Improving management of breech presentation at term

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Implementation of client versus care provider strategies to improve external cephalic version rate: a cluster randomised controlled trial

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Submitted
ABSTRACT

Objective To determine the effectiveness of a client or care provider strategy to improve the implementation of external cephalic version.

Design Cluster randomized controlled trial.

Setting 25 clusters; hospitals and its referring midwifery practices randomly selected in the Netherlands.

Population Singleton breech presentation from 32 weeks gestation onwards.

Methods We randomized clusters to a client strategy (written information leaflets and decision aid), a care provider strategy (one day counselling course focused on knowledge and counselling skills), a combined client- and care provider strategy and care as usual strategy. We performed an intention to treat analysis.

Main outcome measures Rate of external cephalic version in various strategies. Secondary outcomes were the percentage of women counselled and opting for a version attempt. Results. The overall implementation rate of external cephalic version was 72% (1,169 of 1,613 eligible clients) with a range between clusters of 8-95%. Neither the client (OR 0.78 (95% CI 0.41-1.5)) nor the care provider strategy (OR 1.2 (95% CI 0.64-2.3)) showed significant improvements. Results were comparable when we limited the analysis to those women that actually were offered intervention (OR 0.64 (95% CI 0.30-1.4) and (OR 2.0 (95%CI 0.72-4.5)).

Conclusions Neither a client- nor a care provider strategy improved the external cephalic version implementation rate for breech presentation, either on the number of version attempts offered or on the number of women accepting the procedure.
INTRODUCTION

Breech presentation occurs in 3 to 4% of all term pregnancies.¹ The majority of term breech presentation is managed by elective cesarean section, since vaginal breech delivery is associated with significant increased neonatal morbidity and mortality.²⁻⁴ Planned cesarean section rates for breech presentation vary from 60% in the Netherlands up to 90% in the UK and 96% in Australia.⁴⁻⁶ Increased maternal and neonatal morbidity and mortality due to these cesarean sections in subsequent pregnancies, is of concern.⁷⁻¹⁰ External cephalic version (ECV) is an effective and safe treatment to prevent breech presentation at birth, and is recommended in professional guidelines.¹¹⁻¹⁵ One of the main challenges with the introduction of guidelines is that clinicians do not automatically adopt and apply guidelines as intended by the developers.¹⁶⁻¹⁹ This applies also to ECV; the number of breech presentations at birth in the Netherlands has remained stable around 4%.²⁰ Furthermore, an inventory survey among all hospitals in the Netherlands in 2007 reported that 5% of the gynaecologic practices did not perform ECV at all.²¹ In the UK and Australia the number of eligible women who were not offered an ECV attempt ranged from 4% to 33%.²²⁻²⁴ An Australian preference study showed that 39% of women did not choose ECV and a similar study in Israel reported a decrease in women willing to undergo ECV from 54% to 24%.²⁵,²⁶ Based on the figures from above mentioned studies (provided rates of women counselled and opting for ECV), we estimated the implementation rate of ECV to be 50-60%,²⁷ which we consider low and important to improve. Several models have been proposed that describe similar sequences for the systematic planning of guidelines in general terms.¹⁸,²⁸⁻³⁰ First, an analysis of determinants (impeding and enhancing factors) should be performed. A detailed understanding of these determinants is needed to guide the process of designing implementation strategies that will have the potential to produce real change.²⁸,³⁰,³¹ We previously performed a determinant analysis showing that lack of knowledge to counsel clients on ECV, is an important barrier mentioned by care providers. Lack of (well-timed) information, fear of pain or harm to the fetus, the preference to have a planned cesarean section, and negative experiences from relatives are important barriers mentioned by clients.³²,³³ On the basis of these determinants we designed two implementation strategies: a client - and a care provider strategy. We evaluated the effects of these strategies on the actual number of women receiving an ECV attempt.
MATERIAL AND METHODS

In the Netherlands prenatal care is supervised by midwives in primary care, and by obstetricians in secondary care. Midwives take care of low risk pregnancies. If specialized care is needed, midwives refer to an obstetrician in an affiliated hospital. We will refer to this stratified care model as ‘cluster’, meaning a hospital including all surrounding midwifery practices.

We performed a prospective, open-label, cluster randomized clinical trial. Randomization was performed on clusters level in blocks of 12, in a two-by-two factorial design. Clusters were randomized to a client strategy, a care provider strategy, both implementation strategies, or care as usual. We stratified for clusters with or without ECV office hours as we hypothesized that clusters with an organized office hour might have a better baseline implementation of ECV. An ECV office hour was defined as special reserved time for counselling and ECV attempts during the week, with a select group of experienced care providers who perform ECV attempts either in the hospitals or midwifery practices. Clusters all over the Netherlands were randomly selected and invited to participate in this study, until at least 24 clusters had given approval. The allocation sequence was generated by the clinical research unit of the Academic Medical Center. At the moment a cluster agreed to participate, it was randomized and the implementation of the allocated strategy was planned. Researchers and care providers were not blinded for allocated strategies, but participating clients were kept unaware of the different implementation strategies.

Consecutive women with a singleton breech presentation from 32 weeks onwards between January 2011 and August 2012 were eligible for the study. Exclusion criteria were contraindications for ECV according to the national guideline (uterus anomaly, fetal growth restriction, hypertensive disorder, oligohydramnios, (P)PROM), any contraindication for a vaginal delivery and a spontaneous version after 32 weeks.\textsuperscript{14,15}

Calculation of study size was based on the ability to detect a 30% difference in proportion of women undergoing ECV (from 50 to 80%). To detect this difference with a two sided significance level ($\alpha$) of 0.05, a power (1-$\beta$) of 0.80, adjusting for an intra-cluster correlation (ICC) of 0.10, and taking a dropout rate of individual clients of 15% into account, the calculated sample size was 35 clients per cluster and 6 clusters per strategy. Evidence for an appropriate assumption of the ICC for this trial is limited. As clusters encompass both hospitals and midwifery practices, the ICC was assumed to lie somewhere in between the ICCs for studies clustered by hospitals and those clustered by
general practitioners. Based on the incidence of breech presentation and the size of the smaller clusters, we calculated that a nine month inclusion period would be appropriate to include at least 35 clients.

**Interventions**

Based upon a previously performed determinant analysis we developed two implementation strategies to improve the implementation of ECV: a client strategy and a care provider strategy. All clients received standard care. In addition, clusters were subjected to one or both of the implementation strategies.

In clusters allocated to the client strategy women with a fetus in breech presentation after 32 weeks received a leaflet explaining advantages, benefits and risks of ECV and a decision aid to assist them in clarifying personal values and in choosing the treatment which suited their personal values. The leaflet encouraged clients to involve family and significant others in their deliberation, and to discuss all uncertainties with their care providers. The decision aid was originally developed by an Australian research group of Nassar et al., and translated into Dutch. Minor adjustments were made to the leaflet and decision aid after pilot testing the comprehensibility among women with a breech presentation and care providers (n=6). During a kick-off meeting, all participating care providers received the information leaflet and decision aid as well as a short user instruction. They were asked to hand out the leaflet and decision aid to all women with a breech presentation from 32 weeks onwards.

In clusters allocated to the care provider strategy, care providers were invited for a one day counselling course. Participants were informed on the guidelines and relevant literature emphasizing the importance, benefits and risks of ECV. Furthermore, participants were trained in counselling and guiding clients in informed decision making by a counselling coach. After this course, client recruitment was started.

**Data collection, outcome measures and statistical analysis**

Data were prospectively documented in study-files. All clients were handed a study-file at the moment breech was diagnosed from 32 weeks onwards, and were requested to bring their file to all subsequent appointments, until ten days after delivery. Care providers were asked to document all provided care in the study-file, including reasons not to offer ECV, items mentioned during counselling, ECV outcomes and birth outcome. Study-files also included
client-administered questionnaires on provided care, in order to assess if the implemented strategy was provided to the client. Care providers within the four strategies received regular feedback on the number of participants, to remind them to work according to the allocated strategy. Apart from the study files, all eligible clients were identified by checking ECV attempt registers and birth registers for breech birth. For women who had not received a study-file, data were retrospectively extracted from the hospital charts.

The primary outcome of the study was the ECV implementation rate, defined as the number of women who underwent a version attempt as percentage of all women with a breech presentation from 36 weeks gestation eligible for external cephalic version. Secondary outcomes were the percentage of women counselled and opting for a version attempt. Success of ECV was defined as a fetus being in cephalic presentation 30 minutes after the procedure. Outcome measures pertain to the cluster level. Firstly, we calculated the proportion of women who were offered an ECV, who opted for ECV and who actually underwent ECV. Subsequently, we used a logistic regression accounting for clustering of observations (generalized estimating equations, or GEE) to analyze the effect of the interventions on these outcomes. This resulted in an Odds ratio, expressing the probability that a client would receive an ECV within a cluster allocated to the implementation strategy, relative to those clusters not exposed to the strategy. An interaction term was included in the model to assess whether the combination of the client and provider strategy results in an additional increased (or decreased) effect. All analyses were performed according to intention-to-treat analyses: clusters were analyzed in the trial arm they were randomized to, regardless of compliance to the implementation strategy; and clients were included regardless of whether or not they were exposed to the implementation strategy (leaflet and decision aid or trained care provider). We set the level of significance at p<0.05. A descriptive analysis was carried out on data from the study files documenting the process of care, and client questionnaires in order to identify whether the implementation strategy was carried out as planned. In a per-protocol analysis, analyses were repeated in the subgroup of women who were actually subjected to the implementation strategy.
RESULTS
We invited 40 clusters to participate in the study, of which 26 clusters agreed and were randomized. One cluster randomized to combined client and care provider strategy withdrew before implementation of the strategy because of anticipated lack of time to participate. The remaining 25 clusters consisted of 12 teaching hospitals, 10 general hospitals, and three tertiary hospitals with a total of 179 midwifery practices. The size of the clusters ranged from 6,650 to 11,100 births per year (Table 1). Twelve clusters (48%) had a special ECV office hour at time of randomization. Clusters were randomized in the period January 2011 to December 2011. The follow up of clusters after implementation of the strategies was closed at August 31st 2012. In total 1,793 women with a singleton fetus in breech presentation from 32 weeks onwards or unexpected breech presentation at birth were included, with a range of 13 to 159 per cluster. Of these women, 180 (10%) had an apparent reason to not undergo had ECV: 72 (4.0%) had an absolute contraindication for ECV according to the Dutch guidelines, 46 (2.6%) had an indication for a planned cesarean section, and in 62 (3.5%) of women breech presentation was not diagnosed until onset of labor (Figure 1). Thus 1,613 women were eligible for ECV. The mean age was 31 years (range 15 – 45) (Table 1). The percentage of nulliparous women ranged from 53 to 64% between the four strategies (Table 1).
Figure 1. Flow chart

Clusters eligible for inclusion (N = 40)

Not participating in RCT (N = 14 regions)
- ECV is optimal implemented according to care providers (n=5)
- No time to participate in cluster RCT (n=9)

Randomised (N=26)

care as usual
N = 7 clusters

N = 417
Patients with breech presentation

Not eligible (N=32):
- Absolute CI for ECV (N=13)
  - Uterine anomaly
  - Fetal growth restriction
  - Hypertension
  - Oligohydramnios
  - (P)PROM
- Indication for primary CS (N=10)
  - > 1 previous SC
  - CI vaginal birth
  - Placenta praevia
  - Breech not diagnosed until birth (N=9)

Study population: N= 385

client strategy
N = 7 clusters

N = 647
Patients with breech presentation

Not eligible (N=85):
- Absolute CI for ECV (N=32)
  - Uterine anomaly
  - Fetal growth restriction
  - Hypertension
  - Oligohydramnios
  - (P)PROM
- Indication for primary CS (N=22)
  - > 1 previous SC
  - CI vaginal birth
  - Placenta praevia
  - Breech not diagnosed until birth (N=31)

Study population: N= 562

care provider strategy
N = 6 clusters

N = 395
Patients with breech presentation

Not eligible (N=19):
- Absolute CI for ECV (N=8)
  - Uterine anomaly
  - Fetal growth restriction
  - Hypertension
  - Oligohydramnios
  - (P)PROM
- Indication for primary CS (N=6)
  - > 1 previous SC
  - CI vaginal birth
  - Placenta praevia
  - Breech not diagnosed until birth (N=5)

Study population: N= 376

client and care provider strategy
N = 6 clusters

N = 334
Patients with breech presentation

Withdraw before training and provided no data (n=1)

Not eligible (N=44):
- Absolute CI for ECV (N=19)
  - Uterine anomaly
  - Fetal growth restriction
  - Hypertension
  - Oligohydramnios
  - (P)PROM
- Indication for primary CS (N=8)
  - > 1 previous SC
  - CI vaginal birth
  - Placenta praevia
  - Breech not diagnosed until birth (N=17)

Study population: N= 290

Study population:
N = 385

Not eligible (N=32):
- Absolute CI for ECV (N=13)
  - Uterine anomaly
  - Fetal growth restriction
  - Hypertension
  - Oligohydramnios
  - (P)PROM
- Indication for primary CS (N=10)
  - > 1 previous SC
  - CI vaginal birth
  - Placenta praevia
  - Breech not diagnosed until birth (N=9)

Study population: N= 385
<table>
<thead>
<tr>
<th>Cluster characteristics</th>
<th>Care as usual</th>
<th>Client strategy</th>
<th>Care provider strategy</th>
<th>Client + care provider strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of clusters</td>
<td>7</td>
<td>7</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>No. of clusters with special ECV office hours</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>No. of practices (hospital and midwifery)(range)</td>
<td>69 (4-8)</td>
<td>40 (4-13)</td>
<td>46 (3-6)</td>
<td>49 (3-9)</td>
</tr>
<tr>
<td>No. care providers per cluster</td>
<td>32 (4-8)</td>
<td>41 (3-8)</td>
<td>20 (3-6)</td>
<td>29 (4-10)</td>
</tr>
<tr>
<td>Gynaecologists (range)</td>
<td>58 (5-12)</td>
<td>41 (4-8)</td>
<td>20 (0-9)</td>
<td>29 (2-17)</td>
</tr>
<tr>
<td>Midwives within hospital (range)</td>
<td>184 (1-6)</td>
<td>181 (1-8)</td>
<td>110 (1-6)</td>
<td>112 (1-9)</td>
</tr>
<tr>
<td>Midwives out of hospital (range)</td>
<td>181 (1-6)</td>
<td>181 (1-8)</td>
<td>110 (1-6)</td>
<td>112 (1-9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Client characteristics</th>
<th>Care as usual</th>
<th>Client strategy</th>
<th>Care provider strategy</th>
<th>Client + care provider strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of clients (range per cluster)</td>
<td>417 (13-111)</td>
<td>647 (47-117)</td>
<td>395 (19-159)</td>
<td>334 (19-121)</td>
</tr>
<tr>
<td>Age (years) (range)(^)</td>
<td>31 (17-42)</td>
<td>31 (17-44)</td>
<td>30 (15-45)</td>
<td>31 (17-44)</td>
</tr>
<tr>
<td>Nulliparous (%)(*)</td>
<td>218 (53)</td>
<td>307 (60)</td>
<td>222 (64)</td>
<td>174 (58)</td>
</tr>
</tbody>
</table>

Range = lowest and highest value among clusters

\(^{\text{Age}}\) Age: 79 (4.4%) missing values

\(*\text{Parity}\): 214 (11.9%) missing values
**Implementation of ECV**

Overall, the ECV implementation rate attempts was 72%. ECV implementation rates varied considerably across clusters: from 8 to 95% (Figure 2). Four clusters scored below a 50% implementation rate (with a range of 8-46%). Ten (40%) clusters scored an implementation rate of 80% or higher (range 84-95%). Five out of ten clusters with a good implementation rate were clusters in the care as usual group. Sixteen (67%) of the clusters had an implementation rate above the mean. The ECV implementation rate in the clusters with the client strategy was 71% (range 46-95%) compared to 74% (range 8-93%) in the clusters without this strategy (OR 0.78 ((95% CI 0.41-1.5)) (Table 2). The proportion of ECV attempts within the clusters with the care provider strategy was 73% (range 23-94%) compared to 72% (range 8-95%) in the clusters without this strategy (OR 1.2 (95% CI 0.64-2.3)) (Table 3). The combination of both the client and care provider strategy did not result in an additional effect, as the interaction term between ECV implementation rate and the combined intervention was not statistically significant.

In order to explain why ECV implementation rates vary, we looked at the percentage of counselled clients and clients opting for ECV. The implementation for ECV counselling did not significantly differ between the groups: 82% in the clusters with the client strategy and 80% in the clusters with the care provider strategy. Counselling rates were not significantly different between.

**Figure 2.** Range of ECV implementation rate among clusters. The horizontal line represents the mean ECV implementation rate.
Also, the percentage of clients opting for ECV (87% within the client strategy and 91% in the care provider strategy) was not significantly different either one of the strategies and the clusters without these strategies.

Of 1,613 eligible clients, 153 (9.5%) women declined an ECV attempt and 291 (18.0%) were not counselled for ECV by their care provider. In the minority of cases, the study-file or hospital chart provided a reason for not offering ECV (Table 4). The percentage of clients who were not counselled without further explanation, was 20 out of 385 eligible clients (5%) in the care as usual cluster, 83 of 562 (15%) within the client strategy cluster, 94 of 376 (25%) within the care provider strategy cluster, and 22 of 290 (8%) in the cluster where both implementation strategies were enrolled ((OR 0.71 (95% CI 0.34-1.5) for the client strategy, and OR 0.84 (95% CI 0.41-1.7) for the care provider strategy).

Table 3. Effect of care provider strategy on counselled clients, clients who opt for ECV and the number of ECV attempts, among all eligible women for ECV

<table>
<thead>
<tr>
<th></th>
<th>No care provider strategy</th>
<th>Care provider strategy</th>
<th>Care provider strategy OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling for ECV (of eligible clients)</td>
<td>N= 947 (%; range*)</td>
<td>N= 666 (%; range*)</td>
<td>1.1 (0.53-2.20)</td>
</tr>
<tr>
<td>Opting for ECV (of counselled clients)</td>
<td>692 (88; 51-100)</td>
<td>485 (91; 63-100)</td>
<td>1.2 (0.64-2.2)</td>
</tr>
<tr>
<td>ECV attempts (of eligible clients)</td>
<td>686 (72; 8-95)</td>
<td>483 (73; 23-94)</td>
<td>1.2 (0.64-2.3)</td>
</tr>
</tbody>
</table>

*range among clusters included in the strategy
### Table 4. Reasons why eligible clients were not counselled for ECV.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Care as usual (N=385, %, range*)</th>
<th>Client strategy (N=562, %, range*)</th>
<th>Care provider strategy (N=376, %, range*)</th>
<th>Client + Care provider strategy (N=290, %, range*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT COUNSELED</td>
<td>42 (11; 0-85)</td>
<td>114 (20; 5-45)</td>
<td>99 (26; 7-65)</td>
<td>36 (12; 6-40)</td>
</tr>
<tr>
<td>Reasons other than contraindication in guidelines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV, Hep B, anticoagulants</td>
<td>5 (0-77)</td>
<td>4 (1-13)</td>
<td>1 (0-7)</td>
<td>2</td>
</tr>
<tr>
<td>Macrosomia</td>
<td>1 (1-13)</td>
<td>1 (0-7)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Multiple factors decreasing success rate</td>
<td>2 (1-13)</td>
<td>12 (1-13)</td>
<td>0 (0-7)</td>
<td>3</td>
</tr>
<tr>
<td>One previous CS</td>
<td>2 (1-13)</td>
<td>4 (1-13)</td>
<td>0 (1-7)</td>
<td>4</td>
</tr>
<tr>
<td>Vaginal blood loss</td>
<td>0 (0-7)</td>
<td>1 (1-7)</td>
<td>0 (1-7)</td>
<td>0</td>
</tr>
<tr>
<td>Adipositas</td>
<td>0 (0-7)</td>
<td>0 (1-7)</td>
<td>1 (1-7)</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>12 (1-13)</td>
<td>9 (1-7)</td>
<td>3 (1-7)</td>
<td>4</td>
</tr>
<tr>
<td>Not counselled for unknown reason</td>
<td>20 (5; 0-15)</td>
<td>83 (15; 0-30)</td>
<td>94 (25; 7-57)</td>
<td>22 (8; 3-20)</td>
</tr>
</tbody>
</table>

*% per strategy and range of % among clusters included in the strategy
Per-protocol analysis

To investigate whether the implementation strategies were not efficacious themselves or did not prove to be effective due to a suboptimal adherence to the strategy-protocols by the care providers, we performed a post-hoc analysis of those clients who were certainly exposed to the implementation strategy. Certain exposure was defined as handing out the client leaflet and decision aid, or fulfilling a list of topics on ECV and breech birth mentioned during counselling, for the client and care provider strategy respectively. We were able to ascertain exposure for 168 out of 852 clients (20%) within the clusters randomized to the client strategy and for 150 out of 666 clients (23%) within the clusters randomized to the care provider strategy. These subgroups did not significantly differ in baseline characteristics compared to the complete study sample (on parity or age). Of these 318 clients, 281 (88%) fulfilled the baseline questionnaire in which 170 (60%) were a priori willing to opt for ECV before counselling. The results of this analysis are shown in Table 5 and 6.

Table 5. Per protocol analysis: Effect of client strategy on counselled clients, clients who opt for ECV and the number of ECV attempts, among all eligible women for ECV; in those clients who were actually exposed to the implementation strategies.

<table>
<thead>
<tr>
<th></th>
<th>No client strategy</th>
<th>Client strategy</th>
<th>Client strategy OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling for ECV (of eligible clients)</td>
<td>169 (88)</td>
<td>150 (89)</td>
<td>0.76 (0.37-1.6)</td>
</tr>
<tr>
<td>Opting for ECV (of counselled clients)</td>
<td>166 (98)</td>
<td>143 (95)</td>
<td>0.58 (0.27-1.3)</td>
</tr>
<tr>
<td>ECV attempts (of eligible clients)</td>
<td>165 (85)</td>
<td>143 (85)</td>
<td>0.64 (0.30-1.4)</td>
</tr>
</tbody>
</table>

Table 6. Per protocol analysis: Effect of care provider strategy on counselled clients, clients who opt for ECV and the number of ECV attempts, among all eligible women for ECV; in those clients who were actually exposed to the implementation strategies.

<table>
<thead>
<tr>
<th></th>
<th>No care provider strategy</th>
<th>Care provider strategy</th>
<th>Care provider strategy OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling for ECV (of eligible clients)</td>
<td>186 (88)</td>
<td>133 (89)</td>
<td>1.2 (0.56-2.4)</td>
</tr>
<tr>
<td>Opting for ECV (of counselled clients)</td>
<td>177 (95)</td>
<td>132 (99)</td>
<td>1.9 (0.83-4.4)</td>
</tr>
<tr>
<td>ECV attempts (of eligible clients)</td>
<td>176 (83)</td>
<td>132 (88)</td>
<td>2.0 (0.72-4.5)</td>
</tr>
</tbody>
</table>
The number of clients counselled, opting for, and having an ECV attempt were higher in all strategies, compared to the intention to treat analyses. Again, no significant difference on ECV attempts was found between the clusters with the client strategy compared to the clusters without this strategy (OR 0.64 (95% CI 0.30-1.4)) or between the clusters with the care provider strategy compared to the clusters without this strategy (OR 2.0 (95% CI 0.72-4.5)). There was no significant interaction when both strategies were implemented; ECV implementation rates were not higher compared to care as usual.

**DISCUSSION**

In this large cluster-randomized clinical trial, we were unable to demonstrate a significant effect of both the client and care provider strategies compared to usual care on the ECV implementation rate. Both in an intention to treat analysis, as well as in a per protocol analysis, in which we only analyzed the women that were counselled for ECV after the implementation strategy was applied correctly. Our study has several strengths and weaknesses. An important strength of the study is that it provides insight in prelabour management of breech presentation in a large cohort, and reasons why ECV is not offered. This knowledge is important to make care providers aware of substandard care with respect to guideline adherence.

Withdrawal of one cluster in the client and care provider strategy caused an imbalance in the number of clusters per implementation strategy. Since we used a factorial design to analyze the effect of the implementation strategies, we do not think that, apart from further reduction in power, this baseline imbalance substantially affected the outcomes of the trial.

Furthermore, we observed a fair overall ECV attempt rate of 72%, but considerable practice variation resulting in lower power to demonstrate potential effects of the implementation strategies.

A main weakness is that many care providers did not adhere to the strategies as intended. In other words, they did not always handed out leaflets, decision aids or discussed all topics on ECV and breech presentation during counselling. However, if we limited our analysis to those women in which the strategies were followed as intended, also no significant differences were found.

A first explanation for the low exposure of clients to the implementation strategies was low. An explanation may be that the implementation of the strategies encompassed several steps, and some could have been better
controlled then others. All care providers were invited for the day course in the care provider strategy and the kick-off meeting for the client strategy. We aimed to have at least one care provider per practice to attend these meetings. This goal was achieved in almost all clusters. Subsequently, care providers were requested to pass on this knowledge to colleagues within their practices and to send all clients for counselling to those care providers who attended the meeting. Disclosure of the study information to all other care providers was beyond our control. Unrolling strategies to single care providers instead of practices, personal communication on initial implementation and during follow-up, would most certainly have resulted in better implementation rates, which was demonstrated in other studies.\textsuperscript{36,37} The introduction and actual implementation of innovations like this - involving all care providers in one region - may take up to two years which requires considerably more capacity and financial resources than we had at our disposal. A second explanation of the low implementation rate of the strategies could be found in the low incidence of breech presentation; breech presentation concerns 10% of pregnancies at 32 weeks gestation, but only 3-4% at 37 weeks gestation. Consequently, on average only one to three clients presented with breech presentations to each care provider during the study period. Due to this low incidence, handing out leaflets, decision aids or providing full counselling will not easily become part of routine practice. We sent reminders, feedback on inclusion and ascertained the availability of information leaflets in order to improve this suboptimal adherence to the implementation strategy, apparently with limited success. Concentration of care in a region, i.e. a small group of care providers taking care for women with a baby in breech position, could be a solution for this. Similar strategies have been successful in other areas, for example in Parkinson disease.\textsuperscript{38}

The per protocol analyses showed better ECV attempt rates among the clients exposed to the implementation strategies compared to the intention to treat analysis. Again, differences between strategies were not significant, but as this subgroup has considerably lower power, we cannot rule out that strategies may potentially be effective if better adhered to. This per protocol analysis may have suffered from selection bias, resulting in lower contrasts between strategies; care providers potentially may have handed out study files more often to those clients willing to consider ECV instead of those clients requesting a planned cesarean section. In view of odds ratio of 2 that we found for the health care provider strategy, uptake of ECV could
potentially be improved by education and awareness of the care provider. We should take into account that in the per protocol analysis, that was limited to women who were actually informed by the care provider, the uptake of ECV was already very high (88%), thus limiting the room for improvement. The potential of this intervention when the ECV rate is low, is potentially higher. Another explanation for the limited contrasts that were observed in the intention to treat and per protocol analyses could be the so called Hawthorne effect: care providers in the care as usual clusters might have put more effort in the counselling for ECV as they knew they were being monitored. Finally, the results may be the consequence of an imbalance in implementation rate of ECV at baseline. The data showed substantial variability among clusters, which might have existed at start of the trial. We did not have implementation rates per cluster at randomization and were not able to stratify for this. Due to the variation, the ICC will be higher as assumed in our power calculation. This results in lower power to demonstrate potential effects of the implementation strategies.

A strength of our study is that we have also monitored the actual exposure of clients to the implementation strategies, which may be a realistic explanation for our findings. Our study reflects circumstances in daily practice. Just as there is extensive empirical evidence that the level of use of guidelines affects outcomes in clients, this is also true for adherence to implementation strategies. We need to take into account whether a strategy has actually been put into practice by professionals in order to determine its benefits. Otherwise, one may incorrectly conclude that an implementation strategy is not efficacious in itself when, in fact, it has not been properly implemented. There might be lack of publications on implementation strategies with insignificant results, potentially indicating a publication bias in favour of those studies with significant results. This might hinder dissemination of knowledge on developed strategies which are effective itself, but which was not shown in the trial due to other influences. Therefore, other research groups may benefit from existing results. Our data showed that the overall ECV implementation rate is 72%. One could argue that this is quite acceptable, as a considerable proportion of women will not opt for ECV, even after counselling. However, we think there is still room for improvement considering the large practice variation and the fact that every elective cesarean section results in an increased maternal and neonatal morbidity and mortality in subsequent pregnancies.
Another finding in our study related to the implementation of ECV is that breech presentations are not accurately diagnosed by care providers. Four percent (62 / 1,793) of breech presentations were not diagnosed until birth, exposing these foetuses to high risks of intrapartum morbidity and mortality. A study by Lau et al. in 1997 already reported on this problem and an intervention trial by Robberts et al. tried to lower the percentage of undiagnosed breech by increasing awareness among care providers and pregnant women to assess fetal presentation in the last trimester. The need for routine ultrasound assessment to confirm the presentation of the foetuses might be indicated to rule out this problem.

Improvement of implementation of guidelines with the focus on contraindications could also improve ECV implementation rates by 4 to 5% as more contraindications are reported in daily practice than given in the guideline. In conclusion, in this cluster randomized controlled trial neither a provider based nor a client based strategy improved ECV implementation. The implementation rates were on average fair, although low in some clusters. Improvement could be realized in those regions with poor implementation rates either by improving care within that region with a specific target at the care provider, or by allocation of management of breech presentation to those centres with high ECV implementation and success rates.
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