**A Systematic Review on Reported Outcomes and Outcome Measures in Female Idiopathic Chronic Pelvic Pain for the Development of a Core Outcome Set.**

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**Abstract**

**Background:** A core outcome set (COS) is required to address inconsistencies in outcome reporting in chronic pelvic pain (CPP) trials.

**Objectives:** Evaluation of reported outcomes and selected outcome measures in CPP trials by producing a comprehensive inventory to inform a COS.

**Search Strategy:** Systematic review of RCT identified fromCochrane Central Register of Controlled Trials (CENTRAL), EMBASE and MEDLINE databases.

**Selection Criteria:** RCT assessing efficacy and safety of medical, surgical and psychological interventions for women with idiopathic CPP.

 **Data Collection and Analysis:** Two independent researchers extracted outcomes and outcome measures. Similar outcomes were grouped and classified into domains to produce a structured inventory.

**Main Results:** Twenty-four trials were identified including 136 reported outcomes and 48 outcome measures. Rates of reporting outcomes varied (4-100%), pelvic pain was the most frequently reported outcome (100%). All trials reported the pain domain however, only half reported quality of life, clinical effectiveness and adverse events. No differences in outcome reporting were observed in five high-quality trials (21%). Univariate analysis demonstrated an association between quality of outcome reporting and methodological quality of studies (rs =0.407, p = 0.048).

**Conclusion:** There is wide variation in reported outcomes and applied outcome measures in CPP trials.While a COS is developed and implemented, we propose an interim use of three commonly reported outcomes in each domain. These include: pain (pelvic pain, dyspareunia, dysmenorrhoea), life impact (quality of life, emotional functioning, physical functioning), clinical effectiveness (efficacy, satisfaction, cost effectiveness, return to daily activities) and adverse events (surgical, perioperative observations, non-surgical).

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**Keywords**

Chronic pelvic pain;

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**Tweetable abstract**

There is significant variation in outcome reporting in CPP trials. Our systematic review forms the basis for the development of a core outcome set.

**Introduction**

Chronic pelvic pain (CPP) is a debilitating condition affecting 15% of women worldwide and is associated with significant long-term morbidity and socio-economic burden. 1 2 CPP is defined as pain lasting longer than six months or recurrent episodes of abdominal/pelvic pain, hypersensitivity or discomfort often accompanied with elimination changes, and sexual dysfunction. 3 It is a challenging disorder to treat due to its poorly understood aetiology and complexities of pain perception and sensation. Standard medical or surgical treatments lack a holistic approach and often fail to improve the severity of symptoms as well as quality of life. 4

Recent Cochrane reviews evaluating the efficacy and safety of surgical and non-surgical therapies for CPP in women have alluded to poor quality of evidence for most comparisons. 5-7 Studies may be of poor quality due to a number of reasons however, the variation in reported outcomes and outcome measures have been noted in Cochrane reviews pertaining to interventions for CPP. 8,9 Such inconsistencies have contributed to and precluded the synthesis of data in high-quality meta-analyses to produce high-quality results. Furthermore, this has prevented clinically relevant conclusions that can ultimately be used to directly benefit patient care. Additionally, the selection of outcomes has been limited and often not relevant to key stakeholders. For example, the lack of quality of life outcomes reported in trials which are of interest to patients with CPP. 6,9

Currently, there is no clear consensus among health professionals, researchers and patients regarding the outcomes and outcome measures that should be collected and reported in randomised control trials (RCTs) assessing potential interventions for CPP. There is no previous research that has specifically identified selected, collected and reported outcomes or outcome measures in RCT evaluating treatments for idiopathic CPP in women.

In this systematic review, we aimed to summarise the available evidence on reported outcomes and outcome measures by comprising an inventory. We also evaluated correlations between methodological quality and quality of outcome reporting of published randomised control trials in this field. Based on our findings, we will recommend the use of interim reported outcomes and outcome measures while the development of a core outcome set (COS) is in progress.

**Methods**

This systematic review was registered with the Core Outcomes Measures in Effectiveness Trials (COMET) Initiative Register, number 981 and with the International Prospective Register of Systematic Reviews (PROSPERO), registration number CRD42019134858. This review was performed on behalf of CHORUS, an International Collaboration for Harmonising Outcomes in Research, and Standards in Urogynaecology and Women’s Health (https//i-chorus.org). This project is part of a wider initiative to develop COS in CPP and completing an inventory of reported outcomes and outcome measures is the initial step in this process. The results from this systematic review will subsequently inform and assist focus groups, Delphi surveys and consensus meetings.

We followed a standardised methodological approach in line with previous experience and expertise developed within CHORUS as well as recommended COMET guidelines in relation to systematic reviews and the development of COS.10-16

**Search strategy**

The design of the present systematic review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline.17 A comprehensive literature search was undertaken using Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE and MEDLINE databases. Searches were performed from database inception to September 2019 using the following MESH search terms: “chronic pelvic pain”, “pelvic pain” and “idiopathic chronic pelvic pain”.

We included randomised control trials assessing the effectiveness of interventions for CPP. The population of interest included women over 18 years of age with CPP. We included all studies investigating psychological therapies, medical and surgical interventions with existing treatments or placebo regimes. We excluded studies in languages other than in English, pilot studies, non-randomised studies, retrospective studies, case-series and case-reports. Secondary analysis studies or studies that used the same population as the initial intervention were considered for inclusion however, duplicate outcomes were only described once.

**Selection of studies and data extraction**

We screened for potentially eligible studies by examining initially titles and subsequently abstracts of the identified studies. Full text articles were retrieved for abstracts meeting the inclusion criteria or in cases when information in the abstract was incomplete or unclear. Full text articles were reviewed and discrepancies regarding suitability for inclusion were resolved by discussion with the senior author (SKD).

Two independent researchers (VG and VV) extracted study characteristics from eligible studies using a piloted Microsoft Excel spreadsheet. Study characteristics included author details, type of journal (general or speciality interventions), number of participants, length of follow up, year and impact factor of journal at publication as well as commercial funding (none, yes or not specified). The impact factor of the journals in the year of publication retrieved from the Incites Journal Reports were considered as an indirect marker of the scientific importance of the published study.18 For the purpose of this systematic review, commercial funding was defined as direct funding received from pharmaceutical companies and/or device manufacturers to contribute to direct costs of the trial (design, medical and/or device needs, patient insurance). Disclosures from authors declaring travel grants or sponsorships from pharmaceutical companies or device manufacturers were not classified as commercial funding.

**Quality assessment of included studies**

Two reviewers (VG, VV) independently assessed the scientific quality of included studies using the JADAD scoring system which consists of five questions: (1) was the study described as randomised; (2) was the method of randomisation appropriate; (3) was the study described as double-blind; (4) was the method of double-blinding appropriate and (5) was there a description of withdrawals and dropouts. Each criterion was scored zero if absent and one if present, total scores ranged from zero to five.19 As with previous similar systematic reviews, we considered a JADAD score of 4 and greater indicative of high quality.

The quality of describing and reporting outcomes in eligible studies was assessed using the Management of Otitis Media with Effusion in Cleft Palate (MOMENT) score system. 20 This score evaluates the following six criteria: (1) the presence of a primary outcome; (2) a clearly defined primary outcome facilitating reproducible measures; (3) clearly stated secondary outcomes; (4) clearly defined secondary outcome facilitating reproducible measures; (5) rationale for selected outcomes and (5) whether methods used will enhance the quality of outcome measurement. Each criterion was scored the following: zero for not mentioned and one for correctly mentioned; total scores ranged from zero to six. We considered a score of 4 or more to define high quality studies.

**Data analysis**

We identified and extracted reported outcomes from the abstract, methods and results sections of studies. These were organised into a comprehensive outcome inventory. Outcome domains were formed by grouping together similar outcomes that shared a common definition. Outcome domains and included outcomes were reviewed by authors to prevent any duplication of outcomes resulting from varying terminology. Our approach to generating outcome domains was adopted from the methodology used by Hopkins et al during the BARIACT study (outcome reporting in bariatric surgery: an in- depth analysis to inform the development of a core outcome set, the BARIACT Study). 21

We also performed a further analysis to identify which outcomes and outcome measures were reported frequently in high quality studies, defined as studies with a JADAD and MOMENT score of 4 and greater. Where disagreements in JADAD and MOMENT scoring between reviewers occurred, a third author was involved for arbitration and consensus in the scoring process.

Univariate association between non-parametric, continuous variables was tested using the Spearman Rho correlation coefficient. We assessed the relationship between quality of outcome reporting (MOMENT score) as the dependent variable and independent variables JADAD scores, study size, year of publication and impact factor of the journal. The strength of correlation was defined as: very weak (0.00-0.19); weak (0.20-0.39); moderate (0.40-0.59); strong (0.60-0.79) and very strong (0.80 and above). All analyses were undertaken using SPSS 25.0 (IBM, Armonk, NY, USA)

**Patient and Public Involvement**

There has been no patient involvement as this study is a systematic review of existing research. However, during the development of a COS, stages such as Delphi surveys and consensus meetings will include patient participation and involvement.

**Results**

The literature search took place on the 22nd September 2019 and we identified 1,310 titles and abstracts. We screened 1,067 titles and abstracts following the exclusion of 243 duplicate records. (Figure S1) We included 24 RCT’s (references of these studies appear in Appendix S1) with a total of 4,064 female participants. (Table S1) The included RCT consisted of 23 (95.8%) primary studies and a single follow-up study (4.3%) . Almost 80% of RCT’s (18 out of 24 trials) evaluated non-surgical treatments. We identified 136 reported outcomes and 48 outcome measures (an inventory of reported outcomes and outcome measures appear in Appendix S2). Figure 1 demonstrates reported outcomes and outcome measures per domain.

The most common domains were: pain (24/24 trials, 100%), life impact (13/24 trials, 54%), adverse events (12/24 trials, 50%) and clinical effectiveness (12/24 trials, 50%). The commonest reported outcomes in the pain domain were pelvic pain (24/24 trials, 17 outcome measures), dyspareunia (7/24 trials, 3 outcome measures) and dysmenorrhoea (5/24 trials, 3 outcome measures). Pelvic pain was reported using 17 outcome measures. These included nine validated instruments (visual analogue scores 0-10, visual analogue scores 0-100, verbal rating scores 0-10, Biberoglu and Behrman scale, Brief Pain Inventory, Multidimensional Pain Inventory, five point subjective self-rating pain scale, the short and full McGill pain questionnaire) and five non-validated instruments (visual analogue scores 1-10, visual analogue scores 0-14, diary pain index, interview pain index, pain characteristics) for assessing severity of pelvic pain. Instruments were considered as validated outcome measures if there was reference to validation studies in the original RCT. The most frequently used instruments were visual analogue scales (18/24 trials , 75%), however various scales were utilised and reported inconsistently. Visual analogue scores such as 0 -10, 1 -10, 1 -14 and 0 -100 were used. The most commonly used visual analogue score was 0-10 (11/24 trials, 46%). (Table S2)

Life impact was reported by half of trials (13/24, 54%) using 29 reported outcomes, 18 outcome measures with 1 outcome measure not reported. (Figure 1) The three most commonly reported life impact outcomes included emotional functioning (6/24 trials, 6 outcome measures), quality of life (5/24, 6 outcome measures ), and physical functioning (4/24 trials, 4 outcome measures). Emotional functioning was reported by six RCT’s using six outcome measures: Hospital and Anxiety Depression scores (HADS), Beck Depression Inventory (BDI), Hamilton Rating Scale for Depression (HRSD), Inventory of Interpersonal Problems (IIP), General Health Question (GHQ-30) and visual analogue scores (0-100). The HADS questionnaire and the BDI were the most frequently (2/5 trials) used to assess emotional functioning. Quality of life was reported using six outcome measures: EuroQOL-5D (EQ-5D), 12-item short form health survey (SF-12), 36-item short form survey (SF-36), Endometriosis health profile (EHP-30), EQ-visual analogue scores (EQ-VAS) and the World Health Organisation Quality of Life (WHOQoL).Outcomes such as sexual function (2/24 trials) , attitudes to pain (2/24 trials) and pain interference (1/24 trials) were infrequently reported. (Table S2)

Clinical effectiveness was reported by 50% of included trials (12/24, 26 reported outcomes, 10 outcome measures, 4 outcome measures not reported). (Figure 1) Outcomes reported in this domain were efficacy (8/24 trials, 7 outcome measures), satisfaction/user acceptability (6/24 trials, 4 outcome measures, 2 outcome measure not reported), cost effectiveness (2/24 trials, 1 outcome measure, 1 outcome measure not reported) and return to daily activities (2/24 trials, 1 outcome measure, 1 outcome measure not reported). The efficacy of interventions was based on the need for additional treatments, persistent pain or long-term complication. The following outcome measures were used to obtain this information: interview, non-specific questionnaire, pain analogue scale 0-10, visual analogue scores 0-100, visual analogue score 1-10, subjective pain rating scale and a short form McGill pain questionnaire. (Table S2)

Adverse events associated with non-surgical and surgical interventions were collected and reported by 12 RCT’s (50%) using 22 reported outcomes, eight outcome measures and nine outcome measures not reported. (Figure 1 and Table S2)

The majority of RCT’s (71%, 17 out 24 trials) were published in obstetrics and gynaecology journals and only a single RCT (4%) featured in a general medical journal. (Table S1) Over two-thirds of included trials (16 out of 24 trials, 67%) did not specify whether they received commercial funding. Eight studies reported on commercial funding status, a single trial (n=24, 4%) received commercial funding whereas seven studies (n=24, 29%) did not. (Table S1)

The quality of outcome reporting scored a median value of 4 (MOMENT score, with a maximum of 6, interquartile range of 3 - 5). The methodological quality scored a median value of 3 (JADAD score, with a maximum of 5, interquartile range of 3– 4) (Table S1) Univariate analysis exhibited a positive correlation (moderate) between quality of outcome reporting and study quality (JADAD score). (Table 1) No relationship was demonstrated between quality of outcome reporting with sample size, quality of study, year of publication and impact factor of journal at the time of publication.

Five out of 24 trials (21%) were high quality studies and received a score of four or greater in the JADAD and MOMENT criteria. The most common reported domains in these trials were: pain (5/5 trials, 13 reported outcomes, 2 outcome measures), adverse events (5/5 trials, 10 reported outcomes, 4 outcome measures, 2 outcome measures not reported), clinical effectiveness (4/5 trials, 12 reported outcomes, 4 outcome measures, 2 outcome measure not reported) and life impact (2/5 trials, 4 reported outcomes, 4 outcome measures). (Table S3) Severity of pelvic pain was the most frequently reported outcome using two outcome measures. These included visual analogue scales 0-10 (4/5 trials) and the McGill pain questionnaire (1/5 trials). (Table S3). Outcomes such as dysmenorrhoea (3/5 trials), dyspareunia (3/5 trials), efficacy of treatments (3/5 trials), satisfaction/user acceptability (3/5 trials) and quality of life (2/5 trials) were also frequently reported outcomes. (Table S3)

**Discussion**

**Main findings:**

This systematic review showed wide variation in reported outcomes and applied outcome measures in RCT’s evaluating interventions for CPP. Rates of reporting outcomes varied between 4% (pain interference) and 100% (pelvic pain). The most commonly reported outcome was pelvic pain and measured frequently using visual analogues scales 0-10. Only half of RCTs reported outcomes in life impact, clinical effectiveness and adverse events domains. However, a range of treatments were evaluated and therefore some domains may not be as relevant to particular interventions. The under-reporting of life impact and clinical effectiveness is concerning and requires attention in future trials. High-quality studies had no differences in reported outcomes or domains. We demonstrated a relationship between quality of outcome reporting and methodological quality of a study but no association was found between outcome reporting quality and study size, year of publication or journal impact factor at time of publication.

**Strengths and limitations:**

To our knowledge, this is the first systematic review investigating variation of reported outcomes and outcome measures in idiopathic CPP trials as well as the quality and publication metrics of trials. Our methodology has been previous studies and is an established study design. Previous systematic reviews such as Cochrane reviews have evaluated the incidence rates of various outcomes related to CPP interventions. We aimed to specifically evaluate the selection and reporting of outcomes, outcome measures and their variations.

This study has limitations. We limited our search to RCTs, potentially missing outcomes from non-randomised studies. Only trials written in English were included at this stage, to minimise issues arising from translating terms and the subsequent taxonomy issues with classifications of outcomes into domains. There are inherent limitations when attempting to classify reported outcomes into domains. At present, there is no universally accepted classification. Grouping of outcomes facilitates taxonomy and ensures that important outcomes are not “missed”. However, for the purpose of developing COS, there is no significant loss or misclassification of information resulting from a degree of duplication or overlapping of outcomes or domains. Outcomes such as pelvic pain are multi-dimensional and can be included in more than one domain. Pelvic pain could be an outcome that represents the effectiveness of an intervention, or be an adverse event. Nevertheless, the final inclusion of outcomes and domains in a COS is the endpoint of a consensus process based on systematic reviews, focus groups and Delphi surveys.

**Interpretation**:

Our study findings, demonstrated heterogeneity in outcome reporting, also found in in other areas of gynaecology. 12-15, 22 The diversity in reported outcomes and outcome measures hinders the comparison and combination of data for meta-analyse, therefore, limiting the value of research in informing clinical practice and improve patient care. 23

The variation in reported outcomes found in this study, may be attributable to a lack of stipulated criteria for trials to report. Researchers often select outcomes arbitrarily and reporting on outcomes that support a specific intervention is a well-known source of bias (positive outcome bias). This may underestimate potential harms and favour less efficacious therapies. In addition, reported outcomes do not always reflect the priorities of all stakeholders such as health professionals, patients and researchers. For example, life impact was reported by only half of trials. Reporting outcomes related to life impact may not be a priority for researchers, however, for women suffering from CPP improvement of pain as well quality of life may be equal priorities. Furthermore, by reporting on outcomes such as pain behaviours and emotional functioning, it encourages the development of targeted psychological therapies. There is increasing evidence for multifaceted care models, incorporating pain management programmes, physiotherapy, psychological therapies alongside gynaecological treatments. 24 Clinical effectiveness was reported in 50% of trials only. However, for national governing bodies, costs of procedures may be a considering factor when implementing new treatments. The wide range of medical, surgical and psychological interventions may also contribute to the variations observed in outcomes and outcome measures.

We highlighted the need for RCT reporting on CPP interventions to use consistent and standardised outcome measures. In our study, severity of pelvic pain was a reported outcome evaluated using 17 different outcome measures. Although, visual analogue scales were most commonly used, such scales varied widely (0-10, 1-10, 0-100 and 0-14). Caution must be exercised when using instruments as these may be condition-specific instruments such as the Oswestery Disability Index for lower backpain. Inconsistencies and the use of non-validated instruments can cause difficulties when comparing interventions in meta-analyses. Furthermore, although instruments may be validated, the validation process and parameters of outcome measures have additional variation.

The variation of outcome measures and frequent use of visual analogues scales to measure severity of pelvic pain was also observed by Gurian et al.25 However, Gurian et al included RCTs treating various causes of CPP such as gastrointestinal, gynaecological and urological pathologies. Our study specifically evaluated RCTs on idiopathic CPP and produced a comprehensive inventory of reported outcomes for the purpose of developing a COS.

There was no association between quality of outcome reporting and study size, impact of journal at publication or year of publication. Therefore, the quality of outcome reporting does not appear higher in journals with a higher impact factor. This may suggest publication bias, as journals might favour results or prioritise other study characteristics rather than quality of outcome reporting. Results from trials could be misleading due to selective reporting and publication bias. This could potentially affect the interpretation and applicability of findings in the field of CPP research. A meta-analysis based on poor-quality studies may inflate the impact of biased study results with a detrimental influence on patient care.

**Conclusion**

Currently, there is no consensus on which outcomes should be used in trials and systematic reviews regarding interventions for CPP. Our findings support the development of a COS to address the inconsistencies and lack of standardisation associated with outcome reporting. Implementation of a COS will reduce outcome reporting bias and ultimately improve patient care by production of comparable data and high-quality evidence. While the process of developing a COS is in progress, we propose the interim use and reporting on all three outcomes in each domain. These are life impact (quality of life, emotional functioning, physical functioning outcomes), pain (pelvic pain, dyspareunia, dysmenorrhoea outcomes), clinical effectiveness (efficacy, satisfaction, cost effectiveness, return to daily activities outcomes) and adverse events (surgical, perioperative observations, non-surgical outcomes). These outcomes have been selected as they represent the most frequently reported ones as well as among those reported in high-quality trials. The purpose of our recommendation is to reduce further research waste during the development of a COS. Trials designed or conducted before COS are established could contribute and be included in a higher-quality meta-analyses.

There is significant variation in reported outcomes and outcome measures in CPP trials. This limits the use of research to inform clinical practice and improve patient care. There is a clear need for the development and implementation of a COS, to promote consistent outcome reporting as well as improve the quality of future research.

**Disclosure of interest**

None declared

**Details of ethical approval**

This systematic review is based on outcomes published in previous trials. No approval was required from an institutional review board.

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**Contribution to authorship**

SKD conceived the idea, VG and VS performed data collection, tabulated data and analysis, VG and VP performed statistical analysis,VG, VS, VP, HJ, RT, SKD contributed to writing the manuscript and approved the final version.

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