

BMJ Open Individuals' beliefs about the biopsychosocial factors that contribute to their chronic musculoskeletal pain: protocol for a qualitative study in the UK

Michael Dunn ^{1,2}, Alison B Rushton ³, Andrew Soundy ¹,
Nicola R Heneghan ¹

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¹School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK

²Physiotherapy Outpatients, St George's University Hospitals NHS Foundation Trust, London, UK

³School of Physical Therapy, Western University Faculty of Health Sciences, London, Ontario, Canada

Correspondence to

Michael Dunn;
Michael.Dunn@stgeorges.nhs.uk

ABSTRACT

Introduction Chronic musculoskeletal pain (CMP) is described as pain that persists for longer than 3 months. At present, no research is available that understands why CMP develops and continues from the perspective of the individual. Research is needed to establish if there are any consistent biopsychosocial factors perceived as contributing to CMP and what informs such beliefs. Understanding individual beliefs will inform more effective communication between clinicians and patients about their CMP, as well as informing future research into the epidemiology of CMP. Interpretative phenomenological analysis will be used as a methodological framework as it explores how individuals make sense of their world through personal experiences and perceptions while preserving individual nuance. The aim of this study is to understand individuals' beliefs and perceptions about the biological, psychological and social factors, which contribute to the development and maintenance of their CMP.

Methods and analysis A qualitative study informed by the Consolidated Criteria for Reporting Qualitative Research using interpretative phenomenological analysis and semistructured interviews. A maximum variation purposive sample of 6–12 adults with CMP will be recruited from the general public in the UK. One semistructured interview will be conducted with each participant via an online video platform with interviews transcribed verbatim. The interview schedule (codesigned with expert patients and informed by existing evidence) identifies three domains of important questions; (1) patient beliefs on why they developed and continue to experience CMP; (2) the relationship between their biopsychosocial experiences and CMP; and (3) the origin of their beliefs. Strategies such as 'member checking' will be employed to ensure trustworthiness.

Ethics and dissemination Ethical approval was granted by the Research Ethics Office at the University of Birmingham (reference ERN_21-0813). Informed consent will be obtained from all participants. The study findings will be submitted for publication in a peer-reviewed journal and for presentation at conferences.

INTRODUCTION

Chronic musculoskeletal pain (CMP) is described as primary or secondary pain

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The methods employed for this qualitative study are rigorous, designed using the Consolidated Criteria for Reporting Qualitative Research.
- ⇒ The inclusion of people with all types of chronic musculoskeletal conditions will establish findings pertinent to a great number of stakeholders.
- ⇒ The flexibility of semistructured interviews will ensure topics important to both the researcher and the participant are discussed while interpretative phenomenological analysis will enable the development of rich data entrenched in the lived experiences of the individual.
- ⇒ The use of virtual interviews for research is relatively new and unexplored, and therefore, it is unclear if this is equally as effective as in-person interviews; it is possible that issues such as internet access and technology literacy may negatively impact the virtual interview process.
- ⇒ Although in line with interpretative phenomenological analysis methods, the small sample size may limit the applicability of the study findings.

arising from bones, joints, muscles or related soft tissues lasting longer than 3 months.¹ The National Health Service spent approximately £4.7 billion on treating musculoskeletal conditions in 2015,² a figure which is likely higher now. Despite this, most recent evidence identifies a 43% current prevalence of CMP across adults in the UK,³ which is steadily rising,⁴ and that 79%–92% of those with CMP continue to experience pain up to 12 years later.^{5–7} This suggests that further research into CMP is required.

Pain is experienced due to a complex interaction between the biological and psychological systems of the body which are influenced by social factors.^{8–10} This interaction can lead to a continued or repeated experience of musculoskeletal pain—CMP—despite no evidence of actual or potential damage to

musculoskeletal structures.^{8 9 11 12} These altered or sensitised mechanisms of musculoskeletal pain have been defined as ‘nociplastic pain’,¹³ and current research shows that beliefs about pain may influence the experience and development of CMP.^{14–16}

A recent Cochrane review of both qualitative and quantitative research concluded that patient beliefs about their musculoskeletal pain shapes their attitudes and behaviours on how to manage it.¹⁷ In addition, studies demonstrate that a patient’s beliefs in the efficacy of an intervention highly correlates with positive outcomes; a finding which is consistent across multiple interventions for CMP.^{18–22} Biomedical approaches currently dominate management of musculoskeletal disorders (eg, imaging, blood tests, physical assessments, pharmaceutical management, manual therapy and surgeries),²³ which may influence individuals’ beliefs toward biological factors being the main cause of CMP. This in turn may reduce the likelihood of successful biopsychosocial management if individuals subsequently do not hold these same beliefs for psychosocial factors. However, this is not currently well understood. Furthering comprehension of individuals’ beliefs on the causes of CMP and where these beliefs originate will provide the opportunity to address unhelpful beliefs and ensure that management approaches are well aligned, thus improving the likelihood of successful management. This will benefit patients, clinicians and researchers.

Furthermore, early risk stratification for disease and proactive management is a strategy that works well for management of other chronic diseases such as heart disease²⁴ and diabetes,²⁵ and therefore, may be a useful strategy for improving management of CMP. However, awareness and understanding of the epidemiology of the disease is required for this to be effective. Many biopsychosocial risk factors for development of CMP are identified in existing research with many epidemiological cohort studies synthesised through several systematic reviews^{26–28} and an in-progress umbrella review.²⁹ Qualitative research exploring patient beliefs around why they develop and continue to experience CMP may identify risk factors for its development, which are not amenable to detection through quantitative methods.^{30 31} Earlier identification of individuals at risk of CMP will provide the opportunity for proactive management as practised for other chronic diseases.

To better manage CMP, a thorough understanding of the biopsychosocial factors that may contribute to its development and prolonged presence is needed. Existing research has explored this through both quantitative^{26–28} and qualitative methods.^{32–34} However, this research tends to be specific to a particular musculoskeletal condition such as lower back pain. To the best of the authors’ knowledge, there is no qualitative research that includes participants with all forms of CMP investigating why they believe they developed and continue to experience CMP. Those with lower back pain may demonstrate beliefs such as damage to and poor healing of the spine³⁴ and

these beliefs may contribute to development of chronic lower back pain.²⁶ Similar beliefs may exist in those with any form of CMP and therefore qualitative research is required to explore this further.

These are complex factors which are influenced by a variety of individual aspects such as race, ethnicity and culture,³⁵ and therefore, this needs to be explored from individual perspectives. Qualitative methods are useful in healthcare research, particularly in the discovery of emerging themes or phenomena which are not amenable to quantitative methods,³⁶ and therefore, are well placed to investigate this further. Interpretative phenomenological analysis methods may be particularly useful as this will observe in detail how participants make sense of their world by exploring personal experiences and perceptions, thus enabling the preservation of individual nuance and meaning inherent to the participants experience of CMP³⁷ which is often lost in larger data sets.³⁸

Aims and objectives

The aim of the study is to understand patients’ beliefs and perceptions on the biological, psychological and social factors which contribute to the development and continued experience of CMP. The objectives are:

1. To explore individuals’ beliefs on the factors that contributed to development and maintenance of their CMP.
2. To explore the biological, psychological and social experiences of individuals and whether they believe there to be any contributory relationship to the development and continued experience of their CMP.
3. To explore where individuals’ beliefs originate.

METHODS AND ANALYSIS

Design and theoretical framework

This qualitative study has been designed using the Consolidated Criteria for Reporting Qualitative Research.³⁹ Research methods are underpinned by interpretive phenomenological analysis (IPA) and data will be collected using semistructured interviews.

IPA is situated as a minimal hermeneutic realist, where there is a belief that an external reality exists but is presented by an individual’s view of it.⁴⁰ Furthermore, it is considered an ideographic approach that can illustrate how individuals make sense of a specific situation and presented in a way that provides details of this. Research that uses IPA seeks to present the uniqueness of the individuals view of the world but at the same time present further understanding through the researchers’ own interpretation. This is referred to as the double hermeneutic.⁴¹

Study setting

This study is hosted by the University of Birmingham. Members of the general public of the UK will be targeted for participation with interviews taking place over video (Zoom) with both the participant and researcher in a quiet and private location.

Sample

A purposive sampling maximum variation approach will be employed to ensure input from patients with a rich variety of backgrounds and experiences.⁴² A distinctive feature of IPA is its commitment to a detailed interpretative account of cases which can therefore only realistically be done on a smaller sample size, aiming for depth rather than breadth.³⁷ Collins and Nicolson³⁸ suggest that analysis of large data sets may result in the loss of ‘potentially subtle inflections of meaning’ (pp 626). Based on this, and in order to ascertain rich detail of the lived experience of participants, the planned sample size range is 6–12 to meet the needs of this IPA study.

Participants

Inclusion criteria

Any adult (>18 years) with musculoskeletal pain which has been present for at least 3 months.

Exclusion criteria

Individuals will be excluded if they: are unable to communicate verbally and fluently in English, have a high risk or evidence of poor tissue healing (eg, autoimmune disorders), have injuries where tissue healing may not be complete at 3 months (eg, fractures), have pain which is non-musculoskeletal related chronic pain (eg, cancer) or if they have CMP in the presence of potential systemic or inflammatory conditions (eg, spondyloarthritis, rheumatoid arthritis).

Recruitment

Potentially eligible participants will be made aware of the study through advertisement. The lead researcher (MD) will make direct email contact with groups of people representative of the inclusion criteria, first through a patient and public involvement (PPI) group of individuals with CMP based at the University of Birmingham, and if necessary thereafter through private physiotherapy practices and chronic pain charities (eg, PainUK). Details of the study may also be circulated on social media with the aim of achieving the desired sample variance.

Potentially eligible and interested participants will contact the lead researcher via email. The lead researcher will provide potentially eligible participants with the participant information sheet (online supplemental file A) and confirm eligibility with the eligibility screening questionnaire (online supplemental file B). Informed consent will then be obtained by the lead researcher (MD), who is a senior musculoskeletal physiotherapist, Good Clinical Practice (GCP) trained and experienced with research.

No prior relationship exists between the potentially eligible participants and the lead researcher (MD). Potentially eligible participants will be aware that the lead researcher (MD) is a senior musculoskeletal physiotherapist in the National Health Service and is trained and experienced with research, but will not be aware of any

other characteristics such as biases, assumptions about or reason for interest in CMP.

Semistructured interviews

One semistructured interview will be conducted by the lead researcher (MD) with each participant within 8 weeks of obtaining informed consent. Semistructured interviews enable the researcher to investigate a specific topic while also allowing the participant to respond in their own terms and discuss topics pertinent to them.⁴³ Particularly, semistructured interviews are useful in exploring meanings and realities of participant experiences and how these might be influenced by discourses, assumptions or ideas which exist in society.⁴⁴

Due to the COVID-19 pandemic, all interviews will be conducted remotely using a secure online video platform (Zoom) to reduce risk to participants and ensure unhindered data collection. An interview schedule has been developed in order to direct and maintain consistency and structure across interviews (online supplemental file C). The interview schedule has been informed by the biopsychosocial model of health, an extensive umbrella review of the factors associated with development of CMP (in preparation for publication), the expertise of the authors (MD, ABR, AS and NRH) and input from patients and public through a meeting with a PPI group with CMP. Details of PPI input have been outlined in accordance with the Guidance for reporting Involvement of Patients and the Public (GRIPP) 2 checklist,⁴⁵ which is presented in [table 1](#). The interview schedule will be piloted to determine effectiveness of language and comprehension as well as timing, and amended as necessary prior to data collection. The semistructured nature allows for the emergence of new themes to develop which are important to the participant and facilitates the maintenance of flowing conversation.⁴³ An iterative approach to the interviews will be taken with questions within the interview schedule being adapted or refined based on preceding interviews.

All interviews are voluntary with participants free to pause the interview at any stage or cease the interview altogether should they choose. Should a participant become distressed at any point during an interview, in accordance with our risk assessment for the study (online supplemental file D), participants will be offered the opportunity to stop and will be signposted to any appropriate services as necessary by the lead researcher. Interviews will be audiorecorded and transcribed verbatim by the lead researcher. All transcripts will be anonymised through the use of participant identification numbers at all times in line with GCP and General Data Protection Regulation (GDPR) guidance. ‘Member checking’ will be employed with interview transcripts returned to participants to review, clarify meaning or add further reflections as they wish to improve trustworthiness of data.⁴⁶

**Table 1** PPI input detailed in accordance with the GRIPP 2 checklist⁴⁵

Aims	<ul style="list-style-type: none"> ▶ assess the feasibility of the project by understanding if people with CMP would participate. ▶ establish if this research was valuable to those with CMP. ▶ establish what language/terminology should be used. ▶ understand how to enhance engagement from potential participants/participants. ▶ trial questions from interview schedule
Methods	MD provided an overview of research plan through a PowerPoint presentation to a group of people who have CMP and other healthcare researchers (N=approximately 20). MD and NRH facilitated interactive discussion among the group through questions which reflected the aims throughout the presentation.
Results	<ol style="list-style-type: none"> 1. The proposed research study was found to be valuable with members expressing a willingness to participate in discussion, volunteering their own beliefs about their CMP. This suggested good feasibility of the study. 2. The group provided valuable insights into the most appropriate terminology and descriptions of CMP to improve participation. Namely, it was advised not to use the term 'persistent musculoskeletal pain' as this was confusing with members unsure if this described their pain. The term 'CMP' was suggested instead. 3. The group advised researchers to be careful not to inadvertently suggest that CMP is psychological and not biological as this may be contentious, affecting participation and engagement in the interview. 4. The group identified that they would like to discuss their thoughts and beliefs around their CMP with a researcher in a semi-structured interview format. 5. The group demonstrated a willingness to openly discuss psychological and social factors they feel influenced their own CMP in response to questions from the interview schedule.
Discussion and conclusions	<p>The PPI group had direct influences on the following aspects of the study:</p> <ol style="list-style-type: none"> 1. The study was found to be feasible and valuable encouraging progression of the study. 2. The term 'persistent musculoskeletal pain' was changed to 'CMP' in the study title, all study documents, interview questions and future publications. 3. The participant information sheet and interview questions were amended to reduce the likelihood of making inadvertent suggestions of the nature of CMP being more psychological than biological. 4. The use of semistructured interviews was confirmed as part of the methods for the study. 5. Interview questions were validated and therefore confirmed as part of the interview schedule.

CMP, chronic musculoskeletal pain; GRIPP, Guidance for Reporting Involvement of Patients and the Public; PPI, patient and public involvement.

Data analysis

The aim for the IPA analysis is that the researcher will observe in detail how participants make sense of their world by exploring personal experiences and perceptions. The lead researcher (MD) and coauthors (ABR, AS and NRH) will interpret and make coherent sense of this by linking with their own personal and professional experience and the findings of extant literature.³⁷ This is dependent on both the participants ability to articulate thoughts and experiences and the researchers' ability to reflect and analyse⁴¹; allowing for both aspects leads to richer analysis.

For the purposes of this research, IPA will use four steps based on Smith and Osborn³⁷ (figure 1).

Strategies to ensure trustworthiness

A review of IPA studies and methods outline several suggestions for the methods of high-quality IPA research.⁴¹ First, the researcher will provide a reflexive account of their role in the dynamic process that occurs during the interviews. Second, the researcher will be open to using a priori theory as a framework within which to situate the analysis. Third, consideration will be made of the hermeneutic circle. Lastly, validation checks of interpretation for the lead researcher (MD) will be made by the coinvestigators (NRH, AS and ABR).⁴⁷ Various further

strategies will be employed including member checking and acknowledging researchers' potential preconceptions to avoid bias.⁴⁶

Study status

Participant recruitment and all subsequent study methods as outlined above have not yet commenced at the time of submission of this protocol for peer review. Participant recruitment will begin shortly after acceptance of this protocol to a peer-reviewed journal. The planned timeline from study commencement to completion is 3 months.

Patient and public involvement

PPI has been integral to the development of this research. The lead researcher has conducted an interactive discussion with members of the public with CMP from the Centre for Precision Rehabilitation for Spinal Pain PPI Group at the University of Birmingham. This is presented in table 1 in accordance with the GRIPP 2 checklist.⁴⁵

ETHICS AND DISSEMINATION

Ethical approval

This study was reviewed and approved by the Research Ethics Office at the University of Birmingham, United Kingdom (reference ERN_21-0813).

Step one: looking for themes in the first case	
Actions <ul style="list-style-type: none"> • Read transcript several times. • Make annotations about what is interesting or significant about what was said. • Transform annotations into emerging theme titles. 	Aims <ul style="list-style-type: none"> • Make sense of individuals' personal and social world. • Achieve slightly higher level of abstraction of original annotations with emerging themes. • Thread back to what was originally said.
Step two: connecting the themes	
Actions <ul style="list-style-type: none"> • List themes and seek connections between them. • Initially themes placed in chronological order then in a more analytical or theoretical order. • Clusters of themes are connected and named as superordinate themes. • Superordinate themes and themes tabulated with a phrase given as an identifier. • Identifier links back to transcript where theme evidenced. • Themes which do not fit in emerging structure and not evidence rich will be dropped. 	Aims <ul style="list-style-type: none"> • To make coherent analytical sense of many individual themes. • Researcher utilises own resources to make sense of interview. • To most strongly represent participants thoughts with superordinate themes. • Ensure superordinate themes link back to what was said.
Step three: continuing the analysis with other cases	
Actions <ul style="list-style-type: none"> • Continue as per step one and two with all transcripts. • Re-review earlier transcripts to assess for superordinate themes which emerge later in analysis. • Construct a final table of superordinate themes based on prevalence in data, richness of evidence, how well they link to other themes and how well articulated in data. 	Aims <ul style="list-style-type: none"> • Continue to identify unique perspectives but also identify new emerging themes. • Identify where data is similar and where it diverges. • Iteratively reanalyse data. • Finalise superordinate themes.
Step four: writing up	
Actions <ul style="list-style-type: none"> • Write narrative argument based on final superordinate themes to answer research aims and objectives. • Use verbatim extracts to evidence arguments made. • Expand upon analysis already made by explaining, illustrating, and nuancing themes. 	Aims <ul style="list-style-type: none"> • Move from final superordinate themes to final statement outlining meaning inherent to experience of participants. • Distinguish clearly between what participant said and researcher's interpretation of it.

Figure 1 IPA methods based on Smith and Osborne.³⁷ IPA, interpretive phenomenological analysis.

Informed consent

In order to reduce risks due to COVID-19, informed consent will be obtained remotely. Participants will have the option to complete an informed consent form electronically and return via email, or to complete a form by hand and return via mail. In both instances, the lead researcher will call the participant to explain and ensure they understand the informed consent form before signing and will remain on the phone with the participant while the informed consent form is completed and

signed. The lead researcher will then countersign the completed informed consent form and return a copy to the participant via email or mail.

Data management

All investigators will comply with GCP standards and all data will be handled in accordance with the Data Protection Act 2018 and GDPR standards.

Audio recordings of interviews will be conducted with a password protected digital recording device. Once



transcribed verbatim by the lead researcher, the audiorecording will be deleted. All study paperwork containing participant data, including interview transcriptions, will be stored securely on a password-protected computer for the purpose of data analysis. Only the named researchers will have access to the data. Once data analysis is completed, the data will be stored securely by the University of Birmingham Research Data Store for 10 years and then destroyed. Participants will be anonymised with no identifiable information in the data analysis or any subsequent dissemination of findings.

Assessment and management of risks

There are minimal risks identified for this study with mitigation strategies in place. One risk is that during interviews participants may become emotionally distressed when discussing their thoughts about their condition. The lead researcher is experienced with this situation through their role as a senior musculoskeletal physiotherapist and in this case will offer the participant the opportunity to take a break and remind that participation is voluntary and that they can choose not to answer any questions or to stop the interview should they wish. Participants will also be offered if they would like a family member present during the interview to ensure their well-being. The lead researcher may also signpost participants to relevant support services if needed (eg, NHS services, Mind, Togetherall, Samaritans). Further information on assessment and management of risks is available through our full risk assessment for this study (online supplemental file D).

Dissemination of findings

The study findings will be submitted for publication in a peer-reviewed journal and the study abstract will be submitted to national and international conferences. A lay summary of finding will be disseminated to participants of this study and to the University of Birmingham's established PPI group.

DISCUSSION

The present evidence base looking at factors associated with CMP is largely composed of quantitative research. While useful, qualitative research will provide greater depth and insights into personal experiences, thus providing richer data which may identify additional emerging causative factors for CMP as well as bolstering existing findings.^{36 48} Methods triangulation in this manner is a widely employed approach in epidemiology research whereby 'if results of different approaches all point to the same conclusion, this strengthens the confidence of the finding'.⁴⁹ IPA is particularly useful in this regard because of the double hermeneutic which will capture the unique view of the individual on why they have CMP but will also elicit further understanding of this through the researchers' own interpretations.⁴¹ This enables influence of interpretation based on the existing

evidence base as well as the professional experiences of the researchers as musculoskeletal physiotherapists (MD, NRH and ABR).

To this end, the planned study may inform future research into risk stratification for CMP and proactive management as practised for other long-term conditions. Epidemiological research has led to risk stratification for long-term conditions with proactive management to prevent its development, which has shown to be effective.^{24 25 50} Findings from a recent systematic review suggest that this may also be a promising line of research in the management of CMP.⁵¹ However, further research is required due to limited applicability of these findings due to most existing research being specific to low back pain only and poor to moderate quality of studies.⁵¹ The proposed study may inform future research with qualitative evidence of factors which may contribute to CMP. Additionally, unhelpful beliefs may be identified which may hinder proactive management such as education and behavioural advice.

Past studies have shown that beliefs shape attitudes and adherence towards healthcare management in individuals with CMP.^{52 53} Furthermore, beliefs may affect communication with healthcare professionals⁵⁴ and effectiveness of intervention.¹⁸⁻²² It is therefore important to understand if unhelpful beliefs exist and the nature of such beliefs in people with CMP. Clinicians may play a vital role in this with research showing that clinicians' attitudes and beliefs inform that of their patients.^{55 56} Further to this, when clinicians' beliefs are biomedical in nature, this is associated with increased time off work, reduced physical activity and poorer adherence to treatment guidelines for their patients.⁵⁵ While this highlights the critical role of clinicians in shaping beliefs, a recent Cochrane review echoed the findings that patient beliefs about their musculoskeletal disorders shape their attitudes and behaviours on how to manage it.¹⁷ The planned study will provide valuable insights into what individuals with CMP believe about their conditions and where this originates.

The planned study will use a small sample and will, therefore, provide the foundations to inform further investigation. This is in line with Medical Research Council and National Institute for Healthcare Research guidance for developing complex interventions to improve healthcare.⁵⁷ Particularly, this embodies the 'Undertake primary data collection' action which encourages use of qualitative research to understand the context within which interventions will operate. This will, therefore, provide foundation research, which will provide clinicians and researchers an opportunity to address unhelpful beliefs and design personalised management approaches.

Twitter Michael Dunn @MikeDunnPhysio, Alison B Rushton @abrushton, Andrew Soundy @Andy_Soundy and Nicola R Heneghan @HeneghanNicola

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Contributors MD is the lead researcher leading in the protocol development, ethical approval, data collection, data analysis and dissemination. NRH, AS and ABR have provided feedback and support in the development of the protocol, all study documents including the design of interview schedule, and the application for ethical review. MD, NRH, AS and ABR have led on the conception and design of the study, will be involved in data interpretation, analysis, conclusions and dissemination. MD drafted the initial manuscript. All authors read, contributed to and agreed the final manuscript. MD is the guarantor.

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ORCID iDs

Michael Dunn <http://orcid.org/0000-0002-6559-663X>

Alison B Rushton <http://orcid.org/0000-0001-8114-7669>

Andrew Soundy <http://orcid.org/0000-0002-5118-5872>

Nicola R Heneghan <http://orcid.org/0000-0001-7599-3674>

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Participant Information Sheet

Study title: Individual beliefs on the biopsychosocial factors that contribute to chronic musculoskeletal pain. A qualitative study.

We would like to invite you to take part in a research study being conducted by the University of Birmingham. Before you decide, it is important for you to understand why the research is being done and what it will involve for you. One of the research team will go through the information sheet with you and answer any questions that you have. Please ask if anything is not clear or if you would like more information.

What is the purpose of the study?

Chronic musculoskeletal pain is defined as pain lasting longer than three months. Existing research identifies many key factors that can contribute to the development and continuation of chronic musculoskeletal pain. We need to understand why individuals feel they develop and continue to experience chronic musculoskeletal pain in order to inform the development of new healthcare approaches to manage these individuals. This study will therefore explore the views, experiences and beliefs of people with chronic musculoskeletal pain.

Why have I been invited?

You have been invited to take part because you have musculoskeletal pain which has been present for longer than three months.

Do I have to take part?

It is entirely your decision whether or not to participate in this study. This information sheet has been given to you by a member of the research team who will be happy to discuss this study with you and answer any questions you may have. Should you decide to take part, the researcher (Mike) who is a highly experienced musculoskeletal physiotherapist will ask you a few questions to confirm that you are eligible to participate and a few questions about your demographic background. If you are eligible to participate, you will be asked to sign a consent form. You are free to withdraw from participating at any time, without giving a reason. You will be able to request that any data held about you can be removed, however once research is published it cannot be removed. For that reason, it is unlikely you will be able to withdraw from the study should you choose to do so beyond four weeks after your interview.

What will happen to me if I take part?

You will be invited to take part in one interview. Owing to the Covid-19 pandemic, the only method being used to conduct the interview is via Zoom. The interview will be arranged for a time and date which is convenient for you.

What will I have to do?

Interviews will be conducted by the lead researcher, who is a registered and practising senior physiotherapist in the NHS, an experienced researcher and trained in conducting interviews. The interview will include questions around your experiences, thoughts and beliefs in relation to why you have chronic musculoskeletal pain. We estimate the **interview will last approximately 60-90 minutes**, but the interviewer will also spend some time chatting with you before and after the interview to answer any questions and check on your wellbeing. Participation in **the**



interview is entirely voluntary and can be stopped at your request at any point. You have the **option to have a family member present** for the interview at your preference.

The researcher will take notes during the interview and **the interview will be audio recorded using a password protected audio recorder**. The audio recordings will be transcribed word for word by the researcher and, once checked, the **audio recording will be deleted**. **You will not be identifiable in the interview transcripts or the audio recordings**. With your consent, the interview transcript will be forwarded to you so you can review this to ensure it is an accurate reflection of the interview, and you can add any further thoughts or reflections if you would like. This process can be completed via post or email at your preference and you will have the opportunity to talk to the interviewer by video or telephone if required.

What are the possible disadvantages of taking part?

There are no known risks for taking part in this study. One potential disadvantage is that talking about your views, beliefs and experiences with musculoskeletal pain may cause you some emotional distress. We will make every effort to ensure you are comfortable at all times and you can ask for the interview to be paused to take a break if required. We can signpost you to relevant services which may benefit you if needed.

What are the possible benefits of taking part?

There is no definite benefit for participants of this study. However, reflection on beliefs and thoughts about contributors to chronic musculoskeletal pain is commonly a part of therapeutic intervention and therefore may provide therapeutic benefit. In addition, participants may feel positive that their experiences, thoughts and beliefs recorded through research may help people in the future.

What will happen when the research stops?

All information collected during the study will be anonymised and will be stored on the University of Birmingham's secure Research Data Store. Information will be stored for ten years following the study in accordance with University of Birmingham's research policy, and then destroyed securely.

What will happen if I don't want to carry on with the study?

If you decide you do not wish to carry on with the study, you are free to withdraw at any time up until your interview. Once you have completed your interview you will have four weeks to get in touch with the lead researcher (Mike) should you wish to withdraw participation and therefore remove your interview data from the study. You do not have to provide any reason for your withdrawal and there are no consequences for withdrawing. You will no longer be able to withdraw beyond four weeks after your interview as the data collected may have already been analysed, combined with other data or submitted for publication. All information which is collected about you for the study is anonymised so your identity is fully protected.

What if there is a problem?

It is unlikely there will be any problems during the study. If you have a concern about any aspect of the study for example the way you have been approached or treated during the study please contact the lead researcher (Mike) who will do his best to answer any questions. If you remain unhappy and wish to complain formally, you can do this by contacting the University of Birmingham's Research Governance Officer at researchgovernance@contacts.bham.ac.uk.

UNIVERSITY OF
BIRMINGHAM**How will we use information about you?**

We will need to use information from you and the interviews for this research project. Your name and contact details will only be used to contact you to arrange the interview. Interview transcripts will be used for the analysis to provide the results for the research study. People who do not need to know who you are will not be able to see your name or contact details. Your information will have a code number instead. We will keep all information about you safe and secure in the University of Birmingham's secure Research Data Store. Once we have finished the study, we will keep some of the data so we can check the results. We will write reports in a way that no-one can work out that you took part in that study. All information that is collected about you in this study will be kept strictly confidential in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR). In accordance with these legislations, confidentiality will only be breached in exceptional circumstances where we are concerned that there is immediate threat to the physical safety of yourself or members of the public.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information by asking the lead researcher, Michael Dunn (details below), or University of Birmingham's data protection officer dataprotection@contacts.bham.ac.uk.

What will happen to the results of the study?

The results of this study will be used to inform future research with the aim of improved healthcare for those with, or likely to develop, chronic musculoskeletal pain. The results will be disseminated in scientific journals and presentations at research conferences. You will not be identifiable in any report, publication or presentation. If you are interested in the results of the study, you can obtain a summary of the results by contacting Michael Dunn (details below) and a short summary will be provided to you.

Who is organising and funding this study?

The research is sponsored by the University of Birmingham.

Who has reviewed the study?

This study has been reviewed by members of the research team with experience and expertise in chronic musculoskeletal pain as well as members of the public. All research conducted by the University of Birmingham has been reviewed by their own Research Ethics Committee.

Contacts for further information or any questions about this study:

Michael Dunn (Mike), Lead Researcher
0208 487 6022
Michael.Dunn@stgeorges.nhs.uk

Thank you for taking the time to read this information sheet.

Participant Information Sheet
Version 1.0
DATE 19/01/2022

Page 3 of 3

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

Individual beliefs on the biopsychosocial factors that contribute to chronic musculoskeletal pain. A qualitative study.

Eligibility Screening Questionnaire

INCLUSION CRITERIA

1) Is the person above age 18: Yes No

2) Musculoskeletal Condition

Brief description of musculoskeletal condition in participants own words:

Click or tap here to enter text.

Details of any diagnosis provided by medical professionals in participants own words:

Click or tap here to enter text.

3) Duration of musculoskeletal complaint: Click or tap here to enter text.

4) Does the person fulfil the inclusion criteria? Yes No

If no, for what reason? Click or tap here to enter text.

**If yes, proceed to check against the exclusion criteria.*

Version 1.0
Date 19/01/2022

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

EXCLUSION CRITERIA

1) Can the person communicate verbally and fluently in English?

Yes No

**If answered no, the person is excluded from participation.*

2) High risk or evidence of poor tissue healing

Has a medical professional (Yes/No): Yes No

- Confirmed non-union of a fracture in your adult life:
- Diagnosed you with an autoimmune disorder:
- Diagnosed you with diabetic neuropathy:
- Diagnosed you with any disorder which may affect your body's ability to heal:

**If answered yes to any of the above, the person is excluded from participation.*

3) Injuries where tissue healing may not be complete at three months

Is your musculoskeletal pain a result of (Yes/No): Yes No

- Major trauma:
- Fractured bones:
- Completely ruptured ligament:
- Completely ruptured tendon:
- Completely ruptured muscle:
- Any condition where healing would take longer than three months:

**If answered yes to any of the above, the person is excluded from participation.*

4) High risk of non-musculoskeletal related pain

Has a medical professional ever reported that your pain is caused by (Yes/No): Yes No

- Cancer:
- Blood vessels (veins/arteries):
- Any internal organs:
- Infection:
- Skin conditions/burns:

Version 1.0
Date 19/01/2022

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

- | | | |
|----------------------------------|--------------------------|--------------------------|
| • Sickle cell disease: | <input type="checkbox"/> | <input type="checkbox"/> |
| | Yes | No |
| • Lupus: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Any non-musculoskeletal cause: | <input type="checkbox"/> | <input type="checkbox"/> |

**If answered yes to any of the above, the person is excluded from participation.*

5) Potential systemic or inflammatory causes of pain

5a) Back Pain

Do you have back pain: Yes No

**If yes, complete the next question. If no, move to question 5b.*

Assessment of Spondyloarthritis (ASAS) International Society criteria for inflammatory back pain (Ozgoemen et al, 2010).

Do you have four out of five of the following (Yes/No): Yes No

- | | | |
|---|--------------------------|--------------------------|
| • Insidious onset to your back pain: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Pain at night with improvement on getting up: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Age of onset <40 years: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Improvement in symptoms with exercise: | <input type="checkbox"/> | <input type="checkbox"/> |
| • No improvement in symptoms with rest: | <input type="checkbox"/> | <input type="checkbox"/> |

**If answered yes to four or more of the above, the person is excluded from participation.*

5b) Do you have pain anywhere other than your back? Yes No

**If yes, complete the next question. If no, move onto question 6.*

Assessment in spondyloarthritis international society classification criteria for peripheral spondyloarthritis or spondyloarthritis in general (Rudwaleit et al, 2009).

1) Do you have a diagnosis of any of the following (Yes/No): Yes No

- | | | |
|---------------|--------------------------|--------------------------|
| • Arthritis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Enthesitis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Dactylitis: | <input type="checkbox"/> | <input type="checkbox"/> |

**If answered no to all the above proceed to question 6. If answered yes to any of the above, complete the next question.*

Version 1.0
Date 19/01/2022

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

- 2) Do you have one or more of the following (Yes/No):
- | | Yes | No |
|---|--------------------------|--------------------------|
| • Psoriasis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Inflammatory bowel disease: | <input type="checkbox"/> | <input type="checkbox"/> |
| • An infection related to your MSK pain: | <input type="checkbox"/> | <input type="checkbox"/> |
| • A blood test result which shows you have Human Leukocyte Antigen (HLA)-B27: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Uveitis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Sacroiliitis on imaging: | <input type="checkbox"/> | <input type="checkbox"/> |

**If answers no to all the above, proceed to question 6. If answer yes to any of the above, complete the next question.*

- 3) Do you have two or more of the following (Yes/No):
- | | Yes | No |
|--|--------------------------|--------------------------|
| • Arthritis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Enthesitis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Dactylitis: | <input type="checkbox"/> | <input type="checkbox"/> |
| • Low back pain in the past | <input type="checkbox"/> | <input type="checkbox"/> |
| • A family history of rheumatoid arthritis, ankylosing spondylitis, sacroiliitis or psoriatic arthritis: | <input type="checkbox"/> | <input type="checkbox"/> |

**If answers yes to questions 1, 2 and 3, the person is excluded from participation.*

6) Based on this exclusion criteria, is the person eligible to participate in this study? Yes No

If no, for what reason: Click or tap here to enter text.

If yes, continue to complete background questionnaire.

References

Ozgoemen, S. Agkul, O. and Khan, MA. (2010). Mnemonic for assessment of the spondyloarthritis international society criteria. *J Rheumatol.* 37: 1978.

Rudwaleit M, van der Heijde D, Landewe R, et al. (2009). The development of Assessment of Spondyloarthritis International Society Classification criteria for axial spondyloarthritis (part II): validation and final selection. *Ann Rheum Dis.* 68: 777-783.

Version 1.0
Date 19/01/2022

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

DEMOGRAPHICS

Which category includes your age?

- 18-25 25-29 30-39 40-49 50-59
60-69 70-79 80-89 90-99

What sex were you assigned at birth?

Male Female Other Please provide details

Is this the same as your current gender?

Yes No

If no, what is your current gender? Click or tap here to enter text.

Which of the below best describes your ethnic background?

White:

- English, Welsh, Scottish, Northern Irish or British
- Irish
- Gypsy or Irish Traveller
- Any other white background Click or tap here to enter text.

Mixed or multiple ethnic groups:

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other Mixed or Multiple ethnic background
Click or tap here to enter text.

Asian or Asian British:

- Indian
- Pakistani
- Bangladeshi
- Chinese
- Any other Asian background Click or tap here to enter text.

Black, African, Caribbean or Black British

- African

Version 1.0

Date 19/01/2022

Participant Number: Click or tap here to enter text.
here to enter text.

Date: Click or tap

- Caribbean
- Any other Black, African or Caribbean background
Click or tap here to enter text.

Other ethnic group

- Arab
- Any other ethnic group Click or tap here to enter text.

What is the highest level of level of education you have completed?

- Less than secondary school education
- Secondary school education (GCSE, O-Level etc)
- College, sixth form or equivalent
- Bachelors degree or equivalent
- Masters degree or equivalent
- Doctoral qualification
- Post-Doctoral qualification

Which of the following categories best describes your employment status?

- Employed, working 1-10 hours per week
- Employed, working 11-20 hours per week
- Employed, working 21-30 hours per week
- Employed, working 30-40 hours per week
- Employed, working 40+ hours per week
- Full time carer for children or dependents
- Part time carer for children or dependents
- In full time education
- In part time education
- Retired
- Not able to work

What is your most recent combined household income per annum?

- | | | |
|--|---|--|
| £0-£20,000 <input type="checkbox"/> | £20,000-£40,000 <input type="checkbox"/> | £40,000-£60,000 <input type="checkbox"/> |
| £60,000-£80,000 <input type="checkbox"/> | £80,000-£100,000 <input type="checkbox"/> | £100,000-£150,000 <input type="checkbox"/> |
| £150,000-£200,000 <input type="checkbox"/> | £200,000+ <input type="checkbox"/> | |

Version 1.0

Date 19/01/2022

Interview Schedule

Research Aim	To understand patients' beliefs and perceptions on the biological, psychological and social factors which contribute to the development and maintenance of chronic musculoskeletal pain.		
Interview Section	Questions/Content	Prompts	Aims
Ethics Statement	<p>Firstly, thank you for participating in this interview. I would just like to remind you that this interview will be audio recorded to ensure an accurate collection of the insights and information you provide. After the interview I will transcribe our conversation. With your consent, I will share the transcription with you and may also get in touch in order to clarify the meaning in certain statements you may make. All information you provide will be kept strictly confidential. You are free to stop the interview and the recording at any point you may choose and you can also terminate the interview altogether if you wish.</p> <p>You have the right to not answer any questions. There are no right or wrong answers in this interview. I am simply interested in your own personal experiences, beliefs and thoughts about 1) your chronic MSK pain and, 2) what we already know from research about factors associated with chronic MSK pain.</p> <p>Before we begin, do you have any further questions?</p>	<ul style="list-style-type: none"> • <i>Can I confirm that you have read and understand the information sheet?</i> • <i>Are you comfortable?</i> • <i>Please feel free to stand and move around at any point in order to be comfortable.</i> • <i>Please feel free to ask for a break if you need to.</i> • <i>Is there anything you don't understand?</i> 	<ul style="list-style-type: none"> • To ensure a complete understanding of the purpose of the interview and what is expected of the participant. • Make sure the participant is comfortable and happy to begin.
Introductory Questions	<ol style="list-style-type: none"> 1. Can you tell me about where you grew up? 2. What is your vocation? 3. Can you tell me about what this involves? 4. Can you tell me about your life at home? 5. Do you have any hobbies, activities or exercise routines you do regularly? 6. Is there anything else which regularly occupies your time? 	<ul style="list-style-type: none"> • <i>Whereabouts in the World did you grow up? What kind of area did you live in? Did you enjoy living there?</i> • <i>How long have you been in your vocation? Did you do something different before then? Have you changed vocation?</i> • <i>Who do you live with? Do you have a partner or spouse at home? Do you have any children? Their age(s)? Is your home life relaxed or quite busy?</i> 	<ul style="list-style-type: none"> • Help participant relax and feel comfortable with talking and opening up. • Build rapport. • To gain insight into the influencers and experiences in the individual's life which may have helped shape their beliefs and perceptions of their chronic MSK pain.

Transition Questions	<ol style="list-style-type: none"> 1. Throughout our conversation I will need to refer to your chronic MSK pain in my questions. How would you like me to refer to this? For example, "back pain" or just "pain", or is there anything else you prefer? 2. Can you tell me how your pain began and experiences up to now? 3. How long have you experienced pain for? 4. Were there any periods when pain was better or worse during this time? 5. When did your pain become a problem for you? 6. Why do you believe you developed this pain? 7. Why do you think you have experienced pain for as long as you have? 8. Do you think you have done everything you can to help yourself get better? If not, what more could you have done? 	<ul style="list-style-type: none"> • <i>How did it start? How has it changed/evolved? Were there any periods of remission and recurrence?</i> • <i>When did it start to cause you to first seek help? When did it first stop you from doing things which were important to you? When did you first start to worry about it?</i> • <i>Can you do everything in the same way that you could before?</i> • <i>Do you think you developed this pain due to injury? Due to aging? Due to changing your activities? Due to thoughts and feelings?</i> 	<ul style="list-style-type: none"> • Begin to guide the interview towards their chronic MSK pain and experiences since onset.
The biopsychosocial model in chronic MSK pain	<p>There is lots of research investigating the factors which contribute to people developing chronic MSK pain. The main question being asked is "why do some people get better when others don't?". The research aims to understand the differences between these two groups of people, those who get better and those who don't, so that healthcare services can provide better care in helping as many people as possible to get better.</p> <p>Myself along with some other researchers have done a large project to summarise as much of the research asking this question as possible from all over the world. The findings show many different things which can contribute to the development of chronic MSK pain. These can be placed into three main categories: factors to do with the individual's body, their thoughts and feelings, or the activities that they do.</p> <p>I have some questions for you regarding your beliefs and thoughts as to whether any factors from these</p>	<ul style="list-style-type: none"> • <i>Do you have any questions?</i> • <i>Do you understand what I mean by factors to do with your body?</i> • <i>Do you understand what I mean by factors to do with your thoughts and feelings?</i> • <i>Do you understand what I mean by factors to do with your activities?</i> 	<ul style="list-style-type: none"> • Inform the participant about the background of the study • Introduce or reaffirm that research shows biological, psychological and social factors can affect chronic MSK pain, and that this is what the questions are based on.

Version 1.0
19.01.2022

	<p>three categories have contributed to your chronic MSK pain. If anything doesn't quite make sense as we go through, please let me know.</p>		
<p>Main Questions: Patient beliefs on biological contributors</p>	<p>This section is about your body. This refers to anything about your body such as physical condition, health, fitness, injuries, age related changes, genetics and any other thing about your body.</p> <ol style="list-style-type: none"> 1. Can you explain what your body was like in the time leading up to the beginning of your pain? 2. Do you think anything about your body at the time contributed to the start of your pain? 3. Can you explain any changes to the structures of your body when your pain started? This can include changes such as injuries or impairments you may have sustained. 4. Do you think these changes to the structure of your body have recovered? If so, how long do you think this took? 5. Do you think these changes have contributed to your pain not going away? 6. Can you explain any changes to your body from the beginning of your pain up to now? 7. Do you think any of these changes have contributed to your continued experience of your pain? 8. Last question for this section, why do you believe these things about your body? Where do these beliefs come from? 	<ul style="list-style-type: none"> • <i>What kind of physical shape were you in? What was your health like at the time?</i> • <i>Do you think your shape, fitness or health contribute to your developing chronic musculoskeletal pain?</i> • <i>Do you think you injured anything?</i> • <i>Do you think these injuries healed? How long did this take?</i> • <i>Has your body changed since developing musculoskeletal pain?</i> • <i>Do you believe these things because someone told you them? Such as a medical professional, friends, family or the internet? Or any other reason why you believe these things?</i> 	<ul style="list-style-type: none"> • To understand the patients experiences and perceptions of their physical shape and health before and throughout having chronic MSK pain and what they believe regarding the influence this has on their experience of pain. • To understand where these beliefs come from.

<p>Main Questions: Patient beliefs on psychological factors</p>	<p>This section is about your thoughts and feelings.</p> <ol style="list-style-type: none"> 1. Can you explain your experiences with regards to thoughts and feelings in the time leading up to the beginning of your pain? 2. Do you think these thoughts and feelings contributed to the start of your pain? 3. Can you explain your experiences with regards to thoughts and feelings at the start of your pain? 4. Do you think these thoughts and feelings contributed to your pain not going away? 5. Can you explain your experiences with regards to thoughts and feelings from the beginning of your pain up to now? 6. Do you think any of these thoughts and feelings have contributed to your continued experience of your pain? 7. Last question for this section, why do you believe these things about your thoughts and feelings? Where do these beliefs come from? 	<ul style="list-style-type: none"> • <i>Were you feeling well psychologically?</i> • <i>Were you experiencing any:</i> <ul style="list-style-type: none"> ○ <i>Increased stress?</i> ○ <i>Anxiety?</i> ○ <i>Depression?</i> ○ <i>Lower mood?</i> ○ <i>Concern?</i> ○ <i>Worry?</i> ○ <i>Fear?</i> ○ <i>Unhappiness?</i> ○ <i>Frustration?</i> ○ <i>Anger?</i> ○ <i>Helplessness?</i> ○ <i>Loss of confidence?</i> ○ <i>Loneliness?</i> ○ <i>Isolation?</i> • <i>How did you feel when your pain first started/happened?</i> • <i>Do you think these feelings could have affected your pain in any way?</i> • <i>Has your thoughts and feelings changed over the course of your pain?</i> • <i>Do you believe these things because someone told you them? Such as a medical professional, friends, family or the internet? Or any other reason why you believe these things?</i> 	<ul style="list-style-type: none"> • To understand the patients experiences and perceptions of their psychological health and health before and throughout having chronic MSK pain and what they believe regarding the influence this has on their experience of pain. • To understand where these beliefs come from.
<p>Main Questions: Patient beliefs on social factors</p>	<p>This section is about the things that you do. This includes things such as your vocation, hobbies, exercise, socialising, family responsibilities and any other activities.</p> <ol style="list-style-type: none"> 1. Can you explain the things you were doing in your life in the time leading up to the beginning of your pain? 2. Do you think these things may have contributed to the start of your pain? 3. Can you explain any changes to the things that you were doing at the start of your pain? 4. Do you think these changes to the things you do may have contributed to your pain not going away? 	<ul style="list-style-type: none"> • <i>Any:</i> <ul style="list-style-type: none"> ○ <i>Exercise routines</i> ○ <i>Hobbies</i> ○ <i>Work</i> ○ <i>Family responsibilities</i> ○ <i>Seeing friends</i> ○ <i>Socialising</i> ○ <i>Household responsibilities such as cooking, cleaning or shopping</i> • <i>Since you developed chronic MSK pain, have you had any change to:</i> <ul style="list-style-type: none"> ○ <i>Exercise routines?</i> ○ <i>Hobbies?</i> ○ <i>Work?</i> ○ <i>Family responsibilities?</i> 	<ul style="list-style-type: none"> • To understand the patients experiences and perceptions of social activities before and throughout having chronic MSK pain and what they believe regarding the influence this has on their experience of pain. • To understand where these beliefs come from.

Version 1.0
19.01.2022

	<p>5. Can you explain the things that you have been doing in your life from the beginning of your pain up to now?</p> <p>6. Do you think any of these things, or any changes to the things you have been doing since having pain, have contributed to your continued experience of your pain?</p> <p>7. Last question for this section, why do you believe these things about the things you do? Where do these beliefs come from?</p>	<ul style="list-style-type: none"> ○ Relationships with friends, partner/spouse? ○ Seeing friends? ○ Socialising? ○ Household responsibilities such as cooking, cleaning or shopping? ○ Getting a good night's sleep? <ul style="list-style-type: none"> ● If any of your activities have changed, do you think this has affected your pain? ● Do you believe these things because someone told you them? Such as a medical professional, friends, family or the internet? Or any other reason why you believe these things? 	
<p>Main questions: Summarising patients main beliefs</p>	<p>These last questions are just to help summarise your main beliefs about the contributors to your chronic MSK pain. Please reflect on your answers from the rest of our conversation to answer these as best as you can.</p> <ol style="list-style-type: none"> 1. Do you think your thoughts and feelings, any changes to the things you do, and any changes to your body you may have described have impacted on one another? 2. What do you think is the main reason you developed chronic MSK pain to begin with? 3. What do you think is the main reason your pain has continued for as long as it has? 4. What do you think needs to happen in order for your chronic MSK pain to improve? 	<ul style="list-style-type: none"> ● Is there any relationship between your body, your thoughts and feelings and your behaviours? Do you think they affect one another? 	<ul style="list-style-type: none"> ● To understand if patients connect their biological, psychological and social experiences and beliefs. ● To distinguish the patients most strongly held beliefs from the discussion.
<p>Conclusion</p>	<p>That's all the questions, is there anything else you would like to add about your beliefs on the factors contributing to your chronic MSK pain?</p> <p>The interview has now finished. Thank you for participating in this study, I really appreciate your time and input.</p>	<ul style="list-style-type: none"> ● Is there anything you would like to ask regarding the analysis of the data or the next steps of the process? 	<ul style="list-style-type: none"> ● Ensure the participant is comfortable with what has been discussed.

School of Sport and Exercise Sciences

Summary Assessment Number

Hazard and Risk Assessment Summary (for research work)

Assessor Location of Activity
(list all locations) Date of Assessment Supervisor (if not above) Activity/Experiment Assessed
(attach protocols)

ASSESSMENT OF HAZARD AND RISK											ACTION REQUIRED				
ACTIVITY/HAZARD (List only hazards from which there is a significant risk of harm under foreseeable conditions)	PERSONS AT RISK (See key)	ACTIVITY INVOLVES...					RISK RATING			LIKELIHOOD of HARM				(For example: Is chemical/biological/manual handling /equipment risk assessment required; Is code of practice(COP)/standard operating procedures(SOP) required. Where risk assessments/COP/SOP exists please attach them)	
		C	B	M	E	R	H	M	L	Y	Pr	Po	R		
1. During interviews, participants may become emotionally distressed when discussing their thoughts and beliefs regarding their condition.	Pa														The interviews will be conducted by a GCP trained, HCPC licensed and practising senior physiotherapist. The researcher will act in accordance with CSP Standards of Professional Practice and UoB Guidance for conducting interviews remotely from home during this period. Participants will be informed that they are free to take a break at any time and reminded that their participation is voluntary and that they can choose not to answer questions or to stop the interview should they wish. The participant will be offered if they would like a family member present during the interview to ensure their own wellbeing. The researcher may also signpost participants to relevant support services (e.g. NHS services, Mind, Togetherall, Samaritans).
2. Whilst undertaking interviews the participant may share with the researcher information which raises concern for their wellbeing. This may	Pa														In the case of concern for the participants health, the researcher, who is also GCP trained, HCPC licenced, and a practising senior physiotherapist in a busy NHS physiotherapy department, will implement an appropriate

<p>8. There is a risk of participants sharing or utilising the researchers video platform contact information for non-study related purposes.</p>	Pg																										<p>strong password which will be shared with only the research participant via a separate and secure email, interviews will only be conducted on sponsor approved and secured platforms, the researcher will use the “waiting room” option when setting up video calls to gate keep the interview, video calls will be locked once the participant has joined preventing uninvited people from joining, settings will be set to have only microphones on with videos off when joining the meeting.</p> <p>The researcher will use a generic profile created for the sole purpose of performing this research project which will be deleted upon completion.</p>
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Key

PERSONS AT RISK		ACTIVITY INVOLVES...		RISK RATING		LIKELIHOOD		RISK SIGNIFICANCE				Date for Review		
Ug	Undergraduate	C	Chemicals	H	High	Y	Yes/ Very High	H	Y	Pr	Po	R	= Significant risk	NA
Pg	Postgraduate	B	Biological fluids/material	M	Medium	Pr	Probable	M						
S	Staff	M	Manual Hazard e.g. trip hazard	L	Low	Po	Possible	L						
C	Contractor	E	Equipment hazard			R	Remote			X	X			
V	Visitor	R	Radioisotope											
Pa	Patient/Experimental subject													
Pu	General Public													
Yp	Young Person													
Nm	New/Expectant Mother													

GUIDANCE FOR WRITING THIS ASSESSMENT CAN BE FOUND [HERE](#)