Sexual & Reproductive Healthcare 32 (2022) 100731

Contents lists available at ScienceDirect

Sexual & Reproductive Healthcare

journal homepage: www.elsevier.com/locate/srhc

Room4Birth – The effect of giving birth in a hospital birthing room designed with person-centred considerations: A Swedish randomised controlled trial

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ARTICLE INFO

Keywords:
Childbirth
Birth room design
Randomised controlled trial
Nulliparous
Birth environment

ABSTRACT

Objective: To evaluate if a birthing room designed with person-centred considerations improves labour and birth outcomes for nulliparous women when compared to regular birthing rooms.
Methods: A randomised controlled trial was conducted at a Swedish labour ward between January 2019 and October 2020. Nulliparous women in spontaneous labour were randomised either to a birthing room designed with person-centred considerations (New room) or a Regular room. The primary outcome was a composite of four variables: vaginal non-instrumental birth; no oxytocin augmentation; postpartum blood loss < 1000 ml; and a positive childbirth experience. To detect a difference of 8% between the groups, 1274 study participants were needed, but the trial was terminated early due to consequences of the Covid-19 pandemic.
Results: A total of 406 women were randomised; 204 to the New room and 202 to the Regular room. There was no significant difference in the primary outcome between the groups (42.2% versus 35.1%; odds ratio: 1.35, 95% Confidence Interval 0.90–2.01; $p = 0.18$). Participants in the New room used epidural analgesia to a lower extent (54.4% versus 65.3%, relative risk: 0.83, 95% Confidence Interval 0.71–0.98; $p = 0.03$) and reported to a higher degree that the room contributed to a sense of safety, control, and integrity (p=<0.001).
Conclusions: The hypothesis that the New room would improve the primary outcome could not be verified. Considering the early discontinuation of the study, results should be interpreted with caution. Nevertheless, analyses of our secondary outcomes emphasise the experiential value of the built birth environment in improving care for labouring women.

Introduction

The majority of births in high- and moderate-income countries take place in hospital-based labour wards and there is an expanded interest in how these environments impact labour and birth outcomes [1–3]. However, knowledge that can support an evidence-based approach to the guiding and designing of birthing rooms is sparse [4,5]. Since medical interventions such as caesarean births, induction of labour and oxytocin augmentation in high-resource hospital settings have increased over the last decades [6], it is essential to understand how the environment can support birth physiology [7]. Particularly since the challenges with overuse of interventions are that they can increase the need

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https://doi.org/10.1016/j.srhc.2022.100731
Received 18 December 2021; Received in revised form 18 April 2022; Accepted 20 April 2022
Available online 26 April 2022

for more interventions, thus potentially doing more harm than good [8]. Research has shown that the birthplace setting influences women's childbirth experience, intervention rates, mode of birth and requirements of intrapartum analgesia [2]. To improve the quality of maternity care in hospital settings, the physical and psychosocial environment needs to be based on women's personal preferences [6,7], since a positive childbirth experience where women have a sense of control is beneficial both in the postpartum period and in a life-long perspective [9].

The birth environment impacts neurophysiological processes in women during labour. For instance, there is a correlation between a perceived calm, private and safe birth environment, and mediated release of hormones, such as oxytocin [7,10]. This relieves pain sensations and leads to more effective labour contractions, which positively affects the birth progress and prevents pathological postpartum blood loss [10]. A stressful and unfamiliar environment could, on the contrary, lead to activation of the woman's defence and stress systems, which inhibit the release of endogenous oxytocin and increase the activation of the sympathetic nervous system [10]. As a result, labour contractions may cease [11], leading to a need for exogenous oxytocin augmentation due to prolonged labour [12].

Previous studies have compared effects of differently designed birthing rooms on birth outcomes, with contradictory results [3,13–15]. Multi-sensory elements within a birthing room, such as music therapy, aromatic oils and visual stimuli may, for instance, contribute to relaxation and distraction from labour pain [13]. Research has also shown that the physical environment can affect the caesarean birth rate [14]. A randomised controlled trial from Denmark [3], found on the contrary no differences in the oxytocin augmentation rate and other birth outcomes for women giving birth in a specially designed birthing room. Based on the identified lack of knowledge concerning the effect of the physical birth environment [4], we aimed to evaluate if a birthing room designed with more person-centred considerations improves labour and birth outcomes for nulliparous women when compared to regular birthing rooms.

Methods

Study design and setting

At a University hospital labour ward in western Sweden, we conducted a randomised controlled open-label superiority trial (RCT). The trial had two parallel groups, comparing effects of two different types of birthing rooms; 1) conventional birthing rooms (Regular room, control group) and 2) a refurbished room designed with person-centred considerations (New room, intervention group). Women, classified as Robson 1 [16], i.e. nulliparous with a single, live, cephalic foetus $>$ 37 gestational weeks, and with a spontaneous onset of labour were recruited between January 2019 and October 2020. Ethical approval was given by the regional ethics board in Gothenburg (Dnr: 478–18) and all study procedures were performed in accordance with the declaration of Helsinki. The study was retrospectively registered at ClinicalTrials.gov (NCT03948815) and conducted in accordance with the CONsolidated Standards Of Reporting Trials (CONSORT). A study protocol has been published [17] and no considerable changes were made after trial commencement.

Maternity care in Sweden is publicly funded and most babies are born in hospitals [18]. The labour ward in which this study was undertaken, served women with singleton, mainly uncomplicated pregnancies of $\geq$34 gestational weeks. In year 2019 the labour ward had 4010 births, of which 30.7% were women classified as Robson 1. In March 2020 a reorganisation due to the Covid-19 pandemic was undertaken, whereby all women in the area with suspected or confirmed infection were provided care at the labour ward. This resulted in a decrease in the overall birth rate and an increase in the rate of complicated pregnancies.

We hypothesised that a birthing room designed with more person-centred considerations intending to surround birthing women with a calm, multisensory environment that offers control and freedom of choice, would positively affect birth outcomes by facilitating the release of endogenous oxytocin, and thereby reduce stress. This would increase the likelihood of a vaginal non-instrumental birth, reduce the need for oxytocin augmentation, prevent pathological postpartum blood loss, and increase childbirth satisfaction. Details about the design, hypothesis and methods have been published in the study protocol [17], but will briefly be described below.

The New birthing room and the seven similarly designed Regular rooms (Fig. 1) were all equipped with the equal level of technology and medical safety. The built design of the New room aimed at increasing the potential for each birthing woman to create an environment where she experienced a sense of safety and familiarity. The room had an entrance hall with a green-coloured curtain that separated the room from the hospital corridor outside (Fig. 2), and it was furnished with functions and features allowing adjustments according to personal preferences. For instance, it was possible to choose from seven programmed audio-visual stimuli projections on two of the walls and there were several lighting options with dimmable functions. All the medico-technical devices in the New room were hidden behind wood-panels that could be rolled up, and the birth bed was located to the side of the room, covered with a green-coloured bedspread. There was also a bathtub placed inside the room and more options for upright birth position than in the Regular rooms.

Population and randomisation

Eligibility criteria for participation were women $\geq$ 18 years classified as Robson 1 in active stage of labour, defined as two of the following three criteria fulfilled at labour ward admission; 2–3 painful contractions within 10 min; spontaneous rupture of membranes; cervix dilated $>$3 cm or effaced and dilated $\geq$1 cm. Participants also needed to understand either Swedish, English, Arabic or Somali or have access to an interpreter. Exclusion criteria were planned caesarean birth and latent phase of labour. At antenatal care clinics, nulliparous pregnant women were informed that there was an ongoing study at the hospital aimed at evaluating the effect of the birthing room's design. Those women who fulfilled the inclusion criteria upon labour ward arrival, were provided with detailed oral and written information by their care provider. This information did not include details about the room, to prevent positive or negative expectations. All labour ward midwives and assistant nurses were introduced in the recruitment strategy prior to commencement of the trial, and through information leaflets available at the labour ward's main office.

Participants were randomly allocated on a 1:1 ratio to either the New room (intervention group), or a Regular room (control group). An agency with no involvement in the trial managed and prepared a block randomisation, computer-generated allocation list. The designated allocations were printed in sealed, opaque, and sequentially numbered envelopes kept in a study box at the labour ward's office. The care providers recruited and obtained signed, informed consent from the participants after confirmed active stage of labour. The sequentially numbered envelope was opened, and the care providers informed the consented women of their allocated room. At randomisation, participants received a unique ID code, which was printed on the envelope. The independent agency ensured that the randomisation process was correctly monitored, which was possible since the allocated room and ID-code was reported two hours after birth. Care was provided according to the same guidelines in both randomised groups. It was not possible to blind participants or care providers due to the nature of the intervention.

Data collection and outcomes

A study midwife collected and registered data from the participants'

Fig. 1. Pictures of A) the Regular birthing room and B) the New birthing room.

Fig. 2. Picture of the entrance hall with a green-coloured curtain in the New room that protected the room from the hospital corridor outside. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

electronic medical records. These data were double-checked by one of the researchers (either LG or MB) and a study assistant nurse and did not include details of the allocated room. The researchers were blinded to the recorded data since only the ID-code was used during data entry. Subsequently, participants answered a self-reported questionnaire (Supplementary Information 1) via a touchscreen tablet two hours after birth while they were still in the birthing room. The self-reported data included questions about overall childbirth experience, fear of birth and birthing room experiences and were collected by an independent agency.

The primary outcome was a composite of the following four variables, where the composite score was 1 if all four variables were fulfilled and 0 if not:

- Vaginal non-instrumental birth (no vaginal instrumental or caesarean birth)
- No oxytocin augmentation of labour
- Postpartum blood loss < 1000 ml
- A positive childbirth experience (rated 7–10 on a Visual Analogue Scale [VAS] 1–10)

Secondary outcomes were the variables in the primary outcome analysed separately, plus use of epidural analgesia, vaginal laceration, and neonatal intensive care admittance.

Other maternal and neonatal outcomes were bath for water immersion, amniotomy, length of labour, duration of oxytocin and epidural analgesia administration, operative birth indication, breastfeeding, hospital stay, skin to skin contact with the neonate, Apgar score, birthing room experiences, and fear of birth through the Fear Of Birth Scale (FOBS) [19,20]. FOBS in its original form measures fear of birth by asking individuals during pregnancy two questions regarding fear and worry about their approaching birth. The two scores are averaged to give a total FOBS score and a value ≥ 60 indicates fear of birth [19]. We used a modified form of the scale where we measured self-reported fear retrospectively two hours postpartum, and fear of giving birth again. To assess participants' experiences of the birthing room, a questionnaire was developed based on the professional experience represented in our research group, and on previous research about childbirth experience and evidence-based design [21]. The questions considered the room's adaptability and overall meaningfulness, and its contribution to the participants' sense of safety, control and integrity ranging from 1 = to a very high degree, to 4 = not at all.

Data collection was stopped earlier than planned (end of October 2020), due to two main consequences related to the Covid-19 pandemic. In the initial phase of the pandemic, the New room could not be used because of the labour ward reorganisation. This resulted in a six-month pause in data collection. When recruitment was restarted, the company that operated the media installation in the New room had shut down due to the Covid-19 pandemic and were unable to offer technical support for the recurring malfunctions in the presentation of the nature scenes. Since we did not have access to the media content, it was impossible to use the New room as intended and recruitment for the trial could not continue.

Sample size and statistical analyses

To detect a difference in the primary composite outcome of 8% between the groups (45% in control vs. 53% in intervention, with a level of significance 0.05, power 80%), 1274 participants (637 per group) were required. To allow for an expected 10% dropout rate, 1401 participants

were needed. This sample size calculation was based on data from the labour ward for the target population (Robson 1 [16]) in 2017 in which the three first parts in the composite score were fulfilled in 47.9%. Among these, based on a Swedish national register study [22], we assumed that 94% could have a positive overall childbirth experience, which implies that 45% fulfils all four parts in the main composite outcome (0.479*0.94 = 0.450). Since both types of birthing rooms had to be vacant to recruit study participants, we calculated the possibility of including one participant each day. Thereby, we anticipated a 3.5-year inclusion period.

Statistical analyses were performed based on the intention-to-treat methodology in accordance with a pre-specified analysis plan. For the few missing data in baseline and outcome variables, stochastic imputation with fully conditional specification was used. For comparison between the two randomised groups, Fisher's non-parametric permutation test was used for continuous variables, Fisher's exact test for dichotomous variables and chi-square test for non-ordered categorical variables. For the primary composite variable, odds ratio (OR) with 95% confidence interval (CI) were calculated. For the dichotomous secondary outcomes, we calculated relative risks (RR) with 95% CI. For continuous secondary outcomes, results are presented using mean differences with 95% CI.

A pre-specified sensitivity analysis of the primary analysis was adjusted for known predictors with multivariable logistic regression, including birth country, maternal age, educational level, mental illness, fear of birth, body mass index, companion support, childbirth preparation, and neonatal birth weight. All significance tests were two-sided and conducted at the 5% significance level. We also performed a post hoc analysis of the group differences in the primary outcome over time, since gradual interior changes were made in the Regular rooms from November 2019. Changes included added decorative lights and more alternatives for upright birth position. The post hoc analysis was also conducted to explore the effect of the pandemic outbreak. For all statistical analyses, SAS System Version 9.4 (Cary, NC, USA) was used.

Results

The study included 406 participants: 350 between 1 January 2019 and 12 March 2020 and 56 between 1 September and 27 October 2020. Of the 406 randomised participants, 204 were allocated to the New room (intervention group) and 202 to a Regular room (control group). A total of 760 eligible women were not recruited mainly due to the non-vacancy of both the New room and a Regular room at their time of admission to the labour ward. Of the included participants, two were lost to follow-up in the self-reporting of data two hours after birth, eight did not meet inclusion criteria and one used neither the New nor a Regular room. All 406 women were included in the intention to treat analysis according to original assigned group (Fig. 3). The intervention group and the control group were similar at baseline (Table 1).

The primary composite outcome occurred in 42.2% of the participants in the intervention group and 35.1% of the participants in the control group. This seven-percentage points difference did not reach statistical significance (OR 1.35; 95% CI 0.90–2.01; $p = 0.18$; Table 2). Synthetic oxytocin for augmentation of labour was used by 48.5% of the participants in the New room and 57.9% of the participants in the Regular room (RR 0.84, 95% CI 0.70–1.01; $p = 0.07$). Women in the New room used epidural analgesia to a lower extent, compared with women in the Regular room (54.4% versus 65.3%, RR 0.83, 95% CI 0.71–0.98; $p = 0.03$). For other secondary outcomes in Table 2, there were no statistically significant differences between the groups. In the pre-specified

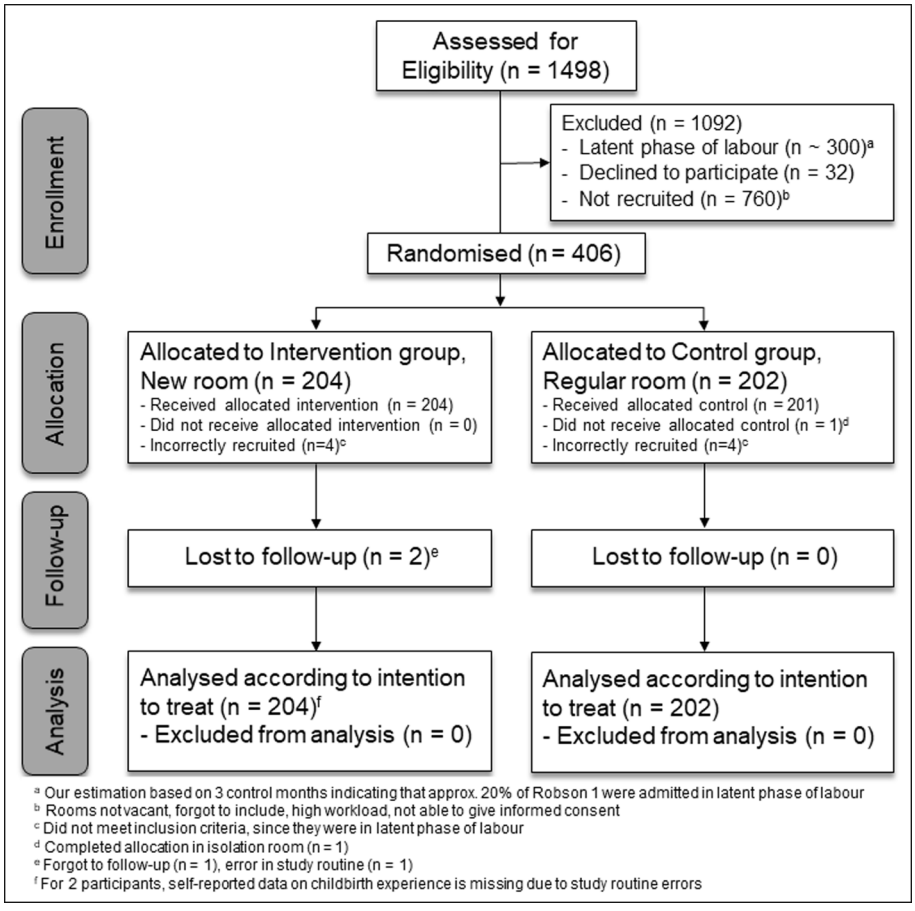

Fig. 3. Flowchart of eligible, enrolled and completing participants (CONSORT figure).

Table 1
Baseline characteristics of the intention to treat population.[a]

Variables	New room (n = 204)	Regular room (n = 202)
Country of birth:		
Sweden	150 (73.5%)	155 (76.7%)
Other Nordic country	7 (3.4%)	2 (1.0%)
Other European country	22 (10.8%)	18 (8.9%)
Country outside Europe	25 (12.3%)	27 (13.4%)
Years in Sweden at randomisation		
Mean (SD)	9.15 (9.8)	12.9 (11.7)
Median (interquartile range)	5 (2; 17)	6 (2; 27)
Maternal age at randomisation (years):		
Mean (SD)	29.6 (4.5)	30.2 (3.9)
Median (interquartile range)	29 (27; 32)	30 (28; 32)
Educational level[b]:		
Compulsory / elementary school (year 1–9)	5 (2.5%)	3 (1.5%)
High school (year 10–12 or equivalent)	48 (23.5%)	35 (17.3%)
University or College	149 (73.0%)	164 (81.2%)
Family situation:		
Cohabiting with other parent	192 (94.1%)	195 (96.5%)
Single	5 (2.5%)	4 (2.0%)
Other family situation	7 (3.4%)	3 (1.5%)
Treatment for mental illness	41 (20.1%)	43 (21.4%)
Counselling for fear of childbirth[c]	5 (2.5%)	7 (3.5%)
Body mass index at first antenatal visit[d]:		
Mean (SD)	23.4 (3.4)	24.2 (4.1)
Median (interquartile range)	22.8 (20.9; 25.5)	23.1 (21.3; 26.3)
Gestational age at birth (days):		
Mean (SD)	280.5 (7.2)	280.0 (6.9)
Median (interquartile range)	281 (276; 286)	280 (276; 285)
Neonatal birthweight (grams):		
Mean (SD)	3520 (417)	3509 (415)
Median (interquartile range)	3520 (3235; 3790)	3493 (3210; 3780)
Childbirth preparation course[b,e]	155 (76.7%)	161 (79.7%)
Support person present during labour[b]:		
Partner	195 (96.5%)	195 (96.5%)
Doula	4 (2.0%)	3 (1.5%)
Other	14 (6.9%)	21 (10.4%)
Nobody	1 (0.5%)	0 (0.0%)

SD = Standard Deviation.
[a] Values are numbers unless stated otherwise.
[b] 2 missing values.
[c] Counselling at a specialised fear of birth clinic.
[d] 7 missing values.
[e] Pregnancy yoga, information at the hospital or other childbirth preparation courses.

sensitivity analysis for the primary composite outcome, the OR adjusted for covariates was 1.26 (95% CI 0.82–1.93, $p = 0.30$).

Participants randomised the New room used bath for water immersion to a higher extent than those randomised to the Regular room (58.8% versus 29.2%; RR 2.01, 95% CI 1.58–2.57; p=<0.001). Furthermore, five neonates in the Regular room (2.5%) were born with Apgar score < 7 at five minutes, and none in the New room (mean difference: 2.5, 95% CI −5.1–0.2, $p = 0.06$). No statistically significant differences were observed between the groups regarding amniotomy and episiotomy rate, length of labour, duration of oxytocin and epidural analgesia administration, postpartum blood loss, operative birth indication, breastfeeding, hospital stay and fear of birth (Table 3). Umbilical cord measures of neonatal acidosis status were only reported in 54% of the participants' observed medical records, since this was not reported routinely at the labour ward. Therefore, this variable was excluded from the analysis. The New room contributed to a significantly higher degree of participants' self-reported safety, control, and integrity (all $p <$ 0.001). It was also to a significantly higher degree reported as overall meaningful and adaptable to personal needs and requirements (both $p <$ 0.001; Fig. 4). No adverse maternal or neonatal events such as maternal or neonatal mortality and severe morbidity occurred in either of the study groups.

The analysis of the per protocol population included 200 participants in the intervention group and 197 in the control group. Reasons for why nine participants were not in accordance with the protocol is presented in Fig. 3. The baseline variables and outcomes indicated consistency with the ITT analyses (Supplementary Information 2–4). Post hoc analysis of differences in the primary outcome between the two groups over time showed a higher proportion of participants in the New room fulfilling all the variables in the primary outcome before the pandemic outbreak and labour ward reorganisation: 43.2% in the New room and 33.3% in the Regular room. For the two months during the pandemic there were, on the contrary, more participants in the control group fulfilling all the variables in the primary outcome (Supplementary Information 5).

Discussion

In this Room4Birth trial, we hypothesised that a birthing room designed with more person-centred considerations would increase the chance of fulfilling all four variables in the primary composite outcome: vaginal, non-instrumental birth, no augmentation of labour with synthetic oxytocin, postpartum blood loss < 1000 ml and a positive childbirth experience. According to our sample size estimation, 1274 study participants were needed to detect a difference of 8% in the primary outcome between women randomised to the New room and the Regular room. However, due to consequences of the Covid-pandemic, the trial was terminated earlier than planned, which is methodologically problematic. Thus, it is difficult to draw reliable conclusions from analysis of the primary outcome and the findings should be interpreted with care. The analysis of data from the 406 study participants did not show any statistically significant difference in the primary outcome between the two randomised groups. Nontheless, results from analyses of secondary outcomes showed that fewer participants in the New room used epidural analgesia than in the Regular room. The New room was also to a higher degree reported as overall meaningful, adaptable to personal needs, and contributing to participants' sense of safety, control, and integrity.

That fewer participants in the New room used epidural analgesia during labour may be related to the fact that they had access to a bathtub inside the room while those in the Regular rooms could only use a bathtub in another room if it was not occupied. Previous research shows that water immersion during labour as an alternative for labour pain relief is related to lower requirements of epidural analgesia [23]. Another interpretation of the finding that fewer women in the New room used epidural analgesia during labour, may be related to the stress-reducing and adaptable environment in the New room conveying a sense of control, integrity, and safety. Previous research has found that a multisensory room design can distract women from labour pain [2,13] and that oxytocin release is enabled by a perceived calm atmosphere where the woman has a sense of control and safety [7,10]. This may also explain why there was a non-significant trend towards fewer participants in the New room receiving intrapartum oxytocin augmentation than participants in the Regular room. However, we observed no differences between groups regarding length of labour from randomisation to birth, or postpartum blood loss, which are also variables that indicate enabled endogenous oxytocin release.

Although there is limited research evidence concerning the impact of the built birth environment, there are some previous studies demonstrating that a specially designed, multisensory room positively affects labour and birth outcomes [13,14]. Unlike the results of our study, a Danish observational, retrospective cohort study [14] showed that means of positive distraction within the room has the potential to lower caesarean birth rates. Another randomised controlled trial from Denmark [3], which had a similar design as our study, showed no effect of the room design on oxytocin augmentation usage during labour. However, further improvements in the study setting might have been

Table 2
Primary and secondary outcomes in the intention to treat population.[a]

	New room (n = 204)	Regular room (n = 202)	Odds ratio [OR]/ Relative risk [RR] (95% CI)	*P*	Difference between group Means (95% CI)
Primary efficacy composite outcome:					
Composite endpoint[b]	86 (42.2%)	71 (35.1%)	OR 1.35 (0.90–2.01)	0.18	7.0 (-2.9; 16.9)
Secondary efficacy outcomes:					
Childbirth experience (VAS 1–10)[c]:					
Mean (SD)	8.22 (2.01)	8.18 (1.76)		0.86	0.04 (-0.33; 0.40)
Median (interquartile range)	9 (7; 10)	8 (7; 10)			
Mode of birth:					
Vaginal non-instrumental	171 (83.8%)	171 (84.7%)			
Vaginal instrumental	19 (9.3%)	15 (7.4%)			
Caesarean birth	14 (6.9%)	16 (7.9%)		0,74	
Oxytocin augmentation	99 (48.5%)	117 (57.9%)	RR 0.84 (0.70–1.01)	0.07	−9.4 (-19.5; 0.8)
Epidural analgesia	111 (54.4%)	132 (65.3%)	RR 0.83 (0.71–0.98)	0.03	−10.9 (-20.9; 1.0)
Post partum blood loss < 1000 ml	179 (87.7%)	183 (90.6%)	RR 1.30 (0.74–2.29)	0.45	−2.8 (-9.4; 3.7)
No severe vaginal laceration[d]	176/190 (92.6%)	174/186 (93.5%)	RR 1.14 (0.54–2.40)	0.88	−0.9 (-6.6; 4.7)
Admitted to neonatal intensive care unit	7 (3.4%)	15 (7.4%)	RR 0.46 (0.19–1.11)	0.12	−4.0 (-8.9; 0.9)

CI = Confidence Interval, OR = Odds Ratio, RR = Relative Risk, SD = Standard Deviation, VAS = Visual Analogue Scale.
[a] Values are numbers unless stated otherwise.
[b] Composite endpoint: Vaginal, non-instrumental birth, no oxytocin augmentation, postpartum blood loss < 1000 ml, positive childbirth experience (7–10 on a VAS). There were no missing data in the primary composite variable.
[c] 2 missing values.
[d] No 2nd degree vaginal injury in need of obstetric surgery, 3rd or 4th degree anal sphincter injury.

limited, since the overall oxytocin augmentation rate and caesarean birth rate were already lower than the average national rate in Denmark [3]. For instance, only around 30% of the participating Robson 1 classified women in both study groups received oxytocin augmentation during labour, which can be compared to the average national rate in Sweden, which was around 58% in 2020 within the same group [24]. In addition, the trial was conducted in a setting where caseload continuity of care was practised. It is well known that midwife-led continuity of care models where one, or a small group of midwives, care for the woman throughout pregnancy, childbirth, and the postpartum period, increase the chance of a spontaneous vaginal birth, childbirth satisfaction, and reduce intrapartum medical interventions [25].

The design of the New room, which aimed at creating a less hospital-like setting, may have contributed to women's sense of safety, control and integrity through the features supporting familiarity. However, it appears to have contributed less than expected to other labour and birth outcomes. As described in the literature, the release of endogenous oxytocin is dependent on birthing women having a sense of safety, relaxation, and control [7], but also on experiencing trusting relationships in a comfortable atmosphere [26], which emphasises the importance of the provided care. That the New room was designed with person-centred considerations does not necessarily mean that women were provided with person-centred care. For instance, the labour ward in which this study was undertaken did not provide continuous one-to-one care by a midwife throughout labour. Previous research shows the benefit of intrapartum continuous support on various birth outcomes, including increased chance of vaginal non-instrumental birth, childbirth satisfaction, shorter length of labour, decreased use of epidural analgesia and fewer neonates with a low five-minute Apgar score [27]. This addresses the need to acknowledge both the built birth environment and psychosocial factors to enable for birth physiology within a hospital setting.

Methodological considerations

Although our trial in part contributes to filling existing knowledge gaps about the birth environment's influence on labour and birth outcomes, we acknowledge that the study has its limitations. The most problematic being the early termination due to consequences of the pandemic, which caused a failure to achieve the intended power, reduced the ability to detect a possible effect in the primary outcome and makes it difficult to determine if the outcome is reliable. Research about how results from terminated trials can ensure maximal benefit for the society is lacking [28], but such published results can be used in meta-analyses in systematic reviews and thus contribute to a more informed design of hospital birthing rooms.

The four variables in the primary composite endpoint were all relevant for the hypothesis of what supports endogenous oxytocin release. To compensate for the limitation of the open-labelled study design, we specifically selected some objective outcomes that were expected to be less easy to manipulate, such as the exact measurement of blood loss and mode of birth. However, the composite endpoint also provided subjective and emotional measurements. As stated in the World Health Organization intrapartum care guidelines [6], birthing women's psychosocial wellbeing needs to be identified as well as biomedical outcomes. The variables chosen in our composite can be directly translated to improve health from birthing women's perspectives. Nevertheless, the use of composite outcomes has also been criticised in the literature, in that the benefits related to only one component of the composite may be wrongly presumed to relate to all the components. Thereby, conclusions can be misleading when taken out of context [29].

Many eligible women who presented at the labour ward were not included in our study, due mainly to non-vacancy of birthing rooms. Regardless of this, the baseline variables of the study sample were representative of the Robson 1-classified women admitted to any of the labour wards at the hospital during the same period of time [24]. A strength of the study was that the participation dropout rate was limited and the results from the pre-specified per protocol analyses did not differ from those of the ITT analyses. A study limitation was that participants and care providers were unable to be blinded to the group allocation. Therefore, it is difficult to know if the design of the New room affected the care providers' care, or if they compensated for the design in the Regular room in an attempt to improve the birth experience for participants in the control group. Previous research indicates that the built environment influence care providers' practices, making it more or less challenging to provide care that facilitates physiological birth [30]. In future research, we will address the challenges of conducting a clinical trial within a complex setting such as a hospital-based labour ward, and whether the design of the room influenced the care providers in their provision of care.

Table 3
Labour and birth outcomes in the intention to treat population.[a]

	New room (n = 204)	Regular room (n = 202)	Relative Risk (95% CI)	*P*	Difference between group Means (95% CI)
Maternal outcomes:					
Bath for water immersion	120 (58.8%)	59 (29.2%)	2.01 (1.58–2.57)	<0.001	29.6 (19.9; 39.3)
Amniotomy[b]	62 (30.4%)	70 (34.7%)	0.88 (0.66–1.16)	0.42	−4.3 (-13.9; 5.3)
Length of labour[c] (hours)					
Mean (SD)	9.08 (5.43)	9.51 (4.98)			
Median (interquartile range)	8.43 (4.58; 12.87)	9.13 (5.8; 12.37)		0.41	−0.42 (-1.45; 0.60)
Length of pushing stage[d] (minutes)					
Mean (SD)	53.3 (39.6)	55.3 (42.6)			
Median (interquartile range)	45 (28; 66)	46 (28; 67)		0.65	−2.0 (-10.50; 6.68)
Duration of oxytocin administration (hours)					
Mean (SD)	4.27 (3.60)	4.12 (4.15)			
Median (interquartile range)	3.07 (1.58; 6.17)	2.95 (1.53; 5.72)		0.77	0.16 (-0.90; 1.20)
Duration of epidural analgesia (hours)					
Mean (SD)	7.95 (4.28)	7.47 (3.62)			
Median (interquartile range)	7.83 (4.63; 10.27)	7.16 (5.27; 9.16)		0.35	0.48 (-0.52; 1.47)
Episiotomy	23 (11.3%)	27 (13.4%)	0.84 (0.50–1.42)	0.62	−2.1 (-9.0; 4.8)
Post partum blood loss in total (ml)					
Mean (SD)	579 (387)	550 (385)			
Median (interquartile range)	453 (300; 732)	433 (300; 680)		0.45	28.9 (-46.9; 105.4)
Indication for vaginal instrumental birth					
Prolonged labour	7/19 (36.8%)	2/15 (13.3%)			
Fetal asphyxia	12/19 (63.2%)	13/15 (86.7%)		0.12	–
Indication for caesarean birth					
Prolonged labour	10/14 (71.4%)	11/16 (68.8%)			
Fetal asphyxia	4/14 (28.6%)	5/16 (31.3%)		0.87	–
Hospital stay[e] (hours)					
Mean (SD)	60.0 (23.5)	59.1 (21.8)			
Median (interquartile range)	55.3 (45.3; 70.5)	56.1 (45.6; 69.3)		0.70	0.89 (-3.54; 5.34)
Breastfeeding within the first 2 h	134 (65.7%)	143 (70.8%)	0.93 (0.81–1.06)	0.32	−5.1 (-14.6; 4.4)
Childbirth experience[f]:					
Rated 10 on a VAS 1–10	74 (36.3%)	65 (32.2%)	1.13 (0.86–1.48)	0.44	4.1 (-5.6; 13.8)
Fear during childbirth (FOB scale 0–100)					
Mean (SD)	15.4 (22.9)	18.2 (23.9)			
Median (interquartile range)	0.8 (0.2; 24.5)	4 (0.3; 32.5)		0.24	−2.76 (-7.32; 1.80)
Cut-off ≥ 60 (Fear during childbirth)	34 (16.8%)	32 (15.8%)		0.89	2.0 (-8.7; 6.7)
Fear of giving birth again (FOB scale 0–100)					
Mean (SD)	12.3 (12.9)	14.1 (12.6)			
Median (interquartile range)	8.6 (0.3; 19.8)	11.8 (1.5; 24.8)		0.15	−1.83 (-4.33; 0.66)
Cut-off ≥ 60 (Fear of giving birth again)	0 (0%)	0 (0%)		NA	
Neonatal outcomes:					
Apgar score < 7 at 5 min	0 (0.0%)	5 (2.5%)		0.06	−2.5 (-5.1; 0.2)
Apgar score < 4 at 5 min	0 (0.0%)	0 (0.0%)		NA	
Neonatal mortality	0 (0.0%)	0 (0.0%)		NA	
Skin to skin for the whole first hour of birth	186 (91.2%)	186 (92.1%)	0.99 (0.93–1.05)	0.88	−0.9 (-6.8; 5.0)

CI = Confidence Interval, SD = Standard Deviation, VAS = Visual Analogue Scale.
[a] Values are numbers unless stated otherwise.
[b] 6 missing values, stochastic imputation.
[c] From randomisation to childbirth.
[d] 22 missing values, stochastic imputation.
[e] From childbirth to maternal discharge.
[f] 2 missing values, stochastic imputation.

The post hoc analysis of fulfilled primary outcome in both study groups over time indicated that the largest differences in proportions occurred in favour of the New room before the pandemic outbreak. This difference could be due to coincidence, since the sample size is limited, but it is impossible not to reflect about the consequences of the environment's effect on birth outcomes during an ongoing pandemic where other social and stress factors might have had an impact. However, the nature of the randomised design ensures that these aspects should influence both randomised groups equally. Therefore, an explanation of these study results needs further investigation.

Conclusion

This prematurely terminated trial including 406 study participants was unable to verify the hypothesis that women randomised to the New room would be more likely to fulfil all the variables in the primary composite outcome; vaginal non-instrumental birth, no use of oxytocin augmentation, postpartum blood loss < 1000 ml, and a positive childbirth experience, compared with women in the Regular rooms. Because of the study limitation caused by the early termination, the trial was underpowered to draw reliable conclusions about the primary outcome. Nonetheless, analysis of our secondary outcomes showed that significantly fewer participants in the New room required epidural analgesia than in the Regular rooms. Furthermore, the New room was to a significantly higher degree reported as contributing to participants' sense of safety, control, integrity, adaptability and meaningfulness. These findings show the value of designing birthing rooms with a conscientious and person-centred approach, aiming for a calm, familiar, comfortable, multisensory hospital birth environment with a possibility to control ambience. More research evaluating the effect of the birthing

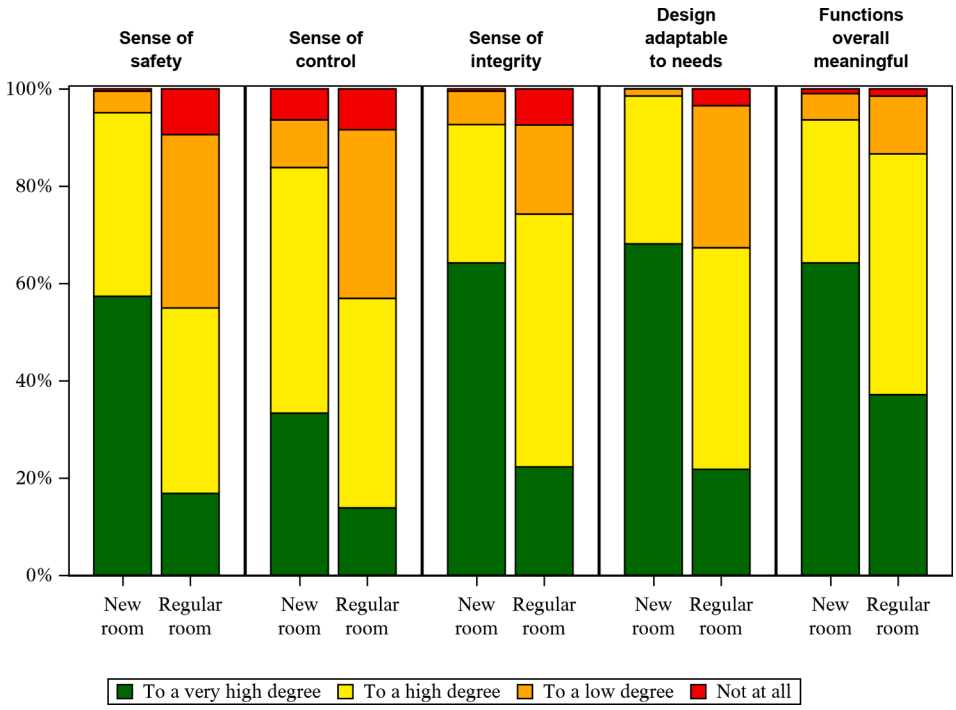

Fig. 4. Study participants' self-reported experiences of the room's contribution to a sense of safety, control, integrity, adaptability, and meaningfulness.

room with an adequately powered sample size is needed to be able to guide the planning and designing of hospital birthing rooms. There is also a need of research exploring the relationship between the built environment and women's long-term childbirth experiences.

Funding

This study was supported by grants from the Swedish Research Council (reference 2018–02406). The funder had no role in the study design, data collection, analysis or interpretation of the results. Neither did the funder have any role in writing the manuscript or in the decision to submit it for publication.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to acknowledge the women and families that participated in this trial, as well as the recruiting care providers at the labour ward. We would also like to thank the study midwife Lisa Björnson Skogström, study assistant nurse Åsa Svanlund, and the study ambassadors and contact midwives Linda Rilby, Sofia Berg, Caroline Johansson and Karin Malmström for their dedicated work in participant recruiting, data acquisition, and coordinating of the complex intervention. We thank the Statistical Consult Group for providing statistical assistance, ImproveIt for collecting and coordinating the self-reported data and Initiva for assistance in the data acquisition. Also, special thanks to project manager Anneli Falk and the University Hospital for cooperation in the conducting of the trial.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.srhc.2022.100731.

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