TITLE:

Perineal Assessment and Repair Longitudinal Study (PEARLS): A matched pair cluster randomised trial.

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Childbirth; perineum; trauma; cluster RCT; quality improvement

ABSTRACT:

Background: Perineal trauma during childbirth affects millions of women worldwide every year. The aim of the Perineal Assessment and Repair Longitudinal Study (PEARLS) was to improve maternal clinical outcomes following childbirth through an enhanced cascaded multi-professional training programme to support implementation of evidence based perineal management.

Methods:

Design: A pragmatic matched pair cluster randomised controlled trial.

Participants: Women (n=3681) sustaining a second-degree perineal tear in one of 22 UK maternity units (clusters) organised in 11 matched pairs.

Intervention: Units in each matched pair were randomised to receive the training intervention either early (Group A) or late (Group B).

Main outcome measures: Outcomes within each cluster were assessed prior to any training intervention (phase 1), and then after Group A (phase 2) and after Group B (phase 3) received the training intervention. Focusing on phase 2, the primary outcome was percentage of women with pain on sitting or walking at 10-12 days postnatal. Secondary outcomes included use of pain relief at 10-12 days postnatal, need for suture removal, uptake and duration of exclusive breastfeeding, and perineal wound infection. Practice based measures included implementation of evidence into practice to promote effective clinical management of perineal trauma.

Analysis: Cluster level paired t-tests were used to compare Groups A and B.

Results: There was no significant difference between clusters in phase 2 of the study in the average percentage of women reporting perineal pain on sitting and walking at 10 – 12 days (mean difference 0.7% 95% CI (-10.1%, 11.4%), p=0.89). The intervention significantly improved over-all use of evidence-based practice in the clinical management of perineal trauma. There was a significant reduction in mean percentages of women reporting perineal wound infections and women needing sutures removed in clusters following the training intervention.

Conclusion: PEARLS is the first RCT to assess the impact of a 'training package on implementation of evidence based perineal trauma management. The intervention did not significantly improve our primary outcome but significantly improved evidence based practice and some relevant secondary clinical outcomes for women.

Trial registry: ISRCTN - 28960026 and NIHR UKCRN - 4785

BACKGROUND:

Around 85% of women who have a vaginal birth sustain perineal trauma, either spontaneously or as a consequence of an episiotomy, and three-quarters of these women will require suturing to facilitate healing of the disrupted tissue[1]. Perineal trauma related symptoms, particularly if they persist, can negatively impact on a woman's physical ability to mobilise and hinders recovery postnatally [2-4].

Evidence of how maternal morbidity arising from perineal trauma could be reduced shorter-term is already available. Cochrane systematic reviews have consistently demonstrated that the continuous suturing of the vagina, perineal muscles and skin using absorbable synthetic suture materials is associated with less perineal pain and less requirement for analgesia[5-7]. Moreover, rapidly absorbable synthetic sutures were less likely to be associated with the need to remove suture materials postnatally. Therefore, there has been high level evidence recommending the use of fast absorbable suture material for the repair of second degree perineal trauma and episiotomy using the continuous suturing technique whenever feasible. This evidence is incorporated into national clinical guidelines informing routine clinical care [8 9].

In the UK trained midwives are responsible for the care of women during normal vaginal births and they also undertake any related perineal assessments and repairs. Obstetricians tend to be involved if the perineal trauma is deemed to be complex, more than a second degree tear or as part of an operative vaginal birth. As part of the preliminary work for the Perineal Assessment and Repair Longitudinal Study (PEARLS), the study team

conducted a comprehensive baseline national survey of a representative sample of midwives in clinical practice. The survey highlighted inadequate implementation of evidence into practice in relation to the management of childbirth-related perineal trauma where only 6% of the midwives used the recommended evidence based suturing technique. Moreover, participants highlighted that one of the main reasons for this gap was related to training [10].

PEARLS formed the main part of a national clinical quality improvement (QI) project. The aim of the Perineal Assessment and Repair Longitudinal Study (PEARLS) was to improve maternal clinical outcomes following childbirth through an enhanced cascaded multi-professional training programme to support implementation of evidence based perineal management.

METHODS:

The study received favourable ethical approval (PEARLS REC reference - 07/MRE 12/2, ISRCTN - 28960026 and NIHR UKCRN - 4785). PEARLS was conducted according to the published study protocol [11].

Participants

It was our intention to test the effectiveness of a QI intervention in increasing the implementation of evidence-based perineal assessment and repair guidance by midwives and obstetricians involved in the provision of intrapartum and postpartum care within the hospital and in the community. To minimise contamination, we used a randomised cluster design where the unit

of randomization and analysis was the maternity unit.

The study groups comprised of 11 matched maternity unit pairs where units (clusters) within a matched pair, were randomly allocated to receive the QI intervention either early (cluster A) or late (cluster B) in the study period. To ensure generalizability of findings it was important that the study reflected differences in workload, staffing levels and demographics of women using the service between the different models of maternity care. An open invitation to participate in the QI project was sent nationally, via the Royal College of Midwives (RCM), to Heads of Midwifery (HoMs) who have responsibility for the management of midwifery services in the UK. Those expressing interest were requested to provide information relating to their population demographics, birth rates and current perineal care and training provision. Twenty-four NHS units expressed an interest to participate, however one unit was subsequently excluded because of a delay in providing information required for matching. The 11 matched pairs required for the study were selected from the remaining 23 units.

Women booked to give birth in participating units were informed of the study during the antenatal period and additional information was made available, if requested. In line with the ethics committee's request and to maintain women's autonomy in deciding whether they wished to be sent study questionnaires and their data used in study analyses, women were only included if they provided valid written consent to participate. Following birth, women who sustained a second-degree perineal tear or episiotomy were

eligible unless they were < 16 years of age, non-English speaking or had suffered a pregnancy loss. Informed consent was obtained prior to discharge home. Women who consented had information on their parity, type of vaginal birth, and methods and materials used for repair of their perineal trauma, entered by the recruiting clinician (either a midwife or an obstetrician) on a trial data entry sheet. Women were provided with a study pack containing a covering letter, 10-12 day questionnaire and pre-paid reply envelope. The woman's General Practitioner (family doctor) was informed about her participation in the study. Women who returned the 10-12 day questionnaire received a second questionnaire and pre-paid return envelope at three months postpartum.

Intervention:

The PEARLS-QI intervention was an interactive multi-professional education package aimed at enhancing the knowledge and clinical skills of midwives and obstetricians to implement evidence based assessment and management of second-degree perineal tears and episiotomy (Box 1).

The intervention was implemented and cascaded within participating units by a locally appointed PEARLS facilitator in each cluster. Facilitators attended a 'train-the-trainers' two-day workshop organised by the PEARLS team. To minimise risk of contamination, the study team held two separate workshops, with study facilitators invited to attend one of these depending on whether their unit was randomised to receive the intervention early or late (Groups A and B) respectively. As this was a pragmatic study, facilitator's could decide

how they organised implementation of the PEARLS-QI intervention within their units, with ongoing advisory support from the trial team.

Data collection:

Data were collected at three time points. Baseline demographic and obstetric data were collected prior to implementing the intervention (phase 1).. Main trial data were collected following implementation of the PEARLS-QI intervention in clusters randomised to receive it early compared to the matched clusters, which did not receive it (phase 2). To assess sustainability of the effects of the PEARLS-QI intervention, data were then collected following implementation of the intervention in the other cluster in the matched pair (phase 3). Each woman recruited had a study entry form completed by a clinician and was sent a self-complete questionnaire at 10-12 days and three months postnatal. A period of three months was allowed for the PEARLS-QI intervention to be cascaded in all clusters. Recruitment duration varied between matched cluster pairs depending on the size of the cluster.

Primary Outcome:

Based on the findings of Cochrane reviews related to suturing techniques and materials for perineal repair, the use of evidence based suture techniques and materials was associated with a significant reduction in perineal pain on walking or sitting within the past 24 hours as measured at 10-12 days postnatally using a four item scale ranging from 'none' to 'severe' [7 12]. Therefore this was selected as the primary outcome for the study.

Secondary outcomes

Our secondary oucomes were selected from those commonly reported in previous perineal trauma management studies and relevant Cochrane reviews [5 12]. To ensure a woman-centred focus on quality improvement was maintained, Delphi surveys of independent service user groups were undertaken to identify patient reported outcomes (PROMs) considered most important by women who had recently experienced perineal trauma [13].

We assessed several clinical outcomes including perineal wound infection, need for suture removal, use of pain relief during the previous 24 hours, and breastfeeding rates at 10 – 12 days postnatal. At three months postnatal we collected data on women's Edinburgh Postnatal Depression Scale (EPDS) scores, if sexual intercourse had been resumed by nine weeks postnatal, women reported poor wound healing and breast feeding rates. Completed questionnaires were returned to the PEARLS central office.

Practice outcomes

The impact of the PEARLS-QI intervention on use of evidence based perineal assessment and management was evaluated, in particular whether clinicians used continuous non-locking suturing for the vaginal wall and muscle layer, subcuticular suturing for the perineal skin, fast absorbable polyglactin sutures[5 7 12] and whether the woman received an information leaflet advising on postnatal care of her perineal wound [14]. This was assessed using information provided in the study entry sheets.

Sample size:

In a clustered design the effect of clustering needs to be factored into the sample size calculation by means of the intra-cluster correlation coefficient (ICC)[15]. A preliminary sample size calculation was conducted prior to the start of data collection, but was refined using data from phase 1 prior to the commencement of phase 2. The sample size calculation for phase 2 of the trial, when only one group of units had received the QI-intervention, assumed that at 10 - 12 days 75% of women in the control clusters have any pain whilst walking or sitting in the previous 24 hours (primary clinical outcome), the ICC is 0.013, a 1% significance level, and a cluster size of 40. With 16 clusters (8 pairs) this would give the study 95% power to detect a 20% reduction in primary outcome from 75% to 55%[6]. This calculation assumed no benefit in power arising from the matched pairs design. Assuming a response rate of 60% at 10-12 days implied recruiting 67 women in each cluster. The additional clusters (11 matched pairs) in PEARLS would preserve the sample size should any clusters have withdrawn from the study.

Matching, randomization and allocation concealment:

Once participating units were identified, matching of paired clusters and simple randomisation was undertaken at Cardiff University by a researcher involved in designing but not running the study or analysis of data generated from it. The statistician responsible for matching and randomization was blind to any identifiable information about participating units. Moreover, participating units were blind to the identity of the unit they were matched to. Matching criteria included type of maternity unit (obstetric or midwifery led), number of births per annum, availability of a perineal repair guideline, provision of

perineal repair training and availability of postnatal perineal care information for women. Intervention allocation was based on clusters rather than individuals.

Data management

A data entry company manually entered all data into a specialist data entry software (*Snap™*)[16]. To assure quality, completed questionnaires were separated into batches prior to entry, allowing individual accountability to be assigned for each questionnaire. Initial data entry and verification was subsequently validated with at least 10% of questionnaires being checked. Any errors identified resulted in the whole batch and at least two subsequent batches to be fully checked.

Statistical methods

The main data analysis was conducted using *IBM SPSS Statistics* Version 19 [17]. Prior to analysis data were checked statistically for outlying values and logical inconsistencies. Where data from the Entry Details questionnaire were missing or needed to be checked, unit facilitators were contacted and additions or corrections entered onto the databases. The three sets of questionnaires (Entry Details, 10-12 day and three month) were matched within each of the study phases. A preliminary data analysis plan was published prior to the completion of data collection[11]. This was subsequently refined by the central project team and agreed by the project steering group. Analysis was by 'intention to treat'. No imputation methods were used. A 5% 2-sided significance level was used. The main analysis of the primary and

secondary outcomes was conducted by means of a cluster level analysis focusing on phase 2 data as specified in the protocol [11]. Thus the unit of analysis for the comparison between early and late intervention is the cluster (maternity unit) rather than the individual women, reflecting the fact that the maternity unit was the unit of randomisation, and the intervention was delivered to maternity units. In this way any clustering effects (women in the same maternity unit tending to be more similar to each other than to women from other units) are taken into account.

Summary statistics for outcome measures were calculated for each maternity unit and compared between matched intervention and control clusters using the paired t-test (with 10 degrees of freedom unless otherwise stated). For example, the proportion of women with pain when walking or sitting in the past 24 hours was calculated as the summary statistic for each cluster. The mean difference in the summary statistic was then compared between intervention and control clusters using the paired t-test, to enable the matched cluster design to be taken into account [18 19]. If the difference in summary statistics between clusters was highly skewed, the Wilcoxon signed ranks test was used instead of the paired t-test. Slight discrepancies between summary statistics calculated from cluster level data and summary statistics calculated from individual level data may arise because of variations in cluster size. This method of data analysis was a protocol change where matched-pair random effects models using MLWin software was planned[20]. This was because of later concerns about estimating between cluster variability within each cluster pair with a relatively small number of matched clusters. Moreover, small numbers of women experiencing some of the outcome measures resulted in

lack of convergence in those statistical models. Where models could be run, the paired t-test method tended to be conservative, and all statistically significant results using the paired t-test method were also significant using the random effects model (data not shown). Maintenance of the effect of the intervention in phase 3 was tested by comparing results from phase 3 for Group A clusters (9-12 months following implementation of the PEARLS-QI intervention) to the results from phase 2 for Group B clusters (when they had not received PEARLS-QI intervention) using paired t-tests. This method, which still takes into account the randomised nature of the study, was used because Group B clusters had received the intervention by the time phase 3 outcomes were collected.

RESULTS:

The results are based on data from comparison of the 11 matched paired clusters randomly allocated to receiving the PEARLS-QI intervention either early or late in the study period (phase 2). The flow of women and clusters through the study is shown in Figure 1. A total of 3681 women were recruited with 1470 and 2211 women in Group A and Group B clusters respectively. Based on figures of study eligible women during phase 2, the overall recruitment rate was 45% (36% for Group A clusters and 51% for Group B clusters). Summaries of the demographic and obstetric characteristics, reported in phase 2 are presented in Table 1. In both groups combined, a total of 85 women (5.8%) did not meet study inclusion criteria for degree of perineal trauma. One possible explanation is variation in classification of degree of trauma between the clinician conducting the initial examination and

the clinician undertaking the repair. Being a pragmatic RCT based on intention to treat, a decision was made to include data from these women.

Summary results of clinicians' adherence to evidence based practice and women's reported outcomes in Group A and Group B clusters for the three study phases are presented in Tables 2 and 3.

There were no statistically significant differences between Group A and Group B clusters with regards to pain on walking or sitting (the primary outcome measure), need for pain relief or breast feeding rates at 10-12 days postnatal. There was a significant reduction in average reported rates of wound infection ($p=0.03$) and need for suture removal ($p=0.03$) in Group A clusters (Table 4). There was no significant difference in any of the women's reported outcomes at three months postnatal.

There were differences in implementation of evidence-based practice. In the trial comparison (phase 2) there was an improvement in adherence to evidence based management of perineal trauma in Group A clusters compared to Group B clusters. This difference was statistically significant for use of the continuous technique to repair vaginal skin ($p=0.007$), perineal muscles ($p=0.04$) and number of perineal repairs where the continuous suturing technique was used throughout the repair ($p=0.045$). Women in Group A clusters were also significantly more likely to receive information about postnatal management of their perineal wounds ($p<0.001$) (Table 5).

To assess the sustainability of the PEARLS-QI intervention, women's reported outcomes and use of evidence based perineal trauma management

approaches were compared between Group A clusters in phase 3 (9-12 months after delivering the PEARLS-QI intervention) and Group B Clusters in phase 2 (before the delivery of the PEARLS-QI intervention). There was no statistically significant difference between both Groups in any of the assessed outcomes except for number of women receiving information leaflets on postnatal management of their perineal wounds (p=0.003) (Table 6).

DISCUSSION:

The Institute of Medicine defines quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes, consistent with current professional knowledge [21].

PEARLS-QI assessed the effectiveness of implementation of an evidence based standardised multi-professional training package, using a matched pair cluster RCT, on women's health outcomes and content of clinical practice. The gap between the availability of evidence and its implementation in relation to the management of perineal trauma following childbirth was highlighted in a national survey of midwives conducted by our team prior to designing the PEARLS-QI intervention [10]. This gap was also demonstrated in phase 1 of the study where, prior to delivering the QI intervention in any units, only 35.8% and 56.5% of women had perineal repairs carried out using the recommended technique in Group A and B clusters respectively. Interestingly, there was a significant improvement in the use of the continuous suturing technique for perineal repair in Group A clusters (from 35.8% to 72.5%) after delivering the training intervention. Following the delivery of the intervention in Group B clusters in phase 3 of the study, the use of evidence based techniques also

significantly improved. However, the improvements in Group A clusters were not sustained to the level achieved in phase 2, although this was still better than the baseline level in phase 1 (Tables 2, 3 and 6). Despite low rates of use of the continuous suturing technique prior to the PEARLS-QI intervention, most clinicians used the recommended more rapidly absorbed polyglactin suture material[12].[12]. This is probably due to the fact that purchase and use of suture material tends to be decided at an organisational rather than individual clinician level. However, the potential benefits to maternal health, which may accrue from the use of appropriate suturing material, are likely to be dissipated by using less effective perineal suturing techniques. Current evidence supports the use of a continuous non-locking technique for perineal repair over interrupted suturing particularly in relation to perineal pain at 10-12 days postnatal [5]. In spite of an improvement in the use of the recommended suturing technique, we were unable to demonstrate a reduction in women's reported pain outcomes. It is possible that this was due to the fact that a high percentage of women in both Groups (A and B) had subcutaneous sutures inserted to close the perineal skin even prior to delivering the QI intervention. Indeed, this technique of skin closure appears to be associated with a reduction in reported perineal pain [7]. Nevertheless, there was a significant reduction in rates of perineal wound infection in Group A compared to Group B clusters at the end of phase 2. Wound infection was the outcome of most importance for women in the Delphi survey we conducted during the initial project development. Genital tract sepsis was the commonest cause of direct maternal death in the UK during 2006 - 2008 [22]. Sepsis is a complex and poorly understood cause of maternal morbidity and mortality, and highlights

the importance of effective care to minimise infection and need to increase awareness of sepsis among women and clinicians.

To our knowledge PEARLS is the first RCT to test a QI intervention specifically developed to improve use of evidence-based assessment and management of birth related perineal trauma to reduce maternal morbidity. It is the largest study to date to evaluate the impact of use of evidence based perineal repair methods on women's postnatal health. A major strength of the study design was including a long-term assessment phase to measure sustainability of the intervention. It seems that implementation of the intervention changed clinical practice in that use of evidence based techniques for perineal repair were better utilised several months after 'actively' delivering the PEARLS-QI intervention, albeit to a lesser extent compared to phase 2. We can only speculate possible reasons for the inability to sustain the same level of improvement. This could be related to the impact of the training in changing attitudes dissipating, or more likely, related to staff service and training rotations between clinical areas diluting the number of those receiving the QI intervention and still involved in intrapartum care. Thus reinforcing the need for regular, on-going updates in perineal training for those clinicians involved in intrapartum care.

There are numerous examples of delay in implementing evidence into clinical practice associated with poor patient outcomes [23-26]. Several barriers are reported as underlying reasons for this, including lack of resources and organisational support, increased workload and individuals' resistance to

change. Burry and Mead (1998) suggested that to facilitate local implementation of evidence based practice, change should be managed locally, there should be clarity about the expected benefits and that one should ensure involvement of all interested parties [27]. PEARLS was designed as a pragmatic trial, hence in addition to testing the intervention, we wanted to ensure we used a pragmatic approach for its delivery. Therefore, the findings of our national midwifery survey helped us to understand some of the barriers and facilitators to implementation of evidence to enhance management and outcomes of perineal trauma. We believe that use of a local, trained PEARLS facilitator in each cluster increased the sense of local ownership of the project and generalizability of the study findings. Indeed knowledge translation for healthcare professionals and consumers is more likely to be successful if the choice of translation strategy is informed by an assessment of the likely barriers and facilitators [28].

There are some limitations to our study. We did not ask facilitators to document how many clinicians received PEARLS training as we considered that this would have been an additional burden and anticipated that some staff would require on-going training. As the sample size calculation was based on the primary outcome measure, there was low power for some secondary outcomes, which occurred infrequently. Over half of women who met the study inclusion criteria were not recruited, an issue, which reflects the pragmatic nature of the study where service demands can compete with recruitment. This discrepancy could also be a reflection of participants' choice because we were only able to include women within a cluster if they

consented to participate. Thirdly, of the women for whom a completed Entry Detail form was available, the percentages returning 10-12 day questionnaires were 62%, 49% and 57% for phases 1, 2 and 3 respectively, and for the three-month questionnaire were 49%, 40% and 53% respectively. The data analysis assumes questionnaires are missing completely at random; bias might result if this was not the case. However, we note that response rates are comparable in the three phases and between both sets of clusters (e.g. for phase 2, the 10-12 day questionnaire had a response rate of 54% for group A and 55% for group B, and for the 3 month questionnaire had a response rate of 38% for group A and 44% for group B). Finally, the ratio of the number of women in Group A clusters relative to women in Group B clusters was 1.37 for phase 1, 1.75 for phase 2 and 1.36 for phase 3. The reasons for, and implications of, the ratio being higher than 1, and being higher in phase 2 compared to phases 1 and 3 are unknown and could reflect wider individual organisational issues not addressed within the study.

In contrast, there are several strengths to our study. The risk of group contamination is minimised by the use of a cluster design with matched paired maternity centres as the unit of intervention allocation. The pragmatic nature of the trial, cascading the intervention by means of local trained facilitators, and the inclusion of a range of maternity units and birth centres increases the external validity of the study and make the findings generalizable to the UK. Additionally, publication of the trial protocol, pre-specification of the primary outcome, large sample size and extended follow-up period are important further strengths of the study design.

In England, the Clinical Negligence Scheme for Trusts (CNST) handles all clinical negligence claims against member NHS bodies. Membership contributions are influenced by several factors including the achievement of certain risk management and clinical standards. In line with CNST standards, most member NHS hospital are currently addressing clinical training provision in perineal assessment and repair to comply with CNST recommendations. Nevertheless, there is currently no standardised tested package to deliver this training or audit its impact. Similar to the implementation of the evidence based continuous suturing technique, the improvement in women's reported outcomes was not sustained to the same level of original improvement when assessed in phase 3. This highlights that although the PEARLS-QI intervention was effective in improving the implementation of evidence into practice, which had a positive impact on some aspects of women's health, it is important to ensure training is actively embedded within routine clinical care to ensure its impact is sustained. Undoubtedly, this fits in with the current model proposed by CNST where clinicians involved in intrapartum care are expected to receive regular perineal repair and management updates. The extent to which this is currently happening is not known.

Conclusion:

The accurate assessment and appropriate repair of perineal trauma require an awareness and understanding of the supporting evidence, together with a high level of clinical skill and competency to ensure perineal tissues and structures are aligned correctly to promote healing and minimise morbidity.

Delivering and cascading multi-professional training within maternity units by means of the PEARLS-QI intervention was associated with a significant improvement in adherence to evidence based repair practice and some of the women's reported outcomes. However, regular training updates are essential to sustain the same level of improvement. An e-learning version of the PEARLS-QI intervention is now available for online access through StratOG (the RCOG e-learning resource). With approximately 400,000 women sustaining perineal trauma during childbirth per annum in the UK, the clinical impact of this study cannot be underestimated, particularly if viewed in relation to its potential global benefit.

Acknowledgment:

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Conflict of interest

KMKI and CK run perineal repair workshops both nationally and internationally and have developed an episiotomy and second-degree tear

training model with Limbs & Things, UK. Royalty fees generated from the sales of this model are managed at an organizational level and are used to support academic activities related to women's health. KMKI is StratOG editor in Chief for core training modules.

Contributorship statement

DB and CK conceived the original idea. DB, CK, KI, SM (and RH – see acknowledgement) designed the study protocol and secured funding. ST was the PEARLS co-ordinator. PT provided statistical advice and analysis. All the authors contributed to the writing up and approved the final draft.

Box 1: Content of the PEARLS-QI intervention

- Reading material for independent study and self directed learning
- Copies of available evidence based national guidelines for perineal trauma management, postnatal care and pain relief.
- An interactive PEARLS-DVD with audio visual material covering anatomy, basic surgical skills, systematic assessment of perineal trauma, technique of cutting a medio-lateral episiotomy and its repair. The DVD was developed to standardise training, aid facilitators in its delivery and to be accessed by staff, if required, to refresh core information and maintain competency.
- An information leaflet for all women who had repaired perineal trauma providing advice about self-management of their perineal wound, their general health and well-being and advice on who to contact if they had any concerns about healing of their perineum.

Table 1: Demographic and obstetric characteristics from phase 2 entry details in Group A and Group B clusters.

	A Clusters N=532	**B Clusters N= 922**
Mean maternal age in years (SD)	28.9 (5.8)	29.1 (5.7)
Multiparity % (n)	37.0% (194)	35.8% (330)
White ethnic background % (n)	89.3% (475)	87.2% (804)
Type of delivery % (n)		
Spontaneous vaginal	75.8% (403)	74.4% (690)
Forceps	13.9% (74)	12.9% (120)
Ventouse/ suction cup	9.8% (52)	12.0% (111)
Breech	0.6% (3)	0.6% (6)
Other	0% (0)	0% (0)
Perineal trauma at delivery % (n)		
None	0.8% (4)	0.9% (8)
1st degree	1.5% (8)	2.0% (18)
2nd degree	58.9% (307)	61.6% (553)
3rd degree	3.8% (20)	3.0% (27)
4th degree	0% (0)	0% (0)
Episiotomy	33.6% (175)	31.5% (283)
Extended episiotomy	1.5% (8)	1.1% (10)
Percent (n) < 37 weeks gestation	3.4% (18)	3.1% (29)
Mean (SD) birth weight in grams	3461 (485)	3460 (494)

Table 2: Descriptive statistics for the implementation of evidence based guidelines by clinicians in Group A and Group B clusters in the three phases of the study

Evidence based standards	Phase 1		Phase 2		Phase 3	
	A	B	A	B	A	B
Used continuous non-locking suturing technique for vaginal wall - % (n)	56.1% (138)	65.5% (211)	78.5% (347)	67.0% (461)	72.4% (330)	77.3% (519)
Used continuous non-locking suturing technique for muscle layer - % (n)	45.2% (109)	66.1% (195)	75.1% (322)	67.3% (442)	68.1% (310)	76.8% (490)
Used subcutaneous or subcuticular suturing technique for perineal skin - % (n)	67.6% (161)	83.3% (279)	90.0% (388)	79.4% (570)	87.7% (405)	87.7% (582)
Used continuous non-locking suturing for vaginal wall and muscle layer, and used subcutaneous/ subcuticular stitching for perineal skin - % (n)	35.8% (77)	56.5% (156)	72.5% (290)	57.6% (343)	64.6% (274)	73.2% (429)
Used fast absorbable polyglactin suturing material - % (n)	90.6% (259)	84.5% (343)	96.0% (475)	79.8% (681)	92.1% (503)	95.4% (725)
Receiving leaflet - % (n)*	27.7% (52)	25.6% (68)	69.1% (199)	31.4% (155)	64.5% (229)	69.3% (323)

* Information gathered from 10-12 day postal questionnaire

Phase 1: Prior to intervention implementation; Phase 2: After implementation of intervention in Group A units; Phase 3: After implementation of intervention in Group B units.

	Postnatal - Women reported outcomes	Phase 1		Phase 2		Phase 3	
		A	B	A	B	A	B
10-12 days	Primary outcome - Pain walking or sitting in past 24 hours - % (n)	74.5% (140)	75.6% (201)	76.7% (217)	74.1% (363)	78.5% (277)	78.2% (358)
	Total walking and sitting pain scores over past 24 hours - mean (SD)	1.9 (1.6)	1.7 (1.4)	1.7 (1.5)	1.8 (1.5)	1.9 (1.5)	1.8 (1.5)
	Requiring removal of sutures - % (n)	2.1% (4)	2.2% (6)	0% (0)	3.7% (18)	1.4% (5)	2.8% (13)
	Taking pain relief in previous 24 hours - % (n)	29.6% (56)	25.7% (69)	22.9% (66)	31.7% (156)	29.8% (106)	25.0% (116)
	Still breastfeeding - % (n)	65.8% (125)	66.1% (181)	63.9% (186)	67.5% (332)	68.6% (243)	69.2% (324)
	Had perineal wound infection requiring antibiotics - % (n)	6.9% (13)	5.5% (15)	2.8% (8)	6.1% (30)	5.0% (18)	3.9% (18)
3 Months	Edinburgh Postnatal Depression Score ≥13 -% (n)	6.7% (10)	7.6% (16)	11.2% (26)	10.1% (35)	11.8% (36)	10.6% (47)
	Resuming intercourse after 9 weeks or more - % (n)	41.9% (62)	48.6% (101)	53.3% (120)	56.1% (193)	56.0% (163)	50.7% (219)
	Poor or quite poor perineal healing - % (n)	9.3% (14)	4.7% (10)	7.5% (17)	6.7% (23)	7.5% (23)	7.1% (31)
	Still breastfeeding - % (n)	48.3% (71)	50.0% (106)	44.8% (103)	47.6% (165)	45.2% (140)	47.4% (210)

Table 3: Descriptive statistics for women reported outcome measures in A and B clusters in phases 1, 2, and 3

Phase 1: Prior to intervention implementation; Phase 2: After implementation of intervention in Group A units; Phase 3: After implementation of intervention in Group B units.

Table 4: Mean differences in cluster level summary statistics of women's reported outcomes in phase 2.

	Postnatal outcomes	Mean difference (95% CI)	Paired t-test p-value
10-12 days	Percent with pain walking or sitting in past 24 hours	0.7% (-10.1%, 11.4%)	P=0.89
	Mean total walking and sitting pain scores over the previous 24 hrs	0.10 (-0.27, 0.46)	P=0.56
	Percent requiring sutures removed [a]	2.2% (0%, 10.0%)	P=0.03
	Percent taking pain relief in previous 24 hrs	7.6% (-4.3%, 19.5%)	P=0.19
	Percent still breastfeeding	3.1% (-10.4%, 16.6%)	P=0.62
	Percent with perineal wound infection since birth	4.2% (0.4%, 8.0%)	P=0.03
3 months	Percent with Edinburgh Postnatal Depression Score 13+	-1.1% (-8.1%, 6.0%)	P=0.75
	Percent who resumed intercourse after 9 weeks or more	-3.1% (-15.9%, 9.7%)	P=0.60
	Percent with poor or quite poor perineal healing	0.1% (-4.9%, 5.2%)	P=0.95

a) Highly skewed distribution so median (95% CI) and p-value from Wilcoxon test are presented

Note: Mean difference = mean in B clusters – mean in A clusters. Positive mean differences indicate that values are on average higher in the group B (late intervention) clusters

Table 5: Mean differences in cluster level summary statistics of implementation of evidence based perineal repair in phase 2.

Evidence based management	**Mean difference (95% CI)**	**Paired t-test p-value**
Entry details		
Percent with continuous non-locking suturing technique for vaginal wall	-13.9% (-23.2%, -4.6%)	P=0.007
Percent with continuous non-locking suturing technique for muscle layer	-13.0% (-25.3%, -0.8%)	P=0.04
Percent with subcuticular suturing technique for perineal skin	-9.3% (-21.8%, 3.2%)	P=0.13
Percent with EBM technique for all layers[a]	-16.3% (-32.1%, -0.4%)	P=0.045
Fast absorbable polyglactin suture	-17.4% (-36.9%, 2.2%)	P=0.08
10-12 day questionnaire		
Receiving postnatal leaflet	-39.7% (-52.9%, -26.5%)	P<0.001

a) For this variable one cluster provided no data and so this cluster and its pair have been excluded (9 degrees of freedom)

Note: Mean difference = mean in Group B clusters – mean in Group A clusters. Negative mean differences indicate higher values on average in Group A (early intervention) clusters

Table 6: Assessing sustainability – comparison of Group A clusters in phase 3 with Group B (late intervention) clusters in phase 2

	Mean Difference (95% CI)[a]	Paired t-test p-value
Percent with sutures removed	1.9% (-0.8%, 8.1%)	P=0.18
Percent with perineal wound infection since birth	1.0% (-4.0%, 6.1%)	P=0.66
Percent with continuous non-locking suturing technique for vaginal wall	-3.5% (-17.2%, 10.1%)	P=0.57
Percent with continuous non-locking suturing technique for muscle layer	5.1% (-9.3%, 19.5%)	P=0.44
Percent with sub-cuticular suturing technique for perineal skin	-5.8% (-17.8%, 6.1%)	P=0.30
Percent using EBM technique for all layers[b]	1.7% (-16.0%, 19.4%)	P=0.84
Percent using fast absorbable polyglactin suture	-9.4% (-32.4%, 13.7%)	P=0.38
Percent receiving leaflet	-34.5% (-54.2%, -14.8%)	P=0.003

Mean difference = mean in B clusters – mean in A clusters. Negative differences indicate higher mean in A (early intervention) clusters.

a) One cluster had no data at phase 3 and so cluster and it's pair have been excluded (9 degrees of freedom)

b) For this variable one additional cluster has no data and so this cluster and its pair have been excluded (8 degrees of freedom)

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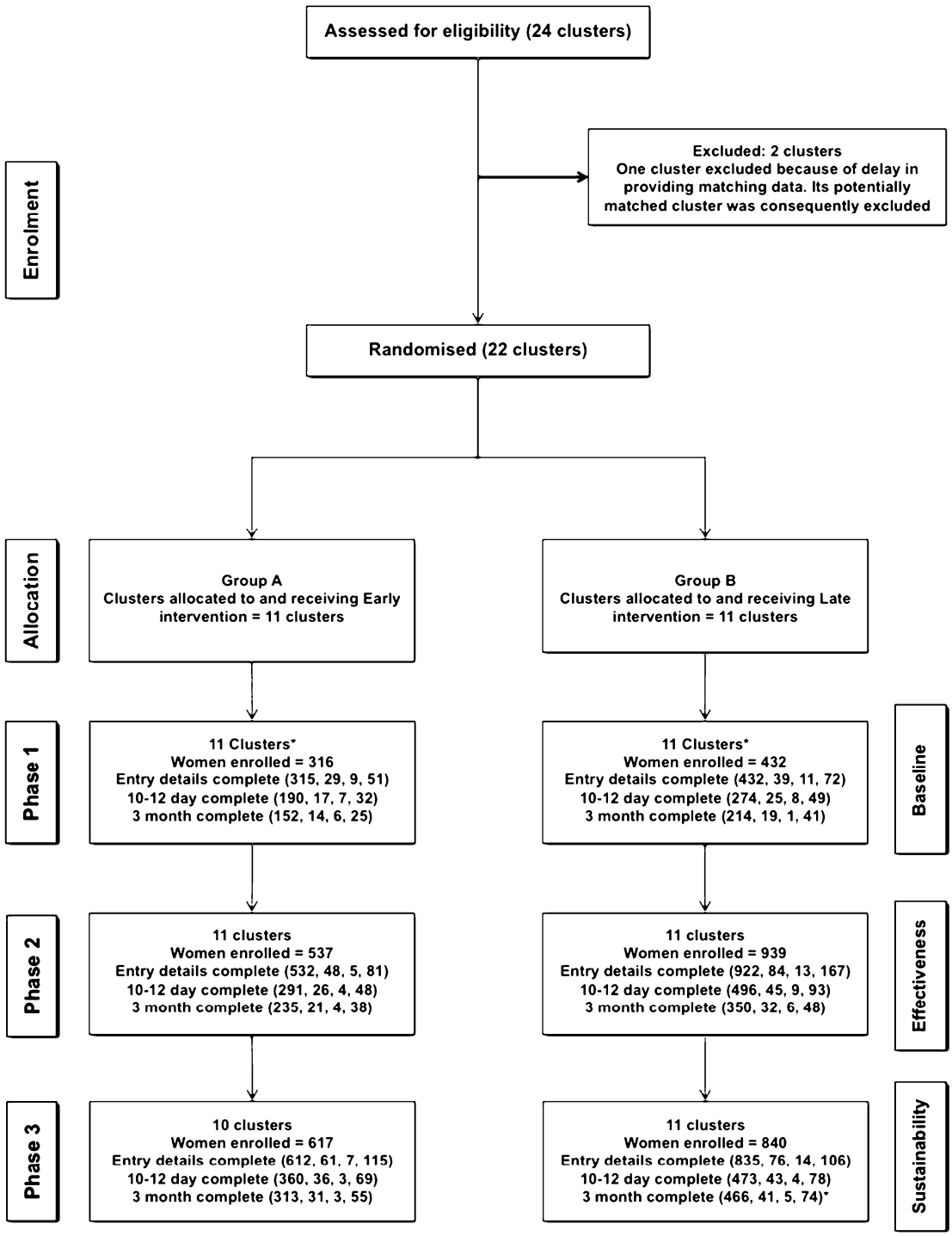
Figure 1: Flow diagram of the progress of clusters and individuals within the clusters throughout the study.



Figures in parentheses indicate number of women, mean number of women per cluster, minimum and maximum number of women in a cluster.

Phase 1: Prior to intervention implementation; Phase 2: After implementation of intervention in Group A units; Phase 3: After implementation of intervention in Group B units.

In Phases 2 and 3, a period of three months was allowed for the PEARLS-QI intervention to be cascaded in all clusters. Recruitment duration varied between matched cluster pairs depending on the size of the cluster.

Additional files provided with this submission:

Additional file 1: PEARLS protocol.pdf, 280K
http://www.biomedcentral.com/imedia/1179750166102394/supp1.pdf
Additional file 2: PEARLS_CLUSTER+CONSORT+checklist.docx, 35K
http://www.biomedcentral.com/imedia/1322559064102395/supp2.docx