BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

BMJ Open

Protocol for a mixed-method cohort study investigating the prevalence and impact of Obsessive-Compulsive Disorder (OCD) in Chronic Pain rehabilitation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-052288
Article Type:	Protocol
Date Submitted by the Author:	11-Apr-2021
Complete List of Authors:	Sloley, Chad; University of Otago Christchurch, Anaesthesia Shipton, Edward A.; University of Otago, Department of Anaesthesia Bell, Caroline; University of Otago Williman, Jonathan; Christchurch School of Medicine and Health Sciences, Public Health and General Practice
Keywords:	Pain management < ANAESTHETICS, Adult psychiatry < PSYCHIATRY, PAIN MANAGEMENT

SCHOLARONE™
Manuscripts

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Title

Protocol for a mixed-method cohort study investigating the prevalence and impact of Obsessive-Compulsive Disorder (OCD) in Chronic Pain rehabilitation

Chad Sloley[1], Edward A. Shipton[1], Caroline J. Bell[2], Jonathan A. Williman[3]

1. Department of Anaesthesia, University of Otago, Christchurch, New Zealand.
2. Department of Psychological Medicine, University of Otago, Christchurch, New Zealand.
3. Department of Population Health, University of Otago, Christchurch, New Zealand.

Correspondence to Chad Sloley; chad.sloley@postgrad.otago.ac.nz

Keywords: Chronic Pain; Obsessive-Compulsive Disorder; Rehabilitation

Abstract

Introduction

While there is considerable and growing research in the individual fields of Obsessive-Compulsive Disorder (OCD) and Chronic Pain, focused research into their potential association remains limited. By exploring this potential association, better theoretical understanding of and better therapeutic approaches to chronic pain management could be developed. The study's aim is to explore the prevalence and impact of OCD on the experience and rehabilitation of Chronic Pain amongst individuals attending a New Zealand Pain Service.

Methods and analysis

This is a cohort study using well validated questionnaires and semi-structured interviews. Participants will be recruited through Community Pain Services from a private rehabilitation-focused company with sites across New Zealand. Participants will complete an OCD screening measure (Obsessive Compulsive Inventory-Revised [OCI-R]). These results will be used to compare results from the Specialist Pain Services benchmarking electronic Persistent Pain Outcomes Collaboration (ePPOC) measure sets, at both participant intake and at completion of each Pain Service programme. Prevalence rates of OCD will be estimated with 95% CI. Generalised linear regression models will be used to explore differences in pain baseline and outcome factors between those with versus those without OCD.

Semi-structured interviews, assessed through Interpretative Phenomenological Analysis (IPA), will be used to provide information on lived experiences of individuals with comorbid chronic pain and OCD. This will be supported through the administration of an Obsessive Beliefs Questionnaire (OBQ-44).

Ethics and dissemination

Ethical approval was obtained from the Health and Disability Ethics Committee (HDEC20/CEN/82). Study results will be disseminated at professional conferences and in peer-reviewed journals. A lay summary of findings will be provided to requesting participants and/or through attendance at a local hui (gathering).

Article Summary

Strengths and limitations of this study

For peer review only

- This is the first study to directly explore prevalence, impact, and experience of OCD on Chronic Pain rehabilitation.
- By using a mixed method design the qualitative component will provide rich information, whereas the quantitative component will help provide generalisable estimates of parameters of interest.
- Use of an OCD screening measure limits the burden on potential participants, already dealing with the demands of involvement in Pain Services, and it encourages greater participation. However, the nature of the information collected via this method is limited as compared to a clinical interview.
- Resource and practical constraints have led to the exclusion of tertiary level Pain Services, which limits the inclusion of a certain subset of Chronic Pain sufferers attending a Pain Service.
- Response bias considerations associated with a cohort study design.

Introduction

Chronic or persistent, non-cancer pain refers to a heterogeneous group of clinical conditions, in which pain persists or recurs for longer than 3 months [1]. It represents an important consideration in the New Zealand public health system. A recent national survey (2017/2018 New Zealand Health Survey) reported that 19.7% of the population, or an estimated 770,000 adults, suffer from chronic pain [2]. While historical views of chronic pain have been predominantly biomedical in focus, it is increasingly recognised that complex interplays between biological, psychological, socio-cultural, and economic factors underlie the development and maintenance of chronic pain [3]. This emphasises the importance of reviewing potential contributing factors as a way of both furthering conceptual understandings as well as supporting effective clinical interventions. Within this framework, a growing body of research is exploring the role of psychopathology in the transition of acute pain into acute persistent pain and subsequently into chronic pain states as well as its role in acting as a significant barrier to intervention/recovery [4].

Obsessive-Compulsive Disorder (OCD) is a neuropsychiatric condition, which is heterogeneous and often chronic, affecting approximately 1% to 3% of the general population [5]. It is a cross-cultural and cross-socioeconomic phenomenon [6]. Geographical and cultural factors contribute to variability in symptom presentation and frequency [7]. At its core, it features persistent obsessions and/or compulsions [8, 9]. Obsessions are defined as “recurrent and persistent thoughts, urges, or images that are experienced as intrusive and unwanted”. Compulsions are defined as “repetitive behaviors or mental acts that an individual feels driven to perform in response to an obsession, or according to rules that must be applied rigidly” [8].

While there is considerable and growing research in OCD, there is limited investigation into its association with chronic pain. While included as part of larger studies on psychopathology comorbidity, to the best of researcher’s knowledge there has only been one direct study into the prevalence of OCD in chronic pain. This reported a high lifetime prevalence of OCD in a sample of those suffering from chronic pain [10]. In addition, there has been no direct investigation into the potential impact that OCD has on chronic pain and its rehabilitative processes or outcomes.

However, a review of literature pertaining to OCD indicates the presence of various aspects that have possible important implications for chronic pain sufferers. In particular, OCD is associated with high rates of diagnostic comorbidity [11]. It overlaps with illness anxiety [12], and is linked to significant disability

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

[13]. Its symptoms are associated with poorer self-reported physical health status [14]. It is associated with a tendency towards threat overestimation and heightened appraisal of potential negative outcomes [15, 16]. It holds a significant association with cognitive rumination, with the latter also noted to contribute to pain catastrophisation [17, 18]. It is associated with impaired functioning of certain neurobiological pathways, including various cortical and subcortical structures, that are linked with complex processes, such as evaluation, affect regulation, reward-based decision making, and goal-directed behaviour [19, 20]. It is associated with deficits in organizational skills that lead to impairment across learning strategy use and memory recall [21-23]. Research also points to subjective doubt being an important feature of OCD [24], with a nascent OCD model postulating an attenuated access to internal states (such as emotions, bodily sensations, muscle tension, and proprioception) [25-27].

Chronic pain and OCD are complex conditions linked with significant disability and distress. In consideration of the aspects and processes highlighted above, further study into the association and impact of OCD on chronic pain and its rehabilitation is merited.

Objectives

The overall aim of this study is to explore the prevalence and impact of OCD amongst Chronic Pain sufferers attending Pain Services in New Zealand. We hypothesise that OCD displays a significantly higher prevalence rate among Chronic Pain sufferers, than the general population. We also hypothesise that it is associated with greater complexity and intensity of pain experiences, greater life interference; greater requirement for clinical input through Pain Service programme, and worse programme outcomes.

To test these hypotheses, this study will:

1) Determine the prevalence of participants with OCD attending an active Pain Service programme and contrast this with rates in the general population.

2) Determine the degree to which OCD tendencies are associated with pain complexity, pain intensity, and daily life interference of individuals that leads into a Pain Service programme.

3) Determine the degree to which OCD tendencies are associated with greater need for clinical input and pain outcomes through Pain Service programmes.

4) Explore how individuals make sense of their experiences of co-occurring Chronic Pain and OCD, and how their accounts of obsessions and compulsions contribute to their pain rehabilitation experiences.

Methods and analysis

Study design

This is a cohort study using questionnaires and semi-structured interviews with participants recruited through Community Pain Services from a rehabilitation-focused company, *Habit Health*. *Habit Health* is one of New Zealand's largest private integrated health, fitness and physiotherapy rehabilitation provider. It incorporates an established Community Pain Service, and comprising seven distinct units across New Zealand.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Inclusion criteria for the study include all individuals over the age of 18 years involved in an active Community Pain Service programme, and who have sufficient English Language proficiency to independently complete report measures.

Pain Services in New Zealand are specialist multidisciplinary services with a core team comprising a Physician, Physiotherapist, Psychologist, and Occupational Therapist. At a community level, Pain Service programmes consist of two stages, with individuals with Chronic Pain issues referred into the first stage. The second stage expands and builds upon services delivered in the first stage, and includes mandatory medical practitioner input and medication review. Progression into a second stage depends on individual needs, complexity of barriers to pain rehabilitation, and resource requirements. As part of standard service practices, *Electronic Persistent Pain Outcome Collaboration* (ePPOC) data sets are administered at intake and on completion (either at stage one or two depending on the individual's service progression) points of individual Pain Service programmes.

Recruitment will occur over a period of 22 months, spanning June 2020 to April 2022. A study flyer, including the primary researcher's (CS) contact details, will be included with initial service documents sent to individuals starting at a Pain Service (Figure 1). Pain Service Key Workers (clinicians performing the initial assessment and managing the overall programme) will also approach already enrolled, and eligible, service clients to inform them of the study and to attain verbal consent for their contact details to be passed on to the primary researcher. The primary researcher would then contact, or be contacted by, assenting individuals to discuss the study details and confirm eligibility. Eligible clients will be emailed a link via *REDCap* web-based survey to complete informed consent and baseline measures including the Obsessive Compulsive Inventory-Revised (OCI-R). Individuals unable to access the online survey will be provided with a physical study pack comprising the study information sheet, informed consent form, an OCI-R measure, and postage-paid return envelope. The primary researcher will follow-up on surveys where there has been no response within 1 to 2 weeks of the survey initially being sent. This will occur via either email or telephone call.

A consented participant's ePPOC data will also be collected at intake and completion points for their Pain Service.

Through purposeful sampling, a small number of individuals indicating OCD–Chronic Pain comorbidity, (either by clinical diagnosis or as supported by high OCI-R and ePPOC results) will be approached to participate in a semi-structured interview. This interview will be conducted following the completion of any active Community Pain Service, and will be focused on exploring the experiences of their conditions and pain rehabilitation. Interviewees will also complete an obsession directed self-report measure (Obsessive Beliefs Questionnaire 44 [OBQ-44]) to assist in providing clinical understanding of participant experiences regarding obsessions.

Figure 1: Study structure

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Measures

Obsessive Compulsive Inventory-Revised (OCI-R)

The OCI-R is an 18 item self-report measure assessing characteristic symptoms of OCD for their prevalence over the past month [28]. Items are rated on a 5-point Likert scale, ranging from '*0 (Not at all)*' to '*4 (Extremely)*', with higher scores indicating a greater presence of OCD associated symptoms. A total score of 21 is suggested as an optimal cut-off score for distinguishing OCD presence [28]. This self-report measure holds good internal consistency, good to adequate short-term test-retest reliability, and fair convergence with clinician-rated measures of OCD [29]. Its use as a screening and research tool has been validated in both clinical [28] and non-clinical samples [30] as well as within the New Zealand context [31].

Obsessive Beliefs Questionnaire 44 (OBQ-44). The OBQ-44 is a 44-item questionnaire, assessing across three factors hypothesized to be associated with obsessive-compulsive symptoms and worry. They include: 1) Responsibility and threat estimation, 2) Perfectionism and intolerance for uncertainty, 3) Importance and control of thoughts [32]. This questionnaire displays good internal consistency with a sample of both clinical and non-clinical participants [32], and correlates with obsessive-compulsive symptoms [33].

Electronic Persistent Pain Outcome Collaboration (ePPOC)

ePPOC incorporates a broad range of patient-reported data items and assessment tools to measure various outcomes across physical, functional, and psychological aspects from specialist Pain Services In Australia and New Zealand [34, 35]. These are completed at intake, completion, and at 3 to 6 months post-completion of an individual Pain Service by service facilitators. Information is electronically stored. Information contributes to locally-held and internationally-held rehabilitation service outcomes databases. The information and measures, forming part of the ePPOC set, that will be accessed for the purposes of this study include:

Patient characteristics: Date of birth; Gender; Ethnicity; Comorbidities.

Medication use: Number of major drug groups.

Brief Pain Inventory (BPI): Measure assessing the location of pain, its severity, and its interference in daily activities.

Pain Self-Efficacy Questionnaire (PSEQ): A client-reported measure assessing the confidence an individual has that they can perform a range of activities, despite the presence of pain [36]. 10 items are rated on a scale from 0 to 6, where 0= "not at all confident" and 6= "completely confident".

Pain Catastrophizing Scale (PCS): A client-reported measure assessing the presence of pain-related thoughts and cognitions that may contribute to more intense pain, increased disability, and emotional distress [37]. Thirteen items are rated on a scale from 0 to 4, where 0 = "not at all" and 4 = "all the time". It provides an overall score as well as subscale scores associated with rumination, magnification, and helplessness.

Depression Anxiety Stress Scale-21 (DASS-21): A client-report measure of the emotional states of depression, anxiety, and stress, appropriate for use in both clinical and research settings [38]. Twenty-one

statements are rated on a 4-point scale as to how much they have applied over the past week. It is indicated as a valid and reliable measure with applicability to the persistent pain population [39].

Healthcare utilization: Pain-related utilization of General Practitioner, specialist, allied health services, presentations to emergency department, admission to hospital, and diagnostic tests undertaken in the past three months.

Data Analysis

OCI-R scores for each participant will be analysed. To answer the question of prevalence rate, an OCI-R total score of 21 will be set as a cutoff mark to dichotomize between OCD presence and non-presence. The OCD prevalence rate of participants will be estimated with 95% 'Wilson' binomial confidence intervals (CI), and rates will be considered greater than the general population if the lower bound of the 95% CI exceeds 3%. Three per cent was chosen as it denotes the upper limit of OCD prevalence rates identified amongst general population studies.

Associations between OCD and experiences of chronic pain will be explored through generalized linear regression models, with individuals' OCI-R total scores included as the explanatory independent variable. Outcomes of interest include those measured via the ePPOC at baseline; pain catastrophizing (PCS), pain intensity and interference ratings (BPI), pain self-efficacy (PSEQ), and length of time that pain has been present. Reported change in pain and in physical abilities between service entry and discharge will be modelled without adjustment for baseline differences. The proportion of participants who transition into Pain Service stage 2 will be determined, and compared by OCI-R using log-binomial or logistic regression models.

Count outcome variables will be analysed through use of Poisson regression model. These will include: Number of times seeing a General Practitioner (GP) and Number of times consulting health professionals prior to the start of the Pain Service.

Non-linear associations between OCI-R and outcomes variables will be modeled using restricted cubic splines. In addition to univariable models, multivariable models will be run with, and adjustment for, potential confounders. The study identifies various confounding variables include: Age; Gender; Ethnicity; depression (DASS-21); and Medication use (Benzodiazepines and Opioids).

Sample size

We estimate we will be able to enroll 150 participants during the study recruitment period. This sample size will allow us to estimate the prevalence of OCD with 95% CI of approximately 5% in width.

Qualitative Analysis

Interviews will be audio recorded and transcribed verbatim. Detailed case-by-case analysis will be done of individual interview transcripts from a sample of 3 to 6 participants, according to an Interpretative

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Phenomenological Analysis (IPA) approach. IPA embraces a focus on exploring how individuals make sense of their world through comprehensive examination of personal perceptions or accounts [40].

Patient and public involvement

No patient or public involvement occurred in the design and planning of the study.

Ethics and dissemination

Ethical approval for the study was granted by the New Zealand Health and Disability Ethics Committees (20/CEN/82). Approval was also attained from a private rehabilitation company, *Habit Health*, to assist in approaching individuals for participation in the study. Participation in the study does not interfere with typical care that individuals receive through their respective Pain Services. Participants will be able to opt-in to the study and will be able to withdraw at any time. The study will look to protect participant anonymity through the use of number coding methods. All information will be securely held. The primary researcher will look to debrief participants should any emotional reactions elicited from completing the surveys occur. In the unlikely event of any safety related concerns being noted, participants will either be referred back to their treating clinicians for further input/care or alternatively be directed to relevant emergency care facilities/entities. Attempts will be made to support culturally appropriate engagement, particularly in relation to the semi-structured interview component of the study. As part of this, procedures and approaches surrounding the interview process (e.g. venue, greetings, opening and closing customs) will be developed to be responsive to the cultural needs of the individual.

No monetary, or other, incentives will be offered to individuals for their participation. The only anticipated direct costs to participants will relate to travel expenses for those involved in the semi-structured interviews.

Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals. In addition, a lay summary of the study findings will be sent to all study participants who wish to access these and/or through attendance at a local hui (gathering).

References

1. International Classification of Diseases 11 [ICD-11]. *MG30 Chronic Pain*. 2019 14/07/2019]; Available from: https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/1581976053.
2. Healthinfo. *Overview of persistent pain*. 2018 [cited 2019 5th May]; Available from: https://www.healthinfo.org.nz/index.htm?Chronic-pain.htm.
3. Edwards, R.R., et al., *The Role of Psychosocial Processes in the Development and Maintenance of Chronic Pain.* The Journal of Pain, 2016. **17**(9): p. T70-T92.
4. Gatchel, R.J., *Psychological Disorders and Chronic Pain: Cause-and-Effect Relationships*, in *Psychological Approaches to Pain Management: A Practitioner's Handbook*, R.J.T. Gatchel, D.C., Editor. 1996, The Guilford Press: New York.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

5. Fornaro, M., et al., *Obsessive-compulsive disorder and related disorders: a comprehensive survey.* Annals of General Psychiatry, 2009. **8**(13): p. 13.
6. Williams, M. and A. Steever, *Cultural Manifestations of Obsessive-Compulsive Disorder*, in *Obsessive-Compulsive Disorder: Etiology, Phenomenology and Treatment*, C.W. Lack, Editor. 2015, Ginger Prince Publications. p. 63-84.
7. Guzick, A.G., et al., *Diagnostic Description and Prevalence*, in *The Wiley Handbook of Obsessive Compulsive Disorders*, J.S. Abramowitz, D. McKay, and E.A. Storch, Editors. 2017, John Wiley & Sons Ltd: Chichester, UK. p. 24-43.
8. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*. Fifth Edition ed. 2013, Arlington, VA: American Psychiatric Association.
9. International Classification of Diseases 11 [ICD-11]. *6B20 Obsessive-Compulsive Disorder*. 2020 11/03/2021]; Available from: https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f1582741816.
10. Mehraban, A., et al., *The High Prevalence of Obsessive-Compulsive Disorder in Patients with Chronic Pain* Iran J Psychiatry, 2014. **9**(4): p. 203-208.
11. Calamari, J.E., et al., *Phenomenology and Epidemiology of Obsessive Compulsive Disorder*, in *The Oxford handbbook of Obsessive Compulsive and Spectrum Disorders*, G. Steketee, Editor. 2012, Oxford University Press: New York. p. 11-47.
12. Reuman, L., et al., *Predictors of illness anxiety symoptoms in patients with obsessive compulsive disorder.* Psychiatry Research, 2017. **256**: p. 417-422.
13. Lochner, C., et al., *Cluster Analysis of Obsessive-Compulsive Symptomatology: Identifying Obsesive-Compulsive Disorder Subtypes.* Isr J Psychiatry Relat Sci, 2008. **45**(3): p. 164-176.
14. Jordan, K.D. and A. Okifuji, *Anxiety Disorders: Differential Diagnosis and Their relationship to Chronic Pain.* Journal of Pain & Palliative Care Pharmacotherapy, 2011. **25**(3): p. 231-245.
15. Admon, R., et al., *Functional and structural neural indices of risk aversion in obessive-compulsive disorder (OCD).* Psychiatry Research: Neuroimaging, 2012. **203**: p. 207-213.
16. Casado, Y., et al., *Emotional processing in obsessive-compulsive disorder.* Journal of Anxiety Disorders, 2011. **25**: p. 1068-1071.
17. Watkins, E.R., *Depressive Rumination and Co-Morbidity: Evidence for Brooding as a Transdiagnostic Process.* J Rat-Emo Cognitive-Behav Ther, 2009. **27**: p. 160-175.
18. Sullivan, M.J.L., W.M. Rodgers, and I. Kirsch, *Catastrophizing, depression and expectancies for pain and emotional distress.* Pain, 2001. **91**: p. 147-154.
19. Calza, J., et al., *Altered Cortico-Striatal Functional Connectivity During Resting State in Obsessive-Compulsive Disorder.* Frontiers in Psychiatry, 2019. **10**.
20. Fettes, P., L. Schulze, and J. Downar, *Cortico-Striatal-Thalamic Loop Circuits of the Orbitofrontal Cortex: Promising Therapeutic Targets in Psychiatric Illness.* Front. Syst. Neurosci. , 2017. **11**(25).
21. Larson, M.J. and A. Clawson, *A Critical Review of Neuropsychological Functioning and Heterogeneity in Individuals with Obsessive-Compulsive Disorder*, in *The Wiley Handbook of Obsessive Compulsive Disorders*, J.S. Abramowitz, D. McKay, and E.A. Storch, Editors. 2017, John Wiley & Sons Ltd: Chichester, UK. p. 155-175.
22. Greisberg, S. and D. McKay, *Neuropsychology of obsessive-compulsive disorder: a review and treatment implications.* Clinical Psychology Review, 2003. **23**: p. 95-117.
23. Tukel, R., et al., *Neuropsychological function in obsessive-compulsive disorder.* Comprehensive Psychiatry, 2012. **53**: p. 167-175.
24. Samuels, J., et al., *An investigation of doubt in obsessive-compulsive disorder.* Comprehensive Psychiatry, 2017. **75**: p. 117-124.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

25. Ezrati, O., J. Friedman, and R. Dar, *Attenuation of access to internal states in high obsessive-compulsive individuals might increase susceptibility to false feedback: Evidence from a visuo-motor hand reaching task.* Journal of Behaviour Therapy and Experimental Psychiatry, 2019. **65**.
26. Lazarov, A., et al., *Obsessive-compulsive tendencies may be associated with attenuated access to internal states: Evidence from a biofeedback-aided muscle tensing task.* Consciousness and Cognition, 2012. **21**: p. 1401-1409.
27. Lazarov, A., et al., *Seeking proxies for internal states in obsessive-compulsive disorder.* Journal of Abnormal Psychology, 2014. **123**(4): p. 695-704.
28. Foa, E.B., et al., *The Obsessive-Compulsive Inventory: Development and validation of a short version.* Psychological Assessment, 2002. **14**: p. 485-496.
29. Rapp, A.M., et al., *Evidence-based assessment of Obsessive-Compulsive Disorder.* Journal of Central Nervous System Disease, 2016: p. 13-29.
30. Hajcak, G., et al., *Psychometric properties of the OCI-R in a college sample.* Behaviour Research and Therapy, 2004. **42**: p. 115-123.
31. Roberts, M.E. and M.S. Wilson, *Factor structure and response bias of the Obsessive-Compulsive Inventory-Revised (OCI-R) in a female undergraduate sample from New Zealand.* Journal of Psychology, 2008. **37**(2): p. 2-7.
32. Obsessive Compulsive Cognitions Working Group, *Psychometric validation of the obsessive belief questionnaire and interpreation of intrusion inventory-Part 2: Factor analyses and testing of a brief version.* Behaviour Research and Therapy, 2005. **43**: p. 1527-1542.
33. Myers, S.G., P.L. Fisher, and A. Wells, *Belief domains of the Obsessive Beliefs Questionnaire-44 (OBQ-44) and their specific relationship with obsessive-compulsive symptoms.* Journal of Anxiety Disorders, 2008. **22**: p. 475-484.
34. Tardif, H., C. Arnold, and K. Eager, *Establishment of the Australian electronic persistent pain outcomes collaboration.* Pain Medicine, 2017. **18**: p. 1007-1018.
35. Wollongong, U.o. *Electronic Persistent Pain Outcomes Collaboration*. 2019 02/11/2019; Available from: https://ahsri.uow.edu.au/eppoc/index.html.
36. Nicholas, M.K., *The pain self-efficacy questionnaire: Taking pain into account.* European Journal of Pain, 2007. **11**: p. 153-163.
37. Sullivan, M.J.L., S.R. Bishop, and J. Pivik, *The pain catastrophizing scale: Development and validation.* Psychological Assessment, 1995. **7**(4): p. 524-532.
38. Osman, A., et al., *The depression anxiety stress scales-21 (DASS-21): Further examination of dimensions, scale reliability, and correlates.* Journal of Clinical Psychology, 2012. **68**(12): p. 1322-1338.
39. Wood, B.M., et al., *The utility of the short version of the Depression Anxiety Stress SCales (DASS-21) in elderly patients with persistent pain: Does age make a difference?* Pain Medicine, 2010. **11**(12): p. 1780-1790.
40. Smith, J.A. and M. Osborn, *Interpretative Phenomenological Analysis*, in *Qualitative Psychology: A Practical Guide to Research Methods* J.A. Smith, Editor. 2015, SAGE: Los Angeles. p. 25-52.

Author contributions

CS and ES were involved in the conception of the study. CS, ES, CB, and JW contributed to the study design. CS prepared the application for ethical approval with input from ES, CB and JW. CS wrote all programme components. All authors reviewed and critiqued the manuscript and approved the final version.

Funding statement

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests statement

All authors have completed the ICMJE uniform disclosure at *www.icmje.org/coi_disclosure.pdf* and declare: no support from any organization for the submitted work; CS is employed on a full-time basis with *Habit Health*; no other relationships or activities that could appear to have influenced the submitted work.

Word Count

3091

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

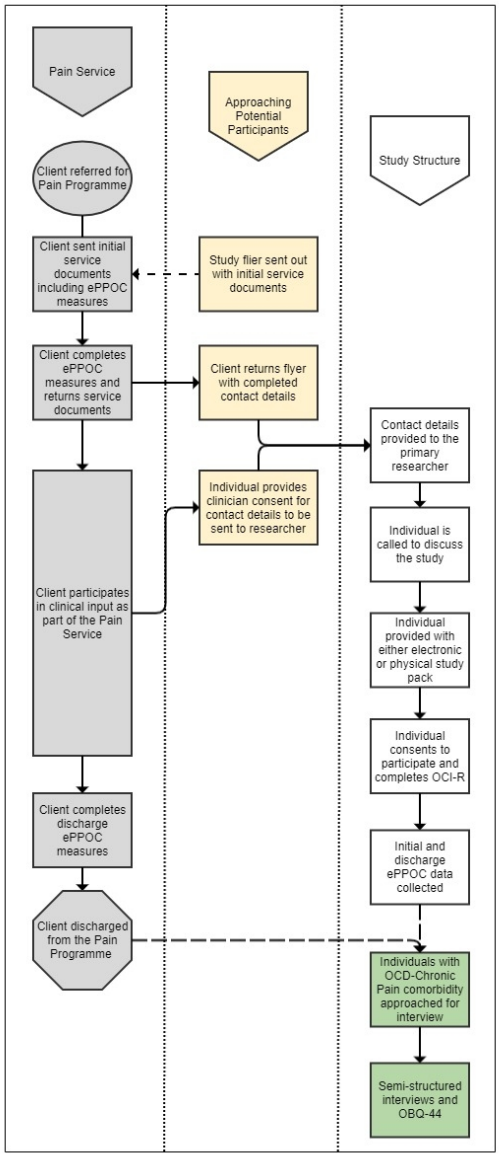

Figure 1: Study structure

285x429mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

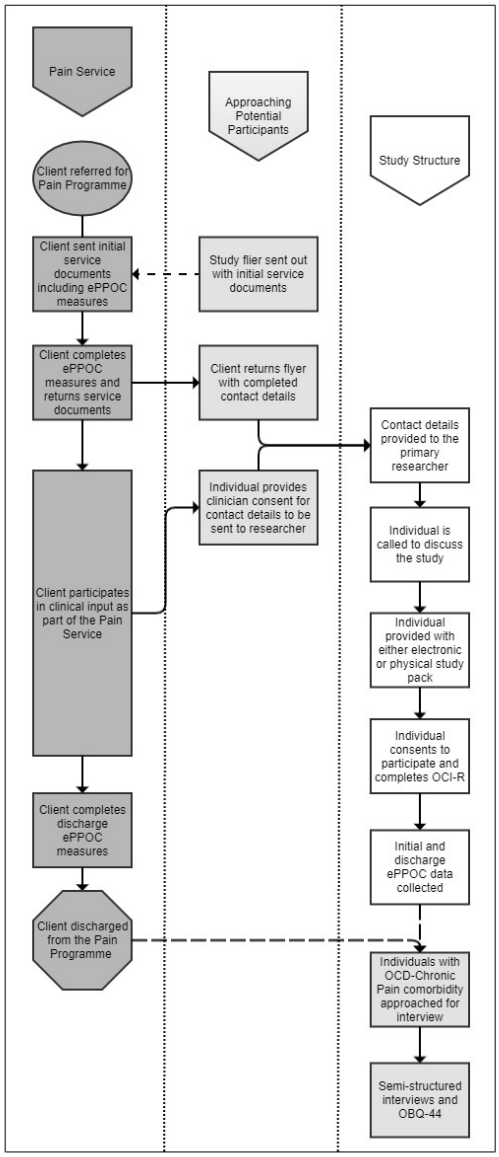

Figure 1: Study structure (Mono Image)

285x429mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2,3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3,4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3,4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5,6
Bias	9	Describe any efforts to address potential sources of bias	2,4
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5,6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

For peer review only

http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

bmjopen-2021-052288 on 13 August 2021. Downloaded from

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

For peer review only

bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

BMJ Open

Protocol for a mixed-method cohort study investigating the prevalence and impact of Obsessive-Compulsive Disorder (OCD) in Chronic Pain rehabilitation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-052288.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Jun-2021
Complete List of Authors:	Sloley, Chad; University of Otago, Department of Anaesthesia Shipton, Edward A.; University of Otago, Department of Anaesthesia Bell, Caroline; University of Otago, Department of Psychological Medicine Williman, Jonathan; University of Otago, Department of Population Health
Primary Subject Heading:	Anaesthesia
Secondary Subject Heading:	Mental health
Keywords:	Pain management < ANAESTHETICS, Adult psychiatry < PSYCHIATRY, PAIN MANAGEMENT

SCHOLARONE™
Manuscripts

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Title

Protocol for a mixed-method cohort study investigating the prevalence and impact of Obsessive-Compulsive Disorder (OCD) in Chronic Pain rehabilitation

Chad Sloley[1], Edward A. Shipton[1], Caroline J. Bell[2], Jonathan A. Williman[3]

1. Department of Anaesthesia, University of Otago, Christchurch, New Zealand.
2. Department of Psychological Medicine, University of Otago, Christchurch, New Zealand.
3. Department of Population Health, University of Otago, Christchurch, New Zealand.

Correspondence to Chad Sloley; chad.sloley@postgrad.otago.ac.nz

Keywords: Chronic Pain; Obsessive-Compulsive Disorder; Rehabilitation

Abstract

Introduction

While there is considerable and growing research in the individual fields of Obsessive-Compulsive Disorder (OCD) and Chronic Pain, focused research into their potential association remains limited. By exploring this potential association, better theoretical understanding of and better therapeutic approaches to chronic pain management could be developed. The study's aim is to explore the prevalence and impact of Obsessions-Compulsions on the experience and rehabilitation of Chronic Pain amongst individuals attending different branches of a New Zealand Pain Service.

Methods and analysis

This is a cohort study using well validated questionnaires and semi-structured interviews. Participants will be recruited through Community Pain Services from a private rehabilitation-focused company with branches across New Zealand. Participants will complete an OCD screening measure (Obsessive Compulsive Inventory-Revised [OCI-R]). These results will be used to compare results from the Specialist Pain Services benchmarking electronic Persistent Pain Outcomes Collaboration (ePPOC) measure sets, at both participant intake and at completion of each Pain Service programme. Prevalence rates of OCD caseness from the OCI-R will be estimated with 95% Confidence Interval (CI). Generalised linear regression models will be used to explore differences in pain baseline and outcome factors between those with high versus low Obsessive-Compulsive symptoms.

Semi-structured interviews, assessed through Interpretative Phenomenological Analysis (IPA), will be used to provide information on lived experiences of individuals with comorbid chronic pain and OCD. This will be supported through the administration of an Obsessive Beliefs Questionnaire (OBQ-44).

Ethics and dissemination

Ethical approval has been obtained from the Health and Disability Ethics Committee (HDEC20/CEN/82). Study results will be disseminated at professional conferences and in peer-reviewed journals. A lay summary of findings will be provided to requesting participants or through attendance at a local hui (gathering).

For peer review only

Article Summary

Strengths and limitations of this study

- This is the first study to directly explore prevalence, impact, and experience of Obsessive-Compulsive symptoms on Chronic Pain rehabilitation.
- By using a mixed method design the qualitative component will provide rich information, whereas the quantitative component will help provide generalisable estimates of parameters of interest.
- Use of an OCD screening measure limits the burden on potential participants, already dealing with the demands of involvement in Pain Services, and it encourages greater participation. However, the nature of the information collected via this method is limited as compared to the use of a clinical interview.
- Resource and practical constraints have led to the exclusion of tertiary level Pain Services, which limits the inclusion of a certain subset of Chronic Pain sufferers attending a Pain Service.
- Response bias considerations associated with a cohort study design.

Introduction

Chronic or persistent, non-cancer pain refers to a heterogeneous group of clinical conditions, in which pain persists or recurs for longer than 3 months [1]. It represents an important consideration in the New Zealand public health system. A recent national survey (2017/2018 New Zealand Health Survey) reported that 19.7% of the population, or an estimated 770,000 adults, suffer from chronic pain [2]. While historical views of chronic pain have been predominantly biomedical in focus, it is increasingly recognised that complex interplays between biological, psychological, socio-cultural, and economic factors underlie the development and maintenance of chronic pain [3]. This emphasises the importance of reviewing potential contributing factors as a way of both furthering conceptual understandings as well as supporting effective clinical interventions. Within this framework, a growing body of research is exploring the role of psychopathology in the transition of acute pain into acute persistent pain and subsequently into chronic (or persistent) pain states as well as its role in acting as a significant barrier to intervention or recovery [4].

Obsessive-Compulsive Disorder (OCD) is a neuropsychiatric condition, which is heterogeneous and often chronic that affects approximately 1% to 3% of the general population [5-7]. It is a cross-cultural and cross-socioeconomic phenomenon [8]. Geographical and cultural factors contribute to variability in symptom presentation and frequency [9]. At its core, it features persistent obsessions and/or compulsions [10, 11]. Obsessions are defined as “recurrent and persistent thoughts, urges, or images that are experienced as intrusive and unwanted”. Compulsions are defined as “repetitive behaviors or mental acts that an individual feels driven to perform in response to an obsession, or according to rules that must be applied rigidly” [10].

While there is considerable and growing research in OCD, there is limited investigation into its association with chronic pain. While included as part of larger studies on psychopathology comorbidity, to the best of the researchers’ knowledge there has only been one direct study into the prevalence of OCD in chronic pain. This reported a high lifetime prevalence of OCD in a sample of those suffering from chronic pain [12].

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

In addition, there has been no direct investigation into the potential impact that OCD has on chronic pain and its rehabilitative processes or outcomes.

However, a review of literature pertaining to OCD indicates the presence of various aspects that have possible important implications for chronic pain sufferers. In particular, OCD is associated with high rates of diagnostic comorbidity [13]. It overlaps with illness anxiety [14], and is linked to significant disability and difficulty [6], including increased suicidal risk [15]. Its symptoms are associated with poorer self-reported physical health status [16] and reduced quality of life[17]. It is associated with a tendency towards threat overestimation and heightened appraisal of potential negative outcomes [18, 19]. It holds a significant association with cognitive rumination, with the latter noted to contribute to pain catastrophisation as well [20, 21]. It is associated with impaired functioning of certain neurobiological pathways, including various cortical and subcortical structures, that are linked with complex processes, such as evaluation, affect regulation, reward-based decision making, and goal-directed behaviour [22, 23]. Dysfunction of dorsal-striatal-centric circuitry is seen to contribute to compulsive behaviour, but is also implicated in learning habits and in addiction [24]. These have some possible important repercussions to consider with regard to Chronic Pain where Dopamine and reward/aversion systems are understood to be involved in the pain/analgesia processes, and where the presence of pain/analgesia can alter levels of activity of the reward system [25]. In turn, Dopamine is also implicated in striatal functioning [24], and is conveyed as an important modulator in habit leaning [26]. OCD is also associated with deficits in organizational skills that lead to impairment across learning strategy use and memory recall [27-29], which may have important implications for how individuals suffering from Chronic Pain engage with rehabilitation-directed information and strategies. Research also points to subjective doubt being an important feature of OCD [30], with a nascent OCD model postulating an attenuated access to internal states (such as emotions, bodily sensations, muscle tension, and proprioception) [31-33].

Chronic pain and OCD are complex conditions linked with significant disability and distress. In consideration of the aspects and processes highlighted above, further study into the association and impact of OCD on chronic pain and its rehabilitation is merited.

Objectives

The overall aim of this study is to explore the prevalence and impact of Obsessive-Compulsive symptoms amongst Chronic Pain sufferers attending Pain Services in New Zealand. We hypothesise that OCD displays a significantly higher prevalence rate among Chronic Pain sufferers, than the general population. We also hypothesise that it is associated with greater complexity and intensity of pain experiences, greater life interference; greater requirement for clinical input through Pain Service programmes, and worse programme outcomes.

To test these hypotheses, this study will:

1) Determine the prevalence of participants with OCD caseness from the OCI-R attending an active Pain Service programme and contrast this with the rates of general population estimates for OCD as derived from previous literature.

2) Determine the degree to which Obsessive-Compulsive symptoms are associated with pain complexity, pain intensity, and daily life interference of individuals that leads into a Pain Service programme.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

3) Determine the degree to which Obsessive-Compulsive symptoms are associated with greater need for clinical input and pain outcomes through Pain Service programmes.

4) Explore how individuals make sense of their experiences of co-occurring Chronic Pain and OCD, and how their accounts of obsessions and compulsions contribute to their pain rehabilitation experiences.

Methods and analysis

Study design

This is a cohort study using questionnaires and semi-structured interviews with participants recruited through Community Pain Services from a rehabilitation-focused company, *Habit Health*. *Habit Health* is one of New Zealand's largest private integrated health, fitness and physiotherapy rehabilitation provider. It incorporates an established Community Pain Service, and comprising seven distinct units across New Zealand. New Zealand holds a relatively unique health system approach, where a government entity, the Accident Compensation Corporation (ACC), acts as the country's sole accident insurance for all work and non-work related injuries for its populace. As part of its mandate, ACC partners with registered health professionals and private rehabilitation companies, such as Habit Health, in order to provide rehabilitative services. Within this framework, the Habit Health Community Pain Service caters to both private and non-private patient referrals.

Inclusion criteria for the study include all individuals over the age of 18 years involved in an active Community Pain Service programme, and who have sufficient English Language proficiency to independently complete report measures.

Pain Services in New Zealand are specialist multidisciplinary services with a core team comprising a Physician, Physiotherapist, Psychologist, and Occupational Therapist. At a community level, Pain Service programmes consist of two stages, with individuals with Chronic Pain issues referred into the first stage. The second stage expands and builds upon services delivered in the first stage, and includes mandatory medical practitioner input and medication review. Progression into a second stage depends on individual needs, complexity of barriers to pain rehabilitation, and resource requirements. As part of standard service practices, *Electronic Persistent Pain Outcome Collaboration* (ePPOC) data sets are administered at intake and on completion (either at stage one or two depending on the individual's service progression) points of individual Pain Service programmes.

Recruitment will occur over a period of 22 months, spanning June 2020 to April 2022. A study flyer, including the primary researcher's (CS) contact details, will be included with initial service documents sent to individuals starting at a Pain Service (Figure 1). Pain Service Key Workers (clinicians performing the initial assessment and managing the overall programme) will also approach already enrolled, and eligible, service clients to inform them of the study and to attain verbal consent for their contact details to be passed on to the primary researcher. The primary researcher would then contact, or be contacted by, assenting individuals to discuss the study details and confirm eligibility. Eligible clients will be emailed a link via *REDCap* web-based survey to complete informed consent and baseline measures including the Obsessive Compulsive Inventory-Revised (OCI-R). Individuals unable to access the online survey will be provided with a physical study pack comprising the study information sheet, the informed consent form, an OCI-R measure, and a postage-paid return envelope. The primary researcher will follow-up on surveys

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

where there has been no response within 1 to 2 weeks of the survey initially being sent. This will occur via either email or telephone call.

A consented participant's ePPOC data will be collected at intake and completion points for their Pain Service as well.

Through purposeful sampling, a small number of individuals indicating OCD–Chronic Pain comorbidity, (either by prior clinical diagnosis or as supported by high OCI-R and ePPOC results) will be approached to participate in a semi-structured interview. This interview will be conducted following the completion of any active Community Pain Service, and will be focused on exploring the experiences of their conditions and pain rehabilitation. Interviewees will also complete an obsession directed self-report measure (Obsessive Beliefs Questionnaire 44 [OBQ-44]) to assist in providing clinical understanding of participant experiences regarding obsessions.

Figure 1: Study structure

Measures

Obsessive Compulsive Inventory-Revised (OCI-R)

The OCI-R is an 18 item self-report measure assessing characteristic symptoms of OCD for their prevalence over the past month [34]. Items are rated on a 5-point Likert scale, ranging from '*0 (Not at all)*' to '*4 (Extremely)*, with higher scores indicating a greater presence of OCD associated symptoms. A total score of 21 is suggested as an optimal cut-off score for distinguishing the presence of OCD [34], which will be utilized by this study to indicate 'caseness' in the absence of a clinician administered diagnostic assessment. This self-report measure holds good internal consistency, good to adequate short-term test-retest reliability, and fair convergence with clinician-rated measures of OCD [35]. Its use as a screening and research tool has been validated in both clinical [34] and non-clinical samples [36] as well as within the New Zealand context [37].

Obsessive Beliefs Questionnaire 44 (OBQ-44). The OBQ-44 is a 44-item questionnaire, assessing across three factors hypothesized to be associated with obsessive-compulsive symptoms and worry. They include: 1) Responsibility and threat estimation; 2) Perfectionism and intolerance for uncertainty; and 3) Importance and control of thoughts [38]. This questionnaire displays good internal consistency with a sample of both clinical and non-clinical participants [38], and correlates with obsessive-compulsive symptoms [39].

Electronic Persistent Pain Outcome Collaboration (ePPOC)

ePPOC incorporates a broad range of patient-reported data items and assessment tools to measure various outcomes across physical, functional, and psychological aspects from Specialist Pain Services In Australia and New Zealand [40, 41]. These are completed at intake, completion, and at 3 to 6 months post-completion of an individual Pain Service by service facilitators. Information is electronically stored. Information contributes to locally-held and internationally-held rehabilitation service outcomes

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

databases. The information and measures, forming part of the ePPOC set, that will be accessed for the purposes of this study include:

Patient characteristics: Date of birth; Gender; Ethnicity; Comorbidities.

Medication use: Number of major drug groups.

Brief Pain Inventory (BPI): Measure assessing the location of pain, its severity, and its interference in daily activities.

Pain Self-Efficacy Questionnaire (PSEQ): A client-reported measure assessing the confidence an individual has in order to perform a range of activities, despite the presence of pain [42]. Ten items are rated on a scale from 0 to 6, where 0 = "not at all confident" and 6 = "completely confident".

Pain Catastrophizing Scale (PCS): A client-reported measure assessing the presence of pain-related thoughts and cognitions that may contribute to more intense pain, increased disability, and emotional distress [43]. Thirteen items are rated on a scale from 0 to 4, where 0 = "not at all" and 4 = "all the time". It provides an overall score as well as subscale scores associated with rumination, magnification, and helplessness.

Depression Anxiety Stress Scale-21 (DASS-21): A client-report measure of the emotional states of depression, anxiety, and stress, appropriate for use in both clinical and research settings [44]. Twenty-one statements are rated on a 4-point scale as to how much they have applied over the past week. It is indicated as a valid and reliable measure with applicability to the persistent pain population [45].

Healthcare utilization: Pain-related utilization of General Practitioner, Specialist, Allied health services, presentations to Emergency department, admission to Hospital, and diagnostic tests undertaken in the past three months.

Data Analysis

OCI-R scores for each participant will be analysed. To answer the question of prevalence rate, an OCI-R total score of 21 (a categorical variable) will be set as a cutoff mark to dichotomize between OCD caseness presence and non-presence. The OCD caseness prevalence rate of participants will be estimated with 95% 'Wilson' binomial confidence intervals (CI), and rates will be considered greater than the general population if the lower bound of the 95% CI exceeds 3%. Three per cent was chosen as it denotes the upper limit of OCD prevalence rates identified amongst general population studies.

Associations between Obsessive-Compulsive symptoms and experiences of chronic pain will be explored through generalized linear regression models, with individuals' OCI-R total scores (a continuous variable)included as the explanatory independent variable. Outcomes of interest include those measured via the ePPOC at baseline; pain catastrophizing (PCS), pain intensity and interference ratings (BPI), pain self-efficacy (PSEQ), and length of time that pain has been present. Reported change in pain and in physical abilities between service entry and discharge will be modelled without adjustment for baseline differences. The proportion of participants who transition into the Pain Service stage 2 will be determined, and compared by OCI-R using log-binomial or logistic regression models.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Count outcome variables will be analysed through use of Poisson regression model. These will include: Number of times seeing a General Practitioner (GP), and; Number of times consulting health professionals prior to the start of the Pain Service.

Non-linear associations between OCI-R and outcomes variables will be modeled using restricted cubic splines. In addition to univariable models, multivariable models will be run with, and adjustment for, potential confounders. The study identifies various confounding variables include: Age; Gender; Ethnicity; Depression (DASS-21); and Medication use (Benzodiazepines and Opioids).

All planned analysis will be presented together, and interpretation of analysis will depend on consistency of results across all measures rather than identifying individual measures that do, or do not, meet certain p value thresholds.

Sample size

The sample size is constrained by resource limitations and the number of patients presenting to Community Pain Services in New Zealand. Based on current projections of enrolment, we estimate we will be able to enroll 150 participants during the study recruitment period. This sample size will allow us to estimate the prevalence of OCD caseness with a 95% confidence interval of approximately 10 percentage points or less in width.

There is currently little information as to what the prevalence of OCD caseness might be in this patient population. Assuming it is 8% or higher, it would provide 80% power to rule out a prevalence of 3% or less.

The absolute number of patients presenting with OCD caseness is likely to be too small to include as a binary variables in logistic regression models, but associations between explanatory variables and Obsessive-Compulsive symptoms will be able to be explored using individuals' OCI-R total scores in linear regression models [46].

Qualitative Analysis

The qualitative component for this study will be performed from a constructivist point of view using an interpretative phenomenological epistemology. In recognizing that both OCD and Chronic Pain conditions are associated with significant complexity, situational impact, and individual/subjective meaning, this study will look to explore how individuals who have these conditions co-occurring make sense of their experiences. It will also look at how subjective accounts of obsessions and compulsions contribute to pain rehabilitation experiences.

Semi-structured, one-on-one, interviews will be conducted with participants (purposeful sampling) indicating OC-Chronic Pain comorbidity (either by clinical diagnosis or as supported by high OCI-R and ePPOC results), as noted through the questionnaire component of the study. These interviews will be conducted following completion of any active Community Pain Service.

An Interpretative Phenomenological Analysis (IPA) approach will be employed to guide information collection and analyses. All interviews will be audio-recorded, transcribed verbatim, and anonymized. The

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

primary investigator (CS), who is a registered Clinical Psychologist and experienced with both Chronic Pain/Rehabilitation and mental health clinical assessment and interventional work, will conduct all the interviews. The primary investigator will also undertake detailed case-by-case analyses of the individual transcripts to identify *patterns of meaning*/themes and formulate towards narrative accounts. Other members of the research team will review these accounts to help support validity of the analyses. Interviews will look to be conducted with a sample of 3 to 6 participants. This number was based on: 1) The aim of this component of the study being an in-depth, rich exploration of individual meaning and experiences rather than on generalizations; 2) Consideration of potential occurrences of suitable participants given estimates of OCD population rates and the study's overall projected sample size; 3) Researcher time and resource availability. This sample size fits appropriately within an IPA approach which emphsizes focus on 'lived experiences' and comprehensively exploring personal perceptions and accounts [47, 48].

Interviewees' will also complete an obsession directed self-report questionnaire (OBQ-44). Interviewee responses to this questionnaire will be qualitatively interpreted to assist in providing clinical understanding of participant experiences of obsessions.

Patient and public involvement

No patient or public involvement occurred in the design and planning of the study.

Ethics and dissemination

This study was granted ethical approval by the New Zealand Health and Disability Ethics Committees (20/CEN/82) and has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000758808). Approval was also attained from a private rehabilitation company, *Habit Health*, to assist in approaching individuals for participation in the study. Participation in the study does not interfere with typical care that individuals receive through their respective Pain Services. Participants will be able to opt-in to the study and will be able to withdraw at any time. The study will look to protect participant anonymity through the use of number coding methods. All information will be securely held. The primary researcher will look to debrief participants should any emotional reactions elicited from completing the surveys occur. In the unlikely event of any safety related concerns being noted, participants will either be referred back to their treating clinicians for further input/care or alternatively be directed to relevant emergency care facilities/entities. Attempts will be made to support culturally appropriate engagement, particularly in relation to the semi-structured interview component of the study. As part of this, procedures and approaches surrounding the interview process (e.g. venue, greetings, opening and closing customs) will be developed to be responsive to the cultural needs of the individual.

No monetary, or other, incentives will be offered to individuals for their participation. The only anticipated direct costs to participants will relate to travel expenses for those involved in the semi-structured interviews.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals. In addition, a lay summary of the study findings will be sent to all study participants who wish to access these and/or through attendance at a local hui (gathering).

References

1. International Classification of Diseases 11 [ICD-11]. *MG30 Chronic Pain*. 2019 14/07/2019]; Available from: https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/1581976053.
2. Healthinfo. *Overview of persistent pain*. 2018 [cited 2019 5th May]; Available from: https://www.healthinfo.org.nz/index.htm?Chronic-pain.htm.
3. Edwards, R.R., et al., *The Role of Psychosocial Processes in the Development and Maintenance of Chronic Pain.* The Journal of Pain, 2016. **17**(9): p. T70-T92.
4. Gatchel, R.J., *Psychological Disorders and Chronic Pain: Cause-and-Effect Relationships*, in *Psychological Approaches to Pain Management: A Practitioner's Handbook*, R.J.T. Gatchel, D.C., Editor. 1996, The Guilford Press: New York.
5. Fornaro, M., et al., *Obsessive-compulsive disorder and related disorders: a comprehensive survey.* Annals of General Psychiatry, 2009. **8**(13): p. 13.
6. Fullana, M.A., et al., *Obsessions and compulsions in the community: Prevalnce, interference, help-seeking, developmental stability, and co-occurring psychiatric conditions.* Am J Psychiatry, 2009. **166**(3).
7. Ruscio, A.M., et al., *The epidemiology of obsessive-compulsive disorder in the national comorbidity survey replication.* Molecular Psychiatry, 2010. **15**: p. 53-63.
8. Williams, M. and A. Steever, *Cultural Manifestations of Obsessive-Compulsive Disorder*, in *Obsessive-Compulsive Disorder: Etiology, Phenomenology and Treatment*, C.W. Lack, Editor. 2015, Ginger Prince Publications. p. 63-84.
9. Guzick, A.G., et al., *Diagnostic Description and Prevalence*, in *The Wiley Handbook of Obsessive Compulsive Disorders*, J.S. Abramowitz, D. McKay, and E.A. Storch, Editors. 2017, John Wiley & Sons Ltd: Chichester, UK. p. 24-43.
10. American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*. Fifth Edition ed. 2013, Arlington, VA: American Psychiatric Association.
11. International Classification of Diseases 11 [ICD-11]. *6B20 Obsessive-Compulsive Disorder*. 2020 11/03/2021]; Available from: https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f1582741816.
12. Mehraban, A., et al., *The High Prevalence of Obsessive-Compulsive Disorder in Patients with Chronic Pain* Iran J Psychiatry, 2014. **9**(4): p. 203-208.
13. Calamari, J.E., et al., *Phenomenology and Epidemiology of Obsessive Compulsive Disorder*, in *The Oxford handbbook of Obsessive Compulsive and Spectrum Disorders*, G. Steketee, Editor. 2012, Oxford University Press: New York. p. 11-47.
14. Reuman, L., et al., *Predictors of illness anxiety symoptoms in patients with obsessive compulsive disorder.* Psychiatry Research, 2017. **256**: p. 417-422.
15. Singh, H., S. Kashyap, and A. Sivakanthan, *An overview of obsessive compulsive disorder and suicidal behaviour.* Open Journal of Psychiatry & Allied Sciences, 2018. **9**: p. 92-97.
16. Jordan, K.D. and A. Okifuji, *Anxiety Disorders: Differential Diagnosis and Their relationship to Chronic Pain.* Journal of Pain & Palliative Care Pharmacotherapy, 2011. **25**(3): p. 231-245.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

17. Huppert, J.D., et al., *Quality of life and functional impairment in obsessive-compulsive disorder: A comparison of patients with and without comorbidity, patients in remission, and healthy controls.* Depression and Anxiety, 2009. **26**: p. 39-45.
18. Admon, R., et al., *Functional and structural neural indices of risk aversion in obessive-compulsive disorder (OCD).* Psychiatry Research: Neuroimaging, 2012. **203**: p. 207-213.
19. Casado, Y., et al., *Emotional processing in obsessive-compulsive disorder.* Journal of Anxiety Disorders, 2011. **25**: p. 1068-1071.
20. Watkins, E.R., *Depressive Rumination and Co-Morbidity: Evidence for Brooding as a Transdiagnostic Process.* J Rat-Emo Cognitive-Behav Ther, 2009. **27**: p. 160-175.
21. Sullivan, M.J.L., W.M. Rodgers, and I. Kirsch, *Catastrophizing, depression and expectancies for pain and emotional distress.* Pain, 2001. **91**: p. 147-154.
22. Calza, J., et al., *Altered Cortico-Striatal Functional Connectivity During Resting State in Obsessive-Compulsive Disorder.* Frontiers in Psychiatry, 2019. **10**.
23. Fettes, P., L. Schulze, and J. Downar, *Cortico-Striatal-Thalamic Loop Circuits of the Orbitofrontal Cortex: Promising Therapeutic Targets in Psychiatric Illness.* Front. Syst. Neurosci. , 2017. **11**(25).
24. Lipton, D.M., B.J. Gonzales, and A. Citri, *Dorsal Striatal Circuits for Habits, Compulsions and Addictions.* Front. Syst. Neurosci., 2019. **13**(28).
25. Mlost, J., A. Wasik, and K. Starowicz, *Role of endocannabinoid system in dopamine signalling within the reward circuits affected by chronic pain.* Pharmacological Research, 2019. **143**: p. 40-47.
26. Graybiel, A.M., *Habits, Rituals, and the Evaluative Brain.* Annu. Rev. Neurosci, 2008. **31**: p. 359-387.
27. Larson, M.J. and A. Clawson, *A Critical Review of Neuropsychological Functioning and Heterogeneity in Individuals with Obsessive-Compulsive Disorder*, in *The Wiley Handbook of Obsessive Compulsive Disorders*, J.S. Abramowitz, D. McKay, and E.A. Storch, Editors. 2017, John Wiley & Sons Ltd: Chichester, UK. p. 155-175.
28. Greisberg, S. and D. McKay, *Neuropsychology of obsessive-compulsive disorder: a review and treatment implications.* Clinical Psychology Review, 2003. **23**: p. 95-117.
29. Tukel, R., et al., *Neuropsychological function in obsessive-compulsive disorder.* Comprehensive Psychiatry, 2012. **53**: p. 167-175.
30. Samuels, J., et al., *An investigation of doubt in obsessive-compulsive disorder.* Comprehensive Psychiatry, 2017. **75**: p. 117-124.
31. Ezrati, O., J. Friedman, and R. Dar, *Attenuation of access to internal states in high obsessive-compulsive individuals might increase susceptibility to false feedback: Evidence from a visuo-motor hand reaching task.* Journal of Behaviour Therapy and Experimental Psychiatry, 2019. **65**.
32. Lazarov, A., et al., *Obsessive-compulsive tendencies may be associated with attenuated access to internal states: Evidence from a biofeedback-aided muscle tensing task.* Consciousness and Cognition, 2012. **21**: p. 1401-1409.
33. Lazarov, A., et al., *Seeking proxies for internal states in obsessive-compulsive disorder.* Journal of Abnormal Psychology, 2014. **123**(4): p. 695-704.
34. Foa, E.B., et al., *The Obsessive-Compulsive Inventory: Development and validation of a short version.* Psychological Assessment, 2002. **14**: p. 485-496.
35. Rapp, A.M., et al., *Evidence-based assessment of Obsessive-Compulsive Disorder.* Journal of Central Nervous System Disease, 2016: p. 13-29.
36. Hajcak, G., et al., *Psychometric properties of the OCI-R in a college sample.* Behaviour Research and Therapy, 2004. **42**: p. 115-123.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

37. Roberts, M.E. and M.S. Wilson, *Factor structure and response bias of the Obsessive-Compulsive Inventory-Revised (OCI-R) in a female undergraduate sample from New Zealand.* Journal of Psychology, 2008. **37**(2): p. 2-7.
38. Obsessive Compulsive Cognitions Working Group, *Psychometric validation of the obsessive belief questionnaire and interpreation of intrusion inventory-Part 2: Factor analyses and testing of a brief version.* Behaviour Research and Therapy, 2005. **43**: p. 1527-1542.
39. Myers, S.G., P.L. Fisher, and A. Wells, *Belief domains of the Obsessive Beliefs Questionnaire-44 (OBQ-44) and their specific relationship with obsessive-compulsive symptoms.* Journal of Anxiety Disorders, 2008. **22**: p. 475-484.
40. Tardif, H., C. Arnold, and K. Eager, *Establishment of the Australian electronic persistent pain outcomes collaboration.* Pain Medicine, 2017. **18**: p. 1007-1018.
41. University of Wollongong. *Electronic Persistent Pain Outcomes Collaboration*. 2019 02/11/2019; Available from: https://ahsri.uow.edu.au/eppoc/index.html.
42. Nicholas, M.K., *The pain self-efficacy questionnaire: Taking pain into account.* European Journal of Pain, 2007. **11**: p. 153-163.
43. Sullivan, M.J.L., S.R. Bishop, and J. Pivik, *The pain catastrophizing scale: Development and validation.* Psychological Assessment, 1995. **7**(4): p. 524-532.
44. Osman, A., et al., *The depression anxiety stress scales-21 (DASS-21): Further examination of dimensions, scale reliability, and correlates.* Journal of Clinical Psychology, 2012. **68**(12): p. 1322-1338.
45. Wood, B.M., et al., *The utility of the short version of the Depression Anxiety Stress SCales (DASS-21) in elderly patients with persistent pain: Does age make a difference?* Pain Medicine, 2010. **11**(12): p. 1780-1790.
46. Hanley, J.A., *Simple and multiple linear regression: sample size considerations* Journal of Clinical Epidemiology, 2016. **79**: p. 112-119.
47. Alase, A., *The interpretative phenomenological analysis (IPA): A guide to a good research approach.* International Journal of Education & Literacy Studies, 2017. **5**(2): p. 9-19.
48. Smith, J.A. and M. Osborn, *Interpretative Phenomenological Analysis*, in *Qualitative Psychology: A Practical Guide to Research Methods* J.A. Smith, Editor. 2015, SAGE: Los Angeles. p. 25-52.

Author contributions

CS and ES were involved in the conception of the study. CS, ES, CB, and JW contributed to the study design. CS prepared the application for ethical approval with input from ES, CB and JW. CS wrote all programme components. All authors reviewed and critiqued the manuscript and approved the final version.

Funding statement

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests statement

All authors have completed the ICMJE uniform disclosure at *www.icmje.org/coi_disclosure.pdf* and declare: no support from any organization for the submitted work; CS is employed on a full-time basis with *Habit Health*; no other relationships or activities that could appear to have influenced the submitted work.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Word Count

3810

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

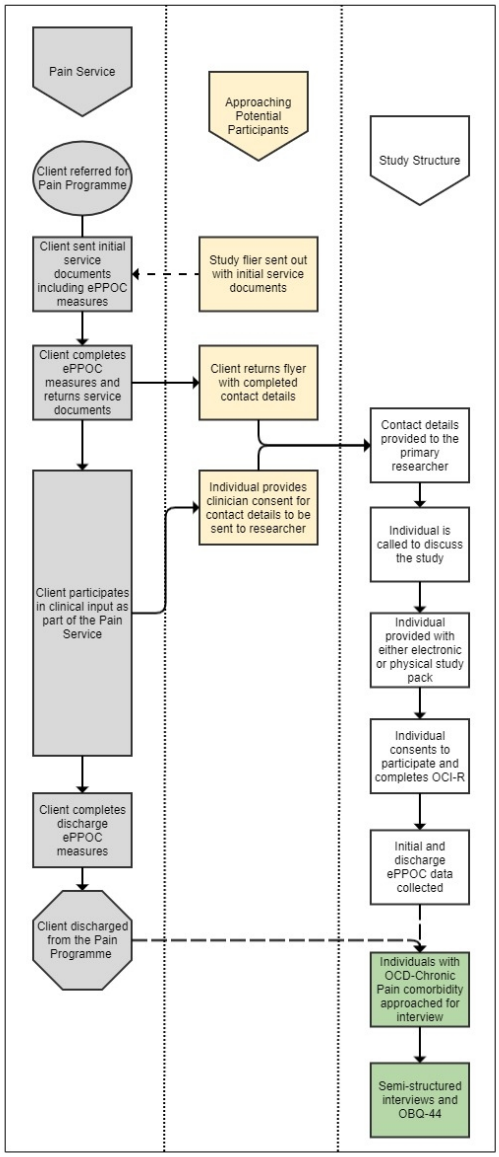

Figure 1: Study structure

285x429mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2,3
Objectives	3	State specific objectives, including any prespecified hypotheses	3,4
Methods			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5,6
Bias	9	Describe any efforts to address potential sources of bias	2,4
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

For peer review only

bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

For peer review only

bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	1
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	2,3
Purpose or research question - Purpose of the study and specific objectives or questions	3,4
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	7
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	7
Context - Setting/site and salient contextual factors; rationale**	3,4
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	5,8
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	8
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	7,8

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	7,8
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	7
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	7
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	7

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	N/A
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	N/A

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	N/A
Limitations - Trustworthiness and limitations of findings	N/A

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	11
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	11

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
DOI: 10.1097/ACM.0000000000000388

For peer review only

BMJ Open: first published as 10.1136/bmjopen-2021-052288 on 13 August 2021. Downloaded from http://bmjopen.bmj.com/ on April 20, 2024 by guest. Protected by copyright.