cope without improving staff communication may shift responsibility unfairly onto women. Training therefore needs to include respectful communication and shared decision-making, not only physical technique.

Equity should be examined in the study's reach and outcomes. Investigators can report attendance and completion by relevant sociodemographic characteristics, provided data collection is proportionate and privacy-protective. If women with lower literacy or greater baseline fear are less likely to complete the sessions, the programme may need redesign. A small average benefit across the entire group can conceal a large benefit for some women or a lack of benefit for others, so qualitative feedback and process evaluation can add useful context without replacing the quantitative primary outcome.

21. Practice implications for nurses and midwives:

Nurses and midwives are well placed to combine antenatal education with practical coping skills because they commonly provide repeated contact across pregnancy, labour, and the postpartum period. A consistent message across staff helps women understand that the ball is optional, pain relief remains available, and changes in clinical circumstances may alter the plan. The professional role is not simply to demonstrate exercises; it includes listening to concerns, evaluating eligibility, checking understanding, supporting autonomy, observing comfort, and communicating with the rest of the team.

A practical service can begin with a small-scale implementation before undertaking a definitive study. The team can evaluate whether women accept the invitation, which session times work, which languages are needed, whether the ball equipment is suitable, how staff document use, and whether the education materials create misconceptions. A short pilot should measure feasibility rather than claim clinical effectiveness. Feedback from women and staff can guide the manual, after which an adequately powered evaluation can estimate outcome differences.

Clinical units should make the ball one item within a broader mobility and comfort policy. It may be used alongside walking, side-lying, supported kneeling, massage, breathing, warmth or water where available, continuous companionship, and analgesic options. This approach matches guidance that encourages comfortable positioning and support tailored to the individual (WHO, 2018; NICE, 2023). The ball should not become a performance measure for staff or a requirement for women to demonstrate that they have tried non-pharmacological coping before receiving another option.

Documentation can be concise but meaningful: eligibility review completed, ball offered, participant choice, approximate use, response, any symptoms, why the intervention stopped, and any subsequent change in the clinical plan. These records support continuity, risk management, and research fidelity. Documentation should not delay care or require staff to complete a lengthy form during an urgent event.

22. Limitations of the current evidence and of this review:

The evidence base has several limitations. Birth-ball trials vary in design, intervention dose, clinical setting, parity, outcome measures, and usual care. Many cannot blind participants or staff, and some depend on self-reported outcomes collected close to the intervention. Smaller studies may be imprecise or vulnerable to selection and reporting biases. Meta-analysis can pool available estimates but cannot correct all weaknesses in the primary research. Effects on pain may be more consistently studied than effects on anxiety, satisfaction, maternal experience, or neonatal safety outcomes.

The evidence for antenatal counseling is also heterogeneous because education programmes differ in duration, theoretical basis, staffing, intensity, and whether they target the general population or women with high fear. A reduction in fear on a validated scale may not translate into a lower intrapartum anxiety score or greater satisfaction unless the care environment reinforces the skills taught. Conversely, women may report a more positive experience even if a measure of pain intensity remains unchanged. Multi-domain measurement is therefore necessary, but adding more outcomes can increase burden and multiplicity concerns.

The integrated intervention is not equivalent to either component alone. A conclusion based on birth-ball trials and counseling trials is an indirect inference about the combination. The additive or synergistic effect of offering both remains to be tested. A combined package may be more useful because it addresses more needs, but it may also be harder to deliver consistently. The proposed quasi-

experimental framework will provide useful real-world information but will retain limitations from non-random assignment and unmeasured confounding.

The present review is narrative and targeted rather than systematic. It does not provide a reproducible database-by-database search log, dual independent screening, formal certainty assessment, or a pooled effect estimate. The included references provide a foundation for study planning, but a manuscript intended for a peer-reviewed journal should undergo an updated and documented systematic search, verification of every full citation, and a formal assessment of study quality. The text should not be interpreted as clinical guidance superseding local protocols or the judgment of a qualified maternity-care professional.

The proposed methods are illustrative. Sample size, contraindications, the exact timing of antenatal sessions, the selected instruments, and the statistical model require local review before recruitment. No effect estimates for the proposed study are provided because no actual dataset has been supplied. Presenting imaginary results would mislead readers and compromise scientific integrity.

23. Research priorities:

The next generation of studies should evaluate clearly described intervention components and outcomes that matter to women. A pragmatic randomized trial would provide stronger causal evidence than a quasi-experimental study if it is feasible and acceptable. Where allocation cannot be randomized, a prospective comparison using multiple sites or a phased roll-out can improve inference if time trends and site effects are explicitly addressed. Studies should include a prespecified primary outcome, validated measures, transparent adverse-event reporting, and sufficient sample size for a clinically meaningful difference.

Direct comparison of usual care, counseling alone, and counseling plus birth-ball familiarization would help determine whether ball practice adds value beyond preparation and attention. A two-arm comparison remains useful for the service question of whether implementing the full package improves outcomes over usual care, but it cannot isolate the contribution of each component. Factorial designs, mediation analysis, and dose-response approaches may clarify mechanisms when sample size and methodological expertise allow. Qualitative interviews can explain why women accept or reject the ball, how they experience counseling, and which programme elements feel respectful or intrusive.

Research should include diverse populations, including women with varying education, language, parity-related history, anxiety levels, and birth preferences. Studies should report whether the intervention is feasible across different staffing models and whether women have genuine access to pharmacological analgesia and companion support. Cost and implementation analyses should evaluate staff time, equipment cleaning, space, training, and opportunity costs. An intervention that improves a score but is not deliverable in ordinary practice may have limited population impact (Mohammed AS, Nadeem, Kumar M, et al., 2026)

Longer-term outcomes are also relevant. A positive or distressing birth experience may influence postpartum well-being and future attitudes toward pregnancy and health care. Follow-up should be designed carefully to avoid overburdening new mothers and should use appropriate measures for postpartum distress when these outcomes are within the study scope. Any such follow-up requires clear consent, privacy protection, and referral if clinically significant distress is detected.

Finally, co-design can improve intervention relevance. Women, midwives, obstetric clinicians, physiotherapists, mental-health professionals, and service managers can help create a manual that is evidence-informed and locally feasible. Co-design should not replace formal evaluation, but it can identify language, workflow, or safety problems before the programme is rolled out widely.

24. Conclusion:

Birth-ball exercise and structured antenatal counseling address complementary aspects of preparation for childbirth. Birth-ball use can provide a supported way to explore movement, upright posture, pelvic mobility, and comfort; published trials and reviews suggest potential reductions in reported labour pain, although results vary and methodological limitations remain. Structured counseling can

explain labour, improve knowledge, support realistic expectations, and respond to fear; targeted psychoeducation studies provide a reason to assess psychological outcomes rather than treat antenatal education as a purely informational activity.

Maternal satisfaction must remain a distinct outcome because it reflects relationships, communication, support, consent, expectations, dignity, and involvement in decisions as well as pain. A programme that offers practical skills but fails to respect the woman's preferences would not represent high-quality maternity care. Ball use should be offered to clinically eligible women who wish to try it, with suitable supervision and a clear path to alternatives and pharmacological pain relief. It must never delay clinical assessment or required treatment.

The evidence supports a careful evaluation of the combined approach, not a claim that its superiority has already been established. A transparent quasi-experimental study can compare routine care with routine care plus a standardized counselling-and-birth-ball package, measure pain, anxiety, and satisfaction independently, document co-interventions and safety, and adjust for prespecified confounders. Acknowledging its limitations will make the results more useful to practice and future research.

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