

Do we need a core outcome set for childbirth perineal trauma research?
A systematic review of outcome reporting in randomised trials evaluating the management of childbirth trauma.

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Running title:

Outcome reporting in childbirth trauma trials.

35 Abstract

36 **Background:** Selecting appropriate outcomes to reflect both beneficial and harmful
37 effects is a critical step in designing childbirth trauma trials.

38 **Objective:** To evaluate the outcomes and outcomes measures reported in
39 randomised controlled trials evaluating interventions for childbirth trauma.

40 **Search strategy:** Randomised trials were identified by searching bibliographical
41 databases including Cochrane Central Register of Controlled Trials (CENTRAL),
42 Medline, and EMBASE.

43 **Selection criteria:** Randomised trials evaluating the efficacy and safety of different
44 techniques in the management of perineal lacerations.

45 **Data collection and analysis:** Two researchers independently assessed studies for
46 inclusion, evaluated methodological quality, and extracted relevant data. The
47 Spearman's rho correlation and the multivariate linear regression analysis using the
48 backward stepwise model were used for analysis ~~of included data~~.

49 **Main results:** Forty-eight randomised trials, reporting data from 20,308 women,
50 were included. Seventeen different interventions were evaluated. Included trials
51 reported 77 different outcomes and 50 different outcome measures. Commonly
52 reported outcomes included pain (34 trials; 70%), wound healing (20 trials; 42%),
53 and anorectal dysfunction (16 trials, 33%). In the multivariate analysis no relationship
54 was demonstrated between outcome reporting quality with year of publication ($p =$
55 $.31$), journal impact factor ($p = .49$), and methodological quality ($p = .13$).

56 **Conclusions:** Outcome reporting in childbirth trauma research is heterogeneous.
57 Developing, disseminating, and implementing a core outcome set in future childbirth
58 trauma research could help ~~to~~ address these issues.

59 **Funding:** None.

60 **Keywords:** Childbirth trauma; core outcome sets; lacerations; outcome variation;
61 and perineal trauma.

62 **Tweetable abstract:** Developing @coreoutcomes for childbirth trauma research
63 could help to reduce #research waste.

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85 **Introduction**

86 Perineal and vaginal trauma during labour and vaginal childbirth, commonly referred
87 as childbirth trauma, affects millions of women worldwide.¹ Research and clinical
88 practice has focused on the perineal muscles and the anal sphincter complex over
89 the last three decades. However, childbirth trauma may involve different organs and
90 compartments of the pelvic floor and the perineum including muscles, nerves,
91 connective tissue, as well as bone trauma. Stretching, compression, and rupture
92 may occur during vaginal birth and result in nerve, muscle, and connective tissue
93 damage.

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95 The incidence of perineal trauma, regardless of its severity, exceeds 91% in
96 nulliparous women and 70% in multiparous women.² The clinical diagnosis of
97 obstetric anal sphincter injury ranges between 1% and 11% of women who deliver
98 vaginally.^{3 4} The reported incidence of levator ani muscle trauma varies widely,
99 ranging between 13% and 26% in these women.⁵⁻⁸ These variations may be
100 secondary to population characteristics, assessment criteria, and diagnostic criteria.
101 ^{1, 9} Short, medium, and long term morbidity associated with childbirth trauma can
102 affect daily activities, psychological wellbeing, sexual function, and overall quality of
103 life. ¹⁰

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105 To date, there is no consensus among healthcare professionals, researchers and
106 patients, regarding the outcomes and outcome measures that should be collected
107 and reported in trials evaluating interventions for the management of childbirth
108 trauma. Variation in outcome reporting, outcome reporting measures, and poor
109 reporting results in significant difficulties in undertaking secondary research,

including pair-wise meta-analysis, network meta-analysis, and individual patient data meta-analysis.¹¹

Although the variation in outcome reporting has been previously investigated and confirmed in several areas relevant to obstetrics and gynaecology no evaluation has been undertaken in childbirth trauma research.¹¹⁻¹⁵

Therefore, we evaluated outcome and outcome measure reporting across published randomised controlled trials evaluating interventions for childbirth trauma. In addition, we investigated ~~relationship~~ associations between outcome reporting quality with other factors including year of publication, journal impact factor, and methodological quality.

Methods

This study is part of a wider project of CHORUS, an International Collaboration for Harmonising Outcomes, Research and Standards in Urogynaecology and Women's Health.

This study was registered with the Core Outcome Measures in Effectiveness Trials Initiative Register (COMET) Initiative, registration number 981, and with the International Prospective Register of Systematic Reviews (PROSPERO), CRD42017077375. Our study was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.¹⁶

Randomised controlled trials were identified by searching: (1) Cochrane Central

Register of Controlled Trials (CENTRAL), (2) Latin American and Caribbean Health Sciences Literature (LILACS), (3) MEDLINE, (4) EMBASE, (5) PsycINFO, and (6) Scopus, from the inception of the database to September 2017. Our search strategy included the MeSH headings childbirth trauma, obstetric anal sphincter injuries, obstetric trauma, perineal lacerations, perineal tears, perineal trauma, and vaginal tears. The reference lists of included studies were examined to identify additional randomised controlled trials. The search strategy is presented in Figure 1.

Eligibility criteria were predetermined. Randomised controlled trials related to perineal trauma, regardless of its degree, were considered eligible for inclusion in our study. Systematic reviews, non-randomised studies, retrospective studies, and case reports were excluded. Studies published in English were included. Two researchers (VP and CD) independently screened the retrieved titles and abstracts of electronically. Potentially eligible for studies were retrieved in full text to assess its eligibility. Any discrepancies between the researchers were resolved by review of a third senior researchers (SKD) and consensus of all authors.

Three researchers (CD, AE and VP) independently assessed the methodological quality of included randomised trials using the Jadad criteria.¹⁷ Each included randomised trial was assessed for randomisation, blinding, withdrawals, and dropouts. An arbitrary decision was made to classify included randomised trials as high quality when they were assessed as achieving a score greater than four points on the JADAD criteria.

Outcome reporting quality was assessed, using the Management of Otitis Media with

Effusion in Cleft Palate (MOMENT) criteria.¹⁸ The MOMENT criteria assess the presence of a primary outcome (1 point); if the primary outcome was clearly defined for reproducible measures (1 point); if the secondary outcomes were clearly stated (1 point); if the secondary outcomes were clearly defined for reproducible measures (1 point); if the authors explain the choice of outcome (1 point); and if the methods that were used were appropriate to enhance quality of measures (1 point). An arbitrary decision was made to classify included randomised trials as high quality when they were assessed as achieving a score greater than four points on the MOMENT criteria.

To evaluate the impact of various confounders that might significantly either contribute or reflect outcome quality we extracted information that was related to the journal's type (general, specialty or subspecialty journal, based on scimago.org indication, impact factor based on InCites, Journal Citation Reports (Web of Science, Clarivate Analytics, Thomson Reuters), participants, interventions and pharmaceutical funding. Funding status was identified in the article text including commercial funding or the donation of equipment, which had facilitated the trial.

Non-parametric correlation coefficients (Spearman's rho) were used to explore the univariate association between continuous factors. The chi-square, Fisher's exact and non-parametric Mann-Whitney tests were used to compare outcome reporting quality between groups according to the type of journal (general vs specialist), funding source (commercial or other), year of publication, and impact factor in the year of publication. All tests were two-tailed. Statistical significance was set at 0.05

and analyses were conducted using SPSS statistical software (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp).

A multivariate linear regression analysis using the backward stepwise model was undertaken to assess relationship between quality of outcome reporting and journal type, impact factor during the year of publication, year of publication, and methodological quality as independent variables and outcome reporting as the dependent variable.

Results

Forty-eight randomised controlled trials, reporting data from 20,308 women, were included (Table S1).¹⁹⁻⁶⁶ Seventeen interventions were evaluated including different techniques (17 trials; 35%), different suture materials (6 trials; 13%), and biofeedback (3 studies; 6%). The majority of trials (71%) were published in general obstetrics and gynaecology journals. Four trials (8%) declared commercial funding. Methodological quality (median = 5, range 2 – 5) and outcome reporting quality (median = 4, range 1 – 6) varied across included trials.

Included trials reported 77 different outcomes and 50 different outcome measures. Outcomes were inconsistently reported across included randomised trials (Table S2). Commonly reported outcomes included pain (34 trials; 70%), wound healing (20 trials; 42%), and anorectal dysfunction (16 trials, 33%) (Table 1). Pain was evaluated using 2 different measurement instruments, including visual analogue scales (17 studies; 50%) and Pain McGill Questionnaire (3 studies; 9%) (Table S3). The majority of trials (85%) evaluated wound healing subjectively, with the exception of

three trials which used the Redness, Oedema, Ecchymosis, Discharge, Approximation (REEDA) scale. Anorectal dysfunction was evaluated using 11 different measurement instruments including anorectal manometry rest pressure (9 studies; 56%), anorectal manometry squeeze measure (7 studies, 44%), and endoanal ultrasound for the detection of sphincter defects (5 studies; 31%). A minority of trials reported quality of life (4 trials; 8%) and patient satisfaction (7 trials; 15%), which were subjectively evaluated.

The median value of the methodological quality was 4 (range 2-5) and the median outcome reporting 4 (range 1-6). When we directly compared the differences between OASIS and non-OASIS studies we observed that non-OASIS studies had better methodological quality scores (4 (3-6) vs 3 (1—6) $p=.013$). There were no differences between the two groups in terms of methodological outcome (5 (2-5) vs 4 (2-5) $pp=.066$). The majority of articles – 34 (71%) were published in obstetrics and gynecology journals, whereas 5 studies (10%) were published in subspecialized journals in the field of urogynecology and pelvic floor disorders. Only 16 studies (33%) used validated questionnaires for the assessment of patient outcomes. Of the remaining studies, 22 (46%) used non-validated methods and 11 (23%) did not specify the methods of outcome assessment. Thirty-five studies (73%) enrolled more than 100 women and ten studies (21%) included more than 500 women. Only four studies (8%) received commercial funding.

To summarize our main findings, we tabulated the most frequently reported outcomes in Table 2, which demonstrates the significant discrepancies in terms of outcome reporting. Outcomes outlined in light grey color are specific to OASIS and are not expected to be reported among studies referring to perineal laceration of mild

severity. Significant discrepancies were observed in terms of reported outcomes when comparing OASIS studies to studies evaluating mild degree lacerations. Specifically, studies on OASIS tended to underreport symptoms related to wound healing, pain and sexual dysfunction problems.

In the multivariate analysis no relationship was demonstrated between outcome reporting quality with year of publication ($p = 0.31$), journal impact factor ($p = 0.49$), and methodological quality ($p = 0.13$) (Table 3).

Discussion

Main findings

Randomised controlled trials evaluating interventions for childbirth trauma have reported many 77 different outcomes and 50 different outcome measures. Outcomes were inconsistently reported across included trials. Commonly reported outcomes included pain, wound healing, and anorectal dysfunction. Of 48 randomised trials, reporting data from 20,308 women, less than a fifth reported information on quality of life and patient satisfaction. Standardised definitions and validated measurement instruments were infrequently used. No relationship was demonstrated between outcome reporting quality with year of publication, journal impact factor, and methodological quality.

On a closer look into outcome measures, we noted that they were specifically described in only a few studies, thus, pointing towards potential reporting bias and flawed findings. Moreover, as previously mentioned, validated questionnaires were

only reported to have been used in 33% of the studies included, thus, pointing the need for future studies in this field that will permit proper interpretation of outcomes. This observation contradicts the actual MOMENT and JADAD scores of included studies which, at a first look, indicate appropriate study design and outcome reporting.

Taking into account our findings, one could assume that current research could be seriously misleading in the field of perineal trauma as selective reporting and potential publication bias prohibit proper interpretation of our findings; hence, future studies in the field should take into account outcomes and outcome measures that have been already reported in previous systematic reviews to investigate the reproducibility of established knowledge, ~~prior to suggesting other potential outcomes and outcome measures.~~

Strengths and limitations

The strength of this systematic review of outcome reporting, includes its prospective registration, comprehensive search strategy, methodological design, and statistical analysis. To our knowledge, this is the first systematic review to describe outcome reporting in randomised controlled trials evaluating interventions for childbirth trauma. In order to prevent bias the review methods including study selection, data collection, and data analysis were guided by the Cochrane Collaboration handbook and COMET initiative handbook.^{67, 68}

Our evaluation has some limitations. Our systematic review included only randomised trials and so may have missed outcomes more frequently reported in observational studies including outcomes related to the medium- and long-term.

Outcomes identified through systematic reviews of randomised trials largely reflect outcomes healthcare professionals and researchers have considered important to collect and measure, particularly where trials pre-date the recent emphasis on patient and public involvement in their design. Outcomes reported in historic trials may not hold the same relevance for other stakeholder groups, such as women with lived experience of childbirth trauma. The majority of trials were performed in high-income countries, the outcomes reported in these trials may not hold the same relevance to healthcare professionals, researchers, and patients living in low- and middle-income countries.

Interpretation

Randomised controlled trials evaluating interventions for childbirth trauma have neglected to report important outcomes including quality of life, sexual dysfunction, and dyspareunia consistently. Poor outcome selection, collection, and reporting limits the usefulness of research to inform clinical practice. Developing a core outcome set could help to address these issues. A consortium of over eighty journals support the Core Outcomes in Women's and Newborn Health (CROWN) initiative which promotes the development, dissemination, and implementation of core outcome sets across women's and newborn health.⁶⁹ Several core outcome sets are currently in development across a broad range of healthcare conditions including infertility, endometriosis, termination of pregnancy, twin-twin transfusion syndrome, pre-eclampsia, and neonatal medicine.^{11, 70-73}

An international consortium of healthcare professionals, researchers, and patients, International Collaboration for Harmonizing Outcomes, Research and Standards in

Urogynaecology and Women's Health (CHORUS), has been established to develop core outcome sets across Urogynaecology and Women's Health.

There is limited guidance regarding the development of core outcome sets.⁶⁸ The COMET initiative suggests three broad stages: (1) identifying potential core outcomes; (2) determining core outcomes using robust consensus methods engaging key stakeholders; and (3) determining how core outcomes should be measured. This study has completed the first step in developing a core outcome set for childbirth trauma by developing an initial long list of potential core outcomes. Further research is required to further develop the long list of potential core outcomes to ensure its holds relevance to women with childbirth trauma and healthcare professionals, researchers, and patients living in low- and middle-income countries.⁷⁴ The development of the core outcome set for childbirth trauma will be informed by the methods used by recently completed core outcome sets including preterm birth.

Pending the development of a core outcome set for childbirth trauma we would recommend the collection and reporting of pain, wound healing, quality of life, and sexual dysfunction. In addition, when considering the management of third and fourth degree tears we would recommend collecting and reporting faecal and flatus incontinence, endoanal ultrasound abnormality, and manometry abnormalities.

Conclusion

Outcome reporting in childbirth trauma research is heterogeneous. Developing, disseminating, and implementing a core outcome set in future childbirth trauma

research could help to increase its reach and relevance to clinical practice.

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Conflicts of interest

The authors report no competing interests. The ICMJE disclosure forms are available as online supporting information.

Author contributions

VP, CD, AE and SKD had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: JMD, SKD Acquisition of data: CD, AE Analysis and interpretation of data: JMD VP Drafting of the manuscript: JMD, VP, SKD Critical revision of the manuscript for important intellectual content: SKD Statistical analysis: VP

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References

1. Hirayama F, Koyanagi A, Mori R, Zhang J, Souza JP, Gulmezoglu AM. Prevalence and risk factors for third- and fourth-degree perineal lacerations during vaginal delivery: a multi-country study. *Bjog*. 2012 Feb;119(3):340-7.
2. Smith LA, Price N, Simonite V, Burns EE. Incidence of and risk factors for perineal trauma: a prospective observational study. *BMC Pregnancy Childbirth*. 2013 Mar 07;13:59.
3. Dudding TC, Vaizey CJ, Kamm MA. Obstetric anal sphincter injury: incidence, risk factors, and management. *Ann Surg*. 2008 Feb;247(2):224-37.
4. Chaparro CM, Neufeld LM, Tena Alavez G, Eguia-Liz Cedillo R, Dewey KG. Effect of timing of umbilical cord clamping on iron status in Mexican infants: a randomised controlled trial. *Lancet*. 2006 Jun 17;367(9527):1997-2004.
5. Kearney R, Miller JM, Ashton-Miller JA, DeLancey JO. Obstetric factors associated with levator ani muscle injury after vaginal birth. *Obstet Gynecol*. 2006 Jan;107(1):144-9.
6. Dietz HP, Gillespie AV, Phadke P. Avulsion of the pubovisceral muscle associated with large vaginal tear after normal vaginal delivery at term. *Aust N Z J Obstet Gynaecol*. 2007 Aug;47(4):341-4.
7. Dietz HP, Lanzarone V. Levator trauma after vaginal delivery. *Obstet Gynecol*. 2005 Oct;106(4):707-12.
8. Schwertner-Tiepelmann N, Thakar R, Sultan AH, Tunn R. Obstetric levator ani muscle injuries: current status. *Ultrasound Obstet Gynecol*. 2012 Apr;39(4):372-83.

- 382 9. Pergialiotis V, Vlachos D, Protopapas A, Pappa K, Vlachos G. Risk factors for
383 severe perineal lacerations during childbirth. *Int J Gynaecol Obstet*. 2014
384 Apr;125(1):6-14.
- 385 10. Lawrence L, Rebecca R, Noelle B, Dusty T, Clifford Q. The effect of perineal
386 lacerations on pelvic floor function and anatomy at six months postpartum in a
387 prospective cohort of nulliparous women. *Birth (Berkeley, Calif)*. 2016
388 10/31;43(4):293-302.
- 389 11. Duffy J, Bhattacharya S, Herman M, Mol B, Vail A, Wilkinson J, et al.
390 Reducing research waste in benign gynaecology and fertility research. *Bjog*. 2017
391 Feb;124(3):366-9.
- 392 12. Hirsch M, Duffy JMN, Kuszniir JO, Davis CJ, Plana MN, Khan KS. Variation in
393 outcome reporting in endometriosis trials: a systematic review. *Am J Obstet Gynecol*.
394 2016 Apr;214(4):452-64.
- 395 13. Duffy J, Hirsch M, Kawsar A, Gale C, Pealing L, Plana MN, et al. Outcome
396 reporting across randomised controlled trials evaluating therapeutic interventions for
397 pre-eclampsia. *Bjog*. 2017 Apr 22.
- 398 14. Duffy J, Hirsch M, Pealing L, Showell M, Khan KS, Ziebland S, et al.
399 Inadequate safety reporting in pre-eclampsia trials: a systematic evaluation. *BJOG*.
400 2017 Oct 14.
- 401 15. Perry H, Duffy JMN, Umadia O, Khalil A. Outcome reporting across
402 randomised trials and observational studies evaluating treatments for Twin-Twin
403 Transfusion Syndrome: a systematic review. *Ultrasound Obstet Gynecol*. 2018 Apr
404 1.
- 405 16. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al.
406 The PRISMA statement for reporting systematic reviews and meta-analyses of

407 studies that evaluate healthcare interventions: explanation and elaboration. BMJ.
 408 2009 Jul 21;339:b2700.

409 17. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et
 410 al. Assessing the quality of reports of randomized clinical trials: is blinding
 411 necessary? Control Clin Trials. 1996 Feb;17(1):1-12.

412 18. Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, et al.
 413 MOMENT – Management of Otitis Media with Effusion in Cleft Palate: protocol for a
 414 systematic review of the literature and identification of a core outcome set using a
 415 Delphi survey. Trials. 2013 March 12;14(1):70.

416 19. Fynes MM, Marshall K, Cassidy M, Behan M, Walsh D, O'Connell PR, et al. A
 417 prospective, randomized study comparing the effect of augmented biofeedback with
 418 sensory biofeedback alone on fecal incontinence after obstetric trauma. Dis Colon
 419 Rectum. 1999 Jun;42(6):753-8; discussion 8-61.

420 20. Eogan M, Daly L, Behan M, O'Connell PR, O'Herlihy C. Randomised clinical
 421 trial of a laxative alone versus a laxative and a bulking agent after primary repair of
 422 obstetric anal sphincter injury. Bjog. 2007 Jun;114(6):736-40.

423 21. Farrell SA, Gilmour D, Turnbull GK, Schmidt MH, Baskett TF, Flowerdew G,
 424 et al. Overlapping compared with end-to-end repair of third- and fourth-degree
 425 obstetric anal sphincter tears: a randomized controlled trial. Obstet Gynecol. 2010
 426 Jul;116(1):16-24.

427 22. Fernando RJ, Sultan AH, Kettle C, Radley S, Jones P, O'Brien PM. Repair
 428 techniques for obstetric anal sphincter injuries: a randomized controlled trial. Obstet
 429 Gynecol. 2006 Jun;107(6):1261-8.

- 430 23. Gamble J, Creedy D, Moyle W, Webster J, McAllister M, Dickson P.
431 Effectiveness of a counseling intervention after a traumatic childbirth: a randomized
432 controlled trial. *Birth*. 2005 Mar;32(1):11-9.
- 433 24. Garcia V, Rogers RG, Kim SS, Hall RJ, Kammerer-Doak DN. Primary repair
434 of obstetric anal sphincter laceration: a randomized trial of two surgical techniques.
435 *Am J Obstet Gynecol*. 2005 May;192(5):1697-701.
- 436 25. Ghahramani L, Mohammadipour M, Roshanravan R, Hajihosseini F,
437 Bananzadeh A, Izadpanah A, et al. Efficacy of Biofeedback Therapy before and after
438 Sphincteroplasty for Fecal Incontinence because of Obstetric Injury: A Randomized
439 Controlled Trial. *Iranian Journal of Medical Sciences*. 2016 07/07/revised
440 07/13/accepted
441 03/10/received;41(2):126-31.
- 442 26. Mahony R, Behan M, O'Herlihy C, O'Connell PR. Randomized, clinical trial of
443 bowel confinement vs. laxative use after primary repair of a third-degree obstetric
444 anal sphincter tear. *Dis Colon Rectum*. 2004 Jan;47(1):12-7.
- 445 27. Nordenstam J, Mellgren A, Altman D, Lopez A, Johansson C, Anzen B, et al.
446 Immediate or delayed repair of obstetric anal sphincter tears-a randomised
447 controlled trial. *BJOG*. 2008 Jun;115(7):857-65.
- 448 28. Oakley SH, Ghodsi VC, Crisp CC, Estanol MV, Westermann LB, Novicki KM,
449 et al. Impact of Pelvic Floor Physical Therapy on Quality of Life and Function After
450 Obstetric Anal Sphincter Injury: A Randomized Controlled Trial. *Female Pelvic Med*
451 *Reconstr Surg*. 2016 Jul-Aug;22(4):205-13.
- 452 29. Peirce C, Murphy C, Fitzpatrick M, Cassidy M, Daly L, O'Connell PR, et al.
453 Randomised controlled trial comparing early home biofeedback physiotherapy with

454 pelvic floor exercises for the treatment of third-degree tears (EBAPT Trial). *Bjog*.
 455 2013 Sep;120(10):1240-7; discussion 6.

456 30. Rydningen M, Dehli T, Wilsgaard T, Rydning A, Kumle M, Lindsetmo RO, et
 457 al. Sacral neuromodulation compared with injection of bulking agents for faecal
 458 incontinence following obstetric anal sphincter injury - a randomized controlled trial.
 459 *Colorectal Dis*. 2017 May;19(5):O134-o44.

460 31. Rygh AB, Korner H. The overlap technique versus end-to-end approximation
 461 technique for primary repair of obstetric anal sphincter rupture: a randomized
 462 controlled study. *Acta Obstet Gynecol Scand*. 2010 Oct;89(10):1256-62.

463 32. Sultan AH, Johanson RB, Carter JE. Occult anal sphincter trauma following
 464 randomized forceps and vacuum delivery. *Int J Gynaecol Obstet*. 1998
 465 May;61(2):113-9.

466 33. Tjandra JJ, Han WR, Goh J, Carey M, Dwyer P. Direct repair vs. overlapping
 467 sphincter repair: a randomized, controlled trial. *Dis Colon Rectum*. 2003
 468 Jul;46(7):937-42; discussion 42-3.

469 34. Williams A, Adams EJ, Tincello DG, Alfirevic Z, Walkinshaw SA, Richmond
 470 DH. How to repair an anal sphincter injury after vaginal delivery: results of a
 471 randomised controlled trial. *Bjog*. 2006 Feb;113(2):201-7.

472 35. Akil A, Api O, Bektas Y, Yilmaz AO, Yalti S, Unal O. Paracetamol vs
 473 dexketoprofen for perineal pain relief after episiotomy or perineal tear. *J Obstet*
 474 *Gynaecol*. 2014 Jan;34(1):25-8.

475 36. Alvarenga MB, de Oliveira SM, Francisco AA, da Silva FM, Sousa M, Nobre
 476 MR. Effect of low-level laser therapy on pain and perineal healing after episiotomy: A
 477 triple-blind randomized controlled trial. *Lasers Surg Med*. 2017 Feb;49(2):181-8.

- 478 37. Aslam R, Khan SA, ul Amir Z, Amir F. INTERRUPTED VERSUS
479 CONTINUOUS SUTURES FOR REPAIR OF EPISIOTOMY OR 2^N DEGREE
480 PERINEAL TEARS. J Ayub Med Coll Abbottabad. 2015 Jul-Sep;27(3):680-3.
- 481 38. Berlit S, Tuschy B, Brade J, Mayer J, Kehl S, Sutterlin M. Effectiveness of
482 nitrous oxide for postpartum perineal repair: a randomised controlled trial. Eur J
483 Obstet Gynecol Reprod Biol. 2013 Oct;170(2):329-32.
- 484 39. Colacioppo PM, Gonzalez Riesco ML. Effectiveness of local anaesthetics with
485 and without vasoconstrictors for perineal repair during spontaneous delivery: double-
486 blind randomised controlled trial. Midwifery. 2009 Feb;25(1):88-95.
- 487 40. Dudley L, Kettle C, Thomas PW, Ismail KM. Perineal resuturing versus
488 expectant management following vaginal delivery complicated by a dehiscence wound
489 (PREVIEW): a pilot and feasibility randomised controlled trial. BMJ Open. 2017 Feb
490 10;7(2):e012766.
- 491 41. Duggal N, Mercado C, Daniels K, Bujor A, Caughey AB, El-Sayed YY.
492 Antibiotic prophylaxis for prevention of postpartum perineal wound complications: a
493 randomized controlled trial. Obstet Gynecol. 2008 Jun;111(6):1268-73.
- 494 42. Fleming VE, Hagen S, Niven C. Does perineal suturing make a difference?
495 The SUNS trial. Bjog. 2003 Jul;110(7):684-9.
- 496 43. Fyनेface-Ogan S, Mato CN, Enyindah CE. Postpartum perineal pain in
497 primiparous women: a comparison of two local anaesthetic agents. Niger J Med.
498 2006 Jan-Mar;15(1):77-80.
- 499 44. Greenberg JA, Lieberman E, Cohen AP, Ecker JL. Randomized comparison
500 of chromic versus fast-absorbing polyglactin 910 for postpartum perineal repair.
501 Obstet Gynecol. 2004 Jun;103(6):1308-13.

- 502 45. Ismail KM, Kettle C, Macdonald SE, Tohill S, Thomas PW, Bick D. Perineal
503 Assessment and Repair Longitudinal Study (PEARLS): a matched-pair cluster
504 randomized trial. *BMC Med.* 2013 Sep 23;11:209.
- 505 46. Kettle C, Hills RK, Jones P, Darby L, Gray R, Johanson R. Continuous versus
506 interrupted perineal repair with standard or rapidly absorbed sutures after
507 spontaneous vaginal birth: a randomised controlled trial. *Lancet.* 2002 Jun
508 29;359(9325):2217-23.
- 509 47. Kindberg S, Stehouwer M, Hvidman L, Henriksen TB. Postpartum perineal
510 repair performed by midwives: a randomised trial comparing two suture techniques
511 leaving the skin unsutured. *BJOG.* 2008 Mar;115(4):472-9.
- 512 48. Leroux N, Bujold E. Impact of chromic catgut versus polyglactin 910 versus
513 fast-absorbing polyglactin 910 sutures for perineal repair: a randomized, controlled
514 trial. *Am J Obstet Gynecol.* 2006 Jun;194(6):1585-90; discussion 90.
- 515 49. Lundquist M, Olsson A, Nissen E, Norman M. Is it necessary to suture all
516 lacerations after a vaginal delivery? *Birth.* 2000 Jun;27(2):79-85.
- 517 50. Morano S, Mistrangelo E, Pastorino D, Lijoi D, Costantini S, Ragni N. A
518 randomized comparison of suturing techniques for episiotomy and laceration repair
519 after spontaneous vaginal birth. *J Minim Invasive Gynecol.* 2006 Sep-Oct;13(5):457-
520 62.
- 521 51. Mota R, Costa F, Amaral A, Oliveira F, Santos CC, Ayres-De-Campos D. Skin
522 adhesive versus subcuticular suture for perineal skin repair after episiotomy--a
523 randomized controlled trial. *Acta Obstet Gynecol Scand.* 2009;88(6):660-6.
- 524 52. Selo-Ojeme DO, Okonkwo CA, Atuanya C, Ndukwu K. Single-knot versus
525 multiple-knot technique of perineal repair: a randomised controlled trial. *Arch*
526 *Gynecol Obstet.* 2016 Nov;294(5):945-52.

527 53. Spencer JA, Grant A, Elbourne D, Garcia J, Sleep J. A randomized
528 comparison of glycerol-impregnated chromic catgut with untreated chromic catgut for
529 the repair of perineal trauma. *Br J Obstet Gynaecol*. 1986 May;93(5):426-30.

530 54. Un-Nisa S, Un-Nisa S, Un-Nisa M. Comparison of Efficacy of Continuous
531 Versus Interrupted Suturing Technique in Episiotomy. *P J M H S*. 2013;7(4):1137-9.

532 55. Upton A, Roberts CL, Ryan M, Faulkner M, Reynolds M, Raynes-Greenow C.
533 A randomised trial, conducted by midwives, of perineal repairs comparing a
534 polyglycolic suture material and chromic catgut. *Midwifery*. 2002 Sep;18(3):223-9.

535 56. Valenzuela P, Saiz Puente MS, Valero JL, Azorin R, Ortega R, Guijarro R.
536 Continuous versus interrupted sutures for repair of episiotomy or second-degree
537 perineal tears: a randomised controlled trial. *BJOG*. 2009 Feb;116(3):436-41.

538 57. Yildizhan R, Yildizhan B, Sahin S, Suer N. Comparison of the efficacy of
539 diclofenac and indomethacin suppositories in treating perineal pain after episiotomy
540 or laceration: a prospective, randomized, double-blind clinical trial. *Arch Gynecol*
541 *Obstet*. 2009 Nov;280(5):735-8.

542 58. Zafar S. Comparison of a Single-Knot Versus Three Layered Technique of
543 Perineal Repair After Vaginal Delivery in Women Requiring Episiotomy: A Double
544 Blind Randomized Controlled Trial. *J Turkish-German Gynecol Assoc*.
545 2008;9(3):129-33.

546 59. Dencker A, Lundgren I, Sporrang T. Short communication: Suturing after
547 childbirth—a randomised controlled study testing a new monofilament material.
548 *BJOG: An International Journal of Obstetrics & Gynaecology*. 2006;113(1):114-6.

549 60. Feigenberg T, Maor-Sagie E, Zivi E, Abu-Dia M, Ben-Meir A, Sela HY, et al.
550 Using Adhesive Glue to Repair First Degree Perineal Tears: A Prospective
551 Randomized Controlled Trial. *BioMed Research International*. 2014.

- 552 61. Gordon B, Mackrodt C, Fern E, Truesdale A, Ayers S, Grant A. The Ipswich
553 Childbirth Study: 1. A randomised evaluation of two stage postpartum perineal repair
554 leaving the skin unsutured. *Br J Obstet Gynaecol.* 1998 Apr;105(4):435-40.
- 555 62. Grant A, Gordon B, Mackrodat C, Fern E, Truesdale A, Ayers S. The Ipswich
556 childbirth study: one year follow up of alternative methods used in perineal repair.
557 *BJOG.* 2001 Jan;108(1):34-40.
- 558 63. Grant A, Gordon B, Mackrodat C, Fern E, Truesdale A, Ayers S. The Ipswich
559 childbirth study: one year follow up of alternative methods used in perineal repair.
560 *BJOG: An International Journal of Obstetrics & Gynaecology.* 2001;108(1):34-40.
- 561 64. Mahomed K, James D, Grant A, Ashurst H. The Southmead perineal suture
562 study. A randomized comparison of suture materials and suturing techniques for
563 repair of perineal trauma. *BJOG: An International Journal of Obstetrics &
564 Gynaecology.* 1989;96(11):1272-80.
- 565 65. Oboro VO, Tabowei TO, Loto OM, Bosah JO. A multicentre evaluation of the
566 two-layered repair of postpartum perineal trauma. *Journal of Obstetrics and
567 Gynaecology.* 2003 2003/01/01;23(1):5-8.
- 568 66. Franchi M, Cromi A, Scarperi S, Gaudino F, Siesto G, Ghezzi F. Comparison
569 between lidocaine-prilocaine cream (EMLA) and mepivacaine infiltration for pain
570 relief during perineal repair after childbirth: a randomized trial. *Am J Obstet Gynecol.*
571 2009 Aug;201(2):186.e1-5.
- 572 67. Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of
573 Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration,
574 2011. Available from www.cochrane-handbook.org.
- 575 68. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST,
576 et al. The COMET Handbook: version 1.0. *Trials.* 2017 June 20;18(3):280.

69. Duffy J, Rolph R, Gale C, Hirsch M, Khan KS, Ziebland S, et al. Core outcome sets in women's and newborn health: a systematic review. *Bjog*. 2017 Sep;124(10):1481-9.
70. Hirsch M, Duffy JMN, Barker C, Hummelshoj L, Johnson NP, Mol B, et al. Protocol for developing, disseminating and implementing a core outcome set for endometriosis. *BMJ Open*. 2016;6(12).
71. Whitehouse KC, Kim CR, Ganatra B, Duffy JMN, Blum J, Brahmi D, et al. Standardizing abortion research outcomes (STAR): a protocol for developing, disseminating and implementing a core outcome set for medical and surgical abortion. *Contraception*. 2017 May;95(5):437-41.
72. Khalil A, Perry H, Duffy J, Reed K, Baschat A, Deprest J, et al. Twin-Twin Transfusion Syndrome: study protocol for developing, disseminating, and implementing a core outcome set. *Trials*. 2017 Jul 14;18(1):325.
73. Webbe J, Brunton G, Ali S, Duffy JM, Modi N, Gale C. Developing, implementing and disseminating a core outcome set for neonatal medicine. *BMJ Paediatrics Open*. 2017;1(1).
74. Duffy J, McManus RJ. Influence of methodology upon the identification of potential core outcomes: recommendations for core outcome set developers are needed. *Bjog*. 2016 Sep;123(10):1599.

Figure Legend

Figure 1. PRISMA Flow Diagram