Effect of early discharge after planned cesarean section on recovery and parental sense of security. A randomized clinical trial

Kruse, Anne Raabjerg; Lauszus, Finn Friis; Forman, Axel; Kesmodel, Ulrik Schiøler; Rugaard, Marie Bender; Knudsen, Randi Karkov; Persson, Eva-Kristina; Uldbjerg, Niels; Blaabjerg Sundtoft, Iben

Published in:
Acta Obstetricia et Gynecologica Scandinavica

DOI (link to publication from Publisher):
10.1111/aogs.14041

Creative Commons License
CC BY-NC 4.0

Publication date:
2021

Document Version
Accepted author manuscript, peer reviewed version

Link to publication from Aalborg University

Citation for published version (APA):

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.
- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain.
- You may freely distribute the URL identifying the publication in the public portal -
Effect of early discharge after planned cesarean section on recovery and parental sense of security. A randomized clinical trial

Anne Raabjerg KRUSE¹, Finn Friis LAUSZUS¹, Axel FORMAN², Ulrik Schiøler KESMODEL³,
Marie Bender RUGAARD⁴, Randi Karkov KNUDSEN⁴, Eva-Kristina PERSSON⁵, Niels ULDBJERG², Iben Blaabjerg SUNDTOFT¹

¹ Department of Obstetrics and Gynecology, Regional Hospital West Jutland, Herning, Denmark
² Department of Obstetrics and Gynecology, Aarhus University Hospital, Aarhus, Denmark
³ Department of Obstetrics and Gynecology, Aalborg University Hospital, Aalborg, Denmark
⁴ Department of Obstetrics and Gynecology, Regional Hospital Horsens, Horsens, Denmark
⁵ Department of Health Sciences, Lund University, Lund, Sweden

Corresponding author
Anne Raabjerg Kruse
Department of Obstetrics and Gynecology, Regional Hospital West Jutland, 7400 Herning, Denmark
Email: annekruse@dadlnet.dk

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/AOGS.14041

This article is protected by copyright. All rights reserved
Conflicts of interest
None

Funding
The project received funding from Brødrene Hartmanns Foundation to finance the activity monitors.
ABSTRACT

Introduction: In some European countries, discharge the day after planned cesarean section has become an accepted procedure. However, little is known about the patients’ perception of early discharge. The aim of this study was to compare early discharge to standard care in relation to parental sense of security. Further, we evaluated postoperative pain, mobilization, and readmission.

Material and methods: We performed a randomized clinical trial including parous, singleton pregnant women with a planned cesarean section at term. The women were allocated to either discharge within 28 hours (intervention group) or after 48 hours (standard care group) following the cesarean section. Women discharged within 28 hours after cesarean section were offered a home visit by a midwife the following day. The primary outcome was the postnatal sense of security, which was reported by the woman and her partner in the “Parents’ Postnatal Sense of Security” questionnaire one week postpartum. Secondary outcomes were pain score, use of analgesics, mobilization, readmission, and contacts with the health care system in the postoperative period.

Results: We included 143 women, of which 72 were allocated to the intervention group and 71 were allocated to the standard care group. There were no differences in baseline characteristics. The two groups did not differ concerning the postnatal sense of security for the women ($P = 0.98$) or the postnatal sense of security for the partners ($P = 0.38$). We found no difference in pain scores, step count, use of analgesics or in number of contacts with the health care system between the groups.

Conclusions: Parental postnatal sense of security is not compromised by discharge within 28 hours followed by a home visit compared to discharge after 48 hours after planned cesarean section among parous women.

Keywords
Enhanced Recovery After Surgery; Postnatal Care; Early Ambulation; Length of Stay; Postoperative Complications; Pain, Postoperative; Patient Preference

Abbreviations
CS cesarean section
Key Message
After planned cesarean section, early discharge within 28 hours can be performed without compromising parents’ postnatal sense of security when compared to discharge after 48 hours in parous women.
INTRODUCTION

The rate of cesarean section (CS) is rising worldwide, in Denmark e.g. from 14% (1998) to 19% (2018).\textsuperscript{1,2} CS typically implies a hospital stay for two to three days, whereas parous women are often discharged within a few hours after an uncomplicated vaginal birth.\textsuperscript{3} However, the period after CS includes recovery from surgery as well as adapting to motherhood.\textsuperscript{4} As in other surgical fields, elements of enhanced recovery have also been implemented after CS.\textsuperscript{4-9} This concept aims to optimize perioperative care by a multimodal approach such as optimal analgesia, early mobilization, and early removal of drains. Further, enhanced recovery aims to reduce the length of hospital stay (LOS), which might imply substantial health care savings.\textsuperscript{4,6,7} Some studies have shown that an introduction of enhanced recovery programs increased the number of patients being discharged the day after CS.\textsuperscript{10,11}

Some parents may appreciate early discharge, as it provides the family including older siblings an opportunity to be together in the home environment. However, it is uncertain if parental sense of security is compromised by early discharge. Regarding satisfaction, some smaller studies found it either increased or unchanged.\textsuperscript{12-14} The different findings might reflect not only differences between the enhanced recovery programs but also differences in the support offered in the form of home visits, telephone calls etc.\textsuperscript{15-17} In Denmark, the primary health care system offers postpartum period care.

The aim of this randomized clinical trial was to assess the sense of security when discharge was performed the day after planned CS in combination with a home visit by a midwife, compared to discharge after two days among parous women and their partners. Furthermore, postoperative pain, use of analgesia, mobilization, and readmission were evaluated.

MATERIAL AND METHODS

This randomized clinical trial was conducted at two Danish hospitals. The Department of Obstetrics and Gynecology at the Regional Hospital West Jutland, Denmark (site A) recruited patients from September 2016 to September 2019. The Department of Obstetrics and Gynecology
at the Regional Hospital Horsens, Denmark (site B) recruited patients from January 2018 to September 2019.

The women were enrolled at the outpatient clinics when the decision of planned CS was made. Exclusion criteria were nulliparity, multiple pregnancy, gestational age < 37 + 0 based on early ultrasound scan, planned prolonged postoperative observation, pre-pregnancy body mass index $\geq 35$ kg/m$^2$, maternal age < 18 years, living alone, or inability to read and write Danish.

Approximately two weeks before CS, these low risk women were randomly assigned to either discharge $\leq 28$ hours (intervention group) or $> 48$ hours after CS (standard care group). With a time limit of 28 hours in the intervention group, discharge before noon the following day could be planned.$^{10,11}$ The women in the intervention group were offered a home visit by a midwife 48 to 72 hours after delivery. At the home visit standard postnatal examinations including neonatal weight control, hearing test and dried blood spot screening for congenital conditions were conducted. Women in the intervention group were not offered a home visit by the midwife if discharge took place after two nights. In these cases, postnatal examinations were performed at the ward. In the standard care group, the time limit of 48 hours was chosen to allow for postnatal examinations before discharge. Women in the standard care group were not offered a home visit by the midwife, but equivalent postnatal examinations were conducted, as recommended 48 to 72 hours after delivery, at the ward. Discharge criteria included no symptoms of postpartum complications, sufficient mobilization and analgesia, normal voiding function, and successfully initiated breastfeeding if anticipated. The women received the same pre- and peroperative care following the principals of enhanced recovery (Supporting Information Table S1).

To measure the parental perception of postnatal care, we used the questionnaire Parents’ Postnatal Sense of Security (PPSS).$^{18-20}$ The questionnaire was developed for use following both vaginal and cesarean delivery one week postpartum. The women filled in the PPSS containing 18 questions answered on a four-point Likert scale (total score 18–72, Cronbach’s alpha 0.88). The partners answered 13 questions (total score 13–52, Cronbach’s alpha 0.77). The highest score represented the highest possible sense of security.

Secondary outcomes were pain scores, use of analgesia, mobilization, complications, readmission, and number of contacts with the health care system. Pain score was measured on a numeric rating.
scale (NRS) from 0 to 10, with 10 representing the highest possible pain. Each woman reported her pain score on a daily basis during the first week. Data was categorized as NRS < 3 and NRS ≥ 3 each day. The woman reported her use of analgesia during the first week. These self-reported measurements were registered in a diary, which the woman returned by mail 28 days after CS. Mobilization was measured as the number of daily steps using a Fitbit Flex wristband (Fitbit Inc, San Francisco, USA). Measurements were performed preoperatively during one day approximately two weeks prior to CS and postoperatively day 1 to 4. Postoperative complications as well as neonatal and maternal readmission within 28 days were registered. Contacts with the health care system within 28 days concerning either the woman or the neonate were reported in the diary by the woman. This included contacts with the general practitioner, the local child health care nurse, and other hospital departments, as well as phone calls, home visits and outpatient visits. The home visit provided as part of the intervention was not included.

Sample size was calculated based on the PPSS score. However, previous studies of the PPSS score for women solely after CS were unavailable. A clinically relevant difference of 3 on the PPSS scale was chosen, and a standard deviation of 6 was used. To detect such a difference with a power of 80% and a 5% significance level, 64 women in each group were required. Allowing for a 10% drop-out, a total estimated sample of 142 patients was needed.

Randomization was conducted using a computerized random number generator (www.randomization.com). The randomization was generated in a 1:1 ratio in blocks of two and four and stratified according to site and body mass index < 30 or ≥ 30 kg/m². Envelopes were sealed individually and opened by the woman when written consent was obtained.

Statistical analyses
Analyses were performed using STATA16 (College Stations, TX, USA). Data was analyzed based on the intention-to-treat principle. Subsequently, per-protocol analyses were performed. Women were included in the per-protocol analysis if, on the day of CS prior to surgery, discharge was intended ≤ 28 hours or > 48 hours, respectively. Hence, women with vaginal delivery or emergency CS were not included in the per-protocol analysis. The total PPSS score was presented as mean values with standard deviations (SD) and compared using Student’s t-test. Normality was assessed by the use of QQ plots and histograms. For our primary outcome PPSS, we found a
substantial proportion of missing values; therefore, we performed an additional analysis adjusting for gestational age in order to account for potential bias induced by non-random distribution of missing data. To further explore if any confounding could arise from non-random drop-out, we performed sensitivity analyses further adjusting the analyses of PPSS, NRS and step count for maternal age, parity and educational level. Categorized outcomes were presented as proportions and tested with Chi-square or Fisher’s exact test as appropriate. Steps were presented as mean values and analyzed using repeated measurements mixed model. LOS was presented as medians and compared using the Wilcoxon rank-sum test. Subgroup analysis of responders and non-responders was performed. A two-sided p-value of 5% was chosen as level of significance.

**Ethical approval**

Approval was obtained from the Danish Data Protection agency (1-16-02-513-15, 2 October 2015) and the Central Denmark Region Ethics Committee (1-10-72-195-15, 21 October 2015). The study was registered at clinicaltrials.gov (NCT02911727, 2 September 2016).

**RESULTS**

A total of 328 women with singleton pregnancies undergoing a planned CS were assessed for eligibility. Of these, 185 women were not included due to either exclusion criteria (n = 62) or declination of participation (n = 123). Reasons for declining participation included unwillingness to be discharged ≤ 28 hours (n = 43; 35%), to be hospitalized > 48 hours (n = 22; 18%) or unspecified reasons (n = 58; 47%). Five women accepted participation, but were not included due to spontaneous onset of labor leading to emergency CS or diagnosed complication in the pregnancy before randomization. A total of 143 women were randomized with 72 women allocated to the intervention group and 71 women to the standard care group. Thus, 143 women were included for intention-to-treat analysis. Self-reported outcomes were missing in 19 cases in each allocated group, corresponding to a response rate of 73% (Figure 1).

Baseline characteristics showed no differences between the intervention and the standard care group, except for difference in gestational age at delivery of approximately two days in the intention-to-treat analysis (P = 0.0034). Previous CS was the primary indication for CS for the majority of women (74%, Table 1).
Among the 72 women in the intervention group, 48 (67%) were discharged ≤ 28 hours. In the standard care group, 67 out of 71 women (94%) were discharged > 48 hours. The median LOS was 27 hours (interquartile range 26–34 hours) in the intervention group and 51 hours (interquartile range 50–53 hours) in the standard care group. A total of eight women delivered either vaginally or by emergency CS with no significant differences in distribution between the groups. The groups were comparable regarding operation time, peroperative blood loss, child birth weight and readmissions (Table 2).

We found similar PPSS scores one week after CS in the allocated groups (difference 0.03, 95% confidence interval (CI) -2.4 to 2.3; \( P = 0.98 \)). The mean PPSS for the women was 61.6 (SD 5.8) in the standard care group and 61.6 (SD 6.7) in the intervention group. For the partners, the mean PPSS were 43.3 (SD 5.9) and 44.3 (SD 4.7; \( P = 0.38 \)), respectively. After post hoc analysis of associations between basic characteristics and PPSS, we included gestational age in the adjustment. The adjusted difference in mean PPSS for the women was -0.7 (95% CI -3.1 to 1.6; \( P = 0.53 \)) in favor of the standard care group. Further, adjusting mean PPSS for the women for maternal age, parity and educational level did not change the conclusion (difference 0.3, 95% CI -2.2 to 2.7; \( P = 0.83 \)). A median of three contacts with the health care system (excluding the offered home visit) was reported in both the intervention and the standard care group (range 0–10 and 0–9, respectively, Table 2).

In the per-protocol analysis, 131 women were included. In the intervention group, seven women were excluded from the per-protocol analysis due to emergency CS, vaginal delivery or preoperative decision of observation for 48 hours postoperatively. In the standard care group, five women were excluded due to emergency CS or unwillingness to be hospitalized for 48 hours. Comparable results were found in the per-protocol analysis (Table 1, Table 2).

Self-reported measurements including PPSS score, pain scores, and information on use of analgesics, were missing for 19 women in each allocated group. Overall, we observed significant differences between responders and non-responders in gestational age, proportion of emergency CS, operation time, child birth weight, and admission to neonatal intensive care unit. Further, LOS
was increased among non-responders in the intervention group (Table 3). However, replacing missing PPSS values with the 10th percentile in the intervention group and the median in the standard care group, no significant difference in PPSS score was observed between the allocated groups for neither the women \((P = 0.10)\) nor the partners \((P = 0.49)\).

In the intervention group, the response rate among women discharged > 28 hours was lower compared to women discharged \(\leq 28\) hours \((63\% \text{ vs. } 87\%, P < 0.042, \text{Table 4})\). However, among the responders in the intervention group we found no difference in mean PPSS score for either the women \((P = 0.64)\) or the partners \((P = 0.98)\) when comparing discharge within or after 28 hours.

A complete dataset for step count was available for 83 women \((58\%)\), partly for 29 women \((20\%)\), and missing completely for 31 women \((22\%)\) with no difference between the groups. Analysis of all available step measurements showed a significant increase in mean step count from 1478 steps \((\text{range 151 to 4904})\) on the day after CS to 4935 steps \((\text{range 544 to 17 198, } P < 0.001, \text{Wilcoxon rank-sum test})\) on day 4. In both the intervention and the standard care groups, the mean step count increased from day 1 to day 4. This increase, however, was significantly higher in the standard care group \((P = 0.031 \text{ repeated measurement analysis, Figure 2})\), but not when adjusting for gestational age, maternal age, parity and educational level \((P = 0.35)\).

Mean pain score (NRS) the day after CS was 5.5 (SD 1.9) in the standard care group and 4.6 (SD 1.7) in the intervention groups \((P = 0.01)\); however, repeated measurements did not show a significant difference in the development in pain score day 1-7 \((P = 0.22)\). Adjusting NRS for gestational age, maternal age, parity and educational level did not change the conclusion \((P = 0.22)\). Further, we observed no significant differences in either the proportion of women with pain score \((\text{NRS}) \geq 3\) or the use of weak analgesics or opioids during day 1 to 7 \((\text{Figure 3, Supporting Information Table S2})\).

**DISCUSSION**

Among 143 low-risk parous women allocated to either early or standard discharge after planned CS, no difference was found in the parents’ postnatal sense of security for either the woman or her partner. Adjustment did not change this finding. Furthermore, pain score, the use of analgesics,
step count, and number of contacts with the health care system revealed no significant differences between the groups.

The randomized design added to the strengths of this study as well as the detailed description of the postoperative period. Further, the postnatal sense of security was assessed among both the women and their partners. We obtained a response rate of 73% in both groups. This is in accordance with postpartum response rates reported in other randomized clinical trials.\textsuperscript{22,23} However, non-responders differed concerning LOS indicating more maternal and neonatal challenges in this group (Table 3). Additionally, pain was one of the reasons for prolonged LOS in the intervention group (Table 4). Nevertheless, sensitivity analysis revealed no difference in PPSS between the two allocated groups by replacing missing PPSS values, according to an assumption of women in the intervention group feeling less secure. Also, a relatively large proportion of step counts were missing, mostly due to technical problems in case of delayed return of the device.

As the power calculation was based on a superiority design, one could argue that we should not draw a non-inferiority conclusion, i.e. that postnatal sense of security was not compromised by early discharge. However, the actual PPSS values were 61.6 (SD 6.7) for the intervention group and 61.6 (SD 5.8) for the standard care group with a difference of 0.03 (95% CI -2.4 to 2.3). As we predefined a value of ± 3 as the minimal, clinically important difference in PPSS, we still find it reasonable to conclude that early discharge is non-inferior to standard care.

Internal validity might be compromised by the low participation rate. An estimate of 620 parous women underwent planned CS at the two sites in the period. It is uncertain to what extent they fulfilled the inclusion criteria, as only 328 were assessed for eligibility. Due to Danish legislation, we could not obtain data on non-participants. However, the results obtained from women recruited at the two hospitals were comparable. Concerning the external validity, one must remember that we included parous women only, which may contribute to the relatively high PPSS scores.\textsuperscript{20} The reason why nulliparous women were not included, is an offer of longer LOS for these women in order to establish breastfeeding. It is also important to take into account that the intervention group was offered not only the routine postnatal care by local health care nurses and general practitioners but also a home visit by a midwife 48 to 72 hours after CS, which was highly valued in accordance with prior studies.\textsuperscript{16,17,24} If the study had been conducted in a setting with another postnatal care
routine, the result might have been different. Furthermore, culture and traditions may be of importance. Thus, the American College of Obstetricians and Gynecologists defines early discharge as discharge within 96 hours after CS\textsuperscript{25} and further, an average LOS after CS ranged from 2.5 days to 9.3 days across 30 different countries.\textsuperscript{26} Other studies reported substantial reductions in LOS after CS during the last decades.\textsuperscript{27,28} However, discharge the day after planned CS is a rather advanced approach, yet possible among selected groups of women provided an efficient follow up.

**CONCLUSION**

Discharge within 28 hours followed by a home visit, in comparison with discharge after 48 hours, can be performed after planned CS in parous women without compromising the parents’ postnatal sense of security.

**References**


14. Tan PC, Norazilah MJ, Omar SZ. Hospital discharge on the first compared with the second day after a planned cesarean delivery: a randomized controlled trial. Obstet Gynecol. 2012;120:1273-82.


Legends

Figure 1. Flow chart of the population.

Figure 2. Mobilization measured by mean daily step count (with 95% CI) day 1 to 4 after cesarean section. CS, cesarean section.

Figure 3. Mean pain score and analgesics in the intervention and standard care group. NRS, numeric rating scale; CS, cesarean section.

Table 1. Basic characteristics of the study population.

This article is protected by copyright. All rights reserved
Table 2. Peri- and postoperative variables in the study population.

PPSS, Parents’ postnatal sense of security.

Table 3. Analysis of responders and non-responders in the intervention group and the standard care group.

Table 4. Reasons for discharge > 28 hours after planned CS among women receiving the intervention.

LOS, length of hospital stay; PPSS, Parents’ postnatal sense of security.

**Supporting Information legends**

Table S1. Description of the perioperative care provided to all women undergoing planned cesarean section.

Table S2. Outcomes in the study population.
Table 1. Basic characteristics of the study population.

<table>
<thead>
<tr>
<th></th>
<th>Intention-to-treat analysis</th>
<th>Per-protocol analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention group (n = 72)</td>
<td>Standard care group (n = 71)</td>
</tr>
<tr>
<td>Maternal age, years, mean (SD)</td>
<td>33.4 (4.5)</td>
<td>32.5 (4.6)</td>
</tr>
<tr>
<td>Numbers of CS before index, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>18 (25)</td>
<td>12 (17)</td>
</tr>
<tr>
<td>1</td>
<td>26 (36)</td>
<td>41 (58)</td>
</tr>
<tr>
<td>≥2</td>
<td>28 (38)</td>
<td>18 (25)</td>
</tr>
<tr>
<td>Indication for CS, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous CS</td>
<td>50 (69.4)</td>
<td>56 (78.9)</td>
</tr>
<tr>
<td>Breech position</td>
<td>8 (11.1)</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Maternal request</td>
<td>4 (5.6)</td>
<td>4 (5.6)</td>
</tr>
<tr>
<td>Othera</td>
<td>10 (13.9)</td>
<td>7 (9.9)</td>
</tr>
<tr>
<td>Gestational age, weeks, mean (SD)</td>
<td>38.7 (0.54)</td>
<td>38.9 (0.48)</td>
</tr>
<tr>
<td>Pre-pregnancy BMI, kg/m², mean (SD)</td>
<td>25.8 (4.0)</td>
<td>25.6 (4.3)</td>
</tr>
<tr>
<td>Smoking during pregnancy, n (%)</td>
<td>8 (11)</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Daily step count prior to CS, mean (range) b</td>
<td>8023 (1837 – 17 791)</td>
<td>7429 (1518 – 15 776)</td>
</tr>
<tr>
<td>Site, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site A</td>
<td>61 (85)</td>
<td>62 (87)</td>
</tr>
<tr>
<td>Site B</td>
<td>11 (15)</td>
<td>9 (13)</td>
</tr>
</tbody>
</table>

* Included previous anal sphincter injury, placenta previa, internal cerclage and inflammatory bowel disease with complications.

* Missing in the intervention group: ITT analysis n = 9, PP analysis n = 6.
Missing in the standard care group: ITT analysis n = 3, PP analysis n = 2.
Table 2. Peri- and postoperative variables in the study population.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intention-to-treat analysis</th>
<th>Per-protocol analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention group (n = 72)</td>
<td>Standard care group (n = 71)</td>
</tr>
<tr>
<td>Operation time, min., mean (SD)</td>
<td>38 (12)</td>
<td>36 (10)</td>
</tr>
<tr>
<td>Peroperative blood loss, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 500 mL.</td>
<td>40 (57)</td>
<td>47 (66)</td>
</tr>
<tr>
<td>≥ 500 mL.</td>
<td>30 (43)</td>
<td>24 (34)</td>
</tr>
<tr>
<td>Child birth weight, g, mean (SD)</td>
<td>3516 (384)</td>
<td>3591 (416)</td>
</tr>
<tr>
<td>Admission to NICU, n (%)</td>
<td>8 (11.1)</td>
<td>6 (8.5)</td>
</tr>
<tr>
<td>Length of hospital stay, median, hours (range)</td>
<td>27 (4–337)</td>
<td>51 (24–78)</td>
</tr>
<tr>
<td>Postoperative complication, n (%)</td>
<td>9 (13)</td>
<td>8 (11)</td>
</tr>
<tr>
<td>Readmissions, n (%)</td>
<td>11 (15)</td>
<td>10 (14)</td>
</tr>
<tr>
<td>Maternal complications</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Neonatal complications</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>PPSS participant, mean (SD)</td>
<td>61.6 (6.7)</td>
<td>61.6 (5.8)</td>
</tr>
<tr>
<td>PPSS partner, mean (SD)</td>
<td>44.3 (4.7)</td>
<td>43.4 (5.9)</td>
</tr>
<tr>
<td>Contacts with the health care system within 28 days, median, n (range)</td>
<td>3 (0–10)</td>
<td>3 (0–9)</td>
</tr>
</tbody>
</table>

* Missing in the intervention group: ITT analysis n = 2, PP analysis n = 1.
* Missing in the intervention group: ITT analysis n = 2.
* Neonatal admission to NICU (neonatal intensive care unit) within primary admission.
* Readmission due to maternal complications included bleeding, wound infection, mastitis, spinal headache and appendicitis.
* Readmission due to neonatal complications included jaundice, tachypnoea, weight loss and infection.
* Missing in the intervention group: ITT analysis women/partners n = 19/19, PP analysis women/partners n = 13/13.
* Missing in the standard care group: ITT analysis women/partners n = 19/21, PP analysis women/partners n = 16/18.
* Missing in the standard care group: ITT analysis n = 19, PP analysis n = 16.
* Missing in the intervention group: ITT analysis n = 18, PP analysis n = 12.
* Missing in the standard care group: ITT analysis n = 19, PP analysis n = 16.
Table 3. Analysis of responders and non-responders in the intervention group and the standard care group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n = 72)</th>
<th>Standard care group (n = 71)</th>
<th>P-value</th>
<th>Intervention group (n = 72)</th>
<th>Standard care group (n = 71)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Responders (n = 53)</td>
<td>Non-responders (n = 19)</td>
<td></td>
<td>Responders (n = 52)</td>
<td>Non-responders (n = 19)</td>
<td></td>
</tr>
<tr>
<td>Maternal age, years, mean (SD)</td>
<td>33.5 (4.5)</td>
<td>33.2 (4.6)</td>
<td>0.84</td>
<td>32.7 (4.8)</td>
<td>31.9 (4.1)</td>
<td>0.57</td>
</tr>
<tr>
<td>Numbers of CS before index, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>14 (26.4)</td>
<td>4 (21.1)</td>
<td>0.84</td>
<td>10 (19.2)</td>
<td>2 (10.5)</td>
<td>0.66</td>
</tr>
<tr>
<td>1</td>
<td>18 (34.0)</td>
<td>8 (42.1)</td>
<td></td>
<td>30 (57.7)</td>
<td>11 (57.9)</td>
<td></td>
</tr>
<tr>
<td>≥2</td>
<td>21 (39.6)</td>
<td>7 (36.8)</td>
<td></td>
<td>12 (23.1)</td>
<td>6 (31.6)</td>
<td></td>
</tr>
<tr>
<td>Gestational age, weeks, mean (SD)</td>
<td>38.8 (0.46)</td>
<td>38.4 (0.67)</td>
<td>0.028</td>
<td>39.0 (0.53)</td>
<td>38.9 (0.28)</td>
<td>0.43</td>
</tr>
<tr>
<td>Pre-pregnancy BMI, kg/m², mean (SD)</td>
<td>25.5 (3.8)</td>
<td>26.6 (4.4)</td>
<td>0.31</td>
<td>25.3 (4.0)</td>
<td>26.4 (5.1)</td>
<td>0.37</td>
</tr>
<tr>
<td>Daily step count prior to CS, mean (SD)</td>
<td>8255 (3665)</td>
<td>7280 (3003)</td>
<td>0.35</td>
<td>7236 (2752)</td>
<td>7967 (3308)</td>
<td>0.36</td>
</tr>
<tr>
<td>Operation time, min, mean (SD)</td>
<td>37 (11.5)</td>
<td>42 (14.3)</td>
<td>0.14</td>
<td>34 (10.1)</td>
<td>39 (7.2)</td>
<td>0.064</td>
</tr>
<tr>
<td>Peroperative blood loss, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 500 mL</td>
<td>31 (58.5)</td>
<td>9 (52.9)</td>
<td>0.69</td>
<td>34 (65.4)</td>
<td>13 (68.4)</td>
<td>0.81</td>
</tr>
<tr>
<td>≥ 500 mL</td>
<td>22 (41.5)</td>
<td>8 (47.1)</td>
<td></td>
<td>18 (34.6)</td>
<td>6 (31.6)</td>
<td></td>
</tr>
<tr>
<td>Child birth weight, g, mean (SD)</td>
<td>3569 (365)</td>
<td>3367 (405)</td>
<td>0.048</td>
<td>3623 (433)</td>
<td>3500 (359)</td>
<td>0.27</td>
</tr>
<tr>
<td>Length of hospital stay, median, hours (range)</td>
<td>27 (9–78)</td>
<td>37.8 (4–337)</td>
<td>0.027</td>
<td>51 (26–76)</td>
<td>50 (24–78)</td>
<td>0.051</td>
</tr>
</tbody>
</table>

*a* Missing in the intervention group: responders n = 5, non-responders n = 4. In the standard care group: responders n = 2, non-responder n = 1.

*b* Missing in the intervention group: non-responders n = 2.

*c* Missing in the intervention group: non-responders n = 2.
Table 4. Reasons for discharge > 28 hours after planned CS among women receiving the intervention.

<table>
<thead>
<tr>
<th>Reason for postponed discharge</th>
<th>No.</th>
<th>LOS, hours (range)</th>
<th>Response rate (%)</th>
<th>PPSS woman mean (SD)</th>
<th>PPSS partner mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical or unspecified reason</td>
<td>6</td>
<td>29–31</td>
<td>83</td>
<td>64.8 (3.5)</td>
<td>42.6 (1.3)</td>
</tr>
<tr>
<td>Pain requiring prolonged LOS</td>
<td>8</td>
<td>49–74</td>
<td>38</td>
<td>60 (4.4)</td>
<td>45.3 (4.2)</td>
</tr>
<tr>
<td>Other*</td>
<td>5</td>
<td>51–337</td>
<td>80</td>
<td>61.3 (4.9)</td>
<td>45.8 (0.5)</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>29–337</td>
<td>63</td>
<td>62.4 (4.4)</td>
<td>44.3 (2.5)</td>
</tr>
</tbody>
</table>

*Includes problems with breastfeeding and postoperative complications.
Figure 1. Flow chart of the population.

Enrollment

Assessed for eligibility (n = 328)

Excluded (n = 185)
  - Not meeting inclusion criteria (n = 62)
  - Declined to participate (n = 123)

Randomized (n = 143)

Allocation

Allocated to intervention (n = 72)
  - Received allocated intervention (n = 65)
  - Did not receive allocated intervention (n = 7)*

Allocated to standard care (n = 71)
  - Received allocated intervention (n = 66)
  - Did not receive allocated intervention (n = 5)**

Follow-Up

Lost to follow-up (n = 0)
Answered questionnaire (n = 53)

Lost to follow-up (n = 0)
Answered questionnaire (n = 52)

Analysis

Included in intention-to-treat analysis (n = 72)
Included in per-protocol analysis (n = 65)

Included in intention-to-treat analysis (n = 71)
Included in per-protocol analysis (n = 66)

*due to emergency CS, vaginal delivery or pre-operative decision of 48h postoperative observation
**due to emergency CS or unwillingness to 48h hospitalization
This article is protected by copyright. All rights reserved