DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

Doctorate in Clinical Psychology : Main Research Portfolio

1) Are Psychological Interventions effective in the management of outcomes for Chronic Pelvic Pain? A Systematic Review ;2) Introduction of Family/Carer Psychoeducation Sessions alongside a Dialectical Behavioural Therapy Programme ; 3) Examining factors influencing the development and maintenance of non-specific abdominal pain.

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Award date:
2022

Awarding institution:
University of Bath

Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology Volume 1 of 2

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Doctorate in Clinical Psychology

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August 2022

Word Counts

Systematic Review…… 11,842

Are Psychological Interventions effective in the management of outcomes for Chronic Pelvic Pain? A Systematic Review

Service-Related Project…… 5,173

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Impact of COVID-19 on Research and Submissions

The outbreak of the COVID-19 pandemic had an impact on two of the three projects within this portfolio: the service-related project and the main research project.

My service improvement project was planned and approved prior to the outbreak of the pandemic, in Autumn 2020. This project entailed the development and delivery of a face-to-face psychological intervention group with the families of service users. The group was due to take place in spring 2020, but all service projects were put on hold at this point due to the impact of COVID. After discussions with the service and my research supervisor, approval was given for the group to move online. However, the group experienced multiple technical difficulties due to IT resources not being fully established at this time. This and the inability to meet group attendees face-to-face may have impacted the experience of the group for participants. In addition, two individuals who had been due to attend the group dropped out prior to the start of the group citing COVID related reasons. All feedback from service-users and their families was also obtained remotely. Additionally, feedback to the service had been planned for delivery at face-to-face meetings, however at this time several regular meetings had been cancelled due to COVID and so feedback occurred on a smaller scale than planned. Although these challenges did make the project logistically more difficult, myself and my placement supervisor felt happy at the end of the project that despite these issues we had still been able to deliver high quality service improvement.

The main way that COVID impacted on my main research project was regarding recruitment. During the initial planning phase of the project, the possibility of recruiting from medical clinics and accident and emergency (A&E) departments had been suggested. My second supervisor, Dr Ed Carlton, was a medic who had agreed to potentially take this forward at the hospital he worked at. However, with the arrival of COVID-19, we quickly realised that recruiting from medical facilities would not be possible. Recruitment therefore was moved online, with more reliance on other ways to contact the targeted participant group. Several ways that this may have impacted the project are discussed in the limitations section of the main research project. Firstly, most participants recruited were of American nationality, which is likely to have influenced findings about accessing healthcare facilities. Secondly, the absence of individuals recruited from A&E departments may mean that participants did not experience “severe” symptoms and may have given lower scores on outcome measures. Recruiting from medical facilities would also have ensured reliable data, as there was evidence during the analysis phase of this project that some individuals may not have fully met the criteria for

study participation. However, the project managed to recruit over the minimum number of participants as indicated via an apriori power analysis. As such, an appropriate amount of data was analysed to ensure adequate statistical power.

Overall, although the COVID-19 pandemic has meant that extra hurdles have had to be overcome within these projects, these have not been unmanageable. I hope that despite these issues, these studies are a valuable addition the literature in their respective research areas.

Abstracts

Are Psychological Interventions effective in the management of outcomes for Chronic Pelvic Pain? A Systematic Review

Background and Aims: Chronic Pelvic Pain (CPP) is a widespread issue in women's health which places significant burden on sufferers, healthcare professionals and healthcare organisations alike. Due to the many causes of CPP, diagnosis, management, and treatment is complex. The need to address biopsychosocial factors in conditions causing CPP means that psychological interventions are increasingly being utilised as part of treatment plans. However, there is scarce research exploring the effectiveness of undiluted psychological interventions for female CPP across aetiologies. The aim of this systematic review is to assess the effectiveness of psychological interventions for CPP outcomes with distinct aetiologies. The review also aims to compare which interventions (if any) work best for distinct CPP subtypes.

Methods: A comprehensive search strategy was used to retrieve RCTs relating to CPP subtypes from databases APA Psycnet, Embase and Pubmed.gov. Inclusion criteria were adult females with a diagnosis of CPP or conditions known to cause CPP. The primary outcome for this review was psychological distress, with secondary outcomes including pain, quality of life and disability. A data extraction form was used to extract key information from the study, including study demographics, psychological interventions, and outcomes. Planned analysis included meta-analysis and narrative synthesis of data. The Risk of Bias tool (second edition) was used to assess risk of bias within studies.

Results: Of 8648 studies screened, 18 met the criteria for review inclusion. Incomplete, missing, or incompatible data meant meta-analysis was not possible. Instead, a narrative review of outcomes was presented. Ten different psychological interventions led to improvements including pain, anxiety, depression, quality of life, and additional symptoms of CPP in five CPP subtypes. Most studies showed at least "some concerns" or "high" risk of bias.

Discussion: This systematic review shows promising preliminary results for using psychological interventions for conditions causing CPP. However, sophisticated statistical analysis could not take place due to data not meeting apriori analysis criteria for meta-analysis. In CPP, further investment in high quality research is needed, particularly in a subset of CPP aetiologies.

Conclusions: Further research with high quality methodology is necessary to conduct further evaluation as to the effectiveness of psychological interventions for CPP and contributing diagnoses.

Keywords: Pelvic pain, women's health, psychology, review, mindfulness, cognitive behaviour therapy

Introduction of Family/Carer Psychoeducation Sessions alongside a Dialectical Behavioural Therapy Programme project

Background

Emotionally Unstable Personality Disorder (EUPD) is a disorder characterised by numerous distressing symptoms, with family members of those affected often struggling to support their loved one. Previous research has shown that family programmes based on Dialectical Behaviour Therapy (DBT) are beneficial for both family members and individuals with EUPD. This project aimed to design, deliver, and evaluate a group for family members of those with EUPD.

Design

A mixed-methods design.

Method

Two service-user/family member dyads took part in the group which consisted of four hour-long sessions. Family members completed the following questionnaires: Warwick Edinburgh Mental Wellbeing Scale (WEMWBS), SCORE-15 measure of family functioning, Burden Assessment Scale and the Pearlin Mastery Scale. Service-users completed the former two of these questionnaires, and both service-users and family members gave feedback. Due to the lower number of project participants, descriptive data is given and discussed.

Results

In the context of the COVID-19 pandemic a DBT family-based group was developed and run in an online format. Participant feedback was predominantly positive and reflected on useful group components. Improvements on the WEMWBS and SCORE-15 questionnaires as seen by some participants are discussed. Suggestions for future group improvement are highlighted, and the Gibbs (1988) cycle was used to reflect on the process of running the group.

Conclusions

Although limited data means that no firm conclusions can be drawn, initial results for the effectiveness of a shortened programme for families of those with EUPD are promising. Findings are discussed in reference to further group development and considerations for future session delivery.

Keywords: Emotionally Unstable Personality Disorder (EUPD), Dialectical Behaviour Therapy (DBT), Family Therapy, Psychology Group, Teletherapy

Examining factors influencing the development and maintenance of Non-Specific Abdominal Pain

Background

Non-specific abdominal pain (NSAP) involves recurrent episodes of acute abdominal pain, however often, no organic cause can be found for this. In other pain disorders, psychological variables including anxiety and depression can contribute to and maintain pain severity. Other cognitive and psychosocial variables have also been shown to impact psychological and physical outcomes in pain populations. However, NSAP research is scarce within pain literature, therefore little is known about what psychosocial factors influence this condition.

Design

The study used an online cross-sectional survey-based design.

Methods

One-hundred and fifty-nine (n=159) participants were recruited and took part in online questionnaires. Data from ninety-nine participants (n=99) using six questionnaires was used in final analysis to assess the relative contributions of the variables anxiety sensitivity, body vigilance, pain catastrophising and trauma to outcomes of anxiety, depression, and pain in NSAP participants. Correlational analyses and multiple regression modelling assessed the relationship between all variables.

Results

Correlational analysis showed significant positive relationships between almost all study variables. Multiple regression analysis showed: trauma and pain catastrophising contributed 6.3% ($p < .001$) and 3.6% ($p < .001$) to depression; respectively. Anxiety sensitivity and body vigilance contributed 11.5%, $p < .001$) and 2.6%, $p < .05$) to anxiety; respectively. Trauma, body vigilance and pain catastrophising contributed 3.3% ($p < .001$), 1.4% ($p < .001$) and 49.9% ($p < .001$) to pain severity; respectively.

Conclusions

This study identifies several variables that provide promising treatment targets for psychological interventions to treat NSAP. Findings are discussed in reference to relationships between study variables and future research implications.

Keywords: Non-Specific Abdominal Pain, Cognitive Behaviour Therapy, Trauma, Biopsychosocial, Persistent Physical Symptoms

Are Psychological Interventions effective in the management of outcomes for Chronic Pelvic Pain? A Systematic Review

June 2022

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Word count: 11,161

Proposed Journal: Clinical Psychology Review

Word limit: Fifty (50) pages including references, appendices and other tabular material

Rationale for proposed journal: The Clinical Psychology Review journal publishes reviews of topics relating to clinical psychology. Papers cover diverse topics including (but not limited to) psychotherapy, cognitive therapies, and behavioural medicine.

Introduction

Chronic Pelvic Pain (CPP) is defined as pain of over six months typically originating from the pelvis, and is often associated with negative behavioural, cognitive, sexual, and emotional consequences (Lamvu, Carrillo, Ouyang and Rapkin, 2021). CPP is estimated to have a worldwide prevalence of 26%, though research shows varying rates including 14.7%, 24% and 25% in the United States, United Kingdom and New Zealand, respectively (Alappattu and Bishop, 2011; Lamvu et al, 2021). CPP can be due to known organic diagnoses including irritable bowel syndrome (IBS), endometriosis or inflammatory bowel disease, but up to 55% of women may have no obvious origin for their pain (Cheong, Smotra and Williams, 2014; Grinberg, Sela and Nissanholtz-Gannot, 2020). Building an evidence base for effective treatment of CPP is complex due to the heterogeneity of conditions that can contribute towards this. Research exploring treatments for CPP subtypes often focuses on singular diagnoses, such as irritable bowel syndrome or endometriosis. However, there is commonly significant co-morbidity in conditions causing CPP, in addition to overlaps in physical and psychological symptoms and outcomes (Speer, Mushkbar and Erbele, 2016). Subsequently, it can be reasonable to view "Chronic Pelvic Pain" as an overarching construct, with guidance having been introduced by organisations regarding the diagnosis and treatment of CPP as one encompassing diagnosis (International Pelvic Pain Society, 2022).

The clinical implications of CPP are vast, with CPP accounting for 10% of laparoscopies, 12% of hysterectomies, and 10% of gynaecology visits in the USA annually, and the cost of conditions associated with CPP exceeding $289 billion and £326 million annually in the USA and UK; respectively (Ball, 2020; Lamvu et al, 2021). Women with CPP often face long waits for diagnoses and treatment, with pain and suffering often continuing despite medical interventions and leading to reduced quality of life, income, and diminished emotional wellbeing (Ball, 2020; Till, 2019). The detrimental impact of CPP for women includes limitations to daily activities and deterioration of romantic relationships, in part due to psychosexual issues and the inability of partners to understand their pain and resulting needs (Romao, Gorayeb, Romao, Poli-Neto and Nogueria, 2013). The huge personal and societal cost of CPP therefore means that there is a significant need to identify effective treatment for this.

Research has increasingly found a range of biopsychosocial factors that can contribute to CPP. The biopsychosocial model suggests that pain and disability represent dynamic interactions among biological, psychological, and social factors which influence each other, and is a widely established approach in pain research (Cohen, Vase, and Hooten,

2021). Psychological factors influence both the experience of pain and treatment outcomes and are therefore important to consider in the maintenance of CPP. For example, psychological factors such as attention and cognition can increase vigilance to pain and catastrophising of pain related sensations, which are both known to increase pain (Linton and Shaw, 2011). Additionally, emotional states such as anxiety and depression are known to increase pain disability, and further fuel negative cognitions about the pain experience (Linton and Shaw, 2011). CPP research corroborates the above theories, as psychosocial factors such as adverse childhood experiences, trauma, psychological distress, psychiatric disorders, and dysfunctional reactions to stress are all mechanisms that can explain the shared characteristics of CPP disorders, with higher rates of these factors being found in CPP populations than non-pain populations (Lamvu et al, 2021).

CPP may however differ from other chronic pain conditions in the beliefs and behaviours that sufferers experience. For example, the location of CPP means that it is often associated with sexual dysfunction, particularly due to pain-avoidance behaviours (Kuile, Weijenborg and Spinhoven, 2010). Sexual dysfunction can negatively impact romantic relationships or sexual wellbeing for women with CPP which then increases psychological distress, negative self-beliefs and further pain catastrophisation and avoidance; all resulting in increased pain (Ayorinde, Macfarlane, Saraswat and Bhattacharya, 2015). Sexual dysfunction may also detrimentally impact fertility and family planning, further fuelling distress and tensions in the families of women with CPP. Women experiencing CPP specifically are also significantly likely to have experienced previous trauma such as sexual abuse, which again may increase the likelihood of relationship dysfunction in addition to higher levels of anxiety and depression (Bryant, Cockburn, Plante and Chia, 2016). Research has also shown that within CPP, there is a lack of knowledge amongst medical professionals about how to treat the condition, in addition to poor communication between sufferers and healthcare providers, meaning that women are more likely to disengage from treatment (Ayorinde et al, 2015). This research has also shown that stigma around pain located within the urogenital area may also discourage women from seeking treatment. CPP therefore differs from other pain conditions in that there are several factors, such as the impact of CPP on sexual function and relationships, which may exacerbate symptoms and psychosocial factors contributing to this. CPP is also frequently misunderstood within healthcare settings, meaning women are less likely to seek treatment which may lead to further increases in pain.

Within other chronic pain disorders, psychological interventions such as Cognitive Behaviour Therapy have been shown to be highly effective in managing the

impact of psychosocial factors that can contribute to pain conditions (Williams, Fisher, Hearn and Eccleston, 2020). Within CPP, evidence does exist for the use of psychological interventions, but existing research is often heavily weighted towards specific CPP subtypes. Disorders such as irritable bowel syndrome are more commonly researched; a recent review of randomised controlled trials (RCTs) for IBS found multiple psychological interventions to be superior to receiving routine IBS care, with cognitive behaviour therapy dominating research and showing effectiveness in symptom management (Black, Thakur, Houghton, Quigley, Moayyedi and Ford, 2020). A systematic review of psychological interventions for endometriosis found promising preliminary results, although the overall quality of studies was found to be "weak" with a high risk of bias (Van Niekerk et al, 2019). However, a review of non-pharmacological treatments for medically unexplained CPP found very little research overall utilising psychological interventions for this group (Cheong et al, 2014). The findings of previous reviews should however be treated with some caution due to review limitations. Studies included within research by Black et al (2020) and Niekerk et al (2019) often combined psychological intervention with other multidisciplinary components, meaning that the effects of psychological treatment could not be fully isolated. Broad inclusion criteria used by Niekerk et al (2019) meant that studies with poor quality and limited generalisability, such as single case studies, were included. Review findings based on poorer-quality studies may therefore have overestimated the benefits of psychological intervention. Taken together, it seems that the evidence-base for effectiveness of psychological interventions for CPP subtypes is inconsistent, further contributing to confusion about effective psychological treatment for this diagnosis overall. Although the term "chronic pelvic pain" is utilised frequently in medical literature, few reviews discuss a transdiagnostic approach for assessing the current state of the literature across and between CPP subtypes. A review assessing higher quality studies such as randomised controlled trials across multiple CPP subtypes would lead to a more consistent representation of the existing state of literature within CPP.

An increasing need to address biopsychosocial factors in pain conditions means the value of a growing evidence-base for CPP treatment is clear. However, psychological interventions should also acknowledge specific patient characteristics such as gender when developing treatments, due to the contributions that this can make to the development of physical and mental health problems (American Psychological Association, 2007). Research often neglects gender as a key factor in differences in prevalence, diagnoses, and treatment of conditions, with many chronic pain disorders

such as chronic constipation, Chronic Fatigue Syndrome, CPP, Fibromyalgia, and Migraines showing a female predominance (Chang and Heitkemper, 2002). Some CPP subtypes are exclusive to female sufferers, such as endometriosis. However, other disorders such as IBS or Inflammatory Bowel Diseases show gender disparities with uncertainty about the pathophysiological and biopsychosocial mechanisms of these. IBS for example has a 2-2.5:1 female-to male ratio (Kim and Kim, 2018), with Inflammatory Bowel Diseases showing interactions between gender and age in the onset of disorders (Shah et al, 2018). This shows that aspects of gender play a key role in the development and maintenance of these disorders, and therefore should not be ignored within treatment. Factors explaining gender disparities in CPP disorder prevalence are complex and can perhaps again be best understood in the context of a biopsychosocial model. Biologically, gender-specific differences including sex hormones, the menstrual cycle, and sex-specific genetic abnormalities are thought to play a role in disorders such as IBS and inflammatory bowel diseases (Chang and Heitkemper, 2002; Greuter, Manser, Pittet and Vavricka, 2020; Shah et al, 2018). Psychosocial gender-related factors are also known to impact CPP disorders, for example sexual abuse history is more commonly found in women, and abuse history is linked with the development of CPP disorders including IBS, inflammatory bowel diseases, interstitial cystitis, and endometriosis (Chang and Heitkemper, 2002; McKernan et al, 2019; Shah et al 2018; Harris et al, 2018). The contributions of gender to the development of CPP disorders should therefore not be disregarded and gender should be incorporated into treatment plans for these disorders.

Gender also appears to effect physiological and psychological symptoms of CPP disorders, as well as likelihood of treatment response. For example, evidence suggests that within IBS and interstitial cystitis physical symptom presentation can be influenced by gender (Kim and Kim, 2018; McKernan et al, 2019). Psychological symptoms are also influenced by gender, with female sufferers of IBS, inflammatory bowel disorders and interstitial cystitis displaying higher levels of anxiety and depression, in addition to reduced quality of life (Kim and Kim, 2018; McKernan et al, 2019). Similarly, women experiencing female only CPP disorders such as endometriosis display increased levels of anxiety and depression, which show a bi-directional relationship with pain severity and are known to influence the experience of pain (Lagana et al, 2017). Researchers have long been aware of the impact of psychological factors in pain, with factors including attention, emotion, coping strategies and illness beliefs all known to influence the development and maintenance of chronic pain (Linton and Shaw, 2011). Behavioural, cognitive, and affective factors are all known to mediate pain by influencing the sympathetic nervous

system and neurochemical factors associated with nociception, in addition to impacting behaviours that increase pain such as hypervigilance, threat appraisal, and avoidant behaviour (Garland, 2012; Turk,2003). Female CPP sufferers show increased incidence of psychological factors that can mediate distress and pain, such as pain catastrophising, hypervigilance to pain, physical sensations and negative coping strategies, (Alappattu and Bishop, 2011; Weijenborg, Le Kuile, Gopie and Spinhoven, 2012). CPP research therefore echoes the findings of previous pain research suggesting a bi-directional relationship between psychological distress and pain/symptom severity. Likelihood of treatment response can also be influenced by gender, for example women are more likely to experience adverse reactions or poor treatment response to pharmacological treatments for IBS and inflammatory bowel diseases (Kim and Kim, 2018; Greuter et al, 2020). Kim and Kim (2018) attributed these response differences as being potentially due to higher levels of psychological distress in females, therefore highlighting the crucial role that gender-related psychological distress can display even within responses to pharmacological treatment. However, despite multiple hypotheses about the mechanisms behind higher prevalence of some CPP disorders in women, the details of this are still largely unknown. This means that although there is awareness of gender differences in this field, the treatment implications of this are limited. Despite this, women not only experience higher rates of chronic pain disorders but appear to experience heightened psychological distress as both a cause and consequence of this. This psychological distress appears to intensify and exacerbate CPP symptoms and pain and can even mediate response to treatment. Women therefore show a CPP profile high in psychological distress, pain, and dysfunction. As such, a subset of research within CPP subtypes should take a female-centred approach, to ensure the needs of this patient group are being addressed.

To the author's knowledge, there is no existing systematic review exploring the effectiveness of psychological interventions for the most common causes of CPP in a solely female population. Existing reviews of CPP disorders have several shortcomings, for example by including interventions which combine psychological therapy with other multidisciplinary treatments, meaning that the effectiveness of psychology cannot be independently assessed (Cheong et al, 2014; Van Niekerk et al, 2019). Other reviews have focused on singular outcomes of psychological intervention, such as quality of life or fatigue, and so do not provide a comprehensive assessment of holistic patient needs (Paulides and Boukema, 2020). Some CPP disorders such as IBD lack an up-to-date systematic review of research, meaning that the evidence base for treatment of these

disorders may have grown and would benefit from further review (Timmer et al, 2011). An overarching review addressing the overall status of high quality CPP literature would therefore be valuable in taking next steps towards further research and suggestions for treatment. The clinical implications of such a review would be beneficial to understand if psychological interventions are effective in managing female CPP subtypes, and if specific psychological modalities are beneficial for distinct CPP aetiologies. Developing an understanding of the current research base across CPP disorders would inform clinical practice by assessing whether certain interventions might work transdiagnostically across the CPP population.

Aims

The primary aim of this systematic review is:

- To assess the effectiveness of psychological interventions for the treatment of CPP

The secondary aims of this systematic review are:

- To address the primary aim in relation to subtypes of CPP
- To address the primary aim in relation to subtypes of psychological intervention
- To use these findings to inform the future development of research

Methods

Registration and Ethics

The protocol for this review was registered in the International Prospective Register of Systematic Reviews in August 2021; PROSPERO registration number CRD42021268349. The systematic review protocol and reporting follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA) guidelines (Moher et al, 2009). This review did not require ethical approval due to its aim of analysing the results of pre-existing studies.

Search Strategy

The search strategy was designed to capture studies assessing the effectiveness of psychological interventions for chronic pelvic pain. EMBASE, Pubmed.gov and APA PsycINFO were searched on the 21st of January 2022 using terms developed by the study research team, with input from an information specialist (JH). Search terms can be found in Appendix A. Three previous CPP reviews were consulted to determine CPP terms

(Cheong et al. 2014; Lamvu et al, 2021; Speer et al, 2016). Other alternative sources such as the guidance from the National Health Service (NHS, 2022), and pelvic pain charities (Pelvic Pain Support Network, 2021) were reviewed with the aim of comprehensively searching CPP subtypes. Tools such as Emtree, Embase PICO search, the APA thesaurus and PubMed MESH terms were used to explore alternative CPP terminology. These resources were also consulted to determine search terms for psychological interventions, including alternative terminology for interventions, such as "acceptance and commitment" or "acceptance and commitment" or "ACT". Systematic reviews similar to the current study were explored to identify psychological interventions to be included in addition to language used to define these (Cheong et al 2014; Daniels, Pauling & Eccelston, 2017). To include a wide range of psychological interventions broad terms were used, such as "psycholog*" or "psycho-therapy" in addition to terms for specific interventions such as "cognitive behav*" or "cognitive behavioural therapy". A full search string example can be seen in Appendix A. NICE guidance for psychological interventions for common mental health disorders (NICE, 2011) was also used to build intervention search terms by further identifying appropriate psychological interventions for inclusion. Finally, Cochrane guidance was also used to develop an appropriate search strategy; for example, by determining the structure of the strategy and guiding the process of study selection (Lefebvre, 2022).

To further ensure a comprehensive search of all relevant literature, at the full-text review stage the references of chosen papers were reviewed to check for further eligible studies. Systematic reviews focusing on specific CPP subtypes were also reviewed to check for studies that may have been missed using this review's search criteria (Black et al, 2020; Imamura et al, 2020; Van Niekerk et al, 2019). These searches occurred in March 2022.

Eligibility Criteria

Studies were included in the review if they were an RCT assessing the effectiveness of any psychological intervention for outcomes of chronic pelvic pain. RCTs were included as several previous reviews have focused on studies which have less robust methodology (Niekerk, 2019), in addition to meeting this review's aim of providing a representative view of the current state of high quality CPP research. As such, studies had to have at least one intervention group in addition to either a control or "treatment as usual" group. Non-blinded studies were included due to the difficulty of blinding participants to research involving psychological intervention (Juul et al, 2021). Of note, to meet the

definition of a "randomised controlled trial" to be included within this review, study authors did not have to refer to their study as an RCT in the published research. To ensure the correct definition of an RCT was met, studies included within this review met the definition of being a "randomised controlled trial" if they met the NICE guidance definition of this (NICE, 2022). Studies were included if they either had a control group within which participants received no treatment, or if the control group for the study was an alternative treatment comparator, such as providing patient education. Studies with alternative treatment comparators as controls were accepted within the review due the fact that studies often took place within healthcare settings, where ethically, participants needed at least some form of lower-level intervention for adequate care. For this study, control groups were separated into "control comparators" or "active comparators", to distinguish between control groups which received some versus no treatment. Eligible study participants were adult women (18+) with CPP, studies were excluded if they did not provide analysis of single-sex data. Studies were included irrespective of CPP aetiology, including CPP with unknown causes. Of note, to ensure a comprehensive search strategy, the condition of "vulvodynia" was included in search terms, as this condition can contribute to chronic pelvic pain. However, studies in which participants experienced localised, isolated vulval pain were excluded, as has been the practice in other systematic reviews exploring pelvic pain (Latthe, Mignini, Gray, Hills, Khan, 2006). In addition, studies in which interventions included forms of biofeedback using external aids, such as electrical monitors and trans-stimulation, were also excluded.

Study interventions met inclusion criteria on the condition that they were psychologically based and utilised a "pure" psychological intervention, for example interventions could not be used alongside another non-psychological intervention as part of a multidisciplinary approach or a stepped-care programme. The exception to this was where participants were already taking medication as part of standard medical care.

Previous reviews investigating the effectiveness of interventions for CPP primarily use pain as the primary outcome measure (Champaneira, Daniels, Raza, Pattison and Khan, 2011; Cheong et al, 2014). However, psychological outcomes have received less focus as an outcome of chronic pelvic pain (Cheong et al, 2014). For this review, primary outcomes were psychological status/outcomes and adverse impacts of treatment. Secondary outcomes included pain or symptoms of distinct CPP subtypes, echoing the aims of previous literature. Secondary outcomes also included other outcomes likely to be researched in studies such as quality of life or levels of participant disability. Due to this being the first systematic review aiming to look at the impact of

psychological interventions for CPP, further unknown outcomes may also be explored in research. Information on further outcomes will be included if there is appropriate data for this.

Due to researcher resources, only studies published in the English language were included. Cochrane guidelines state that the exclusion of studies not published in English rarely changes the outcome of systematic reviews (Nussbaumber-Streit et al, 2019). Unpublished research was excluded from this review to ensure that all data had been peer-reviewed to ensure the validity of results.

Study selection

Covidence systematic review software was used for the management and screening of all studies (Covidence, 2022). All studies generated by the initial search were then screened by the lead researcher, with 20% of studies also being screened at abstract and full text stages by a second reviewer (NS). Discrepancies were resolved through discussion of necessary study inclusion criteria, with all discrepancies being resolved utilising this method.

Inter-rater reliability was "substantial" at both the abstract and full text screening stages, with Cohen's Kappa statistics of 0.76 and 0.69; respectively. Discrepancies were mostly due to differences in opinion on what "psychological interventions" would be included. This was particularly in reference to exclusion of studies in which psychological intervention was included as part of a stepped-care or multidisciplinary programme. All discrepancies in opinion were resolved through discussion.

Data extraction

A data extraction form created prior to screening was used to assess each study's eligibility for the review if it met the review inclusion criteria. The data extraction spreadsheet was created using Excel version 2203 and was used by the lead researcher (TD) to extract all study data. The form included six sections: "Demographics", "Interventions", "Measures", "Outcomes" and "Risk of Bias", with each of these including sub-sections for further information. A full list of extraction headings can be seen in Appendix B. Extracted information included but was not limited to the following: study author(s) and year of publication, CPP aetiology, psychological intervention classification, participant demographics, outcome measures, and study outcomes.

Quality assessment and Risk of bias

Version two of the Cochrane Risk of Bias Tool (ROB 2) was used to assess for risk of bias in studies (Sterne et al. 2019). This is an updated ROB version, considering research providing improvements from the original tool. This tool provides a single result for the estimated risk of bias stemming from bias caused by, randomisation, deviation from the intended intervention, missing outcome data, measurement of the outcome, selection of the reported result. Each estimate is assessed as either, low risk of bias, some concerns, or high risk of bias. This is in line with guidance from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, Savovic, Page, Elbers & Sterne, 2022). The review planned to use Grade of Recommendations, Assessment, Development and Evaluations (GRADE; Guyatt et al, 2008) to further evaluate study quality and certainty of evidence. This tool requires users to rate the quality of evidence of each review outcome, with an overall GRADE quality rating being applied by taking the lowest quality of evidence from all outcomes that are necessary for decision making (Siemieniuk and Guyatt, 2022). Five domains are used to downgrade certainty of evidence: risk of bias, imprecision, inconsistency, indirectness, and publication bias. Assessment of these domains lead to ratings of "very low", "low", "moderate" and "high" certainty.

Data synthesis and analysis

A meta-analysis was planned if there were sufficient studies for this (>3 per identical intervention, outcomes, and comparator/control group) and clinically this made sense to do so. Cochrane guidance does state that meta-analysis can take place if there are two studies with the same intervention and outcome (Deeks, Higgins and Altman, 2019). However, two study researchers (TDD and JD) discussed that at least three studies would be needed to observe trends in data. In addition, research has shown with analysis of previous Cochrane reviews that statistical inference under the random-effects model is challenging with fewer studies, giving evidence that suggests more than two studies are needed for adequate meta-analysis (Jackson and Turner, 2017). Effect sizes would be calculated between intervention and control/comparator arms within each RCT. Analysis would assess "change from baseline" scores from baseline to post-intervention.

The review was assessed as most likely containing continuous data. If studies had the same interventions and outcomes, then their data would be pooled. For continuous data, a standardised mean difference (SMD) model would be used for data analysis. A random effects model was planned due to likely study heterogeneity in interventions and outcomes.

Subgroup analysis:

Subgroup analyses were planned to meet the aims of this review; to assess which psychological interventions work best for which CPP aetiologies. Subgroup analysis would assess the effectiveness of separate models of psychological intervention and highlight differences in distinct CPP aetiologies, e.g., endometriosis or IBS.

Narrative Synthesis

If meta-analysis was assessed as not being appropriate due to incompatible data, then a narrative synthesis would take place. A narrative synthesis was also planned to take place in addition for outcomes which are not assessed in any meta-analysis. This synthesis was planned to be categorised by study outcome categories, with further commentary for subtypes of CPP and study intervention. Narrative synthesis was planned to include the following:

1) Data representing the effectiveness of undiluted categories of psychological intervention for outcomes of CPP, including psychological distress as categorised by factors such as anxiety or depression, in addition to other outcomes including pain, CPP symptomatology and quality of life
2) To address the above information in relation to CPP and psychological intervention subtypes
3) Discussion of the quality of the review evidence, using tools such as ROB2 and GRADE
4) Discussion of limitations of data taken from studies, including noting where data was unavailable/poorly described

Systematic review methodologies such as meta-analysis have extensive gold standard guidelines from sources such as the Cochrane Handbook of Systematic Reviews (Cochrane, 2022). However, guidance for conducting a narrative synthesis of data in the absence of meta-analysis is more scarce and less specific. The following sources were used to create a narrative synthesis for this research:

- Cochrane guidance for narrative data synthesis and analysis (Ryan, 2013)
- Cochrane examples of narrative synthesis approaches used in systematic reviews (Ryan, 2016)
- Guidance from other literature covering the structure and content of systematic reviews (Popay et al, 2006)

- Exploration of narrative synthesis from other reviews including pain assessment and inclusion of randomised controlled trials (Broughton et al, 2021; Bullock et al, 2019)

The above sources gave recommendations for conducting and reporting narrative synthesis including going beyond descriptive data to discuss factors such as the methodological quality of studies and utilising tools including risk of bias measures. Guidance suggested that as well as discussions of patterns in results data, the similarities and differences of study methodologies should be explored. This might include exploration of differing methods to deliver psychological intervention, such as online or therapist delivered intervention. Additional recommendations included grouping study outcomes by theme and tabulating results to provide a clear representation of data. Guidance from Cochrane (Ryan, 2013) also highlighted ways of presenting results in the review discussion, for example including a section on "potential biases in the review process".

Results

Selection and Inclusion of Studies

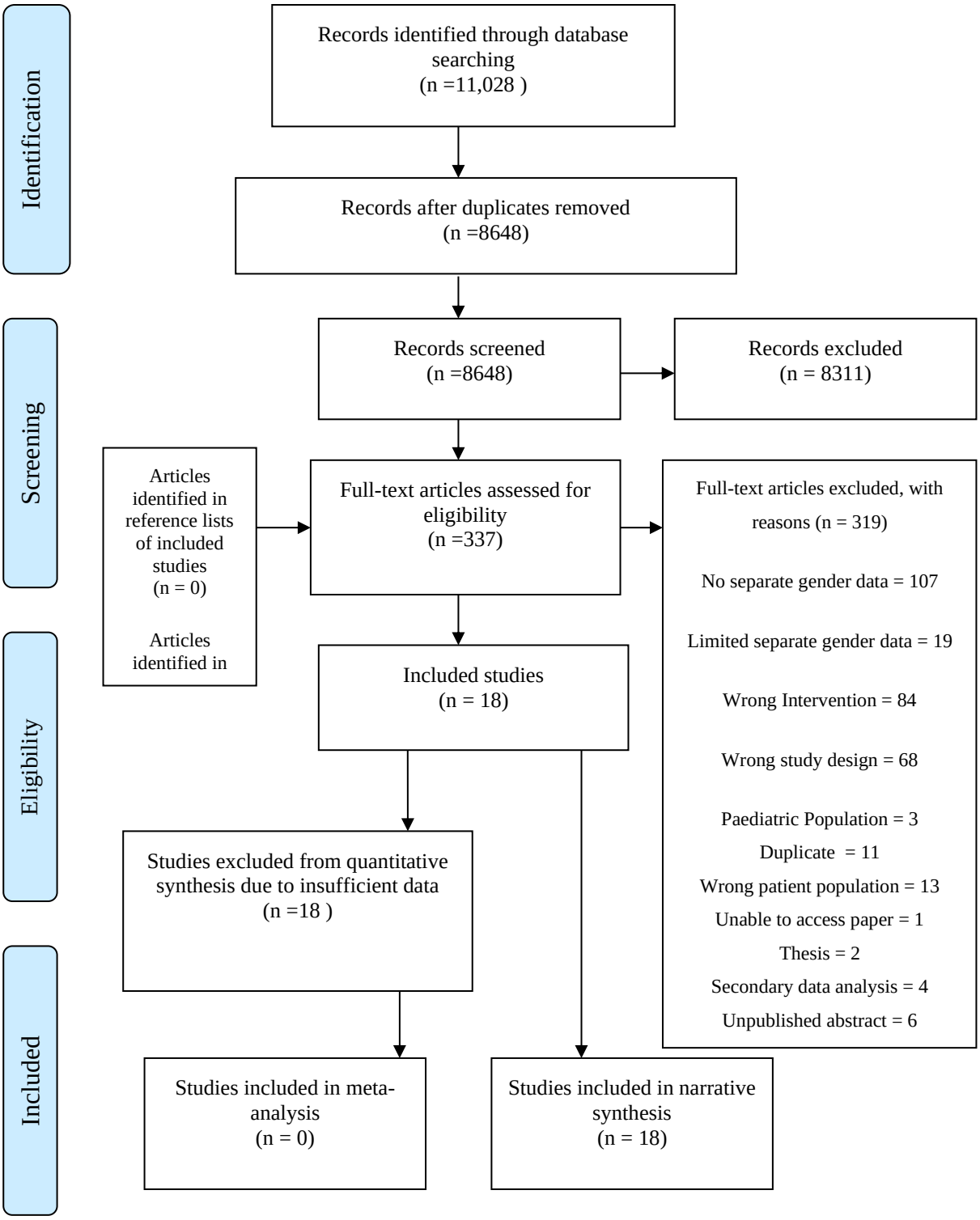
The initial search identified 11,028 studies, resulting in 8648 studies being screened after 2380 duplicates were removed. Three-hundred and seventy-six (376) studies progressed to full text screening, with a final 18 being included as part of the review. A full PRISMA flow diagram for the inclusion/exclusion of studies can be seen in Figure 1. As part of full text screening, ten authors (N=10) were contacted to access full-text versions of studies. Nine out of ten authors responded with this access, with an author on one study failing to reply (Hughes et al, 2017). Some authors were contacted based on the review search identifying abstracts from conferences; these authors were contacted to ascertain whether these abstracts had resulted in published papers. None of the nine studies returned by authors met inclusion criteria, subsequently these ten studies were excluded from the review.

The most common reasons for exclusion of studies were absence of female-specific data, interventions included as part of multidisciplinary treatment or incorrect study design. Studies categorised as having an incorrect intervention often combined psychological interventions with other treatments, such as physiotherapy or additional medication. For example, a study by Kanter et al (2012) was excluded due to the mindfulness intervention being included as a second-line treatment to other interventions such as physiotherapy. A small number of studies were also excluded due to their own

participant criteria, for example Brotto et al (2019) excluded women with pelvic pain from their study, despite meeting other inclusion criteria for this review. Studies which consisted of additional analysis of a previous RCT were excluded, for example studies which explored mediators of outcome change. Due to this review's aim being to extract and analyse female-specific data, studies were also excluded if they only included gender as an additional variable in analysis, for example as a variable in regression. Two studies (Guthrie et al, 1991; Van Lankveld et al, 2001) were included with partial data extraction, due to only some appropriate study data being available. For the former study, this included extraction of all available female-only data, and for the latter, data relating to women with the condition dyspareunia.

Figure 1

PRISMA flow diagram



Characteristics of Included Studies

Study demographics

Full study demographics can be seen in Table 1. Studies were conducted in outpatient settings across eight countries, including the United States of America (N=8), the United Kingdom (N=3), Turkey (N=2), Canada (N=1), India (N=1), Korea (N=1), Taiwan (N=1), and the Netherlands (N=1). Four studies (N=4) took place in group settings, whilst fourteen studies (N=14) took place on an individual basis, either by working 1:1 with a therapist, completing treatment independently, or a combination of both. Two studies (N=2) predominantly took place in virtual format, by using either an App or Internet-based treatment. Five studies (N=5) included treatment with at least one fully qualified Clinical Psychologist, with one study utilising internet-based therapy led by a Clinical Psychologist. Other studies included treatment by a Mindfulness instructor (N-1), Psychiatrist (N=1), "Trained sexologist" (N=1), Doctoral level students in Clinical Psychology (N=1), Psychology graduate students (N=1), a Nurse Practitioner (N=1), or an App (N=1). The remaining six studies (N=6) gave little or no information about the qualifications of individuals delivering the therapy, including terms such as "therapist" or "researcher". One study (N=1) did not include therapeutic sessions but required independent participant use of a cognitive bibliotherapy manual (Van Lankveld et al, 2001). Two studies (N=2) included self-practice over a specific time period, for example research by Forbes et al (2020) required participant App use over sixty days, and a study by Carrico et al (2008) required one-hundred and twelve participant practice sessions of twenty-five minutes over eight weeks. Within the remaining fifteen studies (N=15), mean number of therapeutic sessions was 6.4. Dosage of interventions varied widely, with mean and median dosages at 798 minutes and 680 minutes; respectively.

Interventions

A range of interventions were used in included studies. Interventions included Relaxation (including progressive muscle relaxation; N=4), Cognitive Behaviour Therapy (4), Mindfulness (N= 3), Guided Imagery (N=1), Life Stress and Emotional Awareness Interview (N=1), Interpersonal Psychotherapy (N=1), Pain Management Programme (N=1), Psychotherapy and Relaxation (N=1), Written Emotional Disclosure (N=1) and Cognitive Bibliotherapy (N=1).

Active Comparator

Eleven studies included active treatment comparators against the main study intervention. Treatment comparators included patient education (N=2), support group (N=1), activity scheduling (N=1), time spent resting (N=1), writing about positive events (N=1), expressive writing (N=1), relaxation without additional guided imagery (N=1), powdered ginger (N=1), progressive muscle relaxation (N=1), relaxation with biofeedback (N=1).

Control Comparator

Fourteen studies had control conditions as part of their study design. Control comparators included the study waiting list (N=8) or "care/treatment as usual" (N=3), "enhanced care/treatment as usual" (N=1) or did not include adequate information about the control condition (N=3). No studies used placebo interventions as part of their control condition.

Participant Demographics

Participant demographics can be seen in Table 2, Appendix C; a significant amount of demographic data was missing from studies. Study publication dates ranged from 1982 to 2021. Clinical presentations included six dysmenorrhea studies (N=6), six IBS studies (N=6), four studies with heterogenous CPP aetiology (N=4), and one study each with interstitial cystitis and dyspareunia participants (N=1; N=1). Mean participant sample size was 76, however there was significant variation in sample size, with studies ranging from fifteen to 446 participants (however, within the latter study only a subset of data from twenty-six participants could be included within this review). Only fourteen out of eighteen studies (N=14) gave data on participant age, the total mean age over all studies was 34.3. Of the remaining four studies (N=4), participants were described as female college/university students. Ten studies (N=10) gave information about years of participant education, with four (N=4) giving no further information and four (N=4) describing participants as college/university students. Only six studies (N=6) contained information about participant ethnicity, with all but one study (N=1) having mostly Caucasian participants.

Table 1
Study Demographics

Study	Setting	Condition	Intervention	No. of participants (at randomisation)	Comparators	Number of sessions	Session Duration (mins)	Total Dose (mins)	Outcomes/ Treatment Effect*	Overall risk of bias
Amodei et al 1987	USA	Dysmenorrhoea	Relaxation and Imagery	62	Relaxation alone **Wait List Control**	5 + daily practice	60	?	Pain **Dysmenorrhoea Symptoms** **Medication** **Minutes engaged in "resting"**	High
Bennink et al 1982	USA	Dysmenorrhoea	Relaxation – including Progressive Muscle Relaxation	15	**Wait List Control**	5	30	150	Dysmenorrhoea Symptoms	Some Concerns
Carrico et al 2008	USA	Interstitial Cystitis	Guided Imagery	30	**Time Spent Resting**	112 (14 x 25 mins)		2790	**Pain** Global Response Assessment **Cystitis Symptoms** Self-Efficacy Treatment Evaluation	High
Carty et al 2018	USA	Chronic Urogenital Pain – Heterogenous Causes	Life Stress Interview	70	**Care as Usual**	1	90	90	Depression Anxiety **Pain** **Pelvic Floor Symptoms** Pain Interference	Some Concerns
Celik & Apay 2021	Turkey	Dysmenorrhoea	Progressive Muscle Relaxation	194	**Waiting List**	3-7	30	720 +	**Pain** Dysmenorrhoea Descriptive Information	High

Drossman et al 2003	Canada	IBS	CBT	215*	Education	12	60	720	**Global Well-being** Bowel Disorder Severity **Treatment Satisfaction** QOL	Low
Forbes et al 2019	UK	Chronic Pelvic Pain – Heterogenous Causes	Mindfulness	90	Muscle Relaxation **Care as Usual**	60	10-20	1050	Anxiety Depression Pain Acceptance QOL Mindfulness Pain Self-efficacy Pain-related disability Sexual Health	High
Gaylord et al 2011	USA	IBS	Mindfulness	97	Support Group	8 + half day	180	1440	**Psychological Distress (incl Dep + Anx)** **IBS Symptoms** **QOL** **Visceral Sensitivity** **Mindfulness** Treatment Credibility Adverse Outcomes	High
Guthrie et al 1991	UK	IBS	Psychotherapy and Relaxation	77*	**Treatment as Usual**	6	?	?	Psychiatric Assessment Scale Depression** Anxiety** **Pain** **IBS symptoms**	Some concerns
Halder 2012	India	Dysmenorrhoea	Progressive Muscle Relaxation	75	Powdered Ginger	3	?	?	**Dysmenorrhoea Symptoms**	Some concerns

Henrich et al 2020	UK	IBS	Mindfulness	67	Waiting list	6 + (6 hours homework)	120	1080	Depression **Anxiety** **Gastrointestinal Symptoms** Pain Catastrophising Visceral Sensitivity Mindfulness Treatment Credibility Implicit Association **QOL**	Some concerns
Jang et al 2014	Korea	IBS	CBT	90	Education and holistic symptom management	8	80	640	**IBS Symptom Severity** **QOL** Dysfunctional Attitudes	Some concerns
Lee et al 2019	Taiwan	IBS	CBT	160	Expressive Writing Waiting List	13	?	?	**Depression** **Anxiety** IBS Symptoms	Some concerns
Norman et al 2004	USA	Chronic Pelvic Pain – Heterogenous Causes	Written Emotional Disclosure	48	Written disclosure – positive events	3	20	60	Positive/negative affect **Pain** Catastrophising Disability Emotional Ambivalence	Some concerns
Poleshuck et al 2014	USA	Chronic Pelvic Pain – Heterogenous Causes	Interpersonal Psychotherapy	62	Enhanced Treatment as Usual	8	?	?	**Depression** Pain Interpersonal Problems Incidence of Psychiatric Disorders	Some concerns
Quillen & Denney 1982	USA	Dysmenorrhoea	Pain Management	24	Treatment as Usual	4	120	480	**Menstrual Symptoms/pain**	Some concerns

Van Lankveld et al 2001	The Netherlands	Dyspareunia (And other sexual disorders)	Cognitive Bibliotherapy	26*	Waiting List	?	?	?	***Sexual Dysfunction*** Sexual Dissatisfaction Marital Satisfaction Self-rating scale**	High
Yilmaz & Sahin 2020	Turkey	Dysmenorrhea	CBT	80	Control – no info	6	60	360	**Menstrual Symptoms** **Pain** Menstrual Attitudes **Functional and Emotional adjustment** **Analgesic use**	Some concerns

Treatment Effects are as follows**, bold = significant improvement**, ***italics bold = significant deterioration***, standard = no change/difference to non-intervention comparators, highlighted = not used for comparative analysis
*Participant number relates only to patient sample eligible for study inclusion
**Outcomes for female only data/data for CPP target group were not available

Outcomes (measures)

Due to significant heterogeneity in study clinical populations and outcomes, a diverse range of outcome measures was used.

Primary outcome measures: Psychological Status

Overall psychological status was measured in two studies using the Brief Symptom Inventory 18 (N=2; Derogatis and Melisaratos, 2009), however in one study the measure was only used to assess anxiety and depression.

Depression was measured using the: Beck Depression Inventory (N = 1; Beck, Ward, Mendelson, Mock and Erbaugh, 1961); Brief Symptom Inventory (N=2; Derogatis and Melisaratos, 2009), Centre for Epidemiological Studies Depression Scale (CES-D) (N=1; Radloff, 1971), Depression, Anxiety and Stress Scale-21 (N =1; Lovibond and Lovibond, 1995); Hamilton Depression Scale (N=2; Hamilton, 1960) and Hospital Anxiety and Depression Scale (N=1; Zigmond and Snaith, 1983).

Anxiety was measured in six studies using the Brief Symptom Inventory (N=2), Clinical Anxiety Scale (N=1; Snaith, Baugh, Clayden, Hussain and Sipple, 1982), Depression, Anxiety and Stress Scale-21 (N=1), Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983; N=1) and the State-Trait Anxiety Inventory (N=1; Spielberger, Gorssuch, Lushene, Vagg & Jacobs, 1983).

Secondary outcome measures

Pain

Pain was measured in ten studies, measures included the: Brief Pain Inventory (N=1; Cleeland and Ryan, 1994), Diary card pain ratings (N=2), Multidisciplinary Pain Inventory (N=1; Kerns, Turk and Rudy, 1985), Pain McGill questionnaire (N=2; Melzack, 1975) and the VAS (N=5; Younger, McCue and Mackey, 2009).

Additional CPP symptomatology

For additional CPP symptomatology, six studies (N=6) measured dysmenorrhoea symptoms using: Daily records of menstrual complaints (N=2) Dysmenorrhoea Monitoring Forms (N=3), Menstrual Symptom Questionnaire (N=2; Chesney and Tasto, 1975), Menstrual Distress Questionnaire (N=1; Halder et al, 2012) and the Symptom Severity Scale (N=2; Chesney and Tasto, 1975).

Gastroenterology symptoms were measured in six studies using the Bowel Symptom Severity Scale (N=2; Boyce, Gilchrist, Talley and Rose, 2000), daily diaries of abdominal symptoms (N=1), Functional Bowel Disorder Severity Index (N=1, Drossman et al, 1995), Gastrointestinal Symptom Rating Scale (N=1; Dimenas, et al, 1993), IBS Symptom Severity Scale (N=1; Francis, Morris and Whorwell, 1997), Likert Scales of Abdominal Symptoms (N=1).

Other measures of CPP symptomatology were measured in three studies (N=3), using the Golombok Rust Inventory of Sexual Satisfaction (N=1; Rust and Golombok, 1986), Interstitial Cystitis Symptom Index and Problem Index (IC-SIPI, N=1; O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll, 1997) and Pelvic Floor Distress Inventory (N=1; Barber, Walter and Bump, 2005), Sexual health pelvic problem interference (SHOW-Q pelvic problem subscale; N=1; Learman, Huang, Nakagawa, Gregorich & Kuppermann, 2008).

Quality of Life/Disability

Measures for Quality of Life included the IBS-QOL (N=4; Patrick, Drossman, Frederick, DiCesare and Puder, 1998) and RAND Short-Form-36 (N=1; Ware and Sherbourne, 1992). Disability was measured using the Sickness Impact Profile (N=1; Bergner, Bobbitt, Carter and Gilson, 1981) and Disability Subscale of Pain Related Disability Scale (N=1; Von Korff, Jensen and Karoly, 2000).

Due to the significant heterogeneity of the data, many other outcome measures were available. Other outcomes which were measured across multiple studies included Mindfulness, which was measured using the Five-facet Mindfulness Questionnaire (N=2; Baer, Smith, Hopkins, Krietemeyer and Toney, 2006) and the Cognitive and Mindfulness Revised Scale (N=1; Feldman, Hayes, Kumar, Greeson and Laurenceau, 2006). Other outcomes were a range of biopsychosocial outcomes such as medication use (N=2), pain interference (N=1), or visceral sensitivity (N=2).

Risk of Bias

Results of risk of bias assessments using the ROB-2 tool can be seen in Table 2. Studies were rated as having "low risk of bias" (n=1), "high risk of bias" (n=6) or "some concerns" (n=11). Most studies showed low risk of bias in measurement of outcome; however, many studies lacked an apriori analysis plan and the ability to blind either participants or assessors. Areas in which high risk of bias was most identified included risk of bias due to deviations from the intended interventions, either through failing to

assess assignment or adherence to the intervention, or possible bias in the selection of the reported result.

Table 3

Risk of Bias

Study	Risk of bias arising from the randomisation process	Risk of bias due to deviations from the intended interventions part a) effect of assignment to intervention	Risk of bias due to deviations from the intended interventions part b) effect of adhering to intervention	Missing outcome data	Risk of bias in measurement of outcome	Risk of bias in selection of the reported result	Overall
Amodei et al 1987	+	=	+	+	-	+	+
Bennink et al 1982	=	=	-	-	-	=	=
Carrico et al 2008	-	+	-	=	-	=	+
Carty et al 2018	-	-	-	-	-	=	=
Celik & Apay 2021	-	+	-	=	-	=	+
Drossman et al 2003	-	-	-	-	-	-	-
Forbes et al 2019	-	=	+	-	-	-	+
Gaylord et al 2011	-	-	+	-	-	=	+
Guthrie et al 1991	=	=	-	-	=	=	=
Halder 2012	-	=	-	-	-	=	=
Henrich et al 2020	-	-	-	-	-	=	=
Jang et al 2014	-	=	-	=	-	=	=
Lee et al 2019	=	=	-	-	-	=	=
Norman et al 2004	-	=	-	=	-	=	=
Poleshuck et al 2014	-	-	-	=	-	=	=
Quillen & Denney 1982	=	=	-	-	-	=	=
Van Lankveld et al 2001	+	-	=	-	-	=	+
Yilmaz & Sahin 2020	-	=	-	-	-	=	=

Key:
+; "High Risk of bias"
=; "Some Concerns"
-; "Low risk of bias"

Meta-analysis

All planned meta-analysis could not be completed due to missing or incompatible data. The most common reasons that meta-analysis could not take place were:

- <3 studies exploring the same outcome (e.g. <3 studies exploring visceral sensitivity or overall psychological distress)
- <3 studies using the same psychological interventions (e.g. CBT, mindfulness) to explore the same outcome
- <3 studies using the same comparator group (e.g. control vs comparator treatment) to explore the same outcome (after meeting the two above criteria)
- Forbes et al (2020) – the main finding of this study was that treatment fidelity was extremely poor, consequently data from this study was not deemed appropriate to be included in meta-analysis

Certainty in Evidence – GRADE

As meta-analysis could not be completed, ratings utilising GRADE did not take place. This is in line with recommendations that the GRADE tool should only be used for pooled estimates from studies included in meta-analysis (Granholm, Alhazzani and Moller, 2019).

Narrative Synthesis

In line with the author's apriori analysis plan (PROSPERO ID CRD42021268349), a narrative synthesis was conducted for descriptive analysis of data where meta-analyses were not possible.

Outcomes

Primary outcomes- Psychological Status

Overall psychological wellbeing

Overall psychological status was measured in two studies (N=2) using the Brief Symptom Inventory-18 where mindfulness and a life stress interview were used as interventions. However, within one study (Carty et al, 2019), the measure was only used to assess for anxiety and depression, therefore leaving one study that measured psychological wellbeing overall (N=1; Gaylord et al, 2011) This study (N=1) compared mindfulness against an alternative treatment comparator, which was a support group. The study found no impact of mindfulness on overall psychological wellbeing post-treatment but found a

significant impact on psychological wellbeing after three months. The authors highlighted that this may have been due to the long-lasting impacts of mindfulness after regular practice. However, this study showed "high" risk of bias, meaning the impact of psychological intervention on this outcome could have been overestimated. Overall psychological wellbeing therefore showed improvements after mindfulness intervention in one study.

Anxiety

Anxiety was measured in six studies (N=6) across interventions including mindfulness (N=3), CBT (N=1), psychotherapy and relaxation (N=1) and a life stress interview (N=1). Comparator conditions included control conditions (N=4) and alternative treatment comparators (N=3), with one study including both comparator types. Causes of pelvic pain included heterogenous causes (N=2) and IBS (N =4). Anxiety in one study (N=1) could not be fully explored due to mixed-gender data (Guthrie et al, 1991). Of the five remaining studies, three (N=3) found significant improvements in anxiety from pre- to post-intervention (Gaylord et al 2011; Henrich et al 2020; Lee et al 2019). Interestingly, two of these studies found that the impact of CBT on anxiety was only significant after measuring outcomes at later timepoints; at 18 weeks post-CBT (Lee et al, 2019) and 12 weeks post-mindfulness (Gaylord et al, 2011). This supports the notion of the longer-term impact of psychological intervention after long-term consolidation and application of the interventions. Henrich et al (2020) did not see an improvement in anxiety until the third outcome measurement timepoint of the study, however this might be expected due to this timepoint corresponding with completion of 50% of intervention sessions. Of the two remaining studies which did not find an impact of psychological intervention on anxiety, one of these was likely due to low adherence to the study intervention (N=1). The remaining study which did not find an impact of psychological intervention on anxiety was a life-stress interview (Carty et al, 2019). This was a single session intervention, with measures taken at six-week follow-up. The shorter duration of the intervention (90 minutes) or the time between intervention and post-treatment measurements may have resulted in these insignificant results. Heterogeneity of anxiety measures was high, with five measures being used across six studies. This means that comparisons of the impact of psychological interventions on anxiety should be more cautiously made. Four studies were rated using the ROB2 as having "some concerns" (N=4), whilst two were rated as having "high" risk of bias (N=2). Anxiety therefore saw improvements due to

psychological intervention in 60% (3/5) of studies for which data was available for analysis.

Depression

Depression was measured in seven studies (N=7) across interventions including mindfulness (N=3), CBT (1), life stress interview (N=1), psychotherapy and relaxation (N=1) and interpersonal psychotherapy (N=1). Four studies included a control comparator (N=4), one included an alternative treatment comparator (N=1), and two studies included both control and alternative treatment comparators (N=2). Depression in one study (N=1; Poleshuck et al, 2014) was assessed using two separate measures. Causes of pelvic pain included IBS (N=4) and heterogenous causes (N=3). Depression in one study (N=1; Guthrie et al, 1991) could not be fully explored due to mixed-gender data. Of the remaining six studies (N=6), only two studies (N=2) found psychological therapy significantly improved depression. One study (N=1) found a significant impact of CBT (Lee et al, 2019), with another study utilising interpersonal psychotherapy to improve depression (N=1; Poleshuck et al, 2014). However, within the latter of these studies, the impact on depression was only found after applying additional causal modelling analysis (N=1), meaning that claims for the benefits of psychotherapy for depression should be made with caution if these effects could not be found in main data analysis. Three studies (N=3) which did not find significant effects of psychological intervention on depression did find significant effects of intervention on pain/symptoms (Carty et al 2018; Gaylord et al 2011; Henrich et al 2020), suggesting perhaps that the alleviation of CPP symptoms is not dependent on depression reduction. Using the ROB2, five studies (N=5) were rated as having “some concerns” and two studies (N=2) “high risk of bias. Depression therefore saw improvements due to psychological intervention in 33% of studies (2/6) for which data was available for analysis.

Secondary outcomes

Pain

All eighteen studies (N=18) included some measurement of pain, however ten studies (N=10) measured pain as part of a more comprehensive measure covering symptoms of the research CPP condition overall. In two of these studies (N=2), pain was included as part of a measure of IBS symptom severity but could also be assessed independently from other symptoms (Drossman et al, 2003; Guthrie et al, 1991). In studies in which pain was assessed, interventions used were CBT (N=2), mindfulness (N=1), relaxation and

imagery (N=1), guided imagery (N=1), life stress interview (N=1), relaxation (including progressive muscle relaxation) (N=1), psychotherapy plus relaxation (N=1), written emotional disclosure (N=1), interpersonal psychotherapy (N=1). Of the ten studies (N=10) in which pain was assessed, five studies (N=5) used a control comparator, three (N=3) used an alternative treatment comparator, and two (N=2) studies used both. Six out of 10 studies (N=6) showed significant improvements to pain post psychological intervention (N=6). Interventions that led to reductions in pain were CBT (N=1), guided imagery (N=1), Life Stress Interview (N=1), relaxation including progressive muscle relaxation (N=1), psychotherapy and relaxation (N=1) and written emotional disclosure (N=1). One study (N=1; Drossman et al, 2003) showed improvement across the composite symptom measure which had included pain, but assessment of pain independently did not reveal a significant difference post CBT intervention. Of the three studies (N=3) that did not show improvements in pain, one study's findings were likely due to low intervention adherence (N=1). Six studies (N=6) had "some concerns", one (N=1) had "low" and four (N=4) had "high" risk of bias using the ROB 2 tool. It should also be considered that studies of higher quality tended not to measure pain as an independent construct but measured pain as part of symptom measures specific to the observed CPP disorder (Henrich et al 2020; Gaylord et al, 2011). The absence of higher quality studies from the resulting analysis for pain, in addition to a number of studies included within this section with high risk of bias (N=4) may therefore mean that the impact of psychological interventions on pain overall was overestimated. Statistically however, pain improved due to psychological intervention in 60% of studies (6/10) for which data was available for analysis in this review.

Additional CPP symptomatology

Dysmenorrhoea Symptoms

Six studies (N=6) included some measurement of menstrual symptoms, with one of these (N=1) utilising a dysmenorrhoea descriptive form alongside a separate pain measure. Interventions included relaxation and imagery (N=1), relaxation and progressive muscle relaxation (N=3), pain management techniques (N=1) and CBT (N=1). Five studies (N=5) utilised a control comparator, whilst one (N=1) utilised an active treatment comparator. All studies included dysmenorrhoea as the cause of CPP. Five studies (N=5) found improvement in dysmenorrhea symptoms (Amodei et al, 1987; Celik & Apay, 2021; Halder et al, 2012; Quillen & Denney, 1982; Yilmaz & Sahin, 2020), with one study (N=1) finding no difference between the relaxation group and control group (Bennink et

al, 1982). The study that did not lead to an improvement in dysmenorrhoea symptoms utilised relaxation including progressive muscle relaxation (N=1). Four studies had some concerns (N=4) and two showed "high" risk of bias (N=2) using the ROB 2 tool. Although only two dysmenorrhoea studies (N=2) met the "high" risk of bias criteria, the quality of these studies was generally poor. These studies gave less descriptive and statistical data and had poorer reporting standards. Although several dysmenorrhoea studies included within this review met the definition of an RCT due to their methodology, the study authors did not label their study as an RCT. This suggests that studies that did not label themselves as RCTs might have lower standards of analysis and reporting than those that do. Dysmenorrhoea symptoms therefore saw improvements due to psychological intervention in 83% of studies (5/6) for which data was available for analysis.

Gastrointestinal Symptoms

Six studies (N=6) included some measurement of gastrointestinal symptoms across interventions including CBT (N=3), mindfulness (N=2) and interpersonal psychotherapy and relaxation (N=1). One study measured gastrointestinal symptoms as part of inclusion criteria, but analysed pain levels instead of symptoms as the primary outcome measure (Drossman et al, 2003). Three studies (N=3) included an alternative treatment comparator, two a control comparator (N=2), and one study included both (N=1). All studies included populations with IBS related CPP. Of the remaining five studies, four (N=4) found improvements in gastrointestinal symptoms using mindfulness (N=2), CBT (N=1), and interpersonal therapy and relaxation (N=1). The study that did not find a difference in gastrointestinal symptoms (Lee et al, 2019) did show reductions in depression and anxiety, showing that virtual CBT did improve other study outcomes. Four studies (N=4) had "some concerns", with one study each having "low" (N=1) and "high" (N=1) risk of bias. Gastrointestinal symptoms therefore saw improvements due to psychological intervention in 80% of studies (4/5) for which data was available for analysis.

Other CPP Symptomatology

Other CPP symptomatology was measured in three studies (N=3). There were no changes for interstitial cystitis symptoms using a guided imagery intervention in one study (N=1). There were also no changes to pelvic floor distress or sexual health pelvic problem interference in one study using a mindfulness intervention (N=1). Importantly, one study (N=1) found an adverse impact of utilising cognitive bibliotherapy in women with dyspareunia using the Golombok Rust Inventory of Sexual Satisfaction (N=1; Van Lankveld et al, 2001). However, only twenty-six participants with dyspareunia were included within this trial, so the apparent adverse impact of cognitive bibliotherapy for this clinical population should be treated with significant caution.

Quality of Life

Quality of Life was measured in five studies (N=5) across interventions including CBT (N=2) and Mindfulness (N=3). Four studies had IBS populations (Drossman et al, 2003; Gaylord et al, 2011; Henrich et al, 2020; Jang et al, 2014), whilst one included participants with heterogenous CPP causes (Forbes et al, 2020). Four studies (N=4) included an active treatment comparator whilst one (N=1) utilised a wait-list control condition. Three (N=5) studies found improvements on QOL after using Mindfulness (N=2; Gaylord et al, 2011; Henrich et al, 2020) or CBT (N=1; Jang et al, 2014). Despite Drossman et al (2003) utilising a CBT of a similar duration to Jang et al (2014), the former study did not find improvement of QOL post-intervention. These two groups differed in that one included individual and one group CBT, which may have impacted results. Quality of Life was measured using the IBS-QOL in four out of five studies, meaning that for this outcome domain, comparisons in study data are likely to be more valid. Two studies had some concerns (N=2), two showed “high” risk of bias (N=2) and one showed “low” risk of bias utilising the ROB 2 tool. Quality of Life therefore saw improvements due to psychological intervention in 60% of studies (3/5) for which data was available for analysis.

Mindfulness

Levels of increased mindfulness were measured in three studies (N=3) in which a mindfulness intervention was used. One study (N=1) utilised a control comparator, one (N=1) utilised an alternative treatment comparator, and one study (N=1) used both. Two studies had IBS populations (Gaylord et al, 2011; Henrich et al, 2020), whilst Forbes et al (2020) included women with heterogenous pelvic pain aetiology. Forbes et al (2020)

found no differences on mindfulness scores between the mindfulness group and either comparator group, however as highlighted previously this is likely due to extremely low adherence to intervention. In contrast, both Gaylord et al (2011) and Henrich et al (2020) found that mindfulness interventions increased overall levels of mindfulness between intervention and either active control (Gaylord et al 2011), or wait-list control (Henrich et al, 2020). Both studies also reported reduced IBS symptoms after mindfulness interventions. Furthermore, Henrich et al (2020) found that increases in mindfulness-related concepts such as non-judgemental awareness significantly mediated reductions in IBS symptoms. This limited evidence suggests that there is potential for increases in mindfulness to mediate improvements in IBS symptoms. Research by Forbes et al (2020) and Gaylord et al (2011) were both judged to be at "high" risk of bias by the ROB 2 tool, with Henrich et al (2020) fitting within the" some concerns" category. Promising results for increases in mindfulness levels, and the resulting potential impact on IBS symptoms should therefore be treated with caution, as both studies which found improvements in mindfulness to be "high" risk of bias. In summary, mindfulness levels saw improvements due to psychological intervention in 66% of studies (2/3) for which data was available for analysis.

Disability

Two studies (N=2; Forbes et al, 2020; Norman et al, 2004) directly measured the impact of psychological interventions on disability. Both studies involved populations where the cause of pelvic pain was heterogenous, with the former utilising mindfulness, and the latter testing the effects of emotional disclosure. Norman et al (2004) utilised an alternative treatment comparator group, whilst Forbes et al (2020) utilised both a control and alternative treatment comparator. Neither study found that the intervention significantly impacted levels of disability. However, Norman et al (2004) found participant-specific differences in that those with higher ambivalence and levels of catastrophising showed reduced levels of disability post-intervention. Due to poor treatment fidelity in Forbes (2020), only disability data from Norman et al (2004) can be reliably interpreted. Data from one study, whether this data showed improvements or not, is not enough to give conclusions on the effectiveness of psychological interventions for disability levels. Forbes et al (2020) showed "high" risk of bias and Norman et al (2004) showed "some concerns" using the ROB 2 tool. Disability therefore did not see any improvements within studies for which data was available for analysis.

Other outcomes

For some variables, no change was seen due to psychological intervention, such as using a life stress interview for pain interference (N=1). For other outcomes such as visceral sensitivity, improvements were seen post mindfulness interventions (N=2) and in one case was seen to mediate relationships between the intervention and clinical symptoms (N=1). Reductions were also seen in the use of other medical interventions, such as reductions in analgesia use in studies utilising relaxation or cognitive-behavioural strategies for dysmenorrhoea (N=2). Improvement therefore was seen on a number of these variables, however due to the extremely limited heterogenous data, conclusions cannot be drawn about the impact of psychological therapy on these CPP outcomes.

Outcomes by Intervention

Ten different modalities methods of psychological intervention led to improvements in outcomes for chronic pelvic pain. All four cognitive behaviour therapy studies showed improvement in at least one outcome, including improvements in pain (N=2), anxiety (N=1), depression (N=1), quality of life (N=1), dysmenorrhoea symptoms (N=1) and gastrointestinal symptoms (N=1). Two out of three studies utilising mindfulness led to improvements in at least one outcome, including improvements in mindfulness levels (N=2), anxiety (N=2), quality of life (N=2) and gastrointestinal symptoms (N=2). One study utilising Mindfulness (Forbes et al, 2021) did not lead to improvements in any outcomes, although this is likely to be due to low treatment fidelity. Four out of five studies utilising relaxation including progressive muscle relaxation led to improvements in pain (N=1) and dysmenorrhoea symptoms (N=4). One study using relaxation techniques (N=1) Bennink et al, (1982), did not lead to improvements in any outcome measures. Many psychological interventions were only represented within one study. One study using psychotherapy with relaxation led to improvements in pain and gastrointestinal symptoms. One study (N=1) utilising interpersonal psychotherapy led to improvements in depression. One study (N=1) utilising written emotional disclosure led to improvements in pain, whilst one study (N=1) utilising a life stress interview led to improvements in pain and pelvic pain symptoms. One study (N=1) utilising guided imagery led to improvements in pain and cystitis symptoms. One study (N=1) utilising relaxation and imagery led to improvements in dysmenorrhoea symptoms and reductions in required medication and time spent resting. One study (N=1) utilising pain management led to improvements in dysmenorrhoea symptoms. Importantly, one study (N=1) found an adverse impact of utilising cognitive bibliotherapy in women with

dyspareunia (Van Lankveld et al, 2001). This study included participants with various psychosexual problems, however the data included with this review was the only study to look at women with dyspareunia. The study found that cognitive bibliotherapy was detrimental to sexual dysfunction and led to increased pain relative to participants within a control group. No other study included in this review involved women with dyspareunia, however further exploration of psychological interventions for this group should take place in reviews with less stringent inclusion criteria, for example a review not focusing solely on RCTs. In summary, the most commonly effective study was CBT, with 100% of all included studies (N=4) showing improvement in at least one outcome. Of studies using Mindfulness, 67% of studies (N=2 out of N=3) led to improvements in at least one study outcome, however lack of treatment fidelity in one study is likely to explain the lack of improvement in study outcomes. Of studies using relaxation methods, 80% (N=4 out of N=5) studies showed improvement in at least one study outcome. One study per the following interventions: guided imagery, a life stress interview, interpersonal psychotherapy, psychotherapy and relaxation, pain management, emotional disclosure and relaxation and imagery led to improvements in at least one outcome measure. One study (N=1) utilising cognitive bibliotherapy was the only study which showed an adverse impact of treatment.

Outcomes by CPP condition

Psychological interventions resulted in improvements across five clinical subtypes. These included six dysmenorrhea studies (N=6), six IBS studies (N=6), four studies with heterogenous CPP aetiology (N=4), and one study each with interstitial cystitis and dyspareunia participants (N=1, N=1).

Dysmenorrhea

All six studies including dysmenorrhea participants (N=6) saw psychological interventions resulting in improvements including dysmenorrhoea symptoms, pain, and functional/emotional adjustment, in addition to reductions in medication and time spent resting. It should be noted however that the quality of dysmenorrhoea studies was often poor; including limited demographic information, fewer participants, fewer measures, less sophisticated reporting standards and less information regarding the study intervention. Although these studies could not be assessed using GRADE, it is clear that research in this area was of poorer quality. Several of these studies were older (Amodei

et al 1987; Bennink et al, 1982), perhaps highlighting the improvements in research standards over time.

IBS

All six studies including IBS participants (N=6) saw psychological treatment leading to improvements in areas including global well-being, treatment satisfaction, IBS/gastrointestinal symptoms, pain, psychological distress (including anxiety and depression), mindfulness, visceral sensitivity and quality of life. It is therefore likely that psychological therapy can be significantly beneficial for female IBS.

Interstitial Cystitis

In the single study including participants with interstitial cystitis (N=1) psychological treatment led to improvements in pain and cystitis symptoms. There is therefore some limited evidence for using psychological interventions for symptoms of interstitial cystitis, however further research is needed to confirm this.

Dyspareunia

In the single study including participants with dyspareunia (N=1) cognitive bibliotherapy resulted in an increase in pain post-treatment. It should be noted however, that in this study women with dyspareunia made up only a small subset of participants (N=26). This finding should therefore be interpreted with caution, particularly due to no other study in this review including women with dyspareunia.

CPP with heterogenous causes

In CPP with heterogenous causes (N=4), three out of four studies using psychological interventions led to improvements including pain and pelvic symptoms and depression. For the study in which participants did not show improvements, this was likely due to extremely poor treatment fidelity.

Summary of outcomes by CPP aetiology

In summary, there is strong evidence for using psychological interventions for IBS and dysmenorrhoea, with 100% of studies including these participants showing improvement in at least one outcome. Evidence also suggests that psychological interventions are likely to be beneficial for CPP with heterogenous causes, with 75% of studies showing improvement in at least one outcome. There is limited evidence that psychological

treatment could be beneficial for outcomes in interstitial cystitis. Conversely, there is some limited evidence that cognitive bibliotherapy could in fact have adverse outcomes for the dyspareunia population.

Additional CPP causes

For the following CPP aetiologies, no studies met the inclusion criteria of this review: adenomyosis, endometriosis, fibroids, inflammatory bowel disease/Crohn's/ulcerative colitis, leiomyoma, ovarian cysts, pelvic adhesions, uterus/pelvic organ prolapse.

Discussion

Summary of the main results

The aims of this review were to assess the effectiveness of undiluted psychological interventions for outcomes of Chronic Pelvic Pain with different aetiologies. The review aimed to explore the effectiveness of different models of psychological intervention and to investigate which of these are most suitable for different subtypes of CPP. Overall, the data was extremely heterogenous with differences including a range of measures used to assess similar outcomes, disparities in standards of research and reporting, and differences in the intervention duration, format, and quality. Overall, this review found that psychological interventions were effective for a range of both physiological and psychological outcomes, with all but two studies finding a significant impact of psychological intervention on at least one outcome. For the primary outcome of psychological distress, improvements to anxiety and depression were seen in 60% and 33% of cases; respectively. Overall psychological wellbeing was also assessed in one study and showed improvements three months post-mindfulness intervention. Improvements were also seen in secondary outcomes including pain, CPP symptoms and quality of life. The most tested interventions were CBT, mindfulness, or relaxation-based treatments. However, studies did investigate other psychological methods including interpersonal psychotherapy, written disclosure, or a life stress interview. Two types of CPP aetiology were most frequently found in research: IBS and dysmenorrhoea. Other CPP causes, such as interstitial cystitis or endometriosis, were present in few if any studies that met the inclusion criteria of this review. For some subtypes of CPP, specific psychological interventions dominated the treatment found in research. For example, within dysmenorrhoea, relaxation methods were most frequently applied. For other CPP causes a diverse range of interventions led to positive outcomes. It should be noted however that in one study, participants with dyspareunia were adversely impacted by

cognitive bibliotherapy. Overall, however, psychological interventions appear to be effective for multiple CPP outcomes.

The findings of this review are important for collating and interpreting the heterogenous and disparate evidence-base for using psychological interventions for female CPP. Findings show that CBT, mindfulness, and relaxation treatments are particularly effective for treating a range of CPP outcomes, confirming that clinical practice and future research should aim to further explore and utilise these interventions. Review findings also show that psychological interventions are effective in isolation from other types of interventions, such as physiotherapy. This suggests that clinically, psychological interventions can be used independently if multidisciplinary interventions or stepped-care programmes are not available. Finally, the findings of this study also suggest that some well-researched psychological interventions can be used transdiagnostically across different CPP subtypes. This means that irrespective of CPP cause, and in cases where this is not certain, psychological interventions such as CBT are likely to prove beneficial. This means that clinicians can offer interventions such as CBT with some confidence that this will be helpful for a broad spectrum of patients.

Agreements and disagreements with other studies or reviews

To the author's knowledge, this is the first systematic review attempting to assess the impact of psychological interventions for distinct causes of female CPP. Comparison with pre-existing reviews is therefore difficult, particularly as many other reviews include mixed gender data. The hugely heterogenous data and challenges designing a comprehensive search strategy for this study confirms opinions given in other reviews that the broad topic of CPP does not conform easily to a systematic review (Lamvu et al, 2020). Other recent reviews also found evidence that psychological treatment beneficially impacts both physical and psychological outcomes in CPP subtypes. For example, Black et al (2020) conducted a systematic review and meta-analysis which found that psychological interventions were effective in treating IBS, although none were superior to another. These results corroborate the findings of this review, in that multiple psychological intervention models were found to be effective in CPP subtypes, including IBS. Reviews of CPP subtypes assessing the effectiveness of psychological interventions often highlight the lack of high-quality evidence available, citing an absence of RCTs and high risk of bias (Black et al, 2020; Lamvu et al, 2020; Van Niekerk et al, 2019). This is consistent with the findings of this review, where only one study was found to have "low" risk of bias. The findings of this study also echo the findings of other reviews assessing

psychological interventions for chronic pain disorders. A recent Cochrane review found that the most researched psychological intervention for pain was CBT, which was also the case in this review (Williams et al, 2020). The former review found that CBT positively impacts levels of distress and shows small improvements to pain levels; again, corroborating findings made within this review. However, there were some differences between these reviews; the current review highlighted some promising preliminary results for interventions using principles taken from Acceptance and Commitment Therapy, such as mindfulness, for treatment of anxiety, gastrointestinal symptoms, and quality of life. In contrast, Williams et al (2020) did not find evidence supporting the use of ACT-based principles for chronic pain, although the primary outcome of studies included in the review was acceptance of pain. Both reviews seem therefore to agree on the effectiveness of CBT, but further research utilising therapeutic modalities such as ACT is needed. This study's findings therefore corroborate the views of other reviews and give a firm direction for future research exploring the impact of ACT on pain.

Strengths and limitations

This review had several strengths and limitations. Strengths included utilising the most recent ROB 2 tool to assess risk of bias, which is a more accurate estimation of bias than its predecessor (Moore, Higgins and Sterne, 2021) In addition, inter-rater reliability was "substantial" at both the abstract and full text stages of screening, meaning that there is substantial likelihood that all/most relevant studies found the search strategy were included in this review. Study abstracts also progressed from title to full text screening phase if they appeared to meet most review criteria but specified mixed-sex participants, rather than female-only participants. This ensured that studies could be comprehensively checked for single-sex data, indeed, the study by Guthrie et al (1991) predominantly included mixed-sex data but did include some single-sex analysis. This ensured that no relevant data was unnecessarily excluded based on studies having included both male and female participants. A final strength of this review is that inclusion criteria was for "pure" psychological interventions, to attempt to isolate the effectiveness of these interventions as treatments. However, due to the medical aetiologies behind many CPP subtypes, multimodal treatments including physiotherapy are often used. It is therefore possible that studies were excluded which could have provided additional input when assessing the effectiveness of psychological interventions for CPP.

Another limitation of this research is related to the complexity of the origins of female chronic pelvic pain, in that this can have numerous causes. Some possible causes

of pelvic pain were not included within this study. Musculoskeletal conditions for example can sometimes cause CPP but were not included in the search strategy, as the author judged the inclusion of these conditions as being too broad to answer the specific research question. However, this means that potentially relevant research could have been excluded from this review. Finally, aspects of the review such as assessing risk of bias were only completed by one researcher. Although the ROB 2 is designed to be highly objective, screening by a second individual utilising this tool would have enabled increased certainty of bias of included studies. Unfortunately, due to incomplete/missing study data, it was not possible to conduct meta-analysis within this review, as had been stated in a pre-published analysis plan. Due to lack of meta-analysis GRADE ratings of certainty of evidence also could not be completed. Consequently, an appropriate narrative synthesis was provided. However, more sophisticated statistical analysis would have allowed for more thorough assessment of the effectiveness of distinct psychological treatments for specific CPP subtypes.

Finally, a potential limitation within this study was the inclusion of studies that were of lower quality. This may mean that there could have been an overestimation of the effectiveness of psychological interventions, particularly in CPP subtypes such as dysmenorrhoea in which poorer quality studies were most found. Although the scope of this review was to include all studies that met the technical definition of a "randomised controlled trial", future reviews in this area may wish to exclude poorer quality studies to ensure robustness of findings. This may involve excluding studies which do not meet sufficient standards of reporting or have inadequate participant numbers for appropriate statistical analysis.

Potential biases in the review process

Although the author of this review attempted to conduct a comprehensive, thorough search of the literature, there are several areas in which bias may have been introduced into the study. Firstly, study selection was limited to papers available in English, although several papers at the full text screening stage were available in both English and another language. Secondly, one paper was excluded based on not being able to contact the study authors (Hughes et al, 2017). Although the author assessed these papers as being unlikely to be included in the final review due to study abstracts not revealing single-sex data analysis, this was not a certainty.

Implications for research

A key finding of this review is that there is a clear absence of research relating to psychological interventions for certain female-specific pelvic pain conditions. For example, no studies exploring the effectiveness of psychological interventions for endometriosis met the inclusion criteria for this review. Part of the methodology for this review included searching references of recent systematic reviews relating to the pelvic pain conditions within this paper (Black et al, 2020; Van Niekerk et al, 2019). Although the latter study found eleven studies exploring the effectiveness of psychological interventions for endometriosis, only four of these were RCTs, and all studies combined psychological intervention with other treatment types. This is despite endometriosis being the second most common gynaecological condition in the UK and impacting approximately 1.5 million women (Endometriosis UK, 2022). Additionally, only one study included in this review included participants with interstitial cystitis, with one other meeting the criteria for this review but having excluded women with additional pelvic pain (Brotto et al, 2019). Dyspareunia, a condition found in 7.5% of sexually active British women (Mitchell et al, 2017) was also explored in only one subgroup of participants within this review. There is therefore a drastic need for further research exploring the use of psychological interventions for many CPP subtypes. The apparent lack of female CPP research found in this study is corroborated by recent findings highlighting gender disparities in healthcare and research. A recent government report highlights that the UK has the 12th largest gender health gap globally, and the largest gap in the G20 (Winchester, 2021). Examples of disparities in this report included female dementia sufferers receiving worse treatment than men and women receiving less painkillers after surgery. Recent literature has highlighted women are underrepresented in clinical trials, and that there are significant disparities in research funding given to women for female-specific medical conditions in comparison to funding given to men for male-specific medical conditions (Criado-Perez, 2020). The lack of studies for interventions addressing CPP subtypes highlighted in this review serves to further demonstrate the imperative need for further scientifically rigorous research in female-dominated conditions.

Future research should also facilitate collecting data that is missing from existing CPP literature. Within the studies included in this review, only 22% reported on the ethnicity of participants, with all but one study (Poleshuck et al, 2014) having significantly more Caucasian participants than other ethnic groups. Research has found gender inequalities differ by ethnicity, for example one extensive review found African

Americans experienced more health-based gender disparities than Caucasians (Sagynbekov, 2017). Future research should therefore correct the underrepresentation of different population groups within research.

Conclusions

This review provides preliminary evidence that psychological interventions are effective in treating a range of outcomes in conditions causing Chronic Pelvic Pain. However, results must be interpreted with caution as meta-analysis was not possible, meaning a narrative synthesis was the method of analysis used. Consequently, sophisticated statistical analysis could not take place, meaning that less confidence can be held in the effectiveness of psychological interventions for the CPP population. In addition, most research was rated as having at least “some concerns” using the Risk of Bias tool version two, meaning that lower confidence can be had in the true effects of psychological treatment. A key finding of this review is the need for high quality research such as randomised controlled trials, particularly in health conditions such as endometriosis where this is particularly lacking. Given the recent highlighting of gender-related disparities in healthcare and scientific research, future reviews will hopefully have increased data to explore for assessing the effectiveness of psychological interventions for CPP.

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Introduction of Family/Carer Psychoeducation Sessions alongside a Dialectical Behavioural Therapy Programme

June 2022

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Word count: 5,173

Proposed Journal: Personality Disorders: Theory, Research, and Treatment
Word limit: Thirty-six pages in total (including cover page, abstract, text, references, tables and figures); Abstract 250 words

Rationale for proposed journal: The Journal of Personality Disorders publishes research relating to the diagnosis and treatment of personality disorders. The journal regularly features research on treatment techniques and innovations in managing personality disorders.

Introduction

Emotionally Unstable Personality Disorder (EUPD; American Psychiatric Association, 2013) also known as Borderline Personality Disorder (World Health Organization, 2016), is "characterised by significant instability of interpersonal relationships, self-image, mood, and impulsive behaviour…there is a pattern of rapid fluctuation from periods of confidence to despair, with fear of abandonment…and a strong tendency towards suicidal thinking and self-harm" (National Institute of Clinical Excellence, 2009). People with EUPD experience a range of adverse psychological outcomes, including increased distress, self-harm, and risk of suicide (Lieb, Zanarini, Schmahl, Linehan, and Bohus, 2004). Effective treatments for this disorder are therefore desirable for both sufferers and mental health professionals. EUPD has a direct psychological impact on the individuals who experience this, however, the repercussions for carers and family members can also be severe. Families are often intimately involved in the management of EUPD symptoms, consequently, they often experience increased stress, depression, grief, burden and isolation associated with this (Hoffman, Fruzzetti, and Buteau, 2007).

Dialectical Behavioural Therapy (DBT) is a variation of Cognitive Behaviour Therapy (CBT) supported by extensive empirical evidence (Lieb et al., 2004). DBT was originally developed for women with EUPD showing parasuicidal behaviour (Linehan, 1993), and consists of three core modules: emotion regulation, interpersonal effectiveness, and distress tolerance. Mindfulness sessions occur between each module, and mindfulness techniques are used broadly across DBT (Linehan, 2014). Research suggests that DBT can improve quality of life for those with EUPD, as well as reducing depression, hopelessness, anger, self-harm and hospital visits (Koerner & Dimeff, 2007; Koons et al., 2001; Stiglmayr et al., 2014).

National Institute of Clinical Excellence (NICE) guidelines state that psychological treatment should be available for people with EUPD. Guidelines recommend that the therapeutic modality should be determined by factors including service-user preference and disorder severity (NICE, 2009), however, DBT is recommended specifically for women with EUPD who recurrently self-harm. NICE guidelines also recommend that families of people with EUPD should be involved with their family member's care and should be informed of appropriate support groups. National Health Service (NHS) guidelines suggest that service-user preference should be considered when offering therapy for EUPD, and again highlights DBT as a treatment option (NHS, 2019). However, in contrast to NICE guidance, NHS guidelines do not refer

to involvement of family members in treatment plans; either for their own support or to assist their family member with EUPD.

The importance of treatment for EUPD incorporating systemic approaches is supported by theory that systemic factors are largely influential in the development and maintenance of EUPD. EUPD is a relational disorder where dysfunctional family dynamics and interactional patterns contribute to the prevalence of emotional and behavioural reactivity in sufferers (Thompson, 2022). In part, these issues can arise for people with EUPD due to exposure to dysfunctional relationships during childhood, with invalidating home environments continuing to play a role in emotional dysregulation in adults with EUPD (Lawn and McMahon, 2015). People with EUPD struggle to maintain relationships, which in turn impacts their recovery and capacity to manage symptoms and distressing experiences. In addition, research has shown that families of people with EUPD often lack understanding of this condition, in addition to feeling excluded from the treatment process (MacFarlane, 2004). This lack of understanding and feelings of exclusion therefore serves to increase carer burden and distress, which further exacerbates relational issues and other symptoms of EUPD. Systemic approaches to treatment therefore have the potential to beneficially impact dysfunctional relational dynamics in EUPD families, in turn improving outcomes for both family members and sufferers.

Research suggests that DBT can benefit families of people with EUPD, for example by reducing levels of burden, psychological distress, and somatic symptoms in EUPD carers post DBT intervention Regalado et al. (2011). Family member/carer DBT sessions have also been shown to reduce levels of carer grief, and increase perceptions of mastery (Hoffman, 2005). However, evidence is mixed regarding reductions in family member/carer anxiety and depression after DBT intervention, with both non-significant and positive results being found (Hoffman et al., 2007; Wilks et al., 2017). These contradictory findings could be related to differences in carer anxiety/depression pre-intervention, which has been suggested as a confounding variable in previous research (Ekhdahl, Idyall and Perseius, 2014). Studies have however shown consistent improvements in relational dynamics after family DBT, which in turn resulted in strengthened familial relationships (Hoffman et al., 2005; Ekdahl, et al., 2014; Wilks et al., 2017). Furthermore, the broader effects of these improved family dynamics can mean better wellbeing and health outcomes for the person with EUPD (Ekdahl, et al., 2014; Rathus and Miller, 2000). Improvements appear to be potentially long-term, with these changes enduring six-to-eight-months post-intervention (Liljedahl et al., 2019). This can have positive consequences for the person with EUPD, including improved mood,

relationships and cognitive function (Blum et al, 2008). In summary, DBT interventions involving families/carers of those with EUPD can result in a range of beneficial outcomes for both families and the affected individual. Consequently, evidence suggests that the development and utilisation of DBT family programmes would be valuable to enhance intervention options for both individuals and their familial support systems.

The obvious value of DBT family programmes mean that there have been several attempts to create these, however, a review by Guillen et al. (2020) found that existing family programmes are lengthy; many interventions lasted approximately twelve weeks or more. Commitment to these programmes can be problematic, particularly when considering the sometimes-turbulent lives of EUPD individuals and their families (Ntshingila, Poggenpoel, Myburgh and Temane, 2016). There is therefore a need for shorter family member DBT programmes, in addition to assessment of their effectiveness. Only one study has done this so far; showing shorter carer DBT programmes reduced carer burden and improved family functioning (Liljedahl et al., 2019). There is therefore a clear need for further development of programmes to fully explore the most effective ways to deliver these shorter, family-based interventions.

This service improvement project (SIP) aimed to create and evaluate a short course of DBT related sessions for family members of those with EUPD. The evaluation of these sessions was conducted based on questionnaire and general feedback from individuals with EUPD and their family members. The project was run through the Avon and Wiltshire Mental Health Partnership NHS Trust (AWP), within the Complex Psychological Interventions (CPI) team*.

Project context and commissioning

The group in this project was designed and run within a Bristol CPI team offering secondary care mental health support to service-users with a variety of complex mental health needs. A DBT group for service-users with EUPD is run by the CPI team; the content of which is based on recommendations for DBT work (Linehan, 1993). These groups run alongside service-user 1:1 sessions with a DBT therapist to further consolidate skills. Engaging in the full DBT programme takes approximately 18 months.

The addition of a trainee clinical psychologist to the CPI team allowed for the additional capacity to develop a supporter DBT programme. The need for this intervention had been identified by the clinical psychologists within the service due to the relational component of EUPD, in addition to noticing how service-user distress was often preceded by problematic family interactions. The group design and implementation

received input from an assistant psychologist, a trainee psychologist and four qualified clinical psychologists. In addition, a service-user reference group was consulted for the development of sessions and materials.

**A service-user reference group voiced that they preferred the term "supporters" to "family members and carers" in this project. "Supporter" will therefore be used going forwards to refer to the family members who participated in this project.*

Aims of the project

This project aimed to:

- Create materials for a DBT related module for supporters of individuals with EUPD
- Complete a full programme of sessions for the above module (three sessions in total)
- Evaluate the effectiveness of the module based on service-user and supporter questionnaires
- Explore supporter feedback about the sessions; to facilitate potential further delivery of this group

Methods

Material Development

The trainee psychologist reviewed materials and research compiled by the assistant psychologist in 2018. A literature review was evaluated, expanded and updated to include all research until January 2020. The literature was reviewed to explore:

- The existence of other similar DBT supporter programmes
- The content, duration, and design of the above programmes
- The measures used to evaluate existing programmes
- The effectiveness and acceptability of these programmes

Following this, the trainee consulted with two clinical psychologists to create group materials. Content was influenced by the following programmes: "Family Connections" (Hoffman et al., 2005), "Walking the Middle Path" (Rathus and Miller, 2000), "Project Air" (REF) and "STEPPS" (Blum, Pfohl, St John, Monahan and Black, 2002). These interventions incorporated content including psychoeducation, family skills training, validation, effective self-expression, and self-care (Rathus, Campbell, Miller and Smith, 2015; Gill, Warburton, Simes and Sweller, 2017; Guillen et al., 2020; Blum et al., 2002). Psychologist consultation established that the group should be psychoeducational and

skills-based; mirroring the structure of other successful DBT supporter groups (Guillen et al., 2020).

The trainee then liaised with a service-user reference group to seek input on the material content, structure, and wording. Advised recommended changes included increasing accessible language, adding service-user quotes, and reducing unnecessary content. Materials were then reviewed again, before being appropriately formatted by a member of the service-user reference group in line with NHS trust recommendations.

Intervention Content

Table 4 shows the content of each of the three intervention sessions.

Logistics and Group implementation

To recruit participants for the group, CPI psychologists contacted service-users they were currently supporting for DBT treatment. Service-users were asked if their supporters might be interested in or benefit from the group, before supporters were contacted to ascertain their interest. If the service-user and supporter agreed on the supporter's attendance, the trainee would contact both parties to complete pre-group questionnaires. Consent was taken for anonymised group feedback to be shared with NHS staff, the CPI reference group, for write-up in a doctoral thesis and for possible journal publication.

The trainee and their placement supervisor, a psychologist within the CPI service, agreed to run the group for three consecutive weekly sessions. It was decided that these would run after standard working hours between17:00-18:00; to increase the likelihood of supporter attendance.

Table 4.

Intervention content by session

Session Number	Session content
One	• Build rapport between attendees and facilitators, establish session guidelines, and outline the group structure • Complete pre-intervention questionnaires • Provide psychoeducation about EUPD and DBT. The DBT overview included information on its modules, mindfulness, emotion regulation, distress tolerance and interpersonal effectiveness • Listen to the experiences of a service-user who had recently completed DBT
Two	• Provide psychoeducation about emotion dysregulation and validation • Provide and practice skills training for validating emotions and setting limits within families
Three	• Highlight the importance of self-care • Introduce carer plans to facilitate goal setting around supporting service-users • Further reflection about the content and experience of the group • Complete post-group outcome measures

COVID-19 adaptations and online group delivery

The COVID-19 pandemic began during the development phase of this service improvement project. The pandemic limited face-to-face psychological sessions in health services across the UK, consequently, it was agreed that the group would be moved online. Research highlighting the effectiveness and feasibility of online therapy exists, for example Greenhalgh et al. (2018) found that video consultations are safe, effective, and convenient for patients. However, this study highlighted that using video consultations in busy healthcare settings can be complex and time consuming. In addition, there is an overall absence of literature advising on the delivery of group online psychological intervention. British Psychological Society (BPS) and American Psychological Association guidelines were therefore used to guide the online delivery of the group (British Psychological Association, 2020; American Psychological Association, 2020). Recommendations included practical considerations such as utilising secure video platforms, in addition to ascertaining whether group attendees had suitable internet access and were comfortable using video technology. Skype for Business was utilised as the chosen virtual platform within the CPI service. Attendees were sent a Skype email link prior to group sessions and pre-group questionnaires were completed by phone with the trainee psychologist.

Design

A mixed methods study design was used. The group was scheduled to take place over three consecutive weeks; however, a fourth session was later added. This was due to further time being needed to adequately cover materials and reflect on attendee experiences. Differences in project measures were compared pre- and post-intervention.

Between subjects: Both supporters and service-users were participants. Supporters completed five questionnaires, whilst service-users completed two of these.

Within Subjects: All participants completed the same measures pre- and post-intervention, with the addition of post-group feedback from all participants.

Participants

Service users and supporters were contacted by phone. Service users whose supporters might be suitable candidates for the group were identified through their attendance at Dialectical Behaviour Therapy groups being run within the CPI service for individuals with EUPD. Service users were informed that the group would include components such as psychoeducation about EUPD and DBT, self-care and care planning. The trainee

psychologist explained that the group's purpose was to provide emotional and practical assistance to supporters with the aim of helping them to support their family member. If service-users consented to taking part, supporters were contacted and given the same information as service-users before giving their consent to take part. Four service-users and their supporters were initially identified for group participation, however two sets off individuals did not start the group. One service-user dropped out due to contracting COVID-19, whilst the other could not participate due to prior personal commitments. Two service users and their spouses therefore took part in this project. Both supporters were over eighteen and were assessed as having capacity to participate in sessions and give consent for study outcomes/feedback to be shared.

Measures

Supporters completed the following measures:

1) The Warwick Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007) is a measure of wellbeing used as a routine CPI outcome measure. It is a fourteen-item measure with each item rated on a five-point scale, with higher scores indicating better wellbeing. It has a test-retest reliability of 0.83 and is sensitive to change in health interventions (Stewart-Brown et al., 2011).

2) The Burden Assessment Scale (Reinhard, Gubman, Horwitz, and Minsky, 1994) is a scale to assess the burden on families with a seriously mentally ill family member. It is a 19-item questionnaire with each item rated on a four-point scale from "not at all" to "a lot" with higher scores indicating higher levels of burden. The scale has a reliability of 0.89 (Reinhard et al., 1994) and has been used to evaluate the Family Connections programme (Hoffman, 2005).

3) The Pearlin Mastery Scale (Pearlin and Schooler, 1978) assesses the extent to which an individual regards their life chances as being under their personal control. It is a seven-item scale with each item scored on a four-point scale, with higher scores associated with higher levels of mastery. It has internal reliability ranging from 0.56-0.76 and -0.47 on negatively and positively worded items; respectively (Brady, 2003). This scale has also been used to evaluate the Family Connections programme (Flynn et al., 2017).

4) The SCORE-15 is a measure of global family functioning which was commissioned by the Association of Family Therapy and has been shown to be a valid measure of therapeutic change (Stratton et al., 2013). It is a 15-item scale with each item scored on a 1-5 scale, with higher scores representing higher levels of family dysfunction.

Supporters also completed additional measures:

1) Ratings on a Likert scale of 1-4, where 1 represents poor and 4 represents excellent, on the following four questions:
   a) Please rate the usefulness of the session
   b) Please rate the session delivery
   c) Please rate the session materials
   d) Please rate how relevant the content was to your life
   e) A further question: "how much of the session materials were familiar to you?" was scored on a Likert scale where 1, 2, 3, and 4 represented not at all familiar, slightly familiar, familiar, and very familiar; respectively

2) Supporters also gave open-ended feedback about the group. Attendees were asked about their experience of the group and its online format, as well as suggestions for group improvement. The facilitator also explored the anecdotal impact of the group on familial relationships.

Service-users completed the WEMWBS and SCORE-15. In addition, service-users were asked for general feedback about the group impact on themselves, their supporter, and the relationship between them.

Analysis Plan

Supporters completed the BAS, PMS, SCORE-15 and WEMWBS pre-and post-group, whilst service users completed the latter two questionnaires pre- and post-group. Due to the low number of participants resulting in limited data, descriptive statistics were calculated and presented for each individual's questionnaire scores. Data was also presented in this way for supporter Likert scale questions. Questionnaire scores were presented graphically using bar charts. Open-ended feedback from supporters and service users was collated under the following headings:

- Accessing the group online

- Positive comments about the group
- Highlights of group material
- Suggestions for group improvement

Broad themes were identified from each heading, though full thematic analysis did not take place.

Results

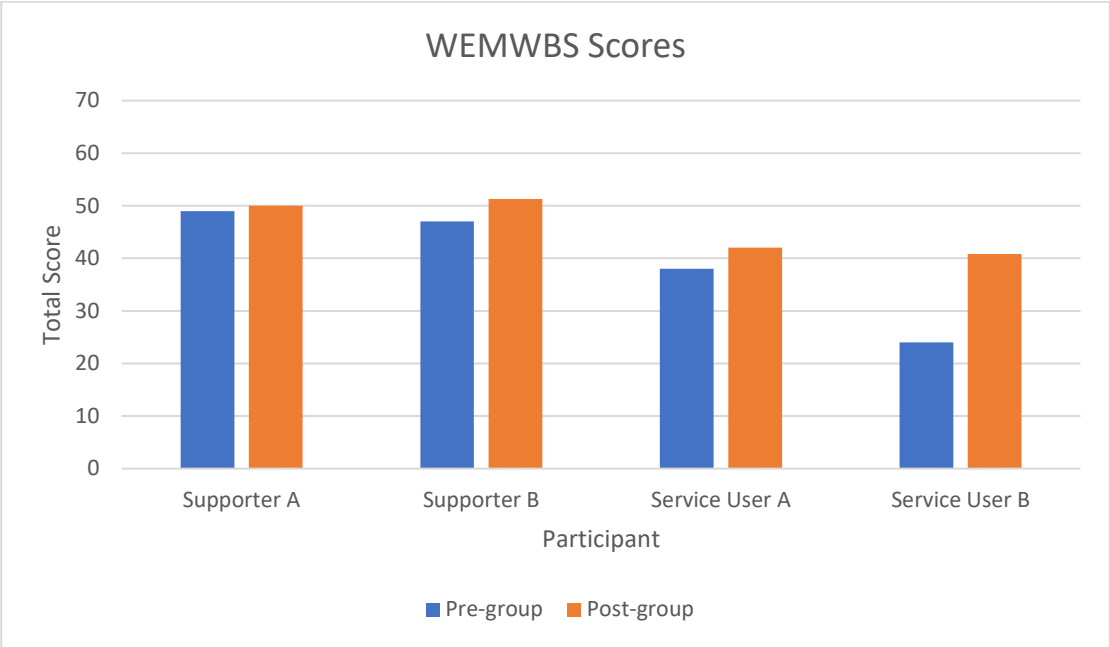
Joint supporter and SU measures

WEMWBS:

Figure 2 shows wellbeing scores pre- and post-group for each project participant. A maximum of seventy points is available, with higher scores indicating better wellbeing. WEMWBS population norms from a 2011 English Health Survey found mean scores of 51.6, with a standard deviation of 8.7 (Warwick Medical School, 2011).

Figure 2.

Warwick Edinburgh Mental Wellbeing (WEMWBS) scores pre- and post-intervention

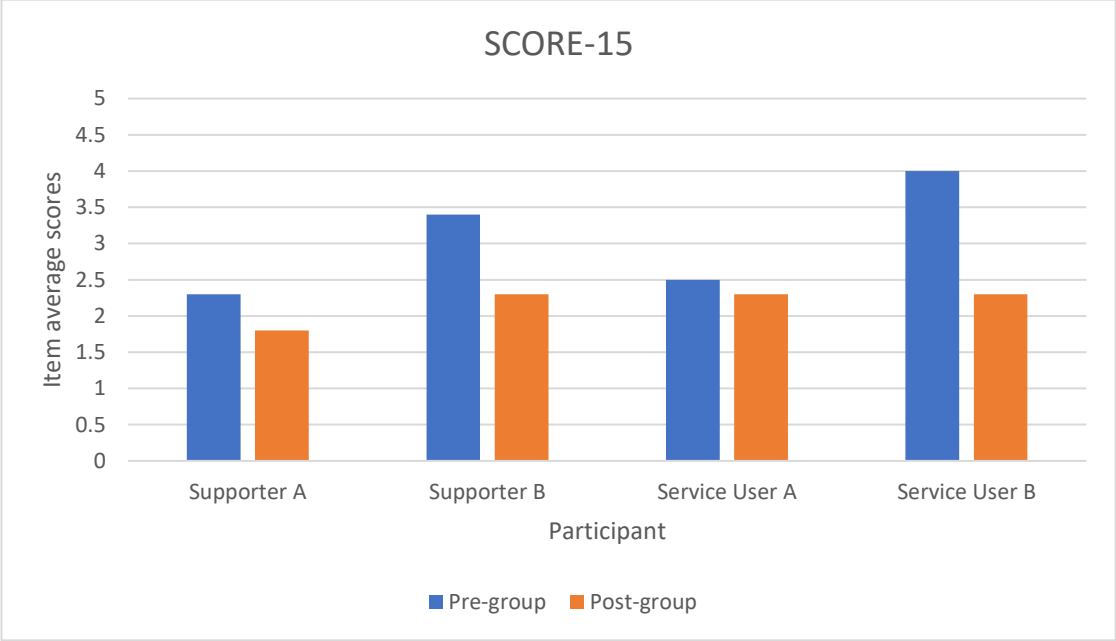


SCORE-15:

Figure 3 shows item average scores for family functioning pre- and post-group as judged by each project participant. Items are scored on a Likert scale of 0-5, with higher scores representing higher family dysfunction. Normative data given by the AFT state that for adults, average scores of 2.0 or over represent “significant problems” within the family, and scores of 3.0 and above represented the top 10% of the study population for the SCORE-15 (Fay et al., 2013).

Figure 3.

SCORE-15 scores pre- and post-intervention



Additional supporter measures

Pearlin Mastery Scale

Figures 4 and 5 show item and total personal mastery scores pre and post-group; respectively. Maximum total and item scores are 28 and 5, with higher scores indicating higher levels of perceived mastery. Items are scored on a 0-5 Likert Scale. In a large Norwegian study, mean item scores ranged between 3.76-4.08, with standard deviations ranging from 0.98-1.17; dependent on the age of participants (Clench-AAs, Nes and Aaro, 2017). However, as Brady (2003) highlights, no score cut-offs exist for the PMS, meaning both total and item scores are open to interpretation.

Figure 4.

Pearlin Mastery Scale – Item average scores

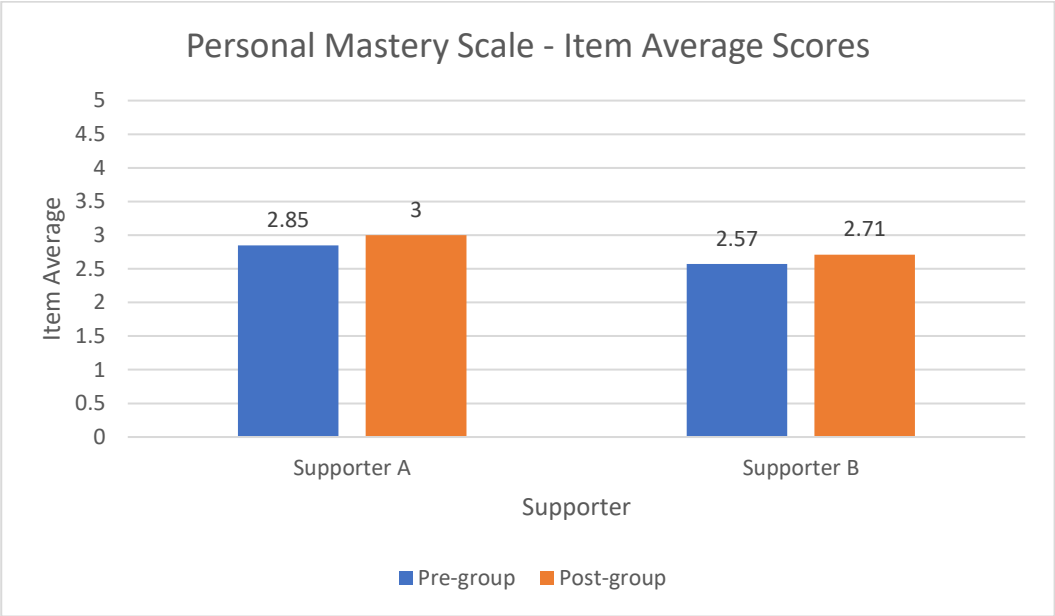
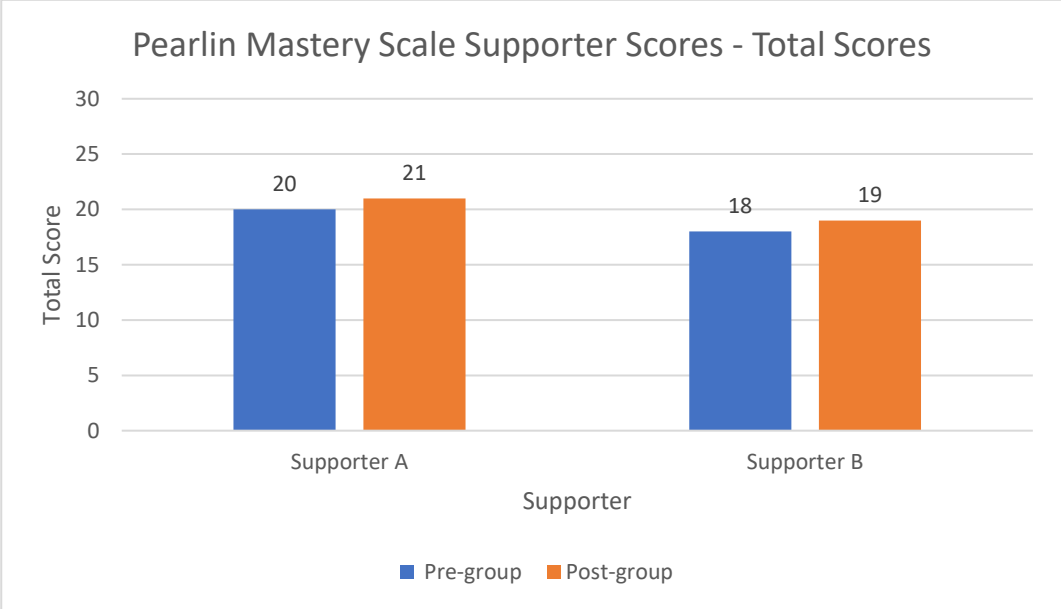


Figure 5.

Pearlin Mastery Scale – Total average scores



Burden Assessment Scale

Unfortunately, due to COVID-19 restrictions, both supporters expressed that many questions on the Burden Assessment Scale were non-applicable. For example, items asked about time spent with friends, at a time when pandemic social restrictions were in place. The maximum score on the BAS is seventy-six; with higher scores representing higher levels of carer burden. Supporter A scored 50 and 28 on the BAS pre- and post-

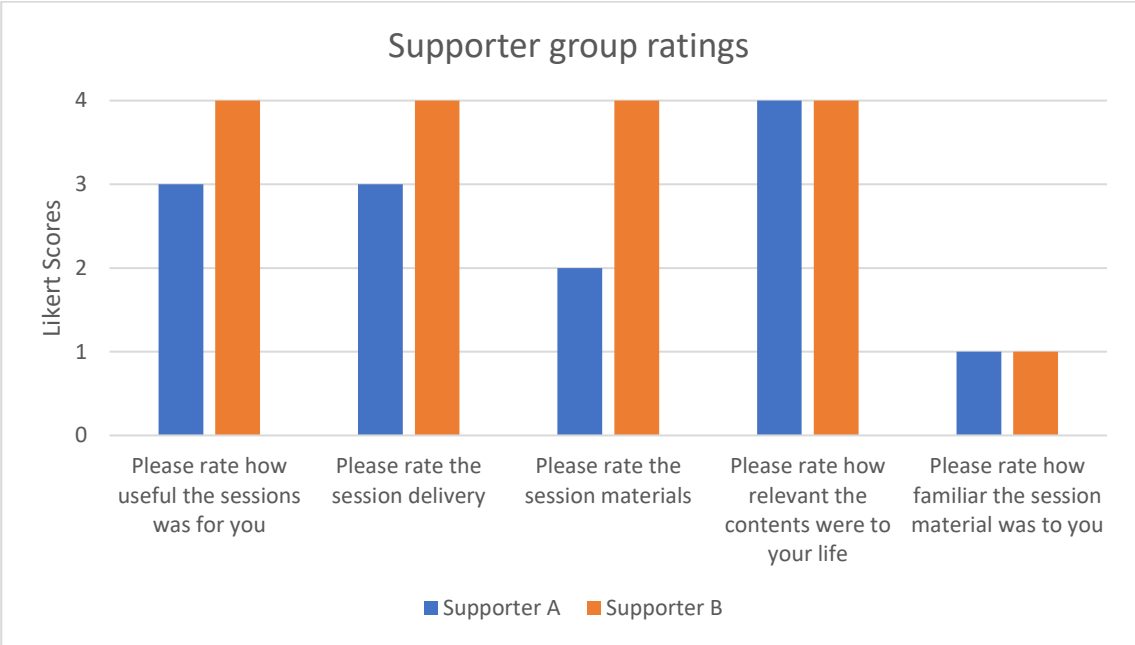
group; respectively. However, they felt unable to complete 4/19 questionnaire items at both data timepoints. Supporter B scored 32 and 23 on the BAS pre- and post-group; respectively. They completed all questionnaire items pre-group but felt unable to complete 3/19 questionnaire items post-group. As such, full descriptive statistics cannot be presented. However, some observations were made for individual BAS questions. For example, supporter A saw improvements on scores on 12/13 of the questions they completed pre- and post-group. Scores showing the biggest reductions were on questions such as “missed days at work”, “felt guilty because you were responsible”, “felt guilty you were not doing enough to help” or being “worried about what the future holds”. Supporter B’s scores varied less than supporter A but showed that there was a reduction in score on questions about feeling they were not doing enough to help. Score reductions on individual BAS questions therefore show potentially promising results for reducing carer burden, although no conclusions can be drawn about this.

Likert Scales

Figure 6 shows supporter ratings for four questions relating to group content and delivery, with higher scores reflect positive views on each question. The exception to this is lower scores representing lower familiarity with group materials on question five.

Figure 6.

Likert scale ratings of group content and delivery



Service-user and supporter open-ended feedback

Project participants were also asked to provide general feedback about their experience of being either a group attendee or being a service user, whose supporter attended the group. Highlights from this feedback can be seen in the below corresponding figures:

Supporter feedback:

- Figure 7a; accessing the group online
- Figure 7b; positive comments
- Figure 7c; highlights of group material
- Figure 7d; suggestions for group improvement

Service user feedback:

- Figure 8a; positive comments
- Figure 8b; suggestions for group improvement

Broad themes from the data were then drawn out and can be seen in Table 5. Positive comments included that the group was generally well received and that both service-users and supporters felt their experiences had been validated. A variety of group components were found to be useful, such as mindfulness and crisis strategies, in addition to discussions around self-care. Themes for group improvement included running follow-up sessions, editing group materials, and

hearing from a supporter whose family member had previously been through DBT. Supporters expressed that accessing the group online was acceptable and included positives such as increased flexibility to attend, although the importance of resolving technical issues was highlighted.

Figure 7a.

Supporter feedback: accessing the group online

How did you find accessing the group online?

Supporter A:

- "It was Ok, it went better than expected"
- Highlighted some connectivity problems and technical issues, but said that apart from this accessing the group went well
- "It made it easier for me to attend at 5pm at the end of the day – I think this would be a useful option even if it wasn't for COVID"
- Reported that they didn't find bonding with the group any harder than they would have in person

Supporter B:

- "Yes, accessing the group online was fine – it was nicer having the group by video rather than it just being a telephone call"
- "The group being online made it easier to access – people don't have to travel, and I wouldn't have been able to attend otherwise as I live in a different city to the psychology service"
- "I had no problems with Teams as I use this for work anyway"
- "Because the group was online, I don't think it should have any more than four carers attending, so we would all get an equal chance to speak"

Figure 7b.

Supporter feedback: positive comments

Positive comments: Supporters

Supporter A:

- "This group is really useful for family and friends, as sometimes (Service User A) is open about what has happened in their DBT group, but sometimes they are not – it means that there are things I am not learning that could be helpful to me"
- Reported that the concepts were useful for applying to all relationships
- Reported they appreciated an added fourth session; "the content would have felt too rushed otherwise and there would not have been enough time to talk"
- "I was really impressed overall. I hope you continue to run it and it is successful"

Supporter B:

- "The group was much better than I expected – I didn't really know what to expect, but I'd read a lot about EUPD and DBT, but this isn't the same as having someone who gives those therapies or has had those therapies explaining what it's like to have EUPD, or the strategies that can be used to manage it"
- "The group helped put things to you in a way that makes sense to your situation"
- "It felt really validating that someone appreciated it isn't easy to be a family member or partner to someone with EUPD…there isn't really anything for family or partners of people undergoing DBT"
- Reported also appreciating four sessions instead of three in order not to rush content

Figure 7c.

Supporter feedback: highlights of group material

What did you find useful from the sessions?

Comments from Supporters A and B:

- Introducing the concept of "wisemind" vs "emotion mind"; one participant pair reported regularly using this knowledge when the service-user was in distress
- Crisis strategies
- Self-care
- "Thinking about the stress bucket and how it applies to me"
- "We made a DBT safety plan together – we've talked about printing out strategies to put on the fridge"
- "It was good to talk about limit-setting, although we've not gone there yet"
- Both supporters acknowledged that a highlight of the group was hearing from a previous service-user who talked about their experience of having DBT. They reported that this increased their understanding and gave them hope for themselves and their partner

Figure 7d.

Supporter feedback: suggestions for group improvement

Suggestions for improvement: Service Users:

Service User B:

- "In the beginning it was hard to listen to them asking me to use my techniques as it felt like a parent/teacher role for them, and I felt disempowered – especially as I was being talked at after one to two sessions when I was a month into my DBT"
- "I found it hard; because my family member is "normal" she got the skills quicker than me, which I found hard to deal with, as I felt I lost control…we then spoke about letting me lead my skills and express my needs so that I could lead my support and they could help"
- The service user expressed they didn't like to being referred to as a "diagnosis", and that it might be worth editing this term in the materials
- "It might be useful have further support sessions; for example, once every three months"
- "It might be good to give carers more information on mindfulness exercises so that they could help us with this when we are in high states of anxiety"

Figure 8a.

Service-user feedback: Positive comments

Positive comments: Service Users

Service User A:

- Reported that it was useful for their partner to get a better idea of what they were learning, so that they could see why it might be helpful for them (the supporter), to do things differently
- Felt it would've been helpful for their supporter to access the group when they had started DBT, rather than being later in their treatment
- "Having my partner in the group means that it felt like there was light at the end of the tunnel – it made me feel more able to talk to them about the changes I wanted to make, and to feel more confident in raising things"
- Reported that the group increased their supporter's openness and understanding
- "The fact that he'd been willing to put the time and effort into attending the group made me feel more supported – it meant a lot to me and really helped our relationship"

Service B:

- "I was happy for them to attend – I felt like a burden and needed someone to validate my actions and diagnosis (to show them I wasn't a bad person)"
- "I found it difficult to explain what DBT was and how it worked"
- "My family member was really positive – almost like they'd been given some hope; that this was manageable, and I was capable of getting better"
- "I had been worried about where their vent was – it felt positive that she could talk to people who didn't know us"
- "They had a better understanding; especially when it came to validating my emotions – even if she didn't agree with them"
- "Something which helped and I believe saved our relationship was learning about the different states of mind, and how to interact with me during these different minds"
- "I gained hope for myself and my family member"
- "I think these support sessions are great, it very much created awareness and almost normalised things for me"

Figure 8b.

Service-user feedback: suggestions for group improvement

Suggestions for improvement: Supporters

Supporter A:

- Highlighted that they were attending these sessions at the end of the service-users DBT, and would've liked to access the group earlier
- "It might have been good if the group was a bit larger, but then (Supporter B) wouldn't have had as much chance to talk, so it would need to be balanced"
- Highlighted the importance of resolving technical issues
- "It would have been good to hear from a supporter in terms of their personal experience as well as a service user"
- "I kind of felt some of the material was a bit generic and not necessarily something that was brought from personal experience"
- "It would be important to make sure that parts of the materials weren't skipped over, as this can make it a bit disjointed"

Supporter B:

- "Long term it would be good to have a possible support network between family members – so there's someone to talk to if you need to"
- "It would be good to have follow-up sessions once you have been able to go away, try things at home, and bring back things that have or haven't worked"
- "At the beginning some of the content was a bit generic; it was good to have more personalised sessions later on – it might even be good to have a 1:1 session if possible, or make more of the session apply to your particular situation"

Table 5.

Summary of open-ended feedback themes

	Supporters	**Service users**
Accessing the group online	• Some technical issues • Generally acceptable • Additional positives to sessions being online, such as flexibility to attend	N/A
Positive comments	• Able to understand and apply concepts to their own lives • Felt their experiences were validated and normalised • Positive feedback about the group overall, and the idea of continuing the group	• Found it helpful for their partner to understand what they were learning • Normalised and validated their experiences • Increased openness, understanding and communication in their relationship • Felt positive that their family member had support • Gave them hope that things could get better
What was useful about the group	• Multiple group components including crisis, mindfulness, and self-care strategies • Introduction of safety-plans	N/A

	• Hearing from a previous service-user about their experience	
Supporter suggestions for improvement	• Would value hearing about the previous experience of a supporter • Felt some of the material was generic • Wondered about the "right" size of the group • Wondered about the timing of supporters accessing the group • Felt it would be helpful to have additional/follow-up sessions	• Sometimes feeling disempowered for example by being told to use their skills, or their partner learning skills more quickly • Some issues with material terminology, e.g., "diagnosis" • Felt it would be helpful to have additional/follow-up sessions

Feasibility and Acceptability

Group attendance and feedback rates were 100%. A fourth group session was added to adequately cover materials and provide time for group reflection, in addition to ensuring that groups did not overrun their allotted one-hour time slot. Permission was given by attendees for this, and feedback was that four sessions were preferred to three. Completing pre-group measures was a prerequisite for group participation, however there were difficulties completing arranged post-group feedback appointments with participants. Consequently, there was variability in when post-group data was collected. For example, supporter A and service-user B gave feedback two- and nine-weeks post-group; respectively, with reasons for these failed appointments being work commitments or participants forgetting. In summary, group feasibility and acceptability were appropriate, however, methods of post-group data collection should be considered for future group implementation.

Feedback to CPI service

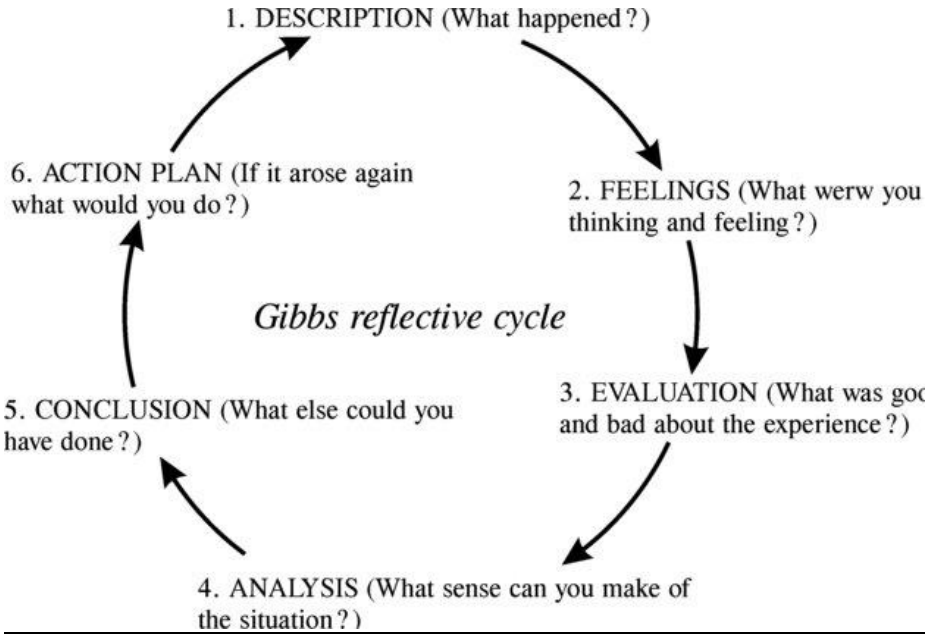
Feedback was given to the CPI service in two ways. Firstly, a presentation on group delivery and outcomes was given to the CPI service-user reference group who had been involved in developing the group content and materials. The group appreciated receiving feedback and was extremely positive about the intervention, in addition to reflecting on the value of open-ended participant feedback. The group highlighted the benefits of future attendees choosing when to access the supporter group, as they felt that preference might differ between families. The presentation was also given to clinical psychologists within the CPI service, with the response being largely positive and expressing optimism about future group development. In addition, the trainee created an information leaflet to recruit for another supporter group in April 2021.

Process reflection: Gibbs (1988) reflection cycle

To reflect on and facilitate continuation of the group, the Gibbs (1988) reflection cycle was used; as seen in Figure 9. A reflection by the trainee psychologist who developed and delivered the group can be found in Appendix A.

Figure 9.

Gibbs reflective cycle (Gibbs, 1988)



Discussion

The aims of this service improvement project were to produce materials for a family/carer DBT module, to evaluate the effectiveness of the module based on supporter and service-user questionnaires, and to evaluate feedback about the project overall. In the context of the COVID-19 pandemic, a supporter DBT group was designed and delivered, albeit in an alternative online format. The group was piloted with two service-users and their supporters, with both attendance and feedback rates at 100%.

Due to the low number of participants no broad conclusions can be drawn from the outcome data, however the project results provided a starting point to explore the benefits of the group and facilitate ideas for further development. The SCORE-15 outcome measure yielded particularly promising results, with all four participants seeing improvements in family functioning from pre- to post-group. One supporter-service-user pair saw scores move from the upper 10% of possible item scores, representing "significant family problems", to scores only slightly above the cut-off for "problematic family interactions". All four participants returned scores representing reduced problematic family interactions. Post-group, one service-user scored within the range for normal family interactions. These initial findings fit with previous research showing that carer DBT can improve family dynamics and therefore result in positive familial relationships (Ekdahl, et al., 2014; Rathus and Miller, 2000). Initial results therefore suggest that this supporter group could be beneficial for interactions and relationships in

families where someone has EUPD, and that this is applicable for service-users and supporters accessing the Bristol CPI service.

All participants saw a minor increase in their scores on the WEMWBS, although for one supporter-service-user pair wellbeing scores had been in the normative range pre-group. Service-user B however saw a drastic improvement in wellbeing post-group with their WEMWBS score increasing by sixteen points, meaning their score was almost within the normative range for well-being. This service-user gave anecdotal reports of several adverse life events at the time of post-group feedback but said the group benefits had lessened the strain on their family relationship, which had led to this improvement in wellbeing.

Minimal improvements in mastery were seen using the PMS. However, data suggests supporters displayed mastery scores within the normative range pre-group. Limited conclusions could be drawn about changes to burden using the BAS, as both supporters felt unable to adequately complete this post-group. This was largely due to the influence of COVID-19 restrictions on participant's lives, for example, many BAS questions related to missing out on time with family and friends. However, reductions on scores on BAS questions that were able to be answered showed potential for this group intervention to reduce carer burden.

Participant score variation could reflect an important point given in feedback, in that differences in scores could reflect the different stages of DBT treatment that service-users were experiencing. All participants felt it was crucial for supporters to have the option to attend the group at the beginning of their family member's treatment, so that the benefits could be maximised. However, feedback from the CPI service and service user reference group highlighted the importance of giving choice about when supporters accessed the group, as preferences might be different between families.

Likert ratings given by supporters conveyed that largely, the content, delivery and familiarity of the course material were appropriate. Supporter A gave 2/4 on the question "please rate the session materials", representing room for improvement regarding future development of these. When asked to elaborate, supporter A explained that in earlier sessions some of the content felt too generic. Feedback should be reviewed to improve materials, such as the session booklet, for future groups and to ensure that these feel person-centred to participants.

General feedback from the group was largely positive, with supporters reporting acceptability of the group online format, and highlighting benefits such as increased opportunity for group attendance because of this. Positive comments from supporters

included feeling validated by having a group that met their own needs and reflecting that the skills taught in sessions were useful. Supporter suggested areas for improvement included the resolution of technical issues, and the opportunity to hear from a supporter whose family member had completed DBT.

Service-users reflected that the group meant they could more easily talk to family members about their experience of DBT and EUPD. They reported feeling more supported by their family members attendance and that their experience of EUPD was normalised. Service-users also expressed appreciation that their supporters had an outlet for their own emotions and experiences of their family member's diagnosis. They described collaboratively utilising DBT techniques from the group with their supporters, including finding ways of adapting these to best meet their needs. One service-user did report some initial difficulties in negotiating techniques with their partner, as they felt disempowered by being told to use their skills when distressed. This highlights the need for discussion about this possible barrier in further groups.

Both supporters and one service-user expressed that follow-up sessions could be useful, and that the group should be offered as soon as service-users entered the CPI service. Future group evaluation should involve outcome measure feedback collected from participants who attended this group relatively early on in service-user DBT treatment.

The successful implementation of this group in addition to positive participant feedback shows that this intervention was both feasible to run and acceptable to participants. The content or organisation of the group may not be generalisable to other NHS mental health settings, however, the initial results from this project are encouraging and promote future group delivery.

Several papers highlight the need for an understanding of which intervention components result in outcome improvement in family DBT groups (Hoffman et al, 2007; Guillen et al., 2020, Wilks et al., 2017). Future development of this group should include measures to assess the usefulness and effectiveness of different group components. This might include participant ratings of which aspects they perceived as being most acceptable/useful. A review by Guillen et al. (2020) highlights the need for methodologically sound research to assess the value of EUPD supporter groups, showing that where possible future evaluation of this group should be guided by empirical or research-based practice. There will inevitably be some dilemmas in adhering to these principles; for example, it may not be ethical to withhold treatment to provide a control

group. Alterations to group evaluation might include re-scrutinising outcome measures or comparing the intervention to another form of support.

The NHS Trust involved with this project were encouraged by the results and are currently recruiting for further groups, whilst using the results of this project to guide further group development. Next steps include reviewing session materials and making decisions around future group facilitators. At the time of writing, the group facilitators have discussed the possibility of involving members of the wider multidisciplinary team (MDT) in group delivery. This might prove beneficial to improve professional relationships, solve potential logistical issues and extend psychological knowledge to other professions, whilst ensuring that MDT members understand the difficulties of families of service-users. British Psychological Association guidelines highlight the importance of providing leadership to promote psychological change within systems (British Psychological Association, 2010); inviting other MDT members to participate in group delivery would facilitate cross-department psychologically informed care. As well as the group continuing within the CPI service, other psychology departments across multiple NHS trusts have expressed interest in running the group due to the successful outcomes of this project. There is also scope for future service improvement projects to be run by other psychology trainees to further evaluate the group with bigger participant samples, or once group materials have been revised.

Questions and challenges around the group's future relate to the COVID-19 pandemic. Firstly, decisions must be made about delivering the group face-to-face or online going forwards. Group continuation will also be influenced by the inevitable long-term pressure of COVID-19 on mental health services and associated resources. A review by Moreno et al (2020) showed COVID-19 will exacerbate mental health problems across society, with problems affecting the public, those with existing mental health conditions, and NHS staff. Inevitably, this rise in mental health issues will put significant additional pressure on the NHS. The resulting impact on many healthcare support groups, especially those not seen as meeting core NHS needs, is therefore uncertain. However, the need to support vulnerable families in which there are complex mental health problems may mean groups such as the current example are more crucial than ever.

To conclude, the future of this group for supporters of people with EUPD looks promising, with results and feedback suggest multiple benefits for group attendees and service-users. The CPI service running this group has developed an action plan for its continuation. This is so that the benefits of this intervention can continue to be

disseminated within this service and other NHS Trusts, and to further improve the lives of individuals with EUPD and their families.

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Examining factors influencing the development and maintenance of Non-Specific Abdominal Pain

June 2022
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Word count: 8111

Proposed Journal: Clinical Journal of Pain
Word limit: None – Abstract 250 words

Rationale for proposed journal:

The Clinical Journal of Pain publishes research exploring all aspects of pain and its effective treatment, including research regarding psychological treatment. The journal cites an interest in publishing psychosocial dimensions of pain.

Introduction

Unexplained persistent physical symptoms are bodily complaints that cannot be sufficiently explained by adequate medical examination and are increasingly becoming a distressing and complex issue for health services and sufferers (Fayaz, Croft, Langford, Donaldson and Jones, 2016; Marks and Hunter, 2015). Pain associated with persistent physical symptoms affects approximately 1-6% of individuals within the UK, and sufferers increasingly access primary and secondary healthcare services (The Royal College of Emergency Medicine, 2017; Eskelinen and Lipponen, 2012; National Institute for Health and Care Excellence; NICE, 2021). Nonspecific, recurrent abdominal pain (NSAP) consists of repeated, acute episodes of pain which are a lead cause for seeking both emergency and outpatient medical assessment and treatment (Daniels, Griffiths and Fisher, 2019; Eskelinen and Lipponen, 2012). NSAP is "not a defined disease but is a collection of conditions…it refers to abdominal or pelvic pain of less than seven days duration for which the diagnosis remains uncertain after clinical examination and baseline investigations" (Morino and Famiglietti, 2012, p. 153-161). Overall, there are many potential causes for abdominal pain, including irritable bowel syndrome, appendicitis, abdominal/bowel cancers, or Crohn's disease (Gotfried, 2022). However, one third of patients presenting at the GP and half of those presenting at emergency departments for abdominal discomfort have no apparent cause for their pain (Daniels et al, 2019; Viniol et al, 2014). The desire of patients and medical staff to obtain a medical diagnosis can consequently lead to excessive medical exploration, potentially including invasive procedures and inappropriate medication prescriptions (Clouse et al, 2006; Daniels et al, 2019). Historically, symptoms or pain without an organic cause have been labelled "medically unexplained symptoms"; however, this term is controversial due to its association with a purely medical model and neglect of the psychosocial factors that are well-known to play a role in pain (Daniels et al, 2019). Modern research and clinical care have increasingly moved towards utilising a biopsychosocial model in treating chronic/persistent pain over the traditional medical model. The biopsychosocial model postulates that pain and disability are multidimensional, dynamic interactions among biological, psychological, and social factors that reciprocally influence each other, and is a widely accepted approach within both research and clinical practice (Cohen, Vase, and Hooten, 2021). The identification of contributing factors relevant to NSAP may lead to successful and potentially less invasive treatments for this pain population.

To understand the biopsychosocial model in reference to NSAP, the relationships between the brain, gut, and psychosocial factors must be considered. Models of pain such as the "imprecision hypothesis" provide a neurobiopsychosocial explanation for the development and maintenance of chronic pain (Moseley and Vlaeyen, 2015). This hypothesis suggests that pain is a conditioned response to multisensory and meaningful events that routinely coincide with or pre-empt nociceptive stimuli. The encoding and processing of these events occur in the context of psychological and cognitive processing. Imprecise encoding of these events when they are paired with a danger message can lead to the overgeneralisation of pain responses in future, similar events where similar stimuli are present. This in turn can lead to beliefs and behaviours around pain, such as pain-avoidant behaviours in the absence of any noxious stimuli. Imprecise encoding of a noxious stimulus via cognitive and psychological processing therefore leads to a conditioned response of pain when specific stimuli are present. Activation of brain "neurotags" or specific patterns of neuronal activity associated with these episodes are strengthened by repeated use and brain plasticity in response to repeated triggering of these processes. Psychological and cognitive factors involved in the original and repeated processing of pain-associated stimuli work to develop and maintain pain, and therefore are important to address in treatment for chronic pain. This theory suggests therefore that psychosocial factors are key to the development and maintenance of NSAP, even in the absence of pain-causing stimuli. Other theories of pain relating to the abdominal organs involved in NSAP include the. Hypothalamic Pituitary Adrenal (HPA) and "brain-gut" axes (Daniels et al, 2019; Drossman, 1998; Drossman, 2016). The HPA system is key to activating the autonomic system stress reaction in response to threat perception, releasing hormones including corticosteroids, adrenaline, and noradrenaline to prime the body to danger (van Bodegom, Homberg and Henckens, 2017). Repeated triggering due to stressors such as pain, trauma, or unfamiliar sensations can result in increased system sensitivity. The brain-gut axis is linked to the HPA and refers to the bidirectional relationship between emotional and cognitive systems and gastrointestinal components controlling sensory, motor, endocrine, immune and inflammatory functions (Drossman, 2016). The brain-gut axis is designed for optimum homeostasis and to ensure that the gastrointestinal network is aligned with the needs of the organism (Mayer and Tillisch, 2011). Paradoxically, this system can work inversely if it becomes dysfunctional. Psychosocial factors can influence abdominal function as a consequence of this system, for example, anxiety and depression are both known to influence the brain-gut system

by inducing the release of corticotrophin-releasing factor, which impacts bowel motility, abdominal pain, digestive secretion, and immune function of the bowels as well as the perception of visceral stimuli (Sibelli et al, 2016). Conversely, physiological phenomenon such as inflammation and injury can ascend CNS pathways and impact brain areas, resulting in greater pain and altered psychological functioning (Drossman, 2016). Consequently, interoceptive information can be contextualised based on current and past environments, whilst cognitive and psychological processes heighten pain and sensitivity of the HPA and brain-gut link to activation (Daniels, et al, 2019). This can result in a hyper-sensitised HPA and brain-gut system, which is easily triggered as the result of multiple factors and results in significant pain and distress. Several theories of pain relating to NSAP including the imprecision hypothesis and HPA/brain-gut axes therefore suggest that psychosocial factors are key to developing and maintaining pain. Evidence suggests that differing functional gastrointestinal disorder (FGID) presentations are likely to be unique expressions of various patterns between the central nervous system and abdominal organs, and that person-specific gene-environment interactions are likely to shape distinctive symptoms (Mayer and Tillisch, 2011). Based on this argument, additional NSAP research may not be necessary if FGIDs are differing symptoms with the same underlying mechanisms; an argument which has been made for using transdiagnostic approaches to target varying presentations of persistent physical symptoms (Balabanovic & Hayton, 2020). However, some psychosocial factors may be particularly salient in NSAP and should be investigated before making assumptions about the potential effectiveness of transdiagnostic abdominal pain treatments.

Exploration of disorders similar to NSAP may provide information as to the psychosocial factors that may be particularly important for this. Irritable Bowel Syndrome is an FGID in which utilisation of the biopsychosocial model has led to the development of effective psychological treatments, due to a greater understanding of the factors that can influence this (Drossman, 2016; Windgassen et al, 2017). One key psychosocial factor which has shown to be important for the potential development of IBS and other pain disorders such as chronic pelvic pain (CPP) is trauma, particularly in relation to historical child abuse (Bradford et al, 2012; Choung, Herrick, Locke, Zinsmeister and Talley, 2014; Sansone and Sansone, 2015). Furthermore, additional evidence shows how the interaction of factors within the biopsychosocial model can impact IBS and CPP outcome, as research has shown that psychological factors such as anxiety and depression could mediate the link between abuse and IBS/CPP

development (Chitkara, van Tilburg, Blois-Martin, Whitehead 2008; (Piontek, Apfelbacher, Ketels, Brunahl and Lowe, 2021; Surdea-Blaga, Baban and Dumitrascu, 2012). The contribution of trauma to the development of pain disorders might also in some part explain the female-dominance that exists in these disorders, as women are more likely than men to experience some types of abuse, such as sexual abuse Bradford et al, 2012). It is therefore important to learn not only which psychosocial factors impact disorder outcomes, but to understand how these factors interact. Psychosocial factors such as trauma may exacerbate psychological distress, which initiates the biological mechanisms that can trigger the development and maintenance of abdominal pain. Research therefore suggests that factors including trauma and associated psychological distress can contribute to several abdominal pain conditions and therefore may be relevant in the development of NSAP.

To understand how psychological distress and increased pain manifests in conditions such as NSAP, the contributions of other factors to this should be investigated to identify "active" components which would be amenable to psychological treatment (Burns, Day and Thorn, 2012). Cognitive behavioural theories of chronic pain highlight the importance of targeting unhelpful thoughts and perceptions, in addition to utilising adaptive behavioural strategies to manage pain and it's resulting impact (Burns, Day and Thorn, 2012) more effectively. Identifying cognitive processes in NSAP which contribute to unhelpful pain beliefs and resulting psychological distress and pain is therefore important to understand how these might be targeted. Sensitivity to anxiety-related sensations and fearful beliefs about the consequences of anxiety is known as "anxiety sensitivity" and is known to contribute to increased pain and psychological distress in pain conditions, including IBS (Hazlett-Stevens, Craske, Mayer, Chang, Naliboff, 2003; Norton et al, 1999). According to the cognitive behavioural model, fear around the adverse impact of anxiety can consequently lead to body vigilance, which refers to attending to and monitoring body sensations and is an attempt to scan the body to detect anxiety (Esteve and Camacho, 2008). Body vigilance is known in IBS and other FGIDs to be associated with greater somatic complaints, anxiety disorders, healthcare utilisation, and increased symptoms (Keough, Timpano, Zawilinski, and Schmidt, 2011; Olatunji, Deacon, Abramaowitz, and Valentiner, 2007; Oudenhove et al, 2016). Detection of pain or anxiety-related body sensations then initiates catastrophisation about what these sensations might mean, which in turn is known to result in increased pain and psychological distress in chronic pain conditions (Leung, 2012). Pain catastrophising rather than overall symptom catastrophising is

particularly important in the context of NSAP, as pain catastrophising relates specifically to negative cognitive and emotional schema during actual and anticipated pain stimulation, which then further exacerbates pain (Quartana, Campbell, and Edwards (2009). This is in contrast to symptom catastrophising, which may lead to catastrophisation of general symptoms rather than pain specifically. The bi-directional relationship between distress and pain in addition to the interaction between cognitive-behavioural variables then maintains pain and distress in a vicious cycle. Factors such as trauma have been shown to result in heightened levels of these processes including pain catastrophising and sensitivity to anxiety-related sensations, in response to the body's threat system attempting to protect the individual from further harm (Windsor, 2020). This suggests that early psychosocial events can lead to a cascade of biological dysfunction, cognitive-behavioural distortion and psychological distress that contributes to pain conditions. A critique of research showing the effectiveness of cognitive-behavioural treatments for pain however is that fewer studies incorporate methodologies such as lagged and cross-sectional lagged research that show definitively that cognitive change causes pain reductions, rather than the opposite being true (Burns, Day and Thorn, 2012). This means that there is still room for additional research in this area, using sophisticated methodologies that would confirm the findings of cognitive-behavioural research so far. Despite this, the importance of psychosocial factors in conditions like NSAP cannot be denied, but the scarcity of NSAP-specific research means that further exploration is needed to confirm the role of these factors in this condition.

The current study aims to identify factors that may be important for the development and maintenance of NSAP. Furthermore, this study seeks to explore whether these factors contribute to key outcomes of pain conditions; pain levels and psychological distress, which are known to have a bi-directional relationship. Although some evidence suggests that symptoms with unexplained organic causes are different expressions of the same dysfunctional systems (Mayer and Tillisch, 2011; Matheis, Martens, Kruse and Enck; 2007), the NSAP population is significantly understudied in contrast to other FGID groups, and there are vast gaps in knowledge about the characteristics and needs of sufferers (Daniels, 2009). Identifying contributing factors to NSAP could lead to intervention recommendations, including psychological interventions which have been proven effective in conditions such as IBS (Tang, Lin and Zhang, 2013). This study's primary aim is to investigate the contributions of psychosocial/cognitive-behavioural factors to pain and psychological distress in NSAP.

This research is also interested in the relationships between these variables, to see if this provides any further insight into this understudied condition.

The following hypotheses were proposed:

1) The following co-variates will all be positively correlated with one another within individuals with current episodes of NSAP; trauma, body vigilance, anxiety sensitivity, pain catastrophising, anxiety, depression, and pain
2) Multiple regression analyses will show trauma, body vigilance, anxiety sensitivity and pain catastrophising contribute to a significant amount of the variance in NSAP outcomes:
    a) Anxiety
    b) Depression
    c) Pain

Method

Ethical Approval and Research Consultation

The research was undertaken by a clinical psychology trainee, with supervision from an internal university researcher. External consultation/supervision was also provided by a qualified medic to ensure an accurate definition of NSAP was given as part of inclusion criteria. Consultation on study measures and documentation was also provided by a university associated "People with Personal Experience" (PPE) group. Two group representatives with experience of mental health conditions and chronic pain provided input. Full ethical approval was granted by the University of Bath Psychology Research Ethics Committee in March 2021 (PREC; reference number 20-243). The approval letter from the PREC committee can be seen in Appendix F.

Design

The study used an online cross-sectional survey-based design. Participants were recruited into the study based on inclusion and exclusion criteria between May 2021 and February 2022.

Sample Size/Power Calculation

Sample size was determined with an apriori power analysis using G-Power.

Using the traditional .05 criterion of statistical significance, power of 80%, and Cohen's F^2 medium effect size of 0.15 a sample size of 85 was required for Multiple Regression analysis. The study researchers did not set an upper limit for recruitment sample size, in order to maximise statistical power. Statistical power was achieved with the use of data from 99 participants.

Recruitment and procedure

Participants were recruited via social media adverts through Instagram, Facebook and Twitter, as well as study advertisement via the University of Bath library. Recruitment was facilitated by organisations and charities relating to chronic pain, such as the British Pain Society (https://www.britishpainsociety.org/). For a full list of participating organisations, please see Appendix G. Recruitment took place between May 2021 and February 2022. During this time, adverts were repeatedly posted on social media to maximise recruitment of new members of social media groups. A weblink was created for participants to access information sheets, inclusion criteria and consent forms before taking part in the study. Electronically completed consent forms were a prerequisite for progression to survey completion. An incentive for study participation was offered in the form of being entered into a prize draw for shopping vouchers. Four prizes of fifty pounds and ten prizes of twenty-five pounds were available.

Participant inclusion criteria included at least three episodes of NSAP in the previous six months, and at least one medical appointment for NSAP that had not resulted in an organic diagnosis. Definitions of abdominal pain subtypes including NSAP are heterogenous. Therefore, the above criteria were based on the existing literature and consultation from a qualified medic who was working in an accident and emergency department and who frequently treated participants with NSAP. Exclusion criteria included an identified organic cause for abdominal pain, such as stomach ulcers or endometriosis, or the presence of other gastrointestinal disorder that did not meet study inclusion criteria. Full inclusion and exclusion criteria in addition to the rationale for these can be found in Appendix H.

Participants

Adults aged 18+ were invited to take part in the study, with participants giving demographic information prior to completing questionnaires. One-hundred and fifty-nine participants (n=159) completed study questionnaires before data was examined for further analysis. Five participant questionnaires (n=5) were excluded due to duplicate

data, such as participants answering the questionnaire multiple times. A further twenty participant questionnaires (n=20) were excluded due to participants initially stating that they had experienced at least three episodes of pain, but later disclosing that they had experienced fewer episodes. Sixteen participant questionnaires (n=16) were excluded based on discrepancies between the number of NSAP episodes participants expressed that they experienced and the number of pain ratings that were then given.

Nineteen participants (n=19) were excluded after data analysis found that these participants gave female names but selected their gender as "male" within demographic questions. These questionnaires were excluded due to being assessed as likely containing unreliable data. Names were assessed as being male or female via searching of both American and British parenting websites (The Bump, 2022), any data belonging to participants with gender neutral names remained in the analysis. Participant questionnaires (n=19) which were excluded due to disparities in gender data were compared to included participant questionnaires (n=19) using independent t-tests for all variables. The results of this analysis can be seen in Appendix J. Most variables showed no significant differences between included and excluded participant questionnaires. Significant differences did exist in the mean number of pain episodes experienced in included ($M= 4$, $SD = 1.29$) and excluded ($M = 3.38$, $SD = 3.37$) questionnaires, $t(118) = 2.29$, $p = 0.024$. Significant differences were also found in depression scores in included ($M = 8.33$, $SD = 2.92$) and excluded ($M= 9.67$, $SD = 1.95$), $t(118) = -2.70$, $p = 0.009$. Due to the small differences in episodes of pain experienced in included/excluded data, in addition to the likely unreliability of excluded data, data from the N = 19 participants remained excluded. As such, ninety-nine participant questionnaires (n= 99) were included in full data analysis.

Measures:

Participants completed five measures as part of the study in addition to an NSAP demographics questionnaire, Table 6 shows the variables and associated outcome measures whilst Appendix I gives a list of demographic questions and shows each study measure.

Table 6.

Variables and outcome measures

Predictor Variable .	Study measure	**Outcome variable**	Study measure
Body Vigilance	Body Vigilance Scale (BVS)	Depression Anxiety	Hospital Anxiety and Depression Scale (HADS)
Anxiety Sensitivity	Anxiety-Sensitivity Index-3 (ASI-3)	Pain	Visual Analogue Scale (VAS)
Pain Catastrophising	Pain Catastrophising Scale (PCS)		
Trauma Questionnaire –	Adverse Childhood Experience Short Form (ACE)		

1) Anxiety Sensitivity Index-3 (ASI-3)

The ASI-3 was developed by Taylor et al (2007) and is an 18-item questionnaire measuring the physical, social, and cognitive concerns that together contribute to Anxiety Sensitivity. Validity of the questionnaire has been supported using large clinical and non-clinical samples, and all ASI-3 subscales show reliability coefficients between 0.73 to 0.91 (Taylor et al, 2007). For the ASI-3, scores of 0-17, 18-35, 36-53 and 54-72 represent low sub-clinical, low, moderate, and high anxiety sensitivity (Farnsworth-Grodd, 2012).

2) Body Vigilance Scale (BVS)

The BVS is a four-item questionnaire assessing attention and vigilance to bodily symptoms (Schmidt et al., 1997). Three items assess attentional focus on and sensitivity to changes in the body, as well as time duration spent attending to bodily sensations. A fourth item rates individual symptoms of panic attacks. Each item is scored on an 11-point likert Scale from 0-10. The BVS is valid in both nonclinical and clinical samples and has an internal consistency of .75 (Bernstein, Zvolensky, Sandin, Chorot and Stickle, 2008; Olatunji et al., 2007). For body vigilance, clinical cut-off scores are not

available, however Olatunji et al (2007) found mean scores of 15.58 and 20.8 in non-clinical and anxiety disorder populations; respectively.

3) Pain Catastrophising Scale (PCS)

The PCS is a 13 item self-report questionnaire measuring pain catastrophising, developed by Sullivan, Bishop and Pivik (1995). Each item is rated on a 0-5 scale. The PCS consists of three subscales: magnification, rumination, and helplessness. The PCS indicates high test-retest reliability of 0.75 and is demonstrated to be a valid measure of PC in clinical samples (Sullivan et al, 1995). For pain catastrophising, the suggested clinical cut-off score is >30 in chronic pain patients (Sullivan, 1995).

4) Adverse Childhood Experiences Questionnaire (ACE)

The ACE was developed by the World Health Organisation and is designed to measure adverse childhood experiences. It includes questions covering family dysfunction, physical, sexual, and emotional abuse, neglect by parents and exposure to violence (World Health Organisation, 2020).

5) Hospital Anxiety and Depression Scale (HADS)

The HADS (Zigmond and Snaith, 1983) is a self-report questionnaire which assesses anxiety and depression in the setting of hospitals or medical outpatient clinics. It consists of fourteen items which result in categorisation of either normal, borderline-normal, or abnormal anxiety/depression. Although the overall score can be used for the HADS, guidelines recommend that the scores for the anxiety and depression subscales are used separately (Zigmond and Snaith, 1983). One review found that the anxiety and depression scales have Cronbach's alpha scores of between 0.68-0.93 and between 0.67-0.90, respectively (Bjelland, Dahl, Haung and Neckelmann, 2002). For anxiety and depression, scores of 0-7, 8-10, 11-14, and 15-21 represent sub-clinical, mild, moderate, and severe depression; respectively (Stern, 2014).

6) Visual Analogue Scale for Pain (VAS)

The VAS is a unidimensional measure of pain intensity and is used across diverse pain populations (Hawker, Mian, Kendzerska, and French, 2011; Woodforde and Merskey, 1972). It consists of a horizontal or vertical line, usually approximately 10 centimetres long, with 0 marking "no pain" and 100 marking "the worst imaginable pain". Cut-off points are available based on previous research and reliability is between 0.71-0.94

(Hawker, et al, 2011). Research shows that virtual versions of this traditionally paper-and-pen tool show high correlations with paper VAS and are a valid yet efficient way of collecting pain data (Haefeli & Elfering, 2006). Although scores using the VAS vary widely dependent on pain type and participant population, previous research in acute pain has suggested categories of 0-30mm as mild pain, 31mm-69mm as moderate pain, and 70mm or more as severe pain (Kelly, 2001).

Analysis plan

Demographic data including an NSAP questionnaire were used to create a profile for participant's experiences of NSAP pain. Descriptive data from measures would be collected in addition to correlational and regression analysis. Histograms were used to assess the distribution of data, which was non-normally distributed showing a positive skew for anxiety, depression and body vigilance and multimodal distribution for pain catastrophising and anxiety sensitivity. Median and inter-quartile range scores would be given for variables due to non-normally distributed data. This was in addition to collation of NSAP demographic data which aimed to create a clinical profile for participants.

Due to non-parametric data, Spearman's correlations were planned to assess for intercorrelation between variables, with any correlations above .80 examined to assess for possible multicollinearity (Open University, 2020). Mann Whitney U tests would take place to assess for gender differences in data to determine the need to control for this variable, however these tests revealed no gender differences.

Prior to regression analysis, assumptions for multiple regression were checked and met using the following methods:

- Linear relationship between each of the dependent and independent variables as assessed by scatterplots
- No multicollinearity within data (VIF statistics <5)
- The values of residuals being independent (Durbin-Watson statistics: pain =1.827, depression = 1.934, anxiety = 1.837)
- The variance of residuals being constant; assessed utilising homoscedasticity of scatterplots
- The values of the residuals being normally distributed as assessed using P-plots
- No influential cases biasing the model (Cook's distance statistics <1 for all data points).

Multiple regression analysis was planned for each of the three outcome variables: anxiety, depression, and pain. Discussion with a statistician established that as multiple regression is not an analysis requiring normally distributed data, positively skewed and multimodal would not require any alterations to the regression process. All variables had continuous data except for gender which was a nominal variable. Nominal variables are commonly translated into dummy variables within multiple regression models (Field, 2009). In this case data representing "male" and "female" genders was recoded into one's and zero's using dummy variable methodology, as advised by a statistician.

For the first stage of each regression model, the following control co-variates would be entered via forced entry method; age, gender, duration of pain episode, length of pain episode. These variables were controlled to attempt to isolate the contributions of individual variables to outcome variables. Although Mann Whitney U tests had determined there were sex-specific data differences, gender would be entered into the model as a control variable due to previous research suggesting that there are gender differences in psychological distress in chronic pain, and that this related to pain outcomes (Munce and Stewart, 2007).

For anxiety, depression would be added into the first stage of the model as a control variable, with anxiety added into the first stage of the depression model as a control variable. This was planned to reduce the impact of each of these factors as a confounding variable for the outcome of the other, due to the known relationship between anxiety and depression. For the second stage of each multiple regression model, stepwise regression would be used due to the large number of variables, and lack of theory identifying the order these variables should be entered into the regression model (Field, 2009, pp. 197-263). Bootstrapping is a method which can increase the robustness of confidence intervals for non-normal data (Sufahani & Ahmad, 2012), however this is not a necessity and is incompatible with the stepwise method of multiple regression. Therefore, bootstrapping was not planned to be used in this analysis. P-values of .05 and confidence intervals of 95% were utilised to assess the relative contributions of the dependent variables of trauma, pain catastrophising, anxiety sensitivity and body vigilance to the overall models for outcomes pain, anxiety and depression. Unstandardised coefficients would be inspected to further investigate the relationship between variables.

Results

Demographics

Demographic data can be seen in Table 7. The participant population was 54.5% male and 45.5% female, from a predominantly white background (71.6%), with a significant portion of participants having completed a bachelor's university degree as their highest level of education (54.5%). Mean age of participants was 33.06 and 32.98 years for men and women; respectively. Participants were predominantly from the United States of America (98%), with just one participant from the United Kingdom (1%).

Table 7.
Participant demographics

Gender (%) .	Age - Mean (SD)	Country of Origin (%)	Education (%)	Ethnicity (%)
Male (54.5%)	33.06(8.01)	USA (99)	No education **(3.0)**	White/Caucasian (**71.8**)
Female (45.5%)	32.98(7.81)	United Kingdom (1)	Finished primary school (11 years old) **(8.0)**	Irish **(7.0)**
			Finished secondary school (16 years old) **(13.1)**	Gypsy or Irish Traveller **(3.0)**
			Finished college, sixth form, or completed another post-school vocational qualification such as an apprenticeship or NVQ **(18.1)**	White and Black Caribbean **(2.0)**
			Completed a University Degree **(54.5)**	White and Black African **(8.0)**
			Completed a Master's Degree **(2.0)**	White and Asian **(4.0)**
			Completed a PhD/Doctorate **(0)**	Indian **(0)**
				Pakistani **(0)**
				Bangladeshi **(1.0)**
				Chinese **(1.0)**
				Any other Asian Background **(1.0)**
				African **(0)**
				Caribbean **(1.0)**
				Any other Black, African or Caribbean Background **(0)**
				Arab **(0)**
				Any other mixed background **(0)**

Descriptive Statistics

Descriptive statistics of median and interquartile range measure scores in addition to clinical cut-off data and scoring categories can be seen in Table 8. Median and inter-quartile range scores on the ASI-3 were 32.0 and 29.0. This score is categorised within the "low" anxiety sensitivity range, although this score was in the upper end of this bracket and was therefore moving towards "moderate" anxiety sensitivity. Median and inter-quartile range scores for the BVS were 21.0 and 13.46. This BVS score indicates similarities to clinical anxiety populations (Mean =20.8). Median and inter-quartile range scores for depression and anxiety were 9.0 and 3.0, and 10.0 and 4.0; respectively. Levels of anxiety and depression were both within the "mild" category, although an increase of one point in median scores of anxiety would have taken this into the "moderate anxiety" range. Median and inter-quartile range scores on the PCS were 26.0 and 22.0, suggesting that participants did not meet the cut-off of >30 for clinically relevant pain catastrophising. Median and inter-quartile range scores for pain severity utilising the VAS scale were 49.0 and 23.42 which can be categorised as "moderate" pain utilising previous research as a guide for VAS cut-offs. The mean duration of pain episodes was approximately 3 hours.

Table 8.

Outcome measure descriptive statistics

Measure **(max score)**	Median	Inter-quartile range	Clinical cut-off	Scoring category
ACE **(10)**	5	6	N/A	N/A
Anxiety Sensitivity Index **(72)**	32.0	29.0	18+	"Low"
Body Vigilance Scale **(40)**	21.0	13.46	N/A	N/A
HADS-Anxiety **(21)**	10.0	4.0	8+	"Mild"
HADS-Depression **(21)**	9.0	3.0	8+	"Mild"
Pain Catastrophising Scale **(52)**	26.0	22.	30+	"Non-problematic"
VAS – pain episode severity **(100)**	49.0	23.42	N/A	N/A

Key:
Adverse Childhood Experiences (ACE)
Hospital Anxiety and Depression Scale (HADS)
Visual Analogue Scale (VAS)

Participant abdominal pain profiles

Data for participant's NSAP profiles can be seen in Table 9. Over seventy-five percent (75.8%) of participants reported having seen their General Practitioner (GP) for their NSAP in the last six months. The number of visits to the GP that was endorsed most was twice (29%). Only 6.1% of participants reported being referred on for specialist investigations, but 28.3% of participants said they were unsure whether this had happened. Similarly, there was uncertainty within participants as to whether they were still under any medical specialties, with 18.2%, 49.5% and 32.3% answering "yes", "no", and "don't know"; respectively. Participants reported being under a variety of specialisms including cardiac services (N=1), internal medicine (N=2), gynaecology (N=7) and gastroenterology (N=2). Approximately three quarters of participants, 72.7%, were still undergoing tests to investigate their NSAP. Over sixty percent (67.7%) of participants had attend A&E in the last six months for their NSAP, although 13.1% could not remember if this had happened. Only 9.1% of individuals reported currently taking medication for their NSAP. Medications included general pain relievers and gastrointestinal medication, with one person (N=1) reporting the use of the opioid-based painkiller Oramorphe.

Table 9.
Participant abdominal pain profile

Demographic Question	Yes (%)	No (%)	Can't remember (%)	Extra information
Referred to GP practice in last 6 months	75.8	20.2	4.0	No. of times (%): 0 = 28 1 = 17 2 = 29 3= 14 4= 10 5= 1 6+ = 1
Referred for specialist investigations	6.1	45.5	8.3	Gastroenterologist (n=1), Pain clinic (n=1)
Still undergoing investigations	72.7	22.2	5.1	
Attended A&E last six months	67.7	19.2	13.1	
Taking medication for NSAP	9.1	90.9	N/A	
Under any medical specialties	18.2	49.5	32.3	Hycosamine (n=1), Ibuprofen (n-=1), Oramorphe (n=1), Amitriptyline (n=1), "pain relievers" (n=1)
Had to access other medical care	4.0	50.5	45.5	Cardiac (n=1), gastroenterology (n=1), gynaecology (n=7), internal medicine (n=2), other (n=2)

Correlational Analyses

Table 10 represents the correlations between variables. A high number of significant positive correlations were found, with only a small number of non-significant correlations existing within the data. All significant correlations found were positive.

Within control variables, gender showed no significant correlations with any other variables. Participant age showed a significant positive correlation with pain severity. Episode length showed a significant positive correlation with body vigilance. Number of pain episodes was significantly positively correlated with body vigilance, pain and pain catastrophising.

In addition to the interactions with control variables highlighted above, the following correlations existed between the dependent variables and outcomes of interest. Anxiety sensitivity and trauma showed significant correlations with all other variables. Depression showed significant correlations with trauma, anxiety sensitivity and anxiety, but not with pain catastrophising, body vigilance or pain. Body vigilance and pain catastrophising were significantly correlated with all variables except for depression. Anxiety was significantly correlated with all other variables except pain. The only variables which showed a non-significant correlation with mean pain scores were anxiety and depression. Pain was significantly correlated with all other variables.

A correlation of .831 between body vigilance and anxiety sensitivity indicated possible multicollinearity. However, literature regarding the coefficient number required for multicollinearity is inconsistent, including estimates of 0.8 (Open University, 2022) and 0.9 (Doohoo, 1997). As anxiety sensitivity and body vigilance are similar but separate theoretical constructs, and VIF estimates were <5 for all planned regression analyses which was the main assessment for multicollinearity, the decision was made to proceed with the apriori regression analysis as planned.

Table 10.
Intercorrelations between variables

	1	2	3	4	5	6	7	8	9	10	11
1. Age	.										
2. Anxiety	-0.006	.									
3. Anxiety Sensitivity	-0.017	.436**	.								
4.Body Vigilance	0.03	.205*	.831**	.							
5. Depression	0.093	.357**	.207*	0.099	.						
6. Episode Length	0.382	-0.012	0.101	.204*	0.176	.					
7. Gender	0.093	-0.099	0.011	-0.081	0.032	-0.032	.				
8. Number of episodes	0.146	-0.09	0.156	.205*	-0.43	0.184	0.034	.			
9. Pain	.226*	0.084	.487**	.597**	-0.024	0.118	0.152	.355**	.		
10. Pain Catastrophising	0.117	.206*	.683**	.723**	0.078	0.121	0.11	.347**	.735**	.	
11. Trauma	0.103	.344**	.617**	.587**	.360**	0.164	-0.148	0.144	0.196	.486**	.

*Significant at .05 level; ** Significant at .01 level
Bold text – control variables

Multiple Regressions

For the dependent variable of anxiety, control co-variates (age, gender, length of pain episode, duration of pain episode) and depression were first entered into the model and accounted for a significant proportion of 26.0% of the variance (adjusted R^2 = .260, F (5, 93) = 7.89, *p < .001)*. Following this, stepwise regression showed that anxiety sensitivity accounted for an additional 11.5% (adjusted R^2 = .375, F (6, 92) = 10.81, *p < .001)* of the variance, and body vigilance a further 2.6% of the variance (adjusted R^2 = .401, F (7, 91) = 10.36, *p < .001)*. In summary, 40.1% of variance was accounted for by study variables, all other variables were excluded from the model.

For the dependent variable of depression, control co-variates (age, gender, length of pain episode, duration of pain episode) and anxiety were first entered into the model and accounted for a significant proportion of 25.7% of the variance (adjusted R^2 = .257, F (5,93) = 7.77, *p <.001)*. Stepwise regression then showed that trauma accounted for an additional 6.3% of the variance (adjusted R^2 = .32, F (6,92) = 8.68, *p <.01)*, and pain catastrophising a further 3.6% of the variance (adjusted R^2 = .356, F (7,91) = 8.73, *p <.05)*. In summary, 35.6% of variance was accounted for by study variables, all other variables were excluded from the model.

For the dependent variable of pain, control co-variates (age, gender, length of pain episode, duration of pain episode) were entered first into the model and accounted for a significant proportion of 6.1% of the variance (adjusted R^2 = .061, F (4,94) = 2.59, *p <.05)*. Stepwise regression showed that pain catastrophising accounted for an additional 49.9% of the variance (adjusted R^2 = .56.0, F (5,93) = 25.90, *p <.001)* of the variance, and trauma a further 3.3% of the variance (adjusted R^2 = .593, F (6,92) = 24.81, *p <.001)*. Finally, body vigilance accounted for a further 1.4% of the variance (adjusted R^2 = .607, F (7,91) = 22.61, *p <.001)* In summary, 60.7% of variance was accounted for by study variables, all other variables were excluded from the model.

Although multiple regression showed contributions of variables to each study outcome measure, unstandardised co-efficients showed that relationships between variables were not always in the expected direction. Study hypotheses had predicted that there would be a positive relationship between all variables. Initial correlational analysis showed a positive relationship between most study variables, however multiple regression analysis showed negative associations between body vigilance and anxiety, trauma and pain, and pain catastrophising and depression. Further interpretation of these findings was made in the exploratory analysis and discussion sections of this report. Multiple regression data standardised and unstandardised co-efficients for anxiety,

depression and pain can be seen in Tables 11, 12 and 13; respectively. Multiple regression data including adjusted R^2 data can be seen in Table 14.

Table 11.

Unstandardised and standardised co-efficients for anxiety

		Unstandardised coefficients		Standardised coefficients (.)		
Model		B	Standard Error	β	*t*	p
1	(Constant)	7.958	1.407		5.657	<.001
	Number of episodes	-0.09	0.184	-0.043	-0.488	0.627
	Episode length	-0.123	0.163	-0.066	-0.755	0.452
	Age	-0.034	0.029	-0.101	-1.14	0.257
	Gender	-0.487	0.464	-0.092	-1.048	0.297
	Depression	0.475	0.08	0.522	5.921	<.001
2	(Constant)	6.693	1.326		5.046	<.001
	Number of episodes	-0.213	0.172	-0.103	-1.238	0.219
	Episode length	-0.153	0.15	-0.082	-1.02	0.31
	Age	-0.014	0.027	-0.044	-0.528	0.599
	Gender	-0.516	0.427	-0.097	-1.21	0.229
	Depression	0.389	0.076	0.427	5.084	<.001
	Anxiety Sensitivity	0.059	0.014	0.359	4.262	<.001
3	(Constant)	7.451	1.344		5.545	<.001
	Number of episodes	-0.173	0.169	-0.084	-1.025	0.308
	Episode length	-0.076	0.151	-0.04	-0.501	0.617
	Age	-0.01	0.027	-0.029	-0.36	0.72
	Gender	-0.648	0.422	-0.122	-1.535	0.128
	Depression	0.363	0.076	0.399	4.787	<.001
	Anxiety Sensitivity	0.104	0.024	0.628	4.268	<.001
	Body Vigilance	-0.116	0.052	-0.322	-2.209	0.03

Table 12.
Unstandardised and standardised co-efficients for depression

		Unstandardised coefficients		Standardised coefficients (.)		
Model		B	Standard Error	β	*t*	p
1	(Constant)	1.533	1.789		0.857	0.394
	Number of episodes	-0.201	0.202	-0.089	-0.995	0.322
	Episode length	0.113	0.18	0.055	0.629	0.531
	Age	0.044	0.032	0.121	1.371	0.174
	Gender	0.283	0.514	0.049	0.552	0.583
	Anxiety	0.576	0.097	0.524	5.921	<.001
2	(Constant)	2.918	1.769		1.65	0.102
	Number of episodes	-0.281	0.195	-0.124	-1.443	0.152
	Episode length	0.017	0.175	0.008	0.1	0.921
	Age	0.025	0.032	0.069	0.797	0.427
	Gender	0.51	0.497	0.087	1.027	0.307
	Anxiety	0.446	0.102	0.406	4.365	<.001
	ACE	0.276	0.089	0.295	3.102	0.003
3	(Constant)	3.146	1.724		1.825	0.071
	Number of episodes	-0.12	0.201	-0.053	-0.596	0.553
	Episode length	0.065	0.171	0.032	0.382	0.703
	Age	0.019	0.031	0.051	0.609	0.544
	Gender	0.802	0.497	0.137	1.612	0.11
	Anxiety	0.482	0.1	0.439	4.801	<.001
	ACE	0.37	0.094	0.394	3.912	<.001
	Pain Catastrophising	-0.063	0.026	-0.247	-2.48	0.015

Table 13.
Unstandardised and standardised co-efficients for pain

		Unstandardised coefficients		Standardised coefficients (.)		
Model		B	Standard Error	β	*t*	p
1	(Constant)	22.266	9.905		2.248	0.027
	Age	0.107	0.215	0.049	0.496	0.621
	Gender	4.33	3.407	0.125	1.271	0.207
	Number of episodes	3.326	1.336	0.247	2.49	0.015
	Episode length	1.311	1.197	0.107	1.096	0.276
2	(Constant)	12.509	6.849		1.826	0.071
	Age	0.13	0.147	0.06	0.882	0.38
	Gender	1.176	2.353	0.034	0.5	0.618
	Number of episodes	0.32	0.96	0.024	0.333	0.74
	Episode length	0.014	0.829	0.001	0.017	0.987
	Pain Catastrophising	1.132	0.109	0.744	10.364	<.001
3	(Constant)	13.164	6.586		1.999	0.049
	Age	0.21	0.144	0.097	1.454	0.149
	Gender	-0.592	2.34	-0.017	-0.253	0.801
	Number of episodes	0.091	0.926	0.007	0.098	0.922
	Episode length	0.199	0.799	0.016	0.248	0.804
	Pain Catastrophising	1.298	0.119	0.853	10.894	<.001
	ACE	-1.245	0.422	-0.224	-2.946	0.004
4	(Constant)	6.214	7.304		0.851	0.397
	Age	0.266	0.144	0.123	1.843	0.069

Gender	-0.035	2.316	-0.001	-0.015	0.988
Number of episodes	0.142	0.91	0.011	0.156	0.876
Episode length	0.093	0.787	0.008	0.118	0.906
Pain Catastrophising	1.115	0.147	0.733	7.563	<.001
ACE	-1.65	0.46	-0.297	-3.589	<.001
Body Vigilance	0.498	0.242	0.212	2.055	0.043

Table 14.
Multiple regression F statistics and R values

		F	*p*	R^2	Adjusted R^2
DV: Anxiety	**Control variables: Total**	7.89	*<0.001*	0.298	0.26
	Anxiety Sensitivity (ASI-3)	10.81	<0.001	0.414	0.375
	Body Vigilance (BVS)	10.36	<0.001	0.443	0.401
DV: Depression	**Control variables: Total**		<0.001	0.295	0.257
	Trauma (ACE)	8.68	0.015	0.361	0.32
	Pain Catastrophising (PCS)	8.73	0.003	0.361	0.356
DV: Pain	**Control variables: Total**	2.59	0.042	0.099	0.061
	Pain Catastrophising (PCS)	25.9	<0.001	0.582	0.56
	Trauma (ACE)	24.81	0.004	0.618	0.593
	Body Vigilance (BVS)	22.61	0.043	0.635	0.607

Exploratory analysis

Due to the unexpected direction of multiple regression relationships highlighted above, additional exploratory analysis took place. All exploratory analysis was conducted by the study researcher but with the guidance of an independent university associated statistician.

Body vigilance and anxiety

As highlighted previously, possible multicollinearity existed between body vigilance and anxiety sensitivity, with multicollinearity being one possible reason for discrepancies in the direction of relationships between correlational and regression analysis (Falk and Miller, 1992). Further exploration of the relationship between body vigilance and anxiety sensitivity was therefore conducted by removing body vigilance as a variable within the multiple regression model for the outcome of anxiety. When body vigilance was removed from the model, anxiety sensitivity remained the only variable as a predictor of anxiety, with it's contribution to the model remaining at 11.5%. Body vigilance had previously contributed an additional 2.8% to the anxiety model, showing that anxiety sensitivity did not account for any additional proportion of the variance once body vigilance was removed. This suggests that body vigilance did indeed make its own independent contribution to the anxiety model outside of anxiety sensitivity, as contributions of anxiety sensitivity did not increase once body vigilance had been removed. Low VIF scores in addition to inconsistency around coefficient estimates required to indicate multicollinearity also raise doubts around this being a reason for the discrepancies in relationship directions found in this study. Therefore, clinical interpretations of this result must also be considered.

Trauma and pain

Further regression analysis was run to understand the relationship between trauma and pain. This regression utilised a forced entry model and included only the study control co-variates (e.g., age, gender etc) in the first stage of the model, followed by pain catastrophising and trauma in the second stage. When trauma was entered into the second stage of the model as the only additional variable, results showed that the relationship between trauma and pain was non-significant (adjusted $R^2 = .078$, $F(1,93) = 2.771$, $p = .099$). However, when pain catastrophising was also added to the second stage of the model, this resulted in the previously found negative significant relationship between trauma and pain. Ninety-five percent confidence intervals (CI) for the impact

of trauma in the exploratory analysis were (- .180, 2.045), meaning that these CI's crossed zero. This shows that trauma had a non-significant relationship with pain, but that interactions between pain catastrophising and trauma led to a negative relationship between trauma and pain in the original regression model. This is an example of one type of "suppressor effect" known to contribute to correlation and regression co-efficient disparities. This is where the original relationship between two variables is so close to zero that the difference in signs simply reflects random variation when an additional predictor is added to the model (Falk and Miller, 1992). Alternatively, this finding could indicate a potential mediating role of pain catastrophising in the relationship between trauma and pain.

Discussion

The hypotheses of this study were that 1) all non-control co-variates within the study would be positively correlated, and 2) trauma, anxiety sensitivity, pain catastrophising and body vigilance would account for significant amount of variance in variables a) anxiety, b) depression and c) pain. Significant positive correlations were found between control variables and the following dependent variables; age and pain severity, pain episode length and body vigilance, number of pain episodes and body vigilance, pain severity and pain catastrophising. Significant positive correlations were also found between most non-control study variables. In the following cases multiple regression showed negative relationships between the following variables: body vigilance accounting for variance in anxiety, trauma accounting for variance in pain and pain catastrophising accounting for variance in depression. Due to the heterogeneity in results neither study hypothesis can be fully accepted, however the results of this study are complex and warrant further interpretation.

This study showed that trauma was positively associated with depression and contributed 6.3% of the overall model, a finding which is echoed in most of the literature exploring the association between these factors (Negele, Kaufhold, Kallenbach and Leuzinger-Bohleber, 2015). This means that those with traumatic history and NSAP are at risk of depression, or alternatively that NSAP sufferers with depression should have trauma accounted for in any psychological treatment they seek for this. Similarly, both body vigilance and pain catastrophising contributed to pain outcomes; again, mirroring previous research (Keough, Timpano, Zawilinski, and Schmidt, 2011; Leung, 2012). However, body vigilance only contributed 1.4% to the overall model whilst pain catastrophising contributed a notable 49.9%, suggesting that the latter variable would be the most beneficial to target in psychological treatment. Finally, anxiety sensitivity was the only factor that showed positive contributions to the anxiety model, accounting for 11.5% of the variance. This highlights that this factor more than the other variables included in this study might lead to reductions in anxiety if this were targeted during interventions.

Due to non-normal data, median and inter-quartile range scores were collected for all study measures. The median score on the ACE measure of trauma was 5 out of a possible total score of 10, indicating high levels of trauma in the study population. This fits with other literature highlighting higher levels of trauma and abuse in individuals who experience a variety of physical and mental health problems (McFarlane, 2010). Descriptive statistic scores for depression, anxiety and anxiety sensitivity sat within the

"low" or "mild" categories for clinical scores, or in the case of pain catastrophising did not meet the clinical cut-off of >30 for problematic catastrophising. This could be due to several reasons. For some measures including the ASI-3 or the PCS, literature gives differing views on what might constitute "problematic" scores. For example, guidance given by Sullivan (1995) indicates that scores of >30 on the PCS represent problematic pain catastrophising, however these same guidelines also describe pain populations with scores <30. For instance, participants with back injuries showed a mean PCS score of 20.9 in comparison to the mean PCS score of 26.0 highlighted within the current study. Interpretation of cut-off guidelines for this measure should therefore be treated with caution. The lower scores seen on some measures in this study might also explain why there were not more participants taking stronger painkillers for their NSAP, as research has shown that a significant number of American citizens are taking opioid-based medication for pain (Grady, Berkowitz & Katz, 2011). Lower scores on study measures may also represent the acute nature of NSAP, although the potential exists for psychosocial and cognitive factors to increase their impact prior to or during NSAP episodes. Individuals who have experienced trauma, depression or increased psychosocial stressors are more likely to experience brain changes and develop dysfunctional pain beliefs or behaviours that can lead from acute to chronic pain (Casey, Grennberg, Nicassio, Harpin and Hubbard, 2008; Feizerfan & Sheh, 2015). It is therefore important that these factors are screened for and targeted within the NSAP population even when pain is not present, to manage potentially damaging pain beliefs and behaviours that could increase the chances of transition from acute to chronic pain.

Several unexpected relationships were found within the data in contrast with this study's hypotheses. Interestingly, there appeared to be no study variable gender differences, contradicting findings that within pain populations, women show higher levels of factors such as pain sensitivity, anxiety, and depression (Barksy, Peekna and Borus, 2001; Bartley and Fillingim, 2013). Further research will need to take place to explore in more depth the possibility of gender differences in NSAP. In correlational analyses anxiety and depression did not show a relationship with pain, again contradicting other research suggesting that these factors are closely connected to pain severity in pain populations (Lerman, Rudich, Brill, Shalev & Shahar, 2015). This may suggest that other variables in this study which were identified as having significant relationships with pain may play more of a role in pain outcomes than overall anxiety and depression, and therefore may be more important to target in treatment.

As highlighted previously, relationship directions between some variables and outcome measures in multiple regression were also unanticipated. The possibility of multicollinearity between anxiety sensitivity and body vigilance as an explanation for a negative relationship between body vigilance and anxiety has been discussed, although variance inflation factor statistics <5 suggested that this was less likely. The current study cannot definitively determine whether multicollinearity existed between body vigilance and anxiety sensitivity when contributing to anxiety due to mixed evidence. Similarities within these constructs clearly exist, with some overlapping question themes within the ASI-3 and PCS, such as queries about sensitivities to body sensations. Within a cognitive-behavioural model, the mechanism between these factors suggests that anxiety sensitivity leads to increased body vigilance, meaning it is logical that the former variable would have a significant impact on the latter. Research has also shown how anxiety sensitivity predicts changes in body vigilance during psychological treatment, further confirming the relationship between these two factors (Schmidt, Lerew, Trakowski, 1997). However, these factors are still theoretically different, with anxiety sensitivity specifying the meaning attributed to anxiety sensations rather than the behavioural practice of scanning for these. The strong correlation between anxiety sensitivity and body vigilance in the current study may represent some overlapping of these constructs and highlight the strength of the anxiety sensitivity and body vigilance mechanism. In the absence of multicollinearity, other interpretations of this study's findings should be considered, such as the possible mediating impact of anxiety sensitivity on body vigilance for outcomes of pain. Mediational analysis was not included as part of the hypotheses of this study, however further research may wish to use more sophisticated statistical modelling to further explore the relationship between these two variables in NSAP.

The negative relationship between trauma and pain was also unexpected, as this contrasts with the evidence-base citing a positive relationship between these two factors (Linton and Shaw, 2011). Additional exploratory analysis revealed the potential impact of pain catastrophising on trauma in the regression model, suggesting that the relationship between trauma and pain would be non-significant prior to pain catastrophising being added to this model. One explanation for this finding is that the negative relationship between trauma and pain was an example of a "suppressor effect" (Falk and Miller, 1992). An alternative clinical interpretation for this finding is that pain catastrophising mediated the relationship with trauma and pain, a finding which has been shown in previous research with chronic pain patients (Neville, Soltani, Pavlova

and Noel, 2018; Gilliam, Craner, Schumann and Gascho, 2019). This finding also confirms previous findings that psychological and cognitive factors mediate the relationship between trauma and pain (Chitkara, van Tilburg et al, 2008; Surdea-Blaga et al, 2012). However, the unexpected negative relationship between trauma and pain due to any mediating impact of pain catastrophising, in addition to confidence intervals for the impact of trauma on pain crossing zero, means that a "suppressor effect" is the most likely of the above explanations. In the absence of a mediating role of pain catastrophising, the potential non-significant impact of trauma on pain could be explained by the way that trauma was measured in this study. Research has suggested that different types of abuse (e.g. physical, sexual) may have differing effects on the likelihood of developing abdominal pain disorders, with some types of abuse being much more likely to result in these problems (Sansone and Sanstone, 2015). The practice of using one overall "trauma" score from the ACE questionnaire in this study may therefore have impacted the relationship between trauma and pain. In summary, there is a clear relationship between pain catastrophising and pain, however further research is needed to fully unpick this, in addition to exploring how trauma may additionally interact with these variables. This is in addition to considering how best to measure trauma in NSAP populations.

The negative correlation between pain catastrophising and depression in this study was also unexpected. However, the absence of a significant relationship between depression and pain catastrophising in Spearman's analysis suggests the potential absence of a significant relationship between these two variables, meaning the negative relationship found could be explained by the influence of other factors in the regression model.

Finally, a further explanation for unanticipated data relationships might be due to data unreliability. Although several potentially unreliable participant questionnaires were excluded from the analysis, the possibility exists that some remaining data was erroneous. This could potentially be due to the study offering financial reimbursement in the form of shopping vouchers for study participation.

Limitations

Several methodological limitations must be considered when interpreting the results of this study. Firstly, this research took place during the COVID-19 pandemic. Consequently, recruitment was limited to remote data collection, due to the inability to enter medical settings to recruit directly from the NHS. If this study had taken place

outside of the pandemic, recruitment may have targeted a more diverse participant group, for example by being able to recruit via medical clinics or the accident and emergency department. The finding that 67.7% of participants within this study attended A&E for their NSAP in the previous six months highlights that individuals experiencing high levels of distress/pain were identified, however further research may wish to focus solely on those most affected to identify the needs of this population subgroup and ensure the validity of the study participant group. The pandemic may also have affected measure scores, for example anxiety and depression are known to have been influenced by COVID-19 and resulting restrictions (Dennis, Radnitz & Wheaton, 2021; Jia et al, 2020; Rettie & Daniels, 2020), however lower scores on several measures within this study suggest this may not have been the case. Finally, COVID-19 may have influenced demographic questions around accessing healthcare, due to significant reductions in GP consultations and subsequent referrals to other healthcare specialisms due to the pandemic (Watt, Firth, Fisher, Thorlby & Kelly, 2020). The American nationality of participants may also have influenced the results of demographic questionnaires. Despite the introduction of the Affordable Care Act in 2010, in 2019 28.9 million individuals were uninsured in America, a number which is likely to have increased in 2020 (Tolbert, Orgera and Damico, 2020). As such, individuals who were uninsured or for whom accessing healthcare may have influenced insurance premiums or extra payments may have been less likely to access their general practitioner, been referred for specialist medical investigation, or be taking additional medication. Answers to demographic questions may therefore have differed if participants were recruited from countries with more equitable access to healthcare. Additionally, terminology which is more common in the United Kingdom may have been less amenable to participants from America. For example, this study used the term “General Practitioner” (GP), whereas terms such as “family health specialists” may be found more commonly in the USA. A further limitation regarding demographic data regards the proportion of individuals still undergoing testing for their NSAP (67.7%), as a number of these individuals might later receive an organic diagnosis for their pain.

Another limitation of this study was the exclusion of participant data. A total of sixty participant questionnaires (n=60) were excluded from the final study analysis. This study attempted to present study measures to maximise ease of use for participants. Unfortunately, in questionnaire responses several participants showed a lack of comprehension about how to match the number of pain episodes they experienced to ratings of pain severity using a VAS scale. Consequently, some participant data had to

be excluded due to inaccurate response data. In addition, this study's definition of NSAP, requiring participants to have experienced at least three pain episodes over the previous six months, was carefully considered in the context of other abdominal pain disorders. This did however mean that patients who had experienced two episodes of pain within this timeframe were excluded. Future research might seek to clarify which pain measures are easiest to use in an online format for this population, in addition to providing further research based operational definitions of NSAP. The need to exclude study data may also have been impacted by the recruitment method. Though social media recruitment was necessary due to the COVID-19 pandemic, this did have several shortcomings. This included the inability to target the exact participant group required for the research. For example, posts were made to social media groups for general abdominal pain, meaning individuals who did not have NSAP may have participated. This likelihood of participation by non-eligible individuals may have also been heightened by the offer of a financial incentive. Recruitment from medical settings would allow for trained medical professionals to identify participants who conclusively met NSAP criteria, therefore ensuring reliability and validity of data.

Finally, further study limitations relate to study measures. Only self-report measures were used, meaning that data may have been influenced by factors such as social desirability. In the case of the VAS pain measure, participants were required to rate past rather than current pain episodes. This may have resulted in mis-remembering factors such as pain strength, which may have been influenced by how much time had passed since the episode. This study was the first step in research for a very understudied pain population, however future research may wish to identify NSAP participants before using longitudinal methods to collect data. Finally, other measures/methods of vigilance to pain may wish to be considered for future research. Whilst a valid measure for use in this study, the body vigilance scale measures vigilance to all body symptoms, rather than just pain. This may have potentially confounded study results; future research may wish to consider other methods for monitoring vigilance to pain specifically.

Implications for Clinical Practice

Pain catastrophising accounted for a large amount of the variance for the outcome of pain, as such, psychological interventions targeting this construct are highly desirable for the potential alleviation of pain severity. This fits with the current cognitive-behavioural theory of pain which highlights the key role of pain catastrophising in

chronic pain conditions and has used CBT to effectively target this (Pardos-Bascon, Narambeuna, Deal-Costs and Hofstadt-Roman, 2021). Some uncertainty around the validity of pain-catastrophising as a construct does exist however, with some research suggesting that metacognitive beliefs about worry play a bigger role in pain catastrophising than originally thought (Schutze, Rees, Smith, Slater and O'Sullivan, 2019). Although traditional CBT does address beliefs about the role of worry, questioning of the moderate impact that "traditional" CBT has on pain has led to calls for third-wave therapies such as Acceptance and Commitment Therapy (ACT) to become increasingly used in pain treatment (McCracken and Vowels, 2014). ACT promotes psychological flexibility, as well as acceptance and awareness of thoughts and feelings; these are all potential techniques for managing pain catastrophising (Kashdan and Rottenberg, 2010). Currently, NICE guidance (NICE, 2021) suggests considering either ACT or CBT for chronic pain, but states that there is not enough evidence for a preference for one over the other of these treatments. Both therapeutic modalities have been shown to be effective for use in chronic pain, including the large evidence-base showing the effectiveness of CBT, however more research will be needed to identify any differences in their effectiveness for reducing pain catastrophising.

Future Research

Future research may benefit from alternative study methodology, such as prospective research design to understand the relationships between psychosocial variables in NSAP. Sophisticated statistical analysis between the variables identified as significant in this study is crucial to further understand the exact mechanisms between these factors. Methods such as network analysis might be particularly appropriate for future research due to this technique's unique ability to explore complex relationships between study variables and mechanisms (Borgatti, Mehra, Brass and Labianca, 2009). This competency would be particularly desirable given the complicated findings of this study, including the potential mediating influence of inter-linking variables on one another. Giving study measures at the time of NSAP recurrence may allow for greater understanding of NSAP factors, potentially providing a snapshot for which of these are most important for treatment. Recruiting patients from medical clinics would also ensure that participants have clinical levels of distress/pain, which would be important to truly understand the relationship between variables in this population.

Effective psychological treatment of factors known to contribute to outcomes of NSAP including pain, anxiety and depression relies on NSAP sufferers being referred to

psychological services. Previous research has highlighted that individuals admitted to the emergency department with unexplained abdominal pain are often exposed to invasive and potentially unnecessary medical procedures, in addition to being overprescribed pharmaceuticals including opioids (Daniels et al, 2019). This study supports these findings, as 75.8% and 67.7% of study participants reported visiting their general practitioner or the emergency department over the last six months for NSAP concerns. Consequently, a crucial area for future research concerns how best to increase engagement between emergency medicine departments and psychological services. Medical clinicians are often gatekeepers for further healthcare referrals; as such future research should explore the effectiveness of psychoeducational training programmes, inter-professional communication, and service-improvement to advocate for the role of psychology in NSAP treatment.

Conclusions

In conclusion, this study outlines several factors that could contribute to psychological distress and pain in NSAP. Factors including trauma, anxiety sensitivity, body vigilance, and pain catastrophising were shown to influence the outcomes of anxiety, depression, and pain, and could therefore be promising treatment targets for psychological intervention. However, inconsistencies were present in this data which demonstrate the need for further research in NSAP. The clinical implications of this research include identifying methods of therapy that are most beneficial for reducing pain catastrophising. Future research should also focus on ways to engage medical professionals to understand the role of psychological factors in NSAP and to make appropriate referrals to psychology services.

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Executive Summary

Service Improvement Project

Research has shown that for women with Emotionally Unstable Personality Disorder (EUPD), Dialectical Behavioural Therapy (DBT) can improve quality of life and reduce depression, self-harm, anger, hopelessness, and hospital visits (Koerner & Dimeff, 2007; Koons et al, 2001; Stiglmayr et al, 2014). National Institute of Clinical Excellence guidance (NICE, 2009) also recommends that families of people with EUPD should be involved in their care, with research suggesting that DBT can also benefit families and carers (Regelado et al, 2011). This service improvement project took place within a Complex Psychological Intervention (CPI) service within the NHS in 2020. The project involved the design, delivery and evaluation of a group for families and carers of those with EUPD based on principles of DBT. Due to the COVID-19 pandemic the planned face-to-face group was moved online, with both family members and therapists accessing the sessions remotely. Family members completed validated measures pre- and post-group, with additional qualitative feedback being given after sessions were completed. The Gibbs reflective cycle (Gibbs, 1988) was used to reflect on the process of designing and delivering the group. Only a small number of family members (N=2) participated in the pilot delivery of this group, however questionnaire and qualitative feedback was promising, particularly in relation to improvements in family functioning. Service users also gave feedback on their experience of family members receiving support, which was also encouraging. Findings were fed back to the CPI service and an associated service-user representative group. The findings of this project, including the experience of setting this group up remotely, were used to continue to run this group within the service.

Systematic Review

This systematic review focused on the effectiveness of psychological interventions for treating female Chronic Pelvic Pain (CPP). Despite a worldwide prevalence of 26%, there is limited research to guide diagnosis and treatment of CPP. Previous reviews of CPP subtypes tend to focus on specific CPP aetiologies, with these reviews often including poorer quality research as well as studies in which psychological intervention is part of a multidisciplinary approach. As a result, the effects of psychological intervention may have been overestimated for CPP populations. This review drew together results from randomised controlled trials (RCTs) which looked at the effectiveness of psychological interventions for different outcomes of CPP. Psychological interventions were only

included in the review if they were not used in conjunction with other interventions. Clinical groups included women with irritable bowel syndrome, interstitial cystitis, dysmenorrhoea, dyspareunia, and pelvic pain with heterogenous causes. The primary outcome for this review was psychological distress, with secondary outcomes including pain, CPP symptoms, quality of life and disability. Designing this review to capture the range of conditions causing CPP was challenging, with the complexity of this issue reflected in significantly heterogenous data. Eighteen studies were included within the final analysis, although substantial variation in study design meant that meta-analysis was not possible. However, a narrative synthesis revealed promising results for using psychological treatments for CPP outcomes including anxiety, pain and CPP symptoms. The most researched psychological interventions were cognitive behaviour therapy (CBT), mindfulness and relaxation strategies. CBT showed the most promise out of all included studies, with a significant improvement on at least one study outcome shown in all four included studies. Psychological intervention appeared to benefit all CPP subtypes on at least one study outcome. One important result was that, surprisingly, cognitive bibliotherapy led to worse pain outcomes in women with dyspareunia. One of the key findings from this review was the lack of high-quality research relating to specific CPP subtypes, such as endometriosis. The lack of research is discussed in the context of the gender health gap, and suggestions are made for future research and treatment implications.

Main Research Project

Medically unexplained symptoms are increasingly becoming a complex and costly issue for health services worldwide. Currently, recurrent episodes of Non-Specific Abdominal Pain (NSAP) are one of the lead causes for seeking both emergency and outpatient medical treatment (Daniels, Griffiths and Fisher, 2019; Eskelinen and Lipponen, 2012). In the absence of clear medical pathology for many NSAP cases, this study aimed to explore other factors that might contribute to the development and maintenance of this disorder. Psychosocial factors linked to the development of disorders such as NSAP could operate via the Hypothalamic Pituitary Adrenal (HPA) axis or “brain gut” axis, via the bi-directional relationship between the brain and gastrointestinal systems. This research aimed to look at the contributions of pain catastrophising, anxiety sensitivity, trauma, and body vigilance for the outcomes of psychological distress and pain in participants with NSAP. Multiple regression and correlational analysis were used. Due to COVID-19, recruitment took place virtually via adverts placed on relevant charity and social media

pages. Ninety-nine participants were included in full data analysis. There were significant positive correlations between most study variables. The following variables contributed a significant amount of variance for outcomes; anxiety sensitivity and body vigilance to anxiety, trauma and pain catastrophising to depression, and pain catastrophising, trauma and body vigilance to pain severity. However, several unexpected findings were made, with some variables showing significant negative associations with outcomes in regression analyses. Implications are discussed for clinical practice, such as exploring psychological interventions for treatment of pain catastrophising. Areas for future research are discussed, for example investigating ways to engage medical practitioners to refer for psychological interventions.

Acknowledgements

I would like to thank my clinical tutors Anna Strudwick and Ashley Vanstone for their support and guidance over the last few years when I have struggled and doubted myself. The many check-ins have been incredibly helpful, and I appreciate all the time that they have both given for our meetings. I'd also like to thank Dr Rachel Paskell who was particularly supportive in my final year.

I would like to thank Jess Broughton, a fellow clinical psychology trainee from Bath for helping me to navigate the maze of systematic review processes and in giving me encouragement along the way. I would like to thank Nikita Sood, an undergraduate student who was the second screener for my systematic review and has worked conscientiously to help me meet research deadlines, despite having her own workload.

I would like to thank my placement supervisors, Dr Falguni Nathwani, Dr Rowena Pagdin, Dr Sarah Faquhar, Dr Tanagh Williams, Dr Sarah Butler, Dr Josephine Steel, Dr Hannah Mustard and Dr Madeline Pasterfield for all being incredibly helpful throughout the doctorate and for enabling me to develop my skills in a supportive environment. I would particularly like to thank Hannah and Madeline for being so great in my third year by being flexible and helping me make it to the finish line.

I would like to thank Dr Jo Daniels, my research supervisor from whom I have learnt so much over the past few years. I have learnt more than I ever thought I could about good quality research and will take this forward with me into whatever roles I go into. I would also like to thank Jo for being supportive towards the end of final year and giving feedback at times where a lot of other things were happening. I'd also like to thank Dr Ed Carlton for being my second supervisor on my research project.

I'd like to thank my cohort for being an incredible source of support and solidarity – there is no way I could've made it through the last few years without a number of friendships that I'm sure will last a lifetime.

I'd also like to thank my friends and family, particularly for understanding when I haven't always been present and for still managing to find ways to cheerlead me to the finish line. Your support has been immeasurable.

Finally, I'd like to thank the person who has supported me most over the last few years, my partner Andrew. You have fed me, walked me, and provided me with more support than I ever could have asked for during the Doctorate.

I’d like to dedicate this work to my grandad, Malcolm Daisley, who has been one of my biggest supporters and I know will always continue to cheer me on as I move into the future.

Appendices

Appendix A.

Embase search strategy

('pelvis syndrome':ab,ti OR 'pelvic syndrome':ab,ti OR 'pelvic pain':ab,ti OR 'pelvis pain':ab,ti OR 'pelipathia vegetativa':ab,ti OR 'pelvic congestion':ab,ti OR 'dyspareunia':ab,ti OR 'interstitial cystitis':ab,ti OR 'bladder pain syndrome':ab,ti OR 'painful bladder':ab,ti OR 'irritable colon':ab,ti OR 'irritable bowel':ab,ti OR dysmenorrhea:ab,ti OR adenomyosis:ab,ti OR vulvodynia:ab,ti OR endometriosis:ab,ti OR fibroids:ab,ti OR leiomyoma:ab,ti OR 'inflammatory bowel disease':ab,ti OR 'inflammatory bowel':ab,ti OR 'ulcerative colitis':ab,ti OR 'crohn disease':ab,ti OR crohns:ab,ti OR 'ovary cyst':ab,ti OR 'ovarian cyst':ab,ti OR 'uterus prolapse':ab,ti OR 'pelvic organ prolapse':ab,ti OR 'pelvic adhesion':ab,ti) AND ((psychology:ab,ti OR psycho*:ab,ti OR psychotherap*:ab,ti OR 'psycho therap*':ab,ti OR 'cognitive therap*':ab,ti OR 'behavior therap*':ab,ti OR 'behaviour therap*':ab,ti OR 'cognitive behavioral therapy':ab,ti OR 'cognitive behav*':ab,ti OR cbt:ab,ti OR acceptance:ab,ti) AND commitment:ab,ti OR 'acceptance commitment':ab,ti OR act:ab,ti OR mindful*:ab,ti OR relax*:ab,ti OR meditat*:ab,ti OR psychoed*:ab,ti OR 'psycho ed*':ab,ti OR 'self management':ab,ti OR 'non pharma*':ab,ti OR biofeedback:ab,ti OR 'mind body':ab,ti)

***ab,ti = abstract or title**

Appendix B.

Data extraction form outcomes

Study Demographics

- Author name, study date
- Total number of participants
- Per study arm:
  -No. of participants
  - Participant gender
  - Participant mean age

- Participant years of education
- Participant ethnicity
- No. of participants completed post-tx assessment
- Total number of participants who withdrew post-randomisation

- Per Intervention/Active Comparator arm:
  -Type of psychological intervention
  - Number of sessions
  - Dosage; number of minutes of therapeutic intervention
  - Mode of delivery, e.g. individual or group, virtual or face-to-face
  - Level of therapist training
  - Integrity of intervention checked
- Control condition format; waiting list, care as usual, placebo, other
- Outcome measurement tools:
  -Psychological distress
  - Pain
  - Additional CPP subtypes symptomatology
  - Adverse impacts
  - Quality of Life
  - Additional outcomes
- Risk of Bias
  -Risk of bias arising from the randomisation process, due to deviations from the intended interventions (effect of assignment to intervention)
  - Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
  - Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)
  - Missing outcome data
  - Risk of bias in measurement of the outcome
  - Risk of bias in selection of the reported result

Appendix C.

Participant Demographics

Table 2

			Intervention			Active Comparator			Control Comparator		
Medical Condition	Paper	No. of participants	Mean Age (SD)	Education	Ethnicity	Mean Age (SD)	Education	Ethnicity	Mean Age (SD)	Education	Ethnicity
IBS	Drossman et al (2003)	215*	37.9(11.8)	14.9(2.8)	White =84% Black = 11% Asian American =1.4% Hispanic = 1.4% Native American = 0.7% Other = 1.4%	36.1(11.8)	14.7(2.7)	White =88.7 % Black = 8.5% Asian American =0% Hispanic = 1.4% Native American = 1.4% Other = 0%			
	Gaylord et al (2011)	97	44.72(-12.55)	Some college/technical school = 25%	White = 81% African American =	40.89(14.68)	High school graduate =8% Some college/technica	White = 64% African Americ			

				Completed four years of college = 19% Some graduate/professional school = 17% Completed graduate school = 36% Unknown = 3%	14% Other/not disclosed = 6%		l school = 36% Completed four years of college = 23% Some graduate/professional school = 10% Completed graduate school = 21% Unknown = 3%	an = 15% Other/not disclosed = 6%			
	Guthrie et al (1991)	77*	49	?	?	.	.	.	46	?	?
	Henrich et al (2020)	67	35.58(13.73)	A levels = 27.8% Tertiary education = 72.2%	?	.	.	.	35.48(14.71)	A levels = 16.1% Tertiary education = 83.9%	?
	Jang et al (2014)	90	21.9(1.9)	Freshman = 17.9% Sophomore = 12.8%	?	.	.	.	21.2(2.3)	Freshman = 27% Sophomore =	?

				Junior = 23.1% Senior = 46.2%						13.5% Junior = 21.6% Senior = 37.9%	
	Lee et al (2019)	160	19.27	Nursing students: Third year = 43.8% Fourth year = 56.3%	?	19.45	Nursing students: Third year = 43.8% Fourth year = 56.3%	?	18.47	Nursing students: Third year = 43.8% Fourth year = 56.3%	?
CPP - Heterogeneous Causes	Carty et al (2018)	70	44.89(15.34)	High school = 13.5% Some college = 35% Bachelors = 21% Masters = 24% Doctorate = 5%	?	.	.	.	47.72(14.88)	Less than high school = 4% High scool = 8% Ssome college = 24% Bachelors = 40% Masters = 24% Doctorate = 0%	?
	Forbes et al (2019)	90	34.8(9.9)	Years education: 12 years or less = 3.3%	White = 37.5% Black = 21.4%	35.7(5.7)	Years education: 12 years or less = 3.8%	White = 43.5% Black	35(8.6)	Years education: 12 years	White = 53.6% Black

				13-16 = 30% 17-19 = 20% 20+ = 36.7% Still in education = 10%	Central Asian = 3.6% Southern Asian = 28.6% Middle Eastern = 0% Mixed = 0% Other = 7.1% Do not wish to say = 3.6%		13-16 = 15.4% 17-19 = 19.2% 20+ = 57.7% Still in education = 3.8%	= 17.4% Central Asian = 4.3% Southern Asian = 30.4% Middle Eastern = 0% Mixed = 0% Other = 4.3% Do not wish to say = 0%		or less =3.6% 13-16 = 10.7% 17-19 = 10.7% 20+ = 57.1% Still in education = 17.9%	= 10.7% Central Asian = 0% Southern Asian = 10.7% Middle Eastern = 3.6% Southern Asian = 10.7% Mixed = 7.1% Other = 10.7% Do not wish to say = 3.6%
	Norman et al (2004)	48	38.2(11.5)*	14.9(2.1)*	European = 83% African American = 17%	.	.	.	38.2(11.5)*	14.9(2.1)*	European = 83%* African American = 17%*
	Poleshuck et al (2014)	62	36.3(8.2)	< High school = 33.3% High school degree = 21.2% Education beyond high school = 45.5%	African American/Black = 67% Caucasian = 9.1% Hispanic = 18.2% Biracial = 3.6% Native	.	.	.	37.1(9.8)	< High school = 35.7% High school degree = 25% Education beyond	African American = 64.3% Caucasian = 25% Hispanic = 7.1% Native

					American = 3%					high school = 39.3%	American = 16%
Interstitial Cytitis	Carrico et al (2018)	30	44	High school education + = 93%*	100% Caucasian	44	High school education + = 93%*	100% Caucasian	.	.	.
Dysmennorhoea	Amodei et al (1987)	62	20.3*	?	?	30.5* 20.3*	?	?	30.5* 20.3*	?	?
	Bennink et al (1982)	15	19.2*	?	?	19.2*	?	?	19.2*	?	?

	Celik and Apay (2021)	194	Current university students	Current university students	?	.	.	.	Current university students	Current university students	?
	Halder et al (2012)	75	Nursing students	Nursing students	?	Nursing students	?	?	Nursing students	Nursing students	?
	Quillen and Denny (1982)	24	College women	College women	?	.	.	.	College women	College women	?
	Yilmaz and Sahin (2020)	80	First year university students	First year university students	?	.	.	.	First year university students	First year university students	?
Dyspareunia	Van Lankveld et al (2001)	446** 26	35(11)**	?	?	.	.	.	38(12)**	?	?

Table key: *?? = Data Missing*
**= Demographics Given Across Study Groups*
***=Data refers to only selected subset of study participants included within the review*

Appendix D.

Gibbs reflective cycle (1988)

Reflection on group development and delivery by a trainee psychologist, using the Gibbs (1988) reflection cycle.

Description

As a trainee psychologist, part of my doctorate involved developing a SIP within an NHS Trust. The CPI team on my first placement had wanted to create a DBT supporter group for some time and as a trainee, I had the flexibility to develop this. I came to the service having jointly facilitated psychological intervention/psychoeducation groups before. However, I was unfamiliar in working with people with EUPD or their families, which was completely new to me. Prior to developing the supporter group, I attended and co-facilitated the service-user DBT group. Following this, myself, my supervisor, and another psychologist developed materials for the DBT supporter group. My supervisor and I delivered the supporter group after normal working hours and group delivery was moved online due to COVID-19.

Feelings

Initially, I was nervous about running the groups online, and apprehensive about whether attendees would find the sessions useful. This was exacerbated by one supporter-service-user pair expressing high levels of distress in pre-group correspondence. I worried that participants expected the group to solve the complex problems that they faced, which I knew would not be possible. As sessions progressed however, attendees embraced the group content and applied this to their own lives. They increasingly engaged in reflective discussion which was encouraging to see. It felt rewarding developing a professional and trusting relationship with the group, and I felt privileged that members willingly shared information about their relationships and experiences. The feedback we received post-group was predominantly extremely positive. I have had significant job satisfaction in reflecting on the CPI team's achievement in providing this group. This is particularly in the context of COVID-19, as the project had to adapt significantly but was still a success.

Evaluation

It was hugely satisfying to deliver an intervention that is sorely needed but largely absent in clinical care. Collaboration between psychology services and the service-user

reference group proved effective and promoted professional relationships between professionals and service-users. Attendee feedback seemed largely positive, which was reflected in both questionnaire and open-ended feedback. Additionally, the service-user finishing DBT treatment at the time of the group reported group benefits for themselves and their supporter; something I did not necessarily expect. This showed the effectiveness of group content beyond the benefits that individual service-user DBT provided. Unfortunately, technical issues were a drawback of an online group and included audio feedback, camera malfunctioning and poor internet bandwidth. Group attendees were patient with these issues; however, it was important to have two facilitators so that at least one would remain if the other faced technical difficulties. It would have been interesting to see if face-to-face group delivery altered group dynamics. One problem with evaluation was that the length of time post-group before participants completed outcome measures was variable. This therefore will have affected the validity of the data; future group delivery should highlight prior to group commencement that all data will be collected at a specific timepoint after sessions.

Analysis

The positive reception of supporters towards the group might reflect the neglected needs of EUPD families (Hoffman, 2005). Indeed, one supporter reported in pre-group questionnaires that all healthcare support was for their partner, which left them feeling isolated. In addition to group content, the simple act of creating a space for supporters may have contributed to its positive reception. Participant perception of the group content as being useful may be due to psychoeducation and skills teaching components. Both elements have been shown to be effective for reducing adverse outcomes for EUPD families (Guillen et al., 2020). Technical issues seemed significantly worse when using NHS computers compared to home laptops, which should be considered for future groups. Finally, the personal lives of those with EUPD and their families can be tumultuous (Ntshingila et al., 2016); using protocols to maximise the likelihood of timely feedback will be essential for future sessions.

Conclusions

Many things that worked well within this group came from the collaborative relationship between co-facilitators. This was crucial in promoting group cohesion and avoiding technological pitfalls where possible. This should be considered if future facilitators come from a broader multi-disciplinary team. I learnt from this experience

that thorough material revision and input from multiple sources is essential before delivering a new therapeutic group. This process benefits the group on many levels, for example in ensuring the relevance of group content. Initially, I may not have fully comprehended the importance of each of the stages needed for group development. I learnt that utilising technology for an online group requires patience, prior testing, and preparation. Online delivery of the group created a significant amount of administrative work; additional staff support would be needed if the group were to run long-term. If future facilitators are new to the team, they should attend a service-user DBT group in addition to becoming familiar with DBT theory prior to running the supporter group. This is so that group reflection and discussion is optimally beneficial for participants.

Action Plan

- The CPI team will review participant feedback and incorporate this into subsequent revisions of session materials. This will possibly involve input from another clinical psychology trainee.
- Recruitment will begin for the next cohort of this supporter group.
- Decisions will be made as to the delivery mode for future groups; for example, whether to deliver the group face to face post Covid-19, or whether supporters will be allowed to attend online.
- One supporter has agreed to attend future groups to give their own experiences of supporting someone with EUPD through DBT.
- Further discussion will take place around who will deliver future groups. If this involves members of the wider MDT, such as care coordinators, psychological supervision will need to be arranged.
- There is scope for a further service improvement project to take place, with another clinical psychology trainee continuing to collect data around the effectiveness and acceptability of the group.
- This report will be written to the standard of psychological journals and will be submitted for publication

Appendix E.

Definition of Non-Specific Abdominal Pain

Non-Specific Abdominal Pain (NSAP): Abdominal or pelvic pain or a significant portion of time (e.g., 2-3 hours or more) but less than seven days duration for which the diagnosis remains uncertain after clinical examination and/or investigation.

Appendix F.

Ethics Approval Letter

Faculty of
Humanities &
Social Sciences

UNIVERSITY OF
BATH

Bath BA2 7AY · United Kingdom

Miss Tara Daisley Devoy
Department of Psychology
University of Bath
Bath BA2 7AY England

20 May 2021

Dear Miss Daisley Devoy

Full title of study: Exploring factors influencing the development and maintenance of Non-Specific Abdominal Pain
PREC reference number: 20-243

On behalf of the Committee, I am pleased to confirm that you have received full ethical approval for the above proposal and amendment from the Psychology Research Ethics Committee.

If you intend to display recruitment posters/materials, please ensure you obtain the appropriate permission to do so from those who manage the location(s) you choose.

Please inform PREC about any substantial amendments made to the study if they have ethical implications.

Please make sure you quote your unique PREC code, 20-243, in any future correspondence.

Rebecca Wise
On behalf of PREC

Appendix G.

List of participating organisations for Main Research Project recruitment

Pain organisations

- American Chronic Pain Association https://www.theacpa.org/
- Pain Concern https://painconcern.org.uk/
- Pain UK https://painuk.org/

Facebook pages

- **“**Abdominal migraine support group”
- “Living in Chronic Pain”
- “Abdominal migraine support for adults”
- “Sensitive stomach, gastritis, IBS, post abdominal surgery support group”
- “Tell me about your pain”

Twitter

- Shared by lead project supervisor Dr Jo Daniels

Appendix H.

Participant inclusion and exclusion criteria

H1.

Participant inclusion criteria

Criteria	Rationale
At least three episodes in the previous six months of NSAP	Based on ROME-IV criteria that symptoms must be present for a minimum of six months for other unexplained abdominal pain disorders
"Abdominal pain or pelvic pain of a significant portion of time (e.g. 2-3 hours or more but less than seven days duration for which the diagnosis remains uncertain after clinical examination and/or investigation"	Current definition of "Non-specific Abdominal Pain" from research literature (REF) – this represents the episodic rather than continuous nature of pain in this population
Minimum of at least three episodes of pain	• Paediatric literature for "recurrent abdominal pain" (RAP) cites 3+ episodes of symptoms to be categorised as RAP • Medical resources for RAP such as X often cite Apley's 1975 criteria as 3+ episodes
Participants must have had at least one medical appointment for clinical examination or investigation of their pain which has not resulted in a diagnosis	Medic consultation to discuss appropriate number of consultations/appointments required – minimum of at least one means no cause has been identified
Being fluent in English	Ability to understand and complete questionnaires
Being 18+ years old	Adult population is targeted participant population
Having capacity to consent to the research	Standard research procedure

H2.

Participant exclusion criteria

- A diagnosis meaning the participant does not have the cognitive/mental capacity to consent to study participation, e.g. Alzheimer's or a significant Learning Disability
- Pregnancy
- An identified organic cause for abdominal pain, e.g. stomach ulcers, endometriosis, dysmenorrhoea (period pain)
- Any other diagnosed gastrointestinal disorder (medically unexplained or otherwise) that does not meet the inclusion criteria, or has additional symptoms: Please note, this includes Irritable Bowel Syndrome, and so participants will not be able to take part if they have a diagnosis of IBS

Appendix I.

Study measures/questionnaires

I1.

Non-specific Abdominal Pain questions

- How many episodes of NSAP have you had in the past six months? Please type a number, for example: 3

- How long approximately have each of these episodes of NSAP lasted? For example, please write “4 hours” if Episode 1 lasted four hours

- Have you had to attend your General Practitioner (GP) practice for any episodes of NSAP in the last six months?

- How many times have you had to attend your General Practitioner (GP) practice for any episodes of NSAP in the last six months?

- Were you referred on from your General Practitioner (GP) for specialist investigations? If YES please elaborate below about what investigations there were and where you were referred to below

- Are you currently under the care of any medical specialties, e.g. Gynaecology? If YES, please specify which medical specialty this is in the text box below

- Are you still undergoing tests to investigate your NSAP?

- Have you had to attend the Accident and Emergency Department in the last six months for your NSAP?

- Have you had to take any medication for your NSAP episodes? If YES, please write which medications below

- Have you had to access any other type of medical care not mentioned in the other questions for your NSAP? If YES, please elaborate below

I2.

Adverse Childhood Experiences Questionnaire

PLEASE SELECT "YES" or "NO" FOR EACH QUESTION.

Prior to your 18th birthday:

1. Did a parent or other adult in the household **often or very often**…

   Swear at you, insult you, put you down, or humiliate you?

   or

   Act in a way that made you afraid that you might be physically hurt?

   Yes No

2. Did a parent or other adult in the household **often or very often**…

   Push, grab, slap, or throw something at you?

   or

   Ever hit you so hard that you had marks or were injured?

   Yes No

3. Did an adult or person at least 5 years older than you **ever**…

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

Yes No

4. Did you **often or very often** feel that …

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

Yes No

5. Did you **often or very often** feel that …

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

Yes No

6. Was a biological parent **ever** lost to you through divorce, abandonment, or other reason?

Yes No

7. Was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

Yes No

8. Did you live with anyone who was a problem drinker or alcoholic or who used street drugs?

Yes No

9. Was a household member depressed or mentally ill or did a household member attempt suicide?

Yes No

10. Did a household member go to prison?

Yes No

I3.
Anxiety Sensitivity Index

	Very Little (0)	A Little (1)	Some (2)	Much (3)	Very Much (4)
1) It is important for me not to appear nervous	**0**	**1**	**2**	**3**	**4**
2) When I cannot keep my mind on a task, I worry that I might be going crazy	**0**	**1**	**2**	**3**	**4**
3) It scares me when my heart beats rapidly	**0**	**1**	**2**	**3**	**4**
4) When my stomach is upset, I worry that I might be seriously ill	**0**	**1**	**2**	**3**	**4**
5) It scares me when I am unable to keep my mind on a task	**0**	**1**	**2**	**3**	**4**
6) When I tremble in the presence of others, I fear what people might think of me	**0**	**1**	**2**	**3**	**4**
7) When my chest feels tight, I get scared that I won't be able to breathe properly	**0**	**1**	**2**	**3**	**4**
8) When I feel pain in my chest, I worry that I'm going to have a heart attack	**0**	**1**	**2**	**3**	**4**
9) I worry that other people will notice my anxiety	**0**	**1**	**2**	**3**	**4**

	Very Little (0)	A Little (1)	Some (2)	Much (3)	Very Much (4)
10) When I feel "spacey" or spaced out I worry that I might be mentally ill	**0**	**1**	**2**	**3**	**4**
11) It scares me when I blush in front of people	**0**	**1**	**2**	**3**	**4**
12) When I notice my heart skipping a beat, I worry that there is something seriously wrong with me	**0**	**1**	**2**	**3**	**4**
13) When I begin to sweat in a social situation, I fear people will think negatively of me	**0**	**1**	**2**	**3**	**4**
14) When my thoughts seem to speed up, I worry that I might be going crazy	**0**	**1**	**2**	**3**	**4**
15) When my throat feels tight, I worry that I could choke to death	**0**	**1**	**2**	**3**	**4**
16) When I have trouble thinking clearly, I worry that there is something wrong with me	**0**	**1**	**2**	**3**	**4**
17) I think it would be horrible for me to faint in public	**0**	**1**	**2**	**3**	**4**

18) When my mind goes blank, I worry that there is something terribly wrong with me

I4.

Body Vigilance Scale

This scale is designed to index how sensitive you are to internal bodily sensations such as heart palpitations or dizziness. Fill it out according to how you have felt for the **past week**.

1. "I am the kind of person who pays close attention to internal body sensations."

0	1	2	3	4	5	6	7	8	9	10
Not at all					Somewhat					Extremely

2. "I am very sensitive to **changes** in my internal body sensations."

0	1	2	3	4	5	6	7	8	9	10
Not at all					Somewhat					Extremely

3. "On average, **how much time** do you spend each day scanning your body for sensations?"

0	10	20	30	40	50	60	70	80	90	100
Never					Half the time					Constantly

4. "Rate how much attention you pay to each of the following sensations using this scale"

0	10	20	30	40	50	60	70	80	90	100
Never		Slight			Moderate			Substantial		Constantly

1. Heart palpitations
2. Chest pain/discomfort
3. Numbness
4. Tingling
5. Short of breath/smothering
6. Faintness
7. Vision changes
8. Feelings of unreality
9. Feeling detached from self
10. Dizziness
11. Hot flash
12. Sweating/clammy hands
13. Stomach upset
14. Nausea
15. Choking/throat closing

I5.

Hospital Anxiety and Depression Scale

Tick the box beside the reply that is closest to how you have been feeling in the past week.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all When	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all

		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

I6.

Pain Catastrophising Scale

0 – not at all **1** – to a slight degree **2** – to a moderate degree **3** – to a great degree **4** – all the time

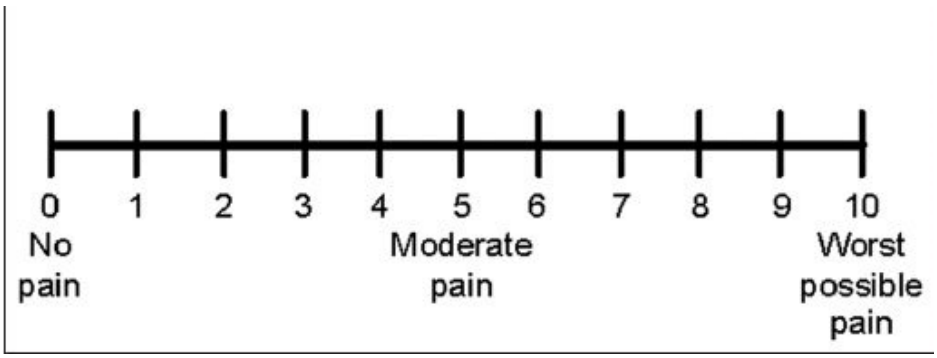
When I'm in pain …

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.
7. ☐ I keep thinking of other painful events.
8. ☐ I anxiously want the pain to go away.
9. ☐ I can't seem to keep it out of my mind.
10. ☐ I keep thinking about how much it hurts.
11. ☐ I keep thinking about how badly I want the pain to stop.
12. ☐ There's nothing I can do to reduce the intensity of the pain.
13. ☐ I wonder whether something serious may happen.

…Total

I7.

Visual Analogue Scale



Appendix J.

Independent t-test results comparing included and excluded data

	Included		Excluded			
	Mean	Standard Deviation	Mean	Standard Deviation	T	P
ACE	3.7	3.11	4.75	2.57	-1.71	0.096
Age	33.06	8	32.04	11.94	0.40	0.694
Anxiety	9.88	2.69	10.71	1.76	-1.86	0.069
Anxiety Sensitivity	32.69	16.04	33.75	9.57	-0.42	0.676
Body Vigilance	21.35	7.38	24	4.77	-2.17	0.097
Depression	8.33	2.92	9.67	1.95	-2.70	0.009
Episode Length	2.82	1.42	3	0.86	-0.61	0.543
Number of episodes	4	1.29	3.38	3.37	2.29	0.024
Pain	48.85	17.67	44.83	9.85	1.50	0.139
Pain Catastrophising	25.84	11.38	25.54	5.96	0.18	0.855

Appendix K.

Instructions for authors for nominated journals

K.1.

Instructions for authors for "Clinical Psychology Review" journal

https://www.elsevier.com/wps/find/journaldescription.cws_home/652?generatepdf=true

K.2.

Instructions for authors for "Personality Disorders: Theory, Research, and Treatment" journal

https://www.apa.org/pubs/journals/per/index?tab=1

K.3.

Instructions for authors for "Clinical Journal of Pain"

https://journals.sagepub.com/author-instructions/bjp#:~:text=British%20Journal%20of%20Pain%20requests,the%20data%20can%20be%20obtained.