Implementation of the external cephalic version in breech delivery
Dutch national implementation study of external cephalic version

Authors

1. MSc, MD F Vlemmix
   Corresponding author
   Academic Medical Centre, Amsterdam
   Department of Gynaecology and Obstetrics,
   Room H4-140.1
   Meibergdreef 9, 1105 AZ, Amsterdam
   f.vlemmix@amc.uva.nl

2. MSc AN Rosman
   Academic Medical Centre, Amsterdam
   Department of Gynaecology and Obstetrics,
   Room H4-140.1
   Meibergdreef 9, 1105 AZ, Amsterdam
   a.n.rosman@amc.uva.nl

3. Dr. MAH Fleuren
   TNO Kwaliteit van Leven (TNO Quality of Life)
   Preventie en Zorg (Prevention and Health)
   Postbus 2215
   2301 CE Leiden
   margot.fleuren@tno.nl

4. Mrs. MEB Rijnders
   TNO Kwaliteit van Leven (TNO Quality of Life)
   Preventie en Zorg (Prevention and Health)
   Postbus 2215
   2301 CE Leiden
   marlies.rijnders@tno.nl

5. Drs. A Beuckens.
   KNOV
   Mercatorlaan 1200, 3528 BL Utrecht
   abeuckens@knov.nl

6. Dr. BC Opmeer
   Academic Medical Centre, Amsterdam
   KEBB, Room J1B-216.1
   Meibergdreef 9, 1105 AZ, Amsterdam
   b.c.opmeer@amc.uva.nl

7. Prof. Dr. JAM van der Post
   Academic Medical Centre, Amsterdam
   Department of Gynaecology and Obstetrics,
   Room H4-236
   Meibergdreef 9, 1105 AZ, Amsterdam
   j.a.vanderpost@amc.uva.nl

8. Prof. Dr. BWJ Mol
   Academic Medical Centre, Amsterdam
   Department of Gynaecology and Obstetrics,
   Room H4-213
   Meibergdreef 9, 1105 AZ, Amsterdam
   b.w.mol@amc.uva.nl

9. Dr. M Kok
   Academic Medical Centre, Amsterdam
   Department of Gynaecology and Obstetrics,
   Room H4-251
   Meibergdreef 9, 1105 AZ, Amsterdam
   marjoleinkok@gmail.com
ABSTRACT

Background
Breech presentation occurs in 3 to 4% of all term pregnancies. External cephalic version (ECV) is proven effective to prevent vaginal breech deliveries and therefore it is recommended by clinical guidelines of the The Royal Dutch Organisation for Midwives (KNOV) and The Dutch Society for Obstetrics and Gynaecology (NVOG). Implementation of ECV does not exceed 50 to 60% and probably less.

We aim to improve the implementation of ECV to decrease maternal and neonatal morbidity and mortality due to breech presentations. This will be done by defining barriers and facilitators of implementation of ECV in The Netherlands. An innovative implementation strategy will be developed based on improved patient counselling and thorough instructions of health care providers for counselling.

Method/design
The ultimate purpose of this implementation study is to improve counselling of pregnant women and information of clinicians to realize a better implementation of ECV.

The first phase of the project is to detect the barriers and facilitators of ECV. The next step is to develop an implementation strategy to inform and counsel pregnant women with a breech presentation, and to inform and educate care providers. In the third phase, the effectiveness of the developed implementation strategy will be evaluated in a randomised trial. The study population is a random selection of midwives and gynaecologists from 60 to 100 hospitals and practices. First outcome Primary endpoints are number of counselled women. Secondary endpoints are process indicators, the amount of children in cephalic presentation at birth, complications due to ECV, the number of caesarean sections and perinatal condition of mother and child. Cost effectiveness of the implementation strategy will be measured.

Trial Registration Number
Dutch Trial Register (NTR): 1878
BACKGROUND

Breech presentation occurs in 3 to 4% of all term pregnancies [1]. In pregnancies complicated by breech presentation, perinatal mortality, neonatal mortality or serious neonatal morbidity are increased as compared to pregnancies where the child is in cephalic position. Breech position at term occurs in 8,000 pregnancies in The Netherlands each year. Until 2000 the mode of breech delivery was controversial. Since publication of the results of the term breech trial, the caesarean delivery rate in women with a child in breech presentation in The Netherlands has increased from 45% to around 80% [2]. Although an elective Caesarean section is safer for the baby, it increases maternal morbidity [3]. Moreover, the uterine scar carries a risk for future pregnancies [4]. External cephalic version (ECV) reduces the rate of non-cephalic presentations at term with 40-50%, and thus the number of caesarean deliveries performed for at term breech presentation, without any increased risk to the baby [5]. The high caesarean delivery rate for breech presentation makes ECV an important obstetric intervention and it is therefore recommended by the Royal College of Obstetricians and Gynaecologists in the Clinical Green Top Guideline 20.

A recent inventory among Dutch gynaecologists showed that 5% of the practices never offered ECV, whereas one practice offered ECV only to multipara (Feitsma et al. 2007). In 28% of the practices an ECV was performed by all gynaecologists, whereas in the other 72% ECV was performed by a smaller team of specialists. The palette of relative contraindications differed widely, and only 19% of the responding clinics registered their success rates. The number of patients refusing ECV was estimated to be 20% to 30%. A recent survey among midwives practices showed that only one in three midwives documented counselling and/or performance of the ECV in the medical files (Beuckens A 2007). From these numbers, one can conclude that at present 60% to 70% of the women with a child in breech position undergoes an ECV. However, this rate is probably an overestimation, as they are based on selfreported rates by midwives and gynaecologists, in the absence of registrations. The true number of women that undergoes ECV for term breech is probably lower than 50%. At present, a prevalence study on the implementation rate of ECV is carried out by TNO quality of Life in a representative sample of 50 midwifery practices in the Netherlands. The results of this study are expected in January 2008. With 6,000 term breech deliveries each year, of which 5,000 are delivered by Caesarean section, there is clearly room for improvement. The number of Caesarean sections for breech delivery can be reduced with approximately 2,000 per year. As the additional costs of a Caesarean section as compared to vaginal delivery are estimated to be euro 1,500, the potential saving of a better implementation of ECV can reduce costs with 2 to 3 million euro per year for direct medical costs only. As women pregnant after a previous caesarean section are at increased risk of complications, and therefore always deliver under responsibility of a gynaecologist, the potential savings are even higher. Many potential effective strategies for implementation are available, but none of them is superior in all aspects. This study will show us if a combined patient-centred strategy to implement ECV - tailored on main barriers - is more cost-effective than usual care. Moreover, the understanding of whether, why and in what setting an implementation intervention is successful is still limited. In this study we will also evaluate the process of implementation to ascertain which elements of the combined patient-centred strategy can be particularly associated with successful implementation of ECV. We are certain that there are no national projects underway similar to the present proposal or related to the healthcare problem of the present proposal. We have close contact with Dr Wouters, who is starting an implementation study on the use of a computerised decision support system (Cost-effectiveness of two strategies to implement the NVOG guidelines on hypertension in pregnancy: An innovative strategy including a computerised decision support system compared to a common strategy of
professional audit & feedback). Moreover, our proposal is a collaborative effort of midwives and gynaecologists, and is supported by both the KNOV and the NVOG. We are not aware of international studies on the subject that are underway.

In The Netherlands, there is professional consensus that an ECV should be offered to all women with a child in breech presentation at or near term. The Royal Dutch Organisation for Midwives (KNOV) has produced a leaflet for patients in which ECV is recommended. The Dutch Society for Obstetrics and Gynaecology (NVOG) as well as the KNOV state in their guidelines on the subject that an ECV should be offered to all women with a child in breech position at term. Nevertheless, the number of women potential suitable for ECV who were not offered an attempt range from 4% to 33% [6-8]. Moreover, a substantial number of women refuse ECV, and opt immediately for Caesarean section. In Australia, Raynes-Greenow and others investigated pregnant women's preferences and knowledge of term breech management [9]. Numbers of women responded that they would or would not choose ECV (39%), and the remaining 22% were uncertain. Yogev and colleagues performed a similar study in Israel [10]. They reported that in 1995, more than half the women (52.7%) had heard of ECV and 53.8% were willing to consider it, whereas in 2001, 73.2% had heard of it but only 23.9% were willing to consider it. Johanson reported that out of a group of 323 pregnant women with a child in breech presentation, 65% opted for external cephalic version after they were informed [11]. Johanson also demonstrated an association between the gynaecologists who provided information and the level of uptake by the women.

The numbers in the Netherlands are unknown. Until publication of the new NVOG and KNOV guidelines in 2001 and 2002, ECV used to be a controversial intervention. Since the introduction of these guidelines, there is no evidence for a raise in the number of performed ECV’s. However, the numbers in birth in breech presentation at term are stable since 2002, indicating a low implementation grade of ECV. Though several clinics have actively implemented the ECV since 2002, this might be not the case in the most hospitals and midwifery practices.

Implementation requires a clear and deliverable evidence based message [12]. However, there are often major discrepancies between best evidence and practice, often resulting in a large variation between professionals [13-17]. Based on this national and international literature and two main barriers for ECV implementation are identified 1) lack of patients' knowledge about risk for and consequences of ECV and breech delivery 2) the attitude and knowledge of midwives and gynaecologists towards ECV. Therefore, the chosen strategy will be patient-centred and contains 1) personal risk communication and 2) personal approach of midwives/ gynaecologists.

In summary, the implementation problem is that ECV is a cost-effective intervention to prevent breech delivery that is recommended in guidelines. However, its implementation is limited, as women with a child in breech position refuse ECV, as ECV is not offered systematically to all women and as ECV is not performed in an optimal setting.
METHODS / DESIGN

Aims
The main objective of the study is to assess barriers and facilitators of implementation of ECV in The Netherlands. We would like to create a broad social basis and awareness for the need of cooperation in care for women with a breech presentation. An innovative implementation strategy will be developed based on improved patient counselling and thorough instructions of health care providers for counselling. Research questions are: What are barriers and facilitators of implementation of ECV in The Netherlands? What are the costs and effects of an innovative implementation strategy based on improved patient counselling and information of health care providers to implement the guidelines on ECV for breech presentation? What is the feasibility of this implementation strategy?

Methods
The proposal will contain three phases. In the first phase, we will identify facilitators and barriers of implementation of ECV and create awareness of the need of improvement. Subsequently, we will develop an implementation strategy targeted on patient counselling and information of health care providers, and evaluate the cost-effectiveness of the developed strategy.

Identification of facilitators and barriers of implementation of ECV
After a topic list has been defined by an expert panel with members from the project group, we will conduct approximately twenty semi-structured interviews with relevant actors who are directly or indirectly involved with ECV. The topic list will be constructed on the basis of existing knowledge and theories on implementation factors, primarily based on the clinical guidelines by the NVOG and KNOV. This list will be used to guide and direct the interviews. In semi-structured interviews and focus groups, patients, gynaecologists and midwives will be asked for their attitude towards ECV. We will assess fear for complications, skills and attitudes. A framework approach will be used to analyse the data and to derive potential factors that might influence the implementation of ECV [18].

In the second step the exploratory findings will be used to develop a series of questionnaires. These will then be distributed among a much larger number of actors. Quantitative analyses will be conducted, accounting for the multilevel nature of the problem and the corresponding data-collection, to study the prevalence of factors that facilitate and/or inhibit the implementation of expectant management in fertility treatment in The Netherlands. In this process, we will take into account regional and socio-economic differences. To identify and explore relevant factors, semi-structured interviews will be held with a sample of actors involved: pregnant women with a child in breech presentation (N=20), general practitioners (N=20), midwives (N=20), gynaecologists (N=20), and representatives of health care insurers. Respondents will be ‘purposively’ selected [19]. Gynaecologists and midwives will be selected on relevant characteristics of their practices (region, hospital). Moreover, we will interview partners of pregnant women separately, but also as a couple. The interviews will be guided by the topic list that is defined on the basis of existing knowledge and theories on implementation [20]. The topic list will be used to direct the interviews, but will be informally and flexible applied in order to prevent us from imposing our preconceptions. The topic list will contain themes that include knowledge of the complications of ECV, about the risks of Caesarean section in terms of short- and long term maternal and neonatal mortality and morbidity, and about available evidence. We will also ask couples about their attitude towards the problem, about their expectations and previous experiences, and about their
beliefs about health care in general. Midwives and gynaecologists will be interviewed on similar subjects, but they will be asked more extensively about the potential effectiveness of ECV (relative risks, numbers needed to treat, numbers needed to harm) as well as the influence of wider societal, organisational, financial, and contextual factors. We expect the following categories of factors to play a role: socio-political factors (opinion stated by opinion leaders, comments in journals, opinion of experts within the own department, attitude of the head of the department), organizational factors, and knowledge and beliefs (doctor and patient level, knowledge, or the lack thereof, about complications of vaginal breech delivery and caesarean section, anxiety for ECV and the demand for Caesarean section (patient level only).

The semi-structured interviews will be analyzed on the basis of a framework approach [21]. The analyses will help us identify the important factors that are most likely to play a role in the implementation of ECV. We expect that we will be able to distil a list of approximately fifteen issues that are of potential importance. The exploratory findings will be used to develop a questionnaire, which is supposed to be extensive and complete. The questionnaire will be sent to all midwives practices and to the departments of obstetrics and gynaecology of all hospitals in The Netherlands. Moreover, all health insures will be targeted.

Ethical approval is not needed in accordance to the prescriptions of the medical ethical committee of the AMC, if individual patients will be approached for semi structured interviews, without provocation of emotional arousal and with anonymous processing of the data. This is the case in the first phase of the implementation study. After development of the implementation strategy, ethical approval will be requested.

Development of an implementation plan

After analysis, the results will be discussed in a final meeting with the study group and representative participants (clients, midwives, gynaecologists). Based on the discussion of these results, an implementation plan, with different actions and interventions, will be developed. Although parts of the plan will highly depend on the obstacles of change to be identified (e.g. knowledge, attitude, behaviour, logistics), we anticipate the following ingredients: 1) An educational brochure/website with evidence, one designed for gynaecologists/midwives and one designed for patients. 2) Group/unit meetings to discuss the protocol, the resistance to it, and how to overcome problems in adaptation. 3) If necessary, a training in counselling patients on ECV for midwives and/or gynaecologists can be developed 4) Reminders; regular self monitoring; regular observation by heads of units. This plan will be developed according to phase 2 to 5 of Grol's 5-step implementation model (Grol 1997). Depending on the results of the proposed project, additional funding will be sought for these phases.

Evaluation of the developed implementation strategies design

A cluster randomised controlled trial with an economic evaluation alongside will be performed. Ethical approval will be requested before the start of this part of the study. Information on counselling of patients, required for ethical approval, will be specified in the first phase of the trial. A set of quality indicators will be extracted from the NVOG and KNOV guidelines. The indicator development will be performed according to the RAND-modified Delphi method [22]. First of all, key recommendations from the guidelines will be extracted by two or three experts, the project leaders. Subsequently, the clinical relevance of all key recommendations for patient’s health benefit and efficacy will be tested in two rounds among an independent panel of 12-15 experts (KNOV and NVOG guideline writers, KNOV and NVOG members, quality of care experts and patients). The key recommendations with the highest scores will be selected and made ready for use, in measurable elements (process indicators). Moreover, measurement instruments will be developed and the participating
hospitals will be informed about the study. A detailed protocol on the randomised controlled trial will be written after finishing the first phase. This is a requirement to receive further funding of the further project. This protocol is not developed yet as it depends mainly in the outcome of the first phase.

This will be followed by a pilot, feasibility study where two different implementation strategies will be tested in four participating hospitals, one primary care centre specialised in ECV and one independent midwifery practice.

After the pilot study a cluster randomised controlled trial will be performed in which two implementation strategies will be evaluated: a patient centred strategy, and a health care provider (midwife and gynaecologist) centred strategy. In the randomised clinical trial, we will allocate centres and their regions at random to four groups: A. Patient information alone. B. Information of health care providers. C. Patient information and Information of health care providers. D. No specific implementation intervention.

Up to 30% of eligible patients is not offered an ECV attempt and up to 40% of counselled patients does not choose for ECV, which might be the result of insufficient information. With the decision aid we intend to increase the number of well informed patients from 50 to 80%. To correct for the degree of similarity among responses within a cluster, a intra-cluster correlation coefficient of 0.10 was integrated in the power analyses. To be able to show the difference of 30% with a power of 80% and an alpha error of 5%, we need 20 clusters of a 30 patients each.

Outcome measures and process indicators

Primary endpoint is the number of patients that has an ECV performed. Secondary endpoints are guidelines’ adherence rates, complications at ECV, the number of children that is in cephalic position at delivery, the number of caesarean sections and the perinatal condition of mother and child. Moreover, we will assess patient knowledge (e.g. ECV, breech delivery, caesarean section), patient decisional conflict and patient satisfaction. We will also calculate costs of both implementation interventions and medical interventions. In case one or both implementation interventions are effective, their cost-effectiveness will be assessed.

Implementation study

An effect and process evaluation will be performed. An effect evaluation of the two strategies will be carried out using the primary and secondary outcome measures and the set of process indicators derived from the NVVOG and KNOV guidelines. This will be done among pregnant women with breech presentation at term and professionals involved in the care for these women. The measurements will be performed in the 50 participating hospitals before and after implementation of the different strategies by a medical record search, added with questionnaires among professionals and patients. The medical records will be searched using standardised registration forms. A process evaluation will be performed to study the feasibility of the two strategies. The extent by which clinicians, midwives and patients used these elements will be measured. Time schedule: Assessment of barriers and facilitators: 12 months, development of the strategies 6 months, randomised clinical trial 12 months, evaluation and report 6 months.
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ECV</td>
<td>External cephalic version</td>
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<tr>
<td>NVOG</td>
<td>Dutch Society for obstetrics and gynaecology</td>
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<td>KNOV</td>
<td>The royal Dutch organisation for midwives</td>
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COMPETING INTERESTS

The study is sponsored by ZonMW; the Dutch organisation for health research and innovation.
The author(s) declare that they have no competing interests.
AUTHORS' CONTRIBUTIONS AND INFORMATION

Ben W.J. Mol (clinical epidemiologist and gynaecologist) has been involved in many projects in the field of Obstetrics and Gynaecology. His thesis, which focused on the evaluation of diagnostic and prognostic tests in sub fertility, was awarded with the Jan Swammerdam prize. In 2002, he has initiated the Dutch OFO-project, a study that aims to evaluate the effectiveness and cost effectiveness of the basic fertility work-up. The key paper of this project has been published in The Lancet (Lancet 2006;368:216-21). A study proposal entitled: Use of probabilistic decision rules in Obstetrics and Gynaecology was granted in the VIDI program of ZonMW, The Netherlands. He has (co-)authored over 150 peer reviewed publications, and he has supervised nine doctorates. He was instrumental in founding a Dutch consortium of obstetricians that cooperates in performing studies in obstetrics (http://www.studies-obsgyn.nl/index.asp). He is chair of the Dutch guideline committee of the NVOG. He is involved in implementation studies in obstetrics.

Pien M. Offerhaus practiced ten years in several independent midwifery practices. In 2001 she graduated in Health Science at the University of Maastricht. From 1995 until 2003 she worked as midwife researcher in several projects, at TNO-PG and later at WOK (UMCN), e.g. a study to assess the adherence and barriers for implementation of the KNOV guideline Anemia for primary care midwives. Since 2003 she is staff member of the Royal Dutch Organisation for Midwives (KNOV), and there she is responsible for the guideline development. In 2006 she was co-auteur of the KNOV guideline ‘External Cephalic Version’. Offerhaus P, Fleuren M, Wensing M. Guidelines on anaemia: effect on primary care midwives in the Netherlands. Midwifery 2005;(21): 204-211

Marlies Rijnders works as a research-midwife at TNO quality of Life. She has extensive experience in conducting research projects in independent midwifery practices: for example the Serinam study, a RCT in 55 midwifery practices, the ECV prevalence study in 50 midwifery practices (both still ongoing) and a retrospective study on satisfaction and mode of delivery in 8 midwifery practices. Furthermore, she conducted 2 studies on ECV: a retrospective study of all ECV between 1996 and 2000 in the Slotervaart Hospital and a prospective study on ECV in the same hospital including expectations and experiences if women with ECV (publication in press). Other research projects she participated in were a cost effectiveness study on screenings strategies for EOGBS and a study on information and informed consent of women with neonatal screening. Finally she was co author of the first midwifery guideline “Anaemia in first line obstetric practice”.

Joris A.M. van der Post is clinical director of obstetrics in the AMC and his main research focus is high risk pregnancy. His thesis dealt with pathophysiology of pre-eclampsia. He is currently involved in management of the Perinatal Research Unit, a collaborative initiative from the departments of obstetrics and neonatology for the monitoring of multicenter clinical studies, and a consortium of perinatal centres in the Netherlands. Work in progress concerns early diagnosis of pre-eclampsia, external version for breech presentation (RCT) and treatment of recurrent abortion (RCT), the value of the intrauterine pressure catheter IUPC trial (RCT).

Brent C. Opmeer (psychologist, methodologist) has participated in the coordination of European collaborative studies (European Communities 4th Medical and Health Research Program COMAC; BIOMED1) concerning health services research and is since 1999 working in the department of Clinical Epidemiology and Biostatistics in the Academic Medical Center. He has been involved in several evaluation studies (RCTs) in the fields of Dermatology, Surgery and Infectious diseases respectively, especially focusing on the economic and methodological perspective. He has conducted a study on methods for determining patients' treatment preferences and trade-offs in health care technology.
assessment research (ZONMW 2001-2003). He is currently involved in several studies in the field of obstetrics, gynaecology and fertility research.
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Additional files provided with this submission:

Additional file 1: honoreringsbrief zonmw ecv.pdf, 1583K