PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): A pilot and feasibility randomised controlled trial.
AUTHORS	Dudley, Lynn; Kettle, Christine; Thomas, Peter; Ismail, Khaled

VERSION 1 - REVIEW

REVIEWER	Alexander Field Colchester Hospital, Turner Road, Colchester, Essex
REVIEW RETURNED	08-Jun-2016

GENERAL COMMENTS	Overall this is an interesting and well written paper that begins to address an important clinical question and I only have a few relatively minor points. In the abstract, line 37 you state that women reported higher satisfaction rates with re-suturing. I think this is somewhat selective interpretation of the results. This was statistically significant at 3 months but not significant at 6 weeks or 6 months. In the aims and objectives you state one of the specific objectives is to gauge participants acceptability of the research plan. This does not seem to be specifically addressed in the discussion and conclusion although presumably the low recruitment rate reflects that participants did not necessarily find the research plan acceptable in addition to the fact that 2 patients allocated resuturing expressed a preference for expectant management. I think that the exclusion criteria were both reasonable and minimal On page 6 line 12 you state that re-suturing was compared to expectant management and there follows a description of the recommended protocol for re-suturing. There is no similar protocol defining or explaining expectant management. Is this antibiotics, hygiene measures, clinical review etc? Was expectant management defined or simply left up to the clinician? On page 6 line 49 you state that the primary outcome is proportion of women with a healed wound at 6-8 weeks following trial entry. Presumably this is a healed wound as judged by an independent assessor? I did wonder given the problems with independent assessment whether the primary outcome ought to be patient satisfaction and return to sexual function rather than assessment by a clinician. On page 9 line 26 you talk about the number of women assessed for eligibility and those meeting the trial inclusion criteria. It is not clear

	who was judging the women for eligibility. Were these the same people as going on to perform the intervention or were they independent or randomisation and treatment process? On page 11 in table 2, I was interested to note that the re-suturing group seemed to be more likely to be young and white and wondered if this might be a potential bias (although I appreciate these are small numbers and this is a pilot study). In addition I wondered if there were any patients who had sustained a 3rd or 4th degree tear? According to table 2 the types of trauma were either spontaneous 2nd or episiotomy but I cannot see that 3rd or 4th degree tears were excluded according to the exclusion criteria (there may simply not have been any?) Although table 1 lists a recommended suturing method for dehisced wounds there is no recommendations for location of repair (e.g. delivery suite or theatres) or indeed anaesthesia. It would be interesting to compare re-suturing under local compared to regional block (or indeed general anaesthesia). There is also no mention of wound prep in terms of pre-op cleansing, use of hydrogen peroxide etc. Again on page 18, line 53 it is stated that re-suturing is associated with improved women's satisfaction. I am not sure this is backed up by the data presented. It is statistically significant at 3 months but not 6 weeks or 6 months. Overall this is an interesting paper of significant relevance to all practising obstetrics.

REVIEWER	Marian Knight National Perinatal Epidemiology Unit, University of Oxford, UK I collaborate with Prof Ismail on a trial of antibiotic prophylaxis after operative vaginal delivery.
REVIEW RETURNED	14-Jun-2016

GENERAL COMMENTS	This paper reports on a feasibility study conducted in preparation for a full RCT of suturing versus expectant management for women with dehisced perineal wounds. The methods used are appropriate and by and large the results appropriately reported. However, there is a tendency throughout to report outcome results as if this were a definitive trial e.g. first line of conclusion in the abstract, first line of discussion section in the main paper, line 4 on page 3 (strengths and limitations section - claims this is the largest RCT to date). It needs to be revised throughout to present this very clearly as a feasibility study and present the outcomes only in terms of estimation of effect size. Minor comments: 1. Reference 13. Would it be more appropriate to cite the more recent Confidential Enquiry reports (for 2009-12 which covers sepsis or 2011-13 when the study took place) rather than 2006-8? 2. An expanded discussion on why the feasibility study failed to recruit would be helpful e.g. a very detailed resuturing protocol which may have been a disincentive to clinician participation, the need for

	a second outcome assessor etc. At the moment I am struggling to see clearly what would need to be changed to facilitate recruitment in a future definitive trial. 3. The authors cite the work of McCulloch et al in relation to surgical trials but make no attempt to consider whether some of the strategies used in surgical trials might be relevant here, for example randomising women to surgeons when the surgeons are not in equipoise i.e. have preference for particular management techniques. Can they discuss possible solutions in the light of this surgical work?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comment: In the abstract, line 37 you state that women reported higher satisfaction rates with re-suturing. I think this is somewhat selective interpretation of the results. This was statistically significant at 3 months but not significant at 6 weeks or 6 months.

This now reads:
In this feasibility study, re-suturing was associated with quicker wound healing and women reported higher satisfaction rates with the outcome at 3 months.

Reviewer 1 comments: In the aims and objectives you state one of the specific objectives is to gauge participants acceptability of the research plan. This does not seem to be specifically addressed in the discussion and conclusion although presumably the low recruitment rate reflects that participants did not necessarily find the research plan acceptable in addition to the fact that 2 patients allocated resuturing expressed a preference for expectant management.

This now reads:
Under women's views: In a nested qualitative study,27 women were interviewed as part of the PREVIEW study to explore their physical and psychological experiences following perineal wound dehiscence; to assess the acceptability of the research plan and ensure that all outcomes relevant to women are included in the definitive trial.
The discussion section has also been amended

Reviewer 1 comments: On page 6 line 12 you state that re-suturing was compared to expectant management and there follows a description of the recommended protocol for re-suturing. There is no similar protocol defining or explaining expectant management. Is this antibiotics, hygiene measures, clinical review etc? Was expectant management defined or simply left up to the clinician?

This now reads:
Secondary re-suturing was compared to expectancy and respective standard operating procedures (SOPs) were developed (not submitted but available from the trial team). The SOP for secondary re-suturing specified that the procedure was to be conducted in theatre. Regional anaesthesia was recommended, with general anaesthesia for those women who had a contraindication for a regional block.

Reviewer 1 comments: On page 6 line 49 you state that the primary outcome is proportion of women with a healed wound at 6-8 weeks following trial entry. Presumably this is a healed wound as judged by an independent assessor?

This now reads:
Wound healing was defined as no areas of dehiscence observed by a clinician independent from the trial team

Reviewer 1 comments: On page 9 line 26 you talk about the number of women assessed for eligibility and those meeting the trial inclusion criteria. It is not clear who was judging the women for eligibility. Were these the same people as going on to perform the intervention or were they independent or randomisation and treatment process?

This now reads:
During the recruitment period, members of the PREVIEW team assessed a total of 321 women for eligibility, of these 128 met the trial inclusion criteria.
Reviewer 1 comments: On page 11 I wondered if there were any patients who had sustained a 3rd or 4th degree tear? According to table 2 the types of trauma were either spontaneous 2nd or episiotomy but I cannot see that 3rd or 4th degree tears were excluded according to the exclusion criteria (there may simply not have been any?)

This now reads:

Under study population: Women, with a dehisced perineal wound within the first 2 weeks following a primary repair of a second degree tear or episiotomy in any of the recruiting sites, were potentially eligible for the RCT.
Women were excluded from the study if they suffered a pregnancy loss, were less than 16 years old, were considered to have a high anaesthetic risk, had sustained a perineal trauma higher than a second degree tear or did not provide a valid written consent to participate.

Reviewer 1 comments: Again on page 18, line 53 it is stated that re-suturing is associated with improved women's satisfaction. I am not sure this is backed up by the data presented. It is statistically significant at 3 months but not 6 weeks or 6 months.

This now reads:
The PREVIEW pilot and feasibility RCT has produced vital information for the future planning of a robust and successful definitive study. Whilst re-suturing was associated with reduced duration to wound healing and improved women's satisfaction with the outcome at 3 months the size and nature of the study preclude from making reliable estimates of effectiveness

Reviewer 1 comments: Although table 1 lists a recommended suturing method for dehisced wounds there is no recommendations for location of repair (e.g. delivery suite or theatres) or indeed anaesthesia. It would be interesting to compare re-suturing under local compared to regional block (or indeed general anaesthesia). There is also no mention of wound prep in terms of pre-op cleansing, use of hydrogen peroxide etc.

Location was referred to later in the manuscript as follows: There were no protocol violations with regards to timing of re-suturing. Despite some organisational barriers all procedures were conducted in maternity theatres by a senior obstetric registrar or Consultant.

In the revision we have also referred to it under interventions as follows: Secondary re-suturing was compared to expectancy and respective standard operating procedures (SOPs) were developed (not submitted but available from the trial team). The SOP for secondary re-suturing specified that the procedure was to be conducted in theatre. Regional anaesthesia was recommended, with general anaesthesia for those women who had a contraindication for a regional block.

Table 1 methods details the following: Standard surgical procedures for secondary suturing should be followed including wound debridement if needed

Reviewer 1 comments: In table 2, I was interested to note that the re-suturing group seemed to be more likely to be young and white and wondered if this might be a potential bias (although I appreciate these are small numbers and this is a pilot study).

We accept the reviewers comment and agree that this is a feasibility study and a more definitive estimate of effect size awaits a larger trial.

Manuscript number 1 reviewer 2 comments have been addressed as follows:

Reviewer 2 comments: There is a tendency throughout to report outcome results as if this were a definitive trial e.g. first line of conclusion in the abstract, first line of discussion section in the main paper, line 4 on page 3 (strengths and limitations section - claims this is the largest RCT to date). It needs to be revised throughout to present this very clearly as a feasibility study and present the outcomes only in terms of estimation of effect size

We have amended the text to address the reviewer's comments

Comment: Reference 13. Would it be more appropriate to cite the more recent Confidential Enquiry reports (for 2009-12 which covers sepsis or 2011-13 when the study took place rather than 2006-8?

This now reads:
In England and Wales, between 2006 and 2008 sepsis was identified as the leading cause of maternal mortality.13 During this triennium, one of the seven women who died from sepsis after a vaginal delivery had an infected perineum following with a second degree tear. Whilst subsequent confidential enquiries have demonstrated a reduction in the rates of deaths from sepsis, it remains one of the leading direct causes of mortality in women following vaginal delivery.14 15

Reference 13 was added as this report detailed the death of a woman from an infected perineum; however we have now referenced 2 further confidential enquiries.
Reviewer 2 comments: An expanded discussion on why the feasibility study failed to recruit would be helpful e.g. a very detailed resuturing protocol which may have been a disincentive to clinician participation, the need for a second outcome assessor etc. At the moment I am struggling to see clearly what would need to be changed to facilitate recruitment in a future definitive trail

We have expanded the discussion section in consideration of the comments above

Reviewer 2 comments: The authors cite the work of McCulloch et al in relation to surgical trials but make no attempt to consider whether some of the strategies used in surgical trials might be relevant here, for example randomising women to surgeons when the surgeons are not in equipoise i.e. have preference for particular management techniques. Can they discuss possible solutions in the light of this surgical work?

We have expanded the discussion section in consideration of the comments above.

The word count for our revised manuscript is 4241.

Many thanks for your time in reviewing our revised manuscript. Our amendments have been highlighted in yellow and we have also submitted a clean copy. Please do not hesitate to contact either Professor Khaled Ismail or myself should any questions arise regarding this re-submission of manuscript number 1. We shall look forward to hearing from you.

VERSION 2 – REVIEW

REVIEWER	Alexander Field Southend University Hospital Prittlewell Chase Southend-on-sea United Kingdom
REVIEW RETURNED	16-Aug-2016

GENERAL COMMENTS	I am happy to recommend for publication as it stands as the authors have addressed all of the points I had raised previously.

Correction

Dudley L, Kettle C, Thomas PW, *et al*. Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): a pilot and feasibility randomised controlled trial. *BMJ Open* 2017;**7:**e012766. doi:10.1136/bmjopen-2016-012766

The superscript "3" should not be next to author Lynn Dudley as this is not one of their affiliations.

BMJ Open 2017;**7**:e012766corr1. doi:10.1136/bmjopen-2016-012766corr1