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Doctoral Thesis:

Psychological variables involved in chronic pain outcomes: The role of pain catastrophizing and self-compassion

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Word Counts

	Main Text	Appendices (including tables, figures and references)	Total
Thesis abstract	241	-	241
Literature Review	6839	3491	10330
Research paper	7307	5400	12707
Critical Appraisal	3997	636	4633
Ethics Section	5378	1428	6806
Total	**23762**	**10955**	**34717**

Thesis Abstract

Psychological variables have been shown to be important in the experience of chronic pain. One such variable, pain catastrophizing, has repeatedly been demonstrated as a significant predictor of pain intensity. With the aim to explore the relationship between pain catastrophizing and pain intensity, a systematic review of published empirical research was undertaken. The results suggested that there is a significant relationship between pain intensity and pain catastrophizing on a cross-sectional basis. However this relationship becomes more complex when additional psychological factors are controlled for or considered as mediating or moderating variables. The limitations of the review and implications of findings are discussed.

The second section of this thesis is an empirical study that considered the relationship between chronic pain-related outcomes and a more recently emerging psychological variable in the field of chronic pain, self-compassion. This took a cross-sectional self-report questionnaire design. Recruitment took place in NHS chronic pain clinics, community support groups, social media websites and online forums (N = 210). This research suggested that, while some aspects of self-compassion were significantly correlated with pain intensity and pain-related disability, together they could not explain a unique amount of variance in either outcome variable once other psychological variables were controlled for in hierarchical regression models. Limitations of the study and clinical implications are discussed.

The third section of this thesis takes the form of a critical appraisal which further discusses the process of conducting the research element of this thesis.

Declaration

This thesis records work undertaken for the Doctorate in Clinical Psychology at the Division of Health Research at Lancaster University from August 2013 to November 2014.

The work presented here is the author's own, except where due reference is made. The work has not been submitted for the award of a higher degree elsewhere

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Acknowledgements

Firstly gratitude is expressed to all the people who took part. A special mention to Alan Pendleton who helped me develop my questionnaire by offering feedback in the early stages. Also thanks to everyone who aided in recruitment - your support at getting my sample size to a number I never imagined could happen has been incredible.

Of course, thanks to all the other trainees (both 2010 and 2011, and the in-betweeners) for supporting me to this point in my journey. It's been a pleasure training with you all and I hope to celebrate with all 48ish of you soon!

To all the people who have helped me get my stats and SPSS up to scratch (I hope!). Thanks to Leanne Messham for SPSS club. What a great idea. Let's hope we never have to reinstate it. Thanks to both my thesis supervisors, Jane and Alice, for their invaluable input.

To all my family and in-laws – thank you for the unwavering support and for letting me ignore you. I can't wait to spend quality time with you all again soon. Also to everyone to whom I have been an absent friend. Thank you for understanding and still being there at the end. To Jo, my temporary housemate. Thanks for the bed, the sleepy tea, and for all things ornithological.

A very big thanks to Gaz, who offered continuous cups of decaf coffee, who became superdad without question, who gave me reason to look beyond the deadline and kept suggesting things for my ever expanding bucket list. I could in no way have got through this (emotionally, physically, practically) without you. No more studying I swear!

And finally to Amelie, who inspired me to work towards being compassionate to myself and to become 'good enough' in every aspect of my life. You gave me perspective, you showed patience. You kept me going with all your hugs, the little Scouse accent ('mummy werk?') and the excited shouting when I came home. I have missed you honeybunch.

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Section Three: Critical Appraisal

Critical Appraisal of the Paper 'An exploration of the relationship between self-compassion and chronic pain'

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Aims of the Critical Appraisal

This critical appraisal aims to provide reflection on the research paper entitled 'An exploration of the relationship between self-compassion and chronic pain'. It will focus on the strengths and limitations of the research, with discussions about conceptualisation of constructs studied and difficulties faced with conducting research both online and with a chronic pain population. I will begin by summarising the research in order to provide the necessary background information.

Summary of the Research

The research I undertook was a cross-sectional, self-report questionnaire study which aimed to investigate the relationship between self-compassion and chronic pain intensity and pain-related disability. It was hypothesised that there would be a negative significant relationship between self-compassion and chronic pain outcomes so that as self-compassion increased, pain intensity and pain-related disability decreased. All participants were required to have experience of pain which persisted three months or more beyond expected healing time. Questionnaires were available on an online questionnaire hosting website, although potential participants could request a paper version. All participants completed a number of demographic, pain-related and psychological measures. These included the 26-item Self-Compassion Scale (SCS) [16], a 0 to 10 numerical rating scale for pain intensity [2] and the 7-item Pain Disability Index [20]. A total sample size of 210 was achieved. Results showed that self-compassion did not explain any further variance in either pain intensity or pain-related disability once other variables, e.g. depression, anxiety, pain acceptance and pain catastrophizing, were controlled for within a multiple regression model.

Background to Choosing the Thesis Topic

The potential role of self-compassion in the experience of chronic pain was an issue I was introduced to while on placement in a chronic pain management service. Within this one

service, which used a Cognitive-Behavioural framework, I noticed that aspects of other psychological models were drawn upon, including mindfulness and psychodynamic principles. Additionally, clinicians would often cite Paul Gilbert's work [11] on Compassionate Mind Therapy and were discussing adding elements of this into the psychology sessions. This fluidity in the use of specific models contrasted with my knowledge of one Acceptance and Commitment Therapy programme which remained true to the model by not introducing elements of other models.

This consideration for adopting compassion-focussed techniques into a CBT-based programme sparked my interest in the research into self-compassion and chronic pain. When I searched for empirical studies, I discovered that there was very little published on the role of self-compassion in chronic pain, especially linked to pain-specific outcomes such as pain-related disability and intensity. While I was developing my idea further I attended a conference and various Special Interest Groups within the British Psychological Society (BPS) where the idea of developing a compassion-focused pain management group was discussed.

As this was not rooted in empirical evidence, this cemented my decision to undertake a quantitative study in order to add to the small but hopefully growing number of studies into this field. I also felt there was a need to build on the published quantitative literature to establish an evidence base before attempting to undertake qualitative research which would be grounded more in people's experiences of self-compassion from a chronic pain perspective.

Conceptualisation Considerations

The process of undertaking this research, along with the literature review, highlighted a number of theoretical issues with regards to the conceptualisation of the phenomena studied. While there are specific issues with some of the terms used, as will be discussed,

there is also a wider consideration of cross-cultural issues to be had. This is especially pertinent to concepts such as self-compassion and mindfulness which are rooted in Eastern Buddhist philosophies and have been adopted in Western societies [11], with a resulting shift towards a more medical and scientific view of these concepts [13]. The differing concepts across cultures mean that the results of the research might have been influenced by the different understanding of particular constructs. Additionally, the concept of chronic pain differs across cultures, possibly due to social expectations or healthcare provision [23] This means that the current study might be biased in its selection of participants based on a Western conceptualisation of chronic pain.

More specific difficulties with particular constructs were acknowledged. For example, 'disability' is a concept which differs widely in its definition and is open to much criticism due to the lack of consideration of political and social context [24]. Indeed, previous research has attempted to measure it objectively, for example considering number of days absent from work as an indication of a person's level of disability (e.g. [22]). Elsewhere, self-report measures have been utilised so that the participant indicates the impact of their pain on various aspects of their lives (e.g. [20]). In the current study, this type of self-report measure was used which could be considered pathologising, locating the problem as existing within the individual rather that more generally within society [25]. This is acknowledged as a criticism of the current study but also of the wider research into the conceptualisation of disability across empirical studies. This could have been improved upon in the design stage of the current study by considering what 'disability' means to a group of people who had experience of chronic pain and using this to capture a more representative method for this type of measurement.

There were also issues with the conceptualisation of the predictor variables included in the current research. For example, there is considerable debate among chronic pain

researchers about the nature of pain catastrophizing. It can be considered a 'maladaptive' coping strategy [27] and thus is frequently measured with the Coping Strategies Questionnaire [28]. However, a leading researcher in the field of chronic pain has disagreed with this conceptualisation (L. McCracken, personal communication, February 3rd, 2014). There is also much debate about whether it can be considered a stable or a dynamic trait (e.g. [26]).

Similarly, 'depression' is a term that can be interpreted in a number of ways, considered as a emotion, an 'illness' or a symptom of another construct which can make it difficult to compare results across studies [1]. The particular measure chosen in my research as a measure of depression, the Hospital Anxiety and Depression Scale (HADS), typically uses 'cut-off' scores for 'normal, 'mild', 'moderate' and severe' [32] and this has been open to criticism from research which suggests that scores from this scale should be considered against normative percentiles rather than as categories [6]. Depression and anxiety scores on any measure can be difficult to interpret within a chronic pain population due to the possible overlap of difficulties experienced [3].

Similarly, although there is only currently one published scale to measure self-compassion, there is variation in definitions used in theoretical literature (see [11,17]). There is also variation in the conceptualisation of the subscales of the SCS. For example, 'mindfulness' in the SCS measures the ability to maintain a balanced emotional response at times of difficulty [16], whereas this is defined differently by other researchers who consider mindfulness to be the ability to pay conscious attention to the present moment [13]. This difference in conceptualisation of the construct of mindfulness could explain why no significant relationship was found in my research between the mindfulness subscale of the SCS and pain intensity despite research suggesting that increasing the ability to be present in the moment can improve people's experiences of pain [4].The conceptualisations of the

various constructs used in the current study impact directly on the results. Results must be interpreted with a clear understanding of the how the variables are conceptualised and cannot be taken out of the context of the measures used. This applies to all research which uses the measures discussed and should be a careful consideration of future research.

Strengths and Limitations of the Research

Design.

One of the difficulties that came out of the theoretical considerations was choosing which measures to include. For the SCS, the long version was selected as this was recommended by the author [15]. However, the decision on which pain-related and mood measures to select was less straightforward. This was a difficult and lengthy process which involved consulting with various clinicians and reading a number of journal articles which discussed the issue (e.g. [7]). One of the difficulties I encountered when choosing pain-related measures was ensuring they would be applicable to a heterogeneous chronic pain population. For example, measures have been published which are for particular pain populations, such as lower back pain [9,21]. Moreover, any measure that uses a body map on which people mark where they experience pain (e.g. [5]) was not easily replicable online. Additionally, although the use of visual analogue scales online has been shown to be extremely valid [12], use of this type of scale was not possible as the questionnaire hosting website I was using (www.qualtrics.com) would only allow integer numbers, losing the essence of visual analogue scales. Given that the majority of participants in my study completed the questionnaire online, issues around replicability of scales online will need to be considered by future researchers.

The questionnaire also raised issues around copyright protection. As I had chosen the Hospital Anxiety and Depression Scale (HADS) [32] as the most appropriate measure of anxiety and depression in this population, I was required to set up my questionnaire with a

password as the scale is protected by copyright. Although I made this password very visible on all documentation that carried a link to the website, this might have added a barrier to participation for some people. It is unclear how many people did not get past the password screen as these data were not recorded by the questionnaire hosting website.

Missing Data

Another limitation comes from the issue of missing data. As most responses were recorded online, there was the possibility to limit the amount of data that were missing. This would have involved setting the questions to 'forced response' where the questionnaire hosting website would not have let the participant leave any items blank. However, as some questions were of a sensitive nature, such as the 'sexual behaviour' item on the Pain Disability Index, I felt it more appropriate to allow participants to opt out of particular questions. Indeed, the 'sexual behaviour' item was the item with the most missing data as eight people left this blank.

Allowing people to miss items meant that my completion rate was possibly higher than if I had selected 'forced response' as a number of people might have chosen to exit the questionnaire at the point where they did not wish to answer a question.

Sample considerations

Common difficulties associated with chronic pain, such as fatigue or limited concentration, meant that designing a lengthy questionnaire was problematic. Despite this, the questionnaire took participants around 30 minutes to complete, which is a considerable time to concentrate and possibly be in one physical position. When designing the questionnaire I took into account the burden of completion and chose pain measures that would be short and quick to complete. However, some of the psychological measures were lengthy, with the SCS containing 26-items.

This issue with the length of the questionnaire might have led to people choosing not to complete the questionnaire. A number of people who started the online questionnaire did not reach the end and were therefore excluded from the study (N = 13), however reasons for this cannot be established. This drop-out was seen mainly in the early stages of the questionnaire, meaning that people were not necessarily choosing to exit towards the end. It is unknown if people who requested a paper version found the questionnaire too lengthy to complete as it is assumed that incomplete questionnaires generally would not have been returned.

Recruitment considerations

Participants were recruited both online and through more traditional routes, i.e. NHS clinics and community support groups. Online recruitment was undertaken in order to increase the sample size, and thus power of the study. Additionally, it was hoped this would allow for greater diversity within the sample. Previous research has suggested that online recruitment can achieve these aims, with 16 times more participants taking part online as compared to a pencil-and-paper option [18]. In my study, only 11 people completed a paper version of the questionnaire, compared with 199 people completing online. This also reflects how people were recruited, as only 26 people were recruited using the 'offline' methods of pain clinics and community support groups. Around seven times more participants were recruited online than offline, and just over 18 times more participants chose to complete the questionnaire online.

The original aim for online recruitment was to use only one website, the social media website Twitter (www.Twitter.com). This website can generate a snowball recruitment method, especially when people choose to 'follow' the person conducting the research [19], which I found did occur. The use of a personal profile photo as well as an established history of tweeting prior to study recruitment might have aided this because it meant I already had an

established number of followers who were able to 'retweet' my link. It also meant that my account was not identified as 'spam', i.e. I was a real person sending real tweets, which I know has happened to other researchers using the same website.

My experience of using Twitter was not as quick as the aforementioned authors found it [19], with a slow response despite many hours of finding, and tweeting to, relevant people and groups. I am unsure why this occurred but perhaps my tweets were not reaching people who had chronic pain or wanted to take part in research. Upon reflection, people might use Twitter for a variety of reasons, such as socially or as a distraction to their pain. Therefore a number of people might not have wanted to participate in potentially lengthy research at these times. Additionally, with the rise of people accessing Twitter on their mobile devices, it could be that completing a questionnaire on these devices was too difficult and cumbersome.

After submitting a major amendment to the ethics committee in August 2014, I found that using Facebook (www.Facebook.com) increased my recruitment dramatically. Again, using a snowball sampling technique appeared to work as many people with whom I was 'friends' on this social media website 'shared' my request for participants with their own friends. I was also able to contact groups on this website and this lead to one major Australian online chronic pain support group choosing to post an advert to my research on their website. The results from my research show that the second largest country recruited from was Australia (N = 74), which suggests that this was a successful recruitment strategy.

Ethical considerations

In order to recruit from one particular chronic pain clinic, it was requested that I invited potential participants personally. This involved attending the medical consultant's pain clinics and approaching people in the waiting room. Previous experience working with people with chronic pain has taught me that people were often given upsetting and life-changing information in these appointments. For this reason I ensured I approached people

while they were waiting for appointments rather than afterwards so that I did not risk further adding to any distress. I also allowed people time to settle in the waiting area before I approached them as I was aware that they might be feeling nervous or apprehensive about their appointment.

While attending these clinics and sitting in the waiting area I experienced what could have constituted a breach of confidentiality and thus my ethics approval. For ethical reasons I did not take people's personal details, however I found that a member of staff attempted to give me a list containing the name, date of birth and address of each person coming to the clinic. This was apparently a way of helping me to organise my day so that I knew what time each person would be coming into the waiting room. Additionally it was to help me distinguish between people who were attending for the chronic pain clinic and other non-pain clinics. I did not take this list of personal details and instead approached everyone who came into the waiting room to see if they had an appointment with one of the pain consultants. At this point I could screen people out for whom I did not have the ethical approval to invite into my research.

On two occasions I had to make a decision about excluding people from my study prior to approaching them. These were people who were visibly very distressed upon entering the waiting room. I had not considered this on my ethics application, and took the decision to not approach them so that I did not add to the distress they were experiencing and therefore minimised the harm that my research could do to participants. Upon reflection, this should have been a consideration in the design process of the study.

Another decision I had to make occurred when people contacted me after completing the online questionnaire. As my email address was on the debrief that was provided to all participants at the end of the questionnaire, this meant that I was easily contactable. Some participants chose to send me a simple email to indicate that they had completed the

questionnaire and to express gratitude for conducting research in the field of chronic pain. A small number of other people chose to write longer emails giving me some background context to the answers they had indicated. This was another issue that was not considered in my ethics application and I took the decision to send a polite email in response which indicated that I had received their email but that I was unable to enter into further conversation due to the anonymous nature of my research. I ensured that I deleted these emails so that I did not have personal details stored in my email account. While I had expected people to contact me to exercise their right to withdraw data should they so wish, I had not anticipated participants wanting to enter into communication with me.

Similar issues were experienced when using the social media website Twitter. I found that people were contacting me to indicate that they had completed the questionnaire. Additionally a number of people began 'following' me on this website. While this was at times accounts from chronic pain organisations, I also found that individuals were following me. I had not set up a Twitter account specifically for my research, due to the potential for Twitter to identify a new account as spam. This has meant that people who follow me have access to tweets I posted prior to using Twitter for research purposes. On Facebook I sent requests to chronic pain support groups for permission to post on their group wall. This also would have meant that I would have been contactable by potential participants, however only one group replied and they were able to post a link to my information on my behalf, thus eliminating this potential issue. This type of consideration will be vital to future research as social media becomes more popular for research recruitment. On a larger scale, the issue of participants contacting and 'following' the lead researcher could lead to boundary issues and should be carefully planned for within protocols and ethics proposals.

There were also issues with ensuring participants were properly and immediately debriefed upon completion of the study online. Although the debrief sheet was presented

once participants exited the website at the end of the questionnaire, participants were also given the option to provide their email address to have an electronic copy emailed to them. As there was a delay between participants indicating this and the questionnaire hosting website sending me a notification, participants often received the debrief 24 hours or more after completion of the questionnaire. While the presentation of the debrief sheet upon exit meant that everyone saw it, some participants might have chosen not to read this as they had requested an emailed version. Any future research using these types of systems would benefit from consideration of these issues and design the study appropriately so that each participant is aware that there might be a delay before receiving the debrief sheet. This could be highlighted so that participants ensure they read the debrief sheet that is presented to them regardless of whether they have requested an email version.

Using clinical and non-clinical populations

There was a substantial difference in sample sizes recruited from clinical and non-clinical sources. It is unclear why this is but one suggestion is that people recruited through pain clinics might have been at a time in their lives when they were receiving news about their diagnoses or undergoing difficult procedures. This might have reduced their willingness to take part in research. Additionally, although I made it clear to participants that I was not connected to the pain clinic from which they were recruited, as they received invitations as part of their standard care, i.e. in the post with an appointment letter or while waiting for a consultant appointment, this might have made this distinction less clear. During the process of recruiting within one pain clinic, I learnt that other research was taking part from within the service. As this used similar measures to my research this might have reduced individual's motivation to take part and potentially added to the confusion around my research being separate from the service.

Process issues

One issue that I had not prepared for prior to recruitment was the slight difference in how people who were completing their questionnaires on paper responded to items compared to online participants. For example, some people wrote extra details on their questionnaires, expanding some of the item statements to better reflect their experience. Some people chose to create extra response options so that they could indicate an answer that was between two responses. In these situations I rounded items up, selecting the higher of the two options. This might have led to an inaccurate representation of that person's experience and therefore biased the results slightly. However, as only 11 people completed paper questionnaires, and not all chose to do alter responses, this was not deemed problematic enough to account for in the analyses.

Clinical Implications

Generally the psychological therapy model undertaken in pain management is cognitive behaviour therapy (CBT), or behaviour therapy [8], however in recent years there has been a move towards models which are grounded in positive psychology, such as acceptance based therapies (e.g. [29]). Research has suggested that there is no significant difference in pain outcomes between CBT and Acceptance and Commitment Therapy [31]. This prompts the argument that perhaps chronic pain treatment programmes should be matched to the individual rather than being model-specific [30], although the difficulty associated with identifying the active ingredients in pain management programmes would make this difficult to implement [10]. The findings from my study suggest that targeting self-compassion on top of elements already included in established pain management programmes might not yield any additional benefit for people's pain or levels of disability.

Overall reflections on the research

Despite some of the difficulties encountered with the design and implementation of this research, the process of undertaking quantitative research, especially online, has been an invaluable learning experience. It has allowed me to become more aware of some of the issues with using standardised measures and with conducting research online. A number of ethical issues arose in the course of the study which have been discussed here. This has made me more aware of some of the potential difficulties of conducting research within chronic pain populations. While it has highlighted the benefit of undertaking online recruitment and having questionnaires available online, it also has suggested that there is still a place for paper questionnaires as without this option 11 people would have been unable to access this study. In future research the issues discussed here should be considered at the design stage in order to address issues around conceptualisations of concepts being measured and to prepare for some of the ethical issues that arose.

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Section Four: Ethics Section

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Date: 27.07.2014

Researcher: Jo Jury, Trainee Clinical Psychologist, Lancaster University

Supervisors: Dr Jane Simpson, Lancaster University

Dr X, Clinical Psychologist, XXX NHS Trust

Title: An exploration of the relationship between self-compassion and chronic pain.

Introduction

Chronic pain, defined as pain which continues beyond three months after normal healing would have been expected (Elliott, Smith, Penny, Smith, & Chambers, 1999; Meredith, Ownsworth, & Strong, 2008), is a burgeoning issue in society (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Turk, 1994) and has been estimated to occur in 46 percent of the population (Elliott et al., 1999).

Psychological factors can offer explanations for the wide variation of pain responses in people with similar physiological presentations (e.g. Estlander, 1989; Jensen, Moore, Bockow, Ehde, & Engel, 2011; Linton, 2000; Osborne, Jensen, Ehde, Hanley, & Kraft, 2007; Pincus, Burton, Vogel, & Field, 2002), meaning that pain intensity and pain-related disability are not always explained by the level of injury experienced.

Pain intensity and pain-related disability, despite being conceptually distinct (Solomon, Roopchand-Martin, Swaminathan, & Heymans, 2011), can be partly explained by a number of psychological factors. For example, individual variation in both intensity and disability can be predicted by depression (e.g. Arnow et al., 2011; Ericsson et al., 2002;

Glombiewski, Hartwich-Tersek, & Rief, 2010; Woby, Roach, Urmston, & Watson, 2007), catastrophizing (e.g. Burckhardt, Clark, O'Reilly, & Bennett, 1997; Flor & Turk, 1988; Masselin-Dubois et al. 2013), self-efficacy (e.g. Ayre & Tyson, 2001; Flor & Turk, 1988; Meredith et al., 2006), anxiety (e.g. Meredith, Strong, & Feeney, 2004; Moix, Kovacs, Martin, Plana, & Royuela, 2011), and pain acceptance (McCracken, & Eccleston, 2003; McCracken, Vowles, & Eccleston, 2004).

Another psychological factor that might be important in chronic pain is self-compassion. Although there are a number of ways of defining self-compassion (Gilbert & Procter, 2006), a commonly used definition by Neff (2003) suggests that self-compassion is more than simple kindness to oneself. It also involves considering oneself non-judgementally, being mindful of one's own difficulties and seeing oneself as part of the human race rather than defective in some way.

Whilst research into self-compassion in the psychological literature is in its infancy (Costa & Pinto-Gouveia, 2013), recent research has raised awareness of the relationship between self-compassion and mental health (Baer, Lynkins, & Peters, 2012; MacBeth & Gumley, 2012; Neff, Kirkpatrick, & Rude, 2007; Soysa & Wilcomb, 2013), and self-compassion and general wellbeing (see Barnard and Curry, 2011, for a review of the wellbeing literature).

Self-compassion has recently been studied within a chronic pain population. Costa and Pinto-Gouveia (2013) found that self-compassion score, along with coping style and experiential avoidance, explained a significant proportion of variance in distress (depression, anxiety and stress) amongst a heterogeneous pain population. This study further supports the notion that self-compassion is important for mental health, adding the idea that this is also the case for people with chronic pain. The same authors also found that self-compassion was significantly correlated with acceptance of pain (Costa & Pinto-Gouveia, 2011). No measures

of pain intensity or disability were taken in either of these studies and this has been noted as a limitation (Costa & Pinto-Gouveia, 2013).

However, previous studies have suggested that there might be a link between mindfulness, one of the key aspects of self-compassion (Gilbert, 2009), and pain intensity. For example, McCracken, Gauntlett-Gilbert, and Bowles (2007), found a significant negative relationship between mindfulness and pain intensity, suggesting that the more mindful a person is, the less pain they experience. Therefore it could be argued that a similar relationship might be found between self-compassion and pain intensity.

Although research suggests this relationship might be present, a recent study by Wren et al. (2012), looked at the relationship between self-compassion and chronic pain in an obese adult population and found no evidence of a correlation between self-compassion and pain intensity. However, they did find a significant relationship between self-compassion and scores on the Pain Disability Index, with self-compassion accounting for five percent of the variance in disability.

The results from this study might have been different had their population not been limited to people who were obese. Although, based on previous research, it could be that it is simply the mindfulness element of self-compassion that is correlated with pain intensity. In the study by Wren et al. (2012), self-compassion was analysed as a global score and sub-scales were not analysed. If certain sub-scales were non-significant this would impact upon the global score. It would be useful to explore each aspect of self-compassion in turn to study these relationships further.

Due to the mixed research, and because only one previous study has examined the relationship between self-compassion, pain intensity and disability, this piece of research aims to explore these relationships further. The primary aim is to see if there is a relationship between self-compassion and pain intensity.

It is a timely piece of work because self-compassion and compassion-focused therapies are an emerging phenomenon in clinical psychology, and if research suggests there is a relationship between self-compassion and pain intensity or pain disability within a general chronic pain population, this could provide the beginnings of an evidence-base for using compassion-focussed therapies in the treatment of chronic pain. The main research question employed in this research is:

> Does self-compassion explain any unique variance in chronic pain intensity and pain-related disability above and beyond other psychological factors?

Method

Participants

In order to ascertain the minimum number of participants needed to answer the research question, research literature was consulted. Field (2005) gives an estimation that at least 175 participants will be needed in order to achieve adequate power.

Due to the variations in the recruitment strategy (social media adverts, postal invitation, or face to face invitation), it is difficult to estimate the potential response rate. Postal questionnaires can yield moderately high response rates, with some research in the general population showing rates from 70 (Bergman et al., 2001) to 82 percent (Elliott et al., 1999). A meta-analysis of 152 studies suggests an average response rate of 52 percent (Baruch, & Holtom, 2008). Research within chronic pain populations suggest that this is a suitable estimation, and perhaps at times conservative (e. g. Börsbo, Peolsson, & Gerdle, 2009; Lumley, Smith, & Longo, 2002; Meyer, Tschopp, Sprott, & Mannion, 2009). Online response has been demonstrated as comparable to postal (Kaplowitz, Hadlock, & Levine, 2004), and so it is not expected that the use of online questionnaires will be detrimental to

recruitment. Based on the discussed research, it is estimated that a response rate of 50 percent will be achieved. Therefore a minimum of 350 people need to be invited to take part in this study. Potential participants will be recruited through three channels:

NHS patients

People attending a number of NHS chronic pain services will be invited to take part in this study. People will be given an invitation letter and information sheet as part of their routine care. Depending on the service this could be face to face at an outpatients' appointment, or through the post alongside their opt-in letter from the service. Across four NHS chronic pain services, approximately 300 people will be invited per month. Recruitment is expected to take place over three months, and with a response rate of 50 percent it is expected that 450 people could be recruited via NHS services alone. Even if a more modest response rate of 20 percent is achieved, this will still meet the minimum number of participants required for this study.

Support groups

Six chronic pain community support groups will be approached and asked to give out invitation letters and information sheets to each person who attends the group. Across the six groups, there are approximately 600 members, of which around 150 attend regularly for weekly group sessions. It is presumed that 150 will be the population from which recruitment can take place. Assuming a 50 percent response rate, it is anticipated that 75 participants will be recruited via community support groups.

Social media and online support groups

Adverts will be sent out to promote this research via social media websites such as Twitter and Facebook. Adverts will also be placed on online chronic pain support forums. All forum rules pertaining to adverts for participants will be adhered to. An estimation of

participant numbers recruited via these channels cannot be calculated as there is no way of estimating the total numbers of people accessing these online resources.

Inclusion/exclusion criteria

Participants will be included if they are over the age of 18 to allow for an adult sample. All participants will need to consider themselves to have chronic pain and therefore they will be excluded if they answer 'no' to a screening question prior to consent-giving. Participants will not be able to take part if they are unable to read English. This is due to the included measures' lack of validation in alternative languages.

Design

This study is a quantitative questionnaire design. It is cross-sectional in nature in that questionnaires will be completed at one time point by each participant. Demographic information, such as age, gender, and ethnicity will be collected, as well as basic questions about participants' pain (e.g. pain locations, chronicity).

Measures

Chronic Pain Intensity

Pain intensity will be measured using the Pain Rating Scale (PRS; British Pain Society, 2006). This consists of six items, of which two measure pain intensity ('now' and 'on average last week'), two measure pain distress ('now' and 'on average last week'), one measures pain interference, and one measures relief felt by any treatment. The first five items use a 0-10 numerical rating scale, and the final item uses a 0-100 percent rating scale.

Chronic Pain Disability

The Pain Disability Index (Pollard, 1984) is a seven-item, 11-point Likert scale which measures the impact of pain on seven aspects of people's lives (e. g. recreation, occupation, self-care). Items are scaled from 0 ('no disability') to 10 ('worst disability').

Pain Catastrophising

The Pain Catastrophising Scale (PCS; Sullivan, Bishop, & Pivik, 1995) is a 13-item, five-point Likert scale. It gives an overall score, from 0 to 52, with higher scores indicating greater catastrophising. It is also comprised of three sub-scales – rumination, magnification, and helplessness.

Self-Efficacy

The Pain Self-Efficacy Questionnaire (PSEQ; Nicholas, 1989) is a ten-item, seven-point Likert scale, which measures a person's perception of their ability to accomplish a number of things despite their pain. Scores can range from 0 to 60, and a higher score indicates greater self-efficacy.

Pain Acceptance

The Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles, & Eccleston, 2004) is a 20-item, 7-point Likert Scale with scores ranging from 0 to 70, with a higher score indicating less acceptance of pain. The scale is divided into two subscales - pain willingness and activity engagement.

Self-Compassion

The Self-Compassion Scale (SCS; Neff, 2003) is a 26-item, five-point Likert scale, which gives a global 'self-compassion' score, as well as six sub-scale scores (self-kindness, self-judgement, common humanity, isolation, mindfulness and over-identification).

Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a 14-item, 4-point Likert scale, which incorporates two sub-scales of anxiety and depression. Scores for each sub-scale can be categorised into 'normal' (a score of 0-7), 'mild' (score of 8-10), 'moderate' (score of 11-14), and 'severe' (score of 15-21).

Procedure

Online

If participants decide they would like to complete the questionnaires online, they can follow a link provided in the information sheet. This will take them to Qualtrics, an online survey hosting website, where they will be asked to input a password that is also provided in the information sheet. A password must be requested for copyright reasons. Once the password has been entered participants will be reminded of what the study entails, and will be reminded to read the information sheet, which is available online (a link to this has been provided on the online questionnaire start page). They will then be taken to a screening question in order to fulfil the inclusion criteria. If participants indicate that they have chronic pain, the website will then take them to the consent form. Here, participants must tick all boxes in order to begin the survey. The first question will ask them to generate a 6 character code, made up of letters and numbers, which they can use to exercise their right to withdraw their data at a future date. Once the survey is complete, participants will be presented with debrief information which they will be encouraged to print. For people without a printer, there will be an option for them to enter their email address in order to have a copy of the debrief sheet emailed to them.

Paper

There is an option to request a paper copy of the questionnaires. Prior to posting questionnaires out, the lead researcher will contact the participant in order to screen them for chronic pain. This can be done over the phone or email. If the participant indicates that they have chronic pain, they will need to provide the researcher with their name and address in order for the questionnaire pack to be posted out. Consent will be sought at the start of the questionnaire pack. Participants will be asked to tick a number of boxes then sign and date the form. The questionnaire then proceeds in the same manner as the online questionnaire. Once participants have completed their questionnaire, they are asked to remove the debrief

sheet, write their 6 character code on it, and return the questionnaire pack (including consent form) in a pre-paid envelope.

Proposed Analysis

Data will be analysed using SPSS version 17.0 for Windows. Data will be inspected for outliers and anomalies and analysis of descriptive statistics will be undertaken. Differences between groups will be analysed in order to ensure that all groups (e.g. gender, ethnicity, where recruited from) are statistically similar. If so, data will be pooled and analysed. Preliminary correlations will establish any relationships between variables. Regression models will be developed to see how much variance in pain intensity, and in pain-related disability, can be accounted for by self-compassion. This variable will be entered into the regression model along with other variables that have already been shown to explain significant variance in the empirical literature.

Practical Issues

All costs for photocopying, printing and postage will be covered by the University. There is expected to be minimal travel expenses; any that do occur will be reimbursed to the researcher as per the usual travel expenses procedure. There is expected to be no financial cost to the participant, so no reimbursement will be needed.

All personal data that is provided by participants will be stored electronically in a password-protected document on a secure Lancaster University server. Any paper versions of personal data will be secured in a locked cabinet. Once any personal data has been used (e.g. once questionnaire packs have been sent out), it will be destroyed.

All paper data (e.g. consent forms, completed paper questionnaires) will be scanned and stored electronically in a password protected document on a secure Lancaster University server. Once they have been scanned they will be securely destroyed. All data used for the purpose of analysis will be stored according to the Data Protection Act 1998, and once the

study has ended all electronic files will be transferred to storage in a password-protected file space on the university server. This will be stored for ten years from the date that this research is published. If this research is not published, data will be stored for 10 years following completion of the study.

Ethical Concerns

In order to recruit via online support groups the lead researcher might need to sign up as a member of chronic pain support groups. No deception will take place as the researcher will make it clear she is a researcher and not seeking support for chronic pain. All forums will be examined and rules will be adhered to at all times. For example if the forum states that no adverts for research can be posted then no advert will be posted. Once the study has closed the researcher will close all membership accounts and remove her advert from the site. Any contact with potential participants on these forums will be purely for research purposes.

There is a small, yet realistic, possibility that participants might become upset whilst completing the questionnaires. Information will be provided in the debrief, which is presented at the end of the questionnaire pack, directing them to sources of support.

Personal data will need to be provided to the lead researcher for the purposes of screening, posting paper questionnaire packs out, and emailing debrief sheets. All personal data will be kept in password protected documents on a secure Lancaster University server, and will be destroyed as soon as their purpose has been fulfilled. This is expected to be no more than 7 days.

All participants have the option to withdraw their data whilst they are completing the paper questionnaires by not submitting it. If a participant chooses to withdraw part way through the online questionnaires, completed answers will still be sent through to the researcher. Participants will be made aware of this on the information sheet and at the start of the online questionnaire.

After submission, participants can choose to withdraw their data. Once data has been anonymised and pooled with other participants' data it might not be possible for it to be withdrawn, though every attempt will be made to extract the data, up to the point of publication. Participants can withdraw by contacting the researcher and quoting their unique identification code.

Proposed Timescale

Ethics and R&D submission: April 2014

Data collection: May, June, July 2014

Analysis: June & July 2014

Write up: Jan – September 2014

Submission: September 2014

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Participant Invitation: Version 1 (08.09.2013)

Self-Compassion and Chronic Pain: A Research Project

I would like to invite you to take part in my research study. I am asking people with chronic pain to complete one questionnaire which will take around 40 minutes. This can be done online or on paper. The purpose is to understand the link between self-compassion and your experience of chronic pain.

Before you decide I would like you to understand why the research is being done and what it would involve for you. Please read the attached information sheet for more information.

Part 1 will tell you the purpose of this study and what will happen to you if you take part.

Part 2 will give you more detailed information about the conduct of the study.

Please talk about this study with your family/friends/health professional if you would like.

The research team at Lancaster University is unconnected to any pain service or support group you may be involved in and thus has not had access to any of your personal information, such as your name and address. Therefore we will not know who has received this letter unless you decide to volunteer to take part.

Please note, as this is a study involving people with chronic pain, if you do not have chronic pain please ignore this letter and do not opt in to this study.

Yours sincerely

Jo Jury

Trainee Clinical Psychologist

Lancaster University Doctorate in Clinical Psychology

Participant Information Sheet: Version 2 (25/04/2014)

Self-Compassion and Chronic Pain: A Research Project

Information Sheet: Part 1

Who is inviting me to take part in this study?

The lead researcher is Jo Jury, a Trainee Clinical Psychologist from Lancaster University. This research forms part of her training, and will be supervised by Dr Jane Simpson who is also from Lancaster University.

What is the purpose of the study?

We are asking people to complete a questionnaire in order to study the relationship between self-compassion (the ability to be kind to yourself at difficult times) and chronic pain. This might shape the type of therapy that is offered to people with chronic pain in the future. This study also allows the lead researcher to gain her doctoral level qualification.

Why have I been invited?

You have been invited because you have experience of chronic pain. Invitations have been given out to all people attending certain NHS pain clinics and community support groups. Invitations were also posted online and could be accessed by people who use a social media website for chronic pain information and support. It is expected that 175 people will take part in this study.

What will happen to me if I take part?

If you choose to take part in this study, you will be asked to verify you have chronic pain as this is a requirement for this study. This will be done by phone or email for the paper questionnaire, and will take place before questionnaires are posted out to participants. Similarly, this screening question will be asked before the online questionnaire proceeds. You only need to complete the questionnaire once and there will be no follow up.

What will I have to do?

You will be asked to complete questions about you, your pain, and how you act towards yourself in times of difficulty. It should take around 40 minutes to complete all the questions. Once the questionnaire is submitted, your participation in this study will be complete.

What are the possible disadvantages and risks of taking part?

There is a very small chance that you could become upset whilst taking part in this study. Some of the questions ask about your recent mood, and ask you to think about the pain you experience. If you do become upset, please talk to someone about it, or use the sources of support that can be found at the end of the questionnaire.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Information Sheet: Part 2

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

If you are completing the questionnaire online, your data will be submitted up to the point you stop. If you would like to withdraw your data after you have submitted it, please contact the lead researcher quoting your 6 character code. Once data has been anonymised and pooled with other participants' data it might not be possible for it to be withdrawn, though every attempt will be made to extract you data, up to the point of publication. If you ask to withdraw this does not affect the care and support you receive from the NHS or any support group.

Is there a cut-off for taking part?

This research forms part of a Doctoral award, for which there is a deadline. This means that participation in this study is expected to close later in this year. Once the study has closed, the web link will no longer be active, and the researcher will not be responding to requests for paper questionnaire packs. However, you can still contact the researcher for other purposes, as detailed below.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the lead researcher who will do her best to answer your questions. Contact details can be found towards the end of this information sheet.

This research is being supervised. If you would like to contact the supervisor, please contact Dr Jane Simpson, Research Director at Lancaster University on: 01524 592858, email: j.simpson2@lancaster.ac.uk, or write to: Clinical Psychology, Division of Health Research, Lancaster University, Lancaster, LA1 4YT.

If you are unhappy with any aspect of this research, or would like to make a complaint about this project, please contact Professor Susan Cartwright, Head of the Division of Health Research, Lancaster University on: 01524 592430, email: s.cartwright@lancaster.ac.uk, or write to: Susan Cartwright, Division of Health Research, Furness College, Lancaster University, Lancaster, LA1 4YT.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Lancaster University but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

Yes. Your participation is confidential. The research team at Lancaster University is unconnected to any pain service or support group you may be involved in and thus has not had access to any of your personal information.

Questionnaires will only be identifiable by a 6 digit unique identifier code which you will be asked to generate at the start of the questionnaire.

Anonymised questionnaires are routinely stored securely for ten years following completion of this study. If this study becomes published, data will be stored for ten years following publication. After this time all data will be securely destroyed.

What will happen to the results of the research study?

We plan to publish the results of this study. Results will also be presented to groups of service users and healthcare professionals. Individual data will not be identifiable as data will be pooled and analysed as a group.

Who is organising and funding the research?

This study is being sponsored and funded by Lancaster University. No one is receiving any money for your part in this study.

Who has reviewed the study?

All research in the NHS is considered by a Research Ethics Committee to protect your safety. Furthermore, the research methodology has been reviewed by an internal research team at Lancaster University.

Further information and contact details

If you would like more information or have any questions about the project that need answering before deciding to take part, please leave a message for **Jo Jury** (Trainee Clinical Psychologist) on: **XXXXXXXX**, or email Jo at: **j.jury1@lancaster.ac.uk.** The researcher will get back to you as soon as possible. You can also write to: Jo Jury, Clinical Psychology, Division of Health Research, Furness College, Lancaster University, LA1 4YT.

How can I take part?

There are two ways you can take part in this study:

1) **Online**

If you have internet access and would like to complete the questionnaires online, you do not need to contact the research team. You can simply copy the following web address into your internet browser address bar whenever you are ready to take part:

http://goo.gl/qWFWir

Password: **password1**

(Please note all letters are lower case)

Once you have entered the password you will be able to proceed with the questionnaire.

2) Paper questionnaire pack

If you do not have access to the internet, or would like to complete the questionnaire on paper, you will need to contact the researcher in order to have the questionnaire posted out to you.

To request a paper questionnaire pack, please leave a message for **Jo Jury** (Trainee Clinical Psychologist) on: **XXXXXXX.** Please leave your name and a contact number so that the researcher can phone you back. Alternatively you can email Jo at: **j.jury1@lancaster.ac.uk.** You should receive a response within 48 hours. You can also write (please provide a contact telephone number or email address) to: Jo Jury, Clinical Psychology, Division of Health Research, Furness College, Lancaster University, LA1 4YT.

You will receive the questionnaire through the post. Please complete all sections and return it as soon as possible in the pre-paid envelope.

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

Consent Form: Version 2 (25/04/2014)
Self-Compassion and Chronic Pain: A Research Project

By returning your questionnaire, it is assumed that you agree to the following statements:

I confirm that I have read and understood the information sheet dated 25/04/14 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I agree to take part in the study.

I give permission for my data to be used in this study.

I consent to an anonymised copy of my questionnaire being stored securely for ten years following the completion of this study, or following submission for publication.

I understand that anonymised data collected during the study may be looked at by individuals from Lancaster University, from regulatory authorities or from NHS Trusts, where it is necessary and relevant. I give permission for these individuals to have access to these data.

Participant Debrief Sheet

Self-Compassion and Chronic Pain: A Research Project

Please write the 6 character code you were asked to generate here _____ (paper version only)

Dear Participant,

Thank you for taking part in this study. The aim was to study the psychological factors involved in chronic pain, specifically self-compassion. The current study is testing whether the ability to be compassionate to oneself during times of difficulty impacts on chronic pain intensity.

You are reminded that you are still able to withdraw from this study, as stated in the information sheet. To do this, please leave a message for me (**Jo Jury,** Trainee Clinical Psychologist) on: **XXXXXX,** stating your 6 character code. Please do not leave contact details unless you wish to be phoned back. Please note that this phone number will only be available until 30th September 2014. Alternatively you can email me at: **j.jury1@lancaster.ac.uk**, and I can also be contacted by letter: Jo Jury, Clinical Psychology, Division of Health Research, Furness College, Lancaster University, Lancaster, LA1 4YT. You can also use one of these methods to contact me if you would like to speak to me about this research. Please provide contact details for this purpose.

It is possible that completing these questionnaires has raised some distressing feelings for you. If this is the case, please talk to a friend or family member if you feel comfortable. Alternatively you can contact The Samaritans which is a confidential, 24-hour support line. They can be phoned: **08457 90 90 90**, or you can email them: **jo@samaritans.org**.

If you have any concerns or would like to make a complaint about this project, please contact Professor Susan Cartwright, Head of the Division of Health Research, Lancaster University on: 01524 592430, email: s.cartwright@lancaster.ac.uk, or write to: Susan Cartwright, Division of Health Research, Furness College, Lancaster University, Lancaster, LA1 4YT.

Yours Sincerely,

Jo Jury
Trainee Clinical Psychologist
Lancaster University Doctorate in Clinical Psychology

IRAS Application Form

NHS REC Form | Reference: [redacted] | IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Self-compassion and chronic pain

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(•) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(•) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(•) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (●) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This study will form part of the award of Doctorate in Clinical Psychology.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NHS REC Form | Reference: [redacted] | IRAS Version 3.5

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Self-compassion and chronic pain

Please complete these details after you have booked the REC application for review.

REC Name: [redacted]

REC Reference Number: [redacted]

Submission date: 16/04/2014

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

An exploration of the relationship between self-compassion and chronic pain.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Joanne	Jury

Address [redacted]
Post Code [redacted]
E-mail j.jury1@lancaster.ac.uk
Telephone [redacted]
Fax

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson
Address	Doctorate in Clinical Psychology		
	C16 Furness College		
	Lancaster University		
Post Code	LA1 4YG		
E-mail	j.simpson2@lancaster.ac.uk		
Telephone	01524 592858		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Joanne Jury	☑ Dr Jane Simpson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (•) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Miss	Joanne	Jury
Post	Trainee Clinical Psychology		
Qualifications	BSc(Hons) Psychology with Criminology MSc Health Psychology		
Employer	Lancashire Care NHS Foundation Trust		
Work Address	Doctorate in Clinical Psychology		
	C16 Furness College		
	Lancaster University		
Post Code	LA1 4YG		

Work E-mail	j.jury1@lancaster.ac.uk
* Personal E-mail	j.jury1@lancaster.ac.uk
Work Telephone	
* Personal Telephone/Mobile	[redacted]
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
		Debbie	Knight
Address		Research Support Office, B58 B Floor	
		Bowland Main, Lancaster University	
		Lancaster	
Post Code		LA1 4YT	
E-mail		ethics@lancaster.ac.uk	
Telephone		01594592605	
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version:
Protocol Date:
Funder's reference number:
Project website:

Additional reference number(s):

Ref.Number	Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

There have been a number of studies which have looked at the relationships between chronic pain and psychological factors. It has been found that psychological factors, such as depression, anxiety, and pain catastrophizing are major causes for people with chronic pain experiencing greater levels of pain intensity and disability. The recently studied concept of self-compassion has received very little attention in chronic pain research, and little is known about its relationship to chronic pain intensity.

Self-compassion is the idea that a person can be kind and gentle to themselves in times of difficulty, refraining from self-judgement, and seeing oneself as part of the human race rather than defective in some way. Self-compassion has been shown to improve psychological wellbeing, and recent research has suggested it has a role to play in chronic pain disability and pain-related distress.

It is a timely piece of work because self-compassion and compassion-focused therapies are an emerging phenomenon in clinical psychology, and if research suggests there are relationships between self-compassion, pain intensity and disability, this could provide the beginnings of an evidence-base for using compassion-focussed therapies in the treatment of chronic pain.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The purpose of this study is to aid in completion of a Doctorate in Clinical Psychology. It is primarily educational, but it is anticipated it will fill a gap in the psychological research around self-compassion and chronic pain. As it is expected that this research will be published, the results obtained will be visible in the public domain.

There is no conflict of interest as, although the chief investiagtor works within the NHS as a healthcare professional, she does not work within any of the services that are taking part. Nor does she have any role in any of the support groups that will be approached.

The design of this study has been aided by expert patients who have helped develop all participant documentation. In addition, one chronic pain support group has expressed an interest in running a small pilot study in order to test the suitability of questionnaires. All people taking part in the pilot will be given participant information sheets and debrief sheets.

Recruitment within the NHS will take place in different ways due to variations in the services taking part. For some services, invitation and information sheets will need to be sent out in the post alongside the standard paperwork sent out by the service prior to their first appointment.

For other services, invitation and information sheets will be given out to all people who attend for appointments within pain clinics. This will either be done by healthcare staff, or will be done by the Chief Investigator who will present in the waiting room for particular clinics.

For those recruited via community support groups, invitations will be handed out to all attendees at meetings by a group leader.

Recruitment will also take place via Twitter, a social media website. Adverts will be circulated and sent out to Twitter members who have an interest in chronic pain, self-compassion or clinical psychology. From this advert, followers will be able to click on a link which will take them to an online version of the information sheet. No participants' Twitter account details will be stored anywhere.

When a person chooses to opt in to receive a paper questionnaire pack, they will need to leave contact information with the Chief Investigator, who will contact them in order to screen for chronic pain. If the person indicates that they do have chronic pain, they will then be sent a questionnaire pack in the post. This screening is to reduce unecessary

participation from people who do not have chronic pain and whose data would therefore not be included in this study.

Contact details will be collected in this study for screening and posting purposes. This data will not be shared with anyone. This data will be stored in a password protected document on a secure Lancaster University server. All identifiable data will be destroyed as soon as the questionnaire pack is sent out. No personally identifiable data will be required for people completing online questionnaires, but participants will be asked to generate a unique code in order to have the option to withdraw their data at a later stage.

Consent will be taken prior to a participant completing a questionnaire. Due to the population being invited, it is assumed that all participants will have capacity to consent to take part. Consent forms will be attached to the front of paper questionnaires which participants will need to sign and date. For online questionnaires, participants will need to tick boxes to indicate that they have understood the instructions and they consent to take part before the survey will allow them to move on.

There is a very minimal risk that participants might become distressed during completion of the questionnaires. Due to the anonymity all participants will have, it will not be possible to refer them on to anyone in their care team. However, a debrief will be presented to all participants at the end of the questionnaires which will detail where they can seek support if they are distressed. This will give the contact details of the Samaritans, and other organisations that can support them. It will also ask people to seek support from others around them, or visit their GP.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

(●) Yes - proportionate review ( ) No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Is there a relationship between self-compassion and pain intensity?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Is there a relationship between self-compassion and levels of disability?
Does a person's level of self-compassion explain how much pain they experience?
Does a person's level of self-compassion explain how much they feel disabled by their pain?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Chronic pain is estimated to be experienced by nearly half of the UK population (Elliott et al., 1999), is a large problem in society (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Turk, 1994).

There is a wide variation in people's responses to pain which can't be fully explained by the extent of people's injuries (Katz, 1997), and research over the past 50 years suggests psychological reasons (Linton & Shaw, 2011; Loeser & Melzack, 1999; Melzack & Wall, 1965), particularly for the transition from acute to chronic pain (Linton, 2000), pain-related disability (Pincus, Burton, Vogel, & Field, 2002), adjustment to chronic pain (Jensen, Moore, Bockow, Ehde, & Engel, 2011), pain behaviours (Estlander, 1989), and pain intensity (Osborne, Jensen, Ehde, Hanley, & Kraft, 2007).

The variation in intensity and disability seen within the chronic pain population can be explained somewhat by a number of psychological factors such as depression (e.g. Arnow et al., 2011; Ericsson et al., 2002; Glombiewski, Hartwich-Tersek, & Rief, 2010; Woby,et al., 2007), anxiety (e.g. Meredith, Strong, & Feeney, 2004; Moix, Kovacs, Martin, Plana, & Royuela, 2011), and pain acceptance (McCracken, & Eccleston, 2003; McCracken, Vowles, & Eccleston, 2004).

Another psychological factor that might be important in chronic pain is self-compassion. This involves considering oneself non-judgementally, being mindful of one's own difficulties and seeing oneself as part of the human race rather than defective in some way Neff, 2003). It has shown to be important in mental health (Baer, Lynkins, & Peters, 2012; MacBeth & Gumley, 2012; Neff, Kirkpatrick, & Rude, 2007; Soysa & Wilcomb, 2013), and more general wellbeing (see Barnard and Curry, 2011, for a review of the wellbeing literature).

The research into self-compassion within chronic pain populations is in its infancy. One study examined the relationship between distress and self-compassion within a chronic pain population (Costa & Pinto-Gouveia, 2013), but this did not examine the participants' experience of their pain levels.

Another study which did look at participants' pain levels found that participants with higher levels of self-compassion had lower levels of pain disability (Wren et al., 2012), although this was limited to an obese population and did not find any evidence of a relationship between self-compassion and pain intensity.

There is some suggestion that self-compassion might play a role in pain intensity from the mindfulness literature. The effectiveness of using mindfulness, one of the techniques key to becoming more compassionate towards oneself (Gilbert, 2009), in reducing pain intensity has begun to show some tentative results, albeit with small numbers of participants (Chiesa & Serretti, 2011; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011).

To date research has not studied the relationship between self-compassion and chronic pain intensity within the general chronic pain population. Therefore this piece of research aims address this gap in the research. It aims to see if there is a relationship between self-compassion and pain intensity, and to see if the variation of self-compassion within the population can explain differing levels of pain intensity.

As a secondary aim, this study will look at the relationship between self-compassion and pain-related disability in order to confirm Wren et al.'s findings within a more general chronic pain population.

It is a timely piece of work because self-compassion and compassion-focused therapies are an emerging phenomenon in clinical psychology, and if research suggests there is a relationship between self-compassion and pain intensity, this could provide the beginnings of an evidence-base for using compassion-focussed therapies in the treatment of chronic pain.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Patients from several chronic pain services will be invited to take part in this study. People who attend community chronic pain support groups within North West England will also be invited, and adverts will be sent out on Twitter, a social media website.

Recruitment vis NHS services will be service-specific. All participants will be given an invitation letter and the participant information sheet, and this could be sent out by the service via the post alongside routine paperwork, or given to them by the healthcare professional or Chief Investigator as they come in to a clinic for a routine appointment. This letter will give enough detail so that the participant can give informed consent to take part. It will also detail how a person can opt in to the study; they will have a choice of sending off for a paper questionnaire pack or completing the questionnaire online.

For online completion, participants will need to enter a password (this will be provided in the invitation letter), due to questionnaire copyright requirements. After this, consent will be obtained via a number of tick boxes. For paper completion, participants will need to sign and date a consent form.

All participants will be asked to generate a unique identification code once they have consented. This will allow them to opt out of the research at a later date, should they wish to.

Questionnaire packs (online and paper) will contain demographic questions (e.g. age, gender, ethnicity), and basic questions about their pain (e.g. how long have they experienced it, where in the body do they get pain), and a number of questionnaires to measure psychological factors (e.g. pain-catastrophizing, self-compassion, chronic pain intensity, pain-related disbility). Upon completion, participants will be thanked for taking part and presented with a debrief which will give them details of where to go for support if they feel they need it. If a paper questionnaire has been completed they will be asked to return it in a pre-paid envelope. No further input will be required at this point.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Two expert patients have aided in the design of all patient documentation.

A local community chronic pain support group has been approached and have shown interest in being involved in further design and dissemination of this study. A small group of members will be approached once ethical approval has been obtained. They will be invited to take part in a pilot study in order to test the paper and online questionnaires. They will run through the study as any future participant will, in that they will be given participant information sheets, and debrief sheets will be issued upon completion. They will be asked for feedback on the style, length and ease of the questionnaires. Demographic and pain-related questions might be amended based on this feedback. If this occurs, amendments will be submitted for ethical approval where appropriate.

It is planned that results will be disseminated to the same support group by means of a presentation to be given in one of their meetings.

A seperate presentation will be delivered with the aim of disseminating findings to local healthcare professionals and service users.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Participants need to self-report having experienced chronic pain for at least three months. This will be screened prior to questionnaire completion.
Participants must be aged over 18 in order to ensure this is an adult sample.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Participant has no experience of chronic pain, or their pain has lasted under three months (this is classed as 'acute' or 'subacute' pain).
Paritipant cannot read written English (due to validation of the questionnaires included in this study).
Participant is aged under 18.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent seeking	1	0	5 minutes	Consent will be asked prior to questionnaire completion either online or on paper. To be read and completed by participant who will be alone.
Questions about demographics (age, gender, ethnicity) nature of pain (length, where in body) have they undergone psychological therapy previously for their pain?	1	0	5 minutes	This will be self-reported at a time and place chosen by the participant.
Pain Rating Scale (PRS)	1	0	3 minutes	This will be self-reported at a time and place chosen by the participant.
Pain Disability Index	1	0	3 min	This will be self-reported at a time and place chosen by the participant.
Pain Self-Efficacy Questionnaire	1	0	5 min	This will be self-reported at a time and place chosen by the participant.
Pain Catastrophizing Scale	1	0	3 minutes	This will be self-reported at a time and place chosen by the participant.
Chronic Pain Acceptance Questionnaire	1	0	5 min	This will be self-reported at a time and place chosen by the participant.
Self-Compassion Scale	1	0	5 minutes	This will be self-reported at a time and place chosen by the participant.
Hospital Anxiety and Depression Scale (HADS)	1	0	3 minutes	This will be self-reported at a time and place chosen by the participant.

A21. How long do you expect each participant to be in the study in total?

For participants who request a paper copy, they will enter the study as soon as they have signed their consent form at the start of the questionnaire pack. For those completing online, they will enter the study as soon as they consent and are taken to the front page of the questionnaire.
All participants will complete their participation once their questionnaire has been completed and returned (for online participants, this will occur when they click 'exit' at the end). It is anticipated that participation will take no longer than 40 minutes in total.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is anticipated that minimal adverse effects will occur as a result of this study. Participants will be asked similar questions to those they answer when attending pain clinics. The information sheet, along with the debrief sheet at the end, give participants information about what to do should they feel distressed either during or after the study. This will include information about the Samaritans and other support organisations, and it will direct them towards their GP, friends and family. Participants will also have contact details for the Chief Investigator and her academic supervisor should they wish to talk about the research in any way.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(•) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

It is highly unlikey that participants will become distressed whilst taking part. The questionnaires used in this research are similar to those used routinely within chronic pain services. However, procedures have been put in place to guide participants towards sources of support in the event that they do become distressed.

A24. What is the potential for benefit to research participants?

There are no direct benefits perceived for participants.

A26. What are the potential risks for the researchers themselves? *(if any)*

None

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

This will be service specific, however all NHS participants will be recruited through NHS pain services. In some services, potential participants be given an invitation letter and information sheet by a healthcare professional from within the service, or by the Chief Investigator where needed, as they come for their appointment at the pain clinic. In other services, potential participants will receive an invitation letter and information sheet alongside their opt-in letter for a pain consultant's clinc. The research team will have no role in sending these letters out, and this will be done by a member of the admin team.

For participants recruited via community support groups, invitations and information sheets will be given out at support group sessions. This will be by the group organisers or by the Chief Investigator after a brief introduction. No pressue will be placed on attendees to take a copy of the invitation and information sheets.

For recruitment via Twitter, the Chief Investigator will send out links to the social media advert to people or groups who have an interest in topics relevant to this study (e.g. chronic pain, compassion, psychology). Individuals who follow these Twitter accounts will be able to click through to the advert. This will link them to an online version of the information sheet where they can get information on how to opt in to the study.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

A social media advert will be available online and linked to via Twitter. Tweets will be sent to Twitter accounts that identify themselves as being interested or involved in chronic pain, self-compassion or psychology. The owners of these accounts then have the choice to 're-tweet' this link so that their followers can choose to click on the link for the advert.

A29. How and by whom will potential participants first be approached?

Potential NHS participants will be approached either by a member of staff working in the pain clinic, or by the Chief Investigator as they complete a routine appointment at the clinic. Alternate methods have been arranged for one service where invitation and information sheets will be posted out by the admin staff alongside standard opt-in letters sent by the service.

At support groups, either the Chief Investigator or the group leader will hand out invitations and information sheets to all attendees.

Online recruitment will take place via Twitter, with potential participants seeing a link to the social media advert on their Twitter feed, which they can choose to look at when they log in to Twitter.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All participants will be given enough information in their information sheet to allow them to give informed consent. Just prior to questionnaire completion, participants will be asked to give consent to take part in the research. Consent forms will be attached to the front of all paper questionnaire packs. For online completion, boxes will need to be ticked to say that the participant has read the information sheet and consents to take part before they will be allowed to progress further. It will not be possible to store consent forms from those completing online questionnaires, however they will not be able to proceed with the questionnaire until they have clicked all boxes on the consent form.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have as much time as they wish to consider taking part. Once they have received their invitation letter, they can choose when to send off for a questionnaire pack or to visit the website to complete it online.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

All questionnaires will be provided in English only due to issues linked to the lack of validation of translated versions of the questionnaires included.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files including X-rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
For people who opt-in for a paper questionnaire pack, there will be the need to provide contact information so that they can be asked a screening question prior to the questionnaire pack being posted. They will also need to provide an

address for the pack to be sent to. This communication can be done via email, phone or letter.

Any emails received will be kept by the Chief Investigator on a secure Lancaster University server. This will be stored until the participant has responded to the screening question and a pack has been posted out to the participant. At this point the information will be deleted.

Any postal requests will be opened and if the questionnaire pack is not sent off immediately, the data will be transferred to a password-protected document which will be stored on a secure Lancaster University server. As soon as questionnaires are sent out, any identifiable information will be permanently destroyed. It is anticipated that once a participant opts in, they will be sent a questionnaire pack out within 7 days. Therefore the information will not be stored for longer than this time.

For participants completing online, no identifiable information will be collected unless the participant chooses to provide their email address for the purpose of receiving an electronic copy of the debrief. The debrief is provided at the end of the online questionnaire but it is assumed that not every participant will have access to a printer. If participants choose to give their email address, the Chief Investigator will email them a copy of the debrief and their email details will be deleted.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Any identifiable information will be transferred to a password-protected electronic document and stored on a secure Lancaster University server until it is no longer needed. At this point it will be securely destroyed.

All questionnaires will be identifiable only by a participant-generated 6 character code. Therefore no storage of personal data beyond sending questionnaires out will be required.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The Chief Investigator only, with participant's consent (they will have provided this in order to receive a paper copy of the questionnaire pack, or to enquire further about the research).

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

( ) Yes (●) No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
This is not a clinical trial.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals
☐ Internal report
☐ Conference presentation
☐ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☑ Other (please specify)
Presentations to service users and healthcare professionals.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
Participants will be informed that the research will likely be submitted for publication following university examination, however they will not be directly informed of the results.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi-centre research group
- ☐ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This research has been peer reviewed by two members of the research staff on the DClinPsy programme at the University of Lancaster.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi-centre group
- ☐ Review by educational supervisor
- ☑ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title Forename/Initials Surname
Department	Clinical Psychology Division of Health Research
Institution	Lancaster University
Work Address	Furness College Lancaster University Lancaster
Post Code	LA1 4YG
Telephone	01524 593301
Fax	
Mobile	
E-mail	sarah.heard@lancaster.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The primary outcome measure will be level of pain intensity, measured on a 0-10 scale using the Pain Rating Scale.

A58. What are the secondary outcome measures? *(if any)*

The secondary outcome measures will be:
- Pain disability, which will be measured using the Pain Disability Index. Participants can score between 0 and 70, where a higher score means greater disability.
- Pain distress, measured using the Pain Rating Scale. This is scored from 0 to 10, with a higher score indicating greater levels of distress.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	175
Total international sample size (including UK):	175
Total in European Economic Area:	175

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

This was calculated using guidance from Field (2005) who gives a number of methods for working out sample size when planning a regression analysis. Depending on the model selected, sample size could be anywhere between 119 and 225. A number of 175 was selected because it falls between these two estimations and is suggested by Miles and Shevlin (2001) as appropriate for the number of predictor variables being used in this research study.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

t-tests and graphs will be produced in order to describe the population and look for any differences between groups (for example, gender and reported pain levels).
Correlations will be carried out to investigate the relationships between the variables.
Following this a mediation analysis will be conducted to answer the research questions.

If any item on a questionnaire is missing, it will be replaced by an average of the remaining items. If three or more items are missing on any questionnaire, the questionnaire will be marked as incomplete and not included in any analyses.
The exception to this is where measures use a single question. For example for pain intensity, which is measured using one 0 to 10 scale, missing data will be excluded from analyses.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title	Forename/Initials	Surname

	Dr [redacted]
Post	Clinical Psychologist
Qualifications	D.Clin.Psy
Employer	[redacted]
Work Address	[redacted]
Post Code	[redacted]
Telephone	0[redacted]
Fax	
Mobile	
Work Email	[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Research Support Office, B58 Bowland Main, Lancaster University,
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project
○ Project that is part of a programme grant
○ Project that is part of a Centre grant
○ Project that is part of a fellowship/ personal award/ research training award
○ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
		[redacted]	[redacted]

Organisation [redacted]
Address

Post Code
Work Email [redacted]
Telephone [redacted]
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/04/2014
Planned end date: 29/08/2014
Total duration:
Years: 0 Months: 4 Days: 29

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland

☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 7

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

☑ NHS organisations in England	4
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Social care organisations	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent hospitals	
☐ Educational establishments	
☐ Independent research units	
☑ Other (give details)	3

Local support groups

Total UK sites in study: 7

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the

sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	[redacted]	Title	Dr
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	Dr
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	
Department name		First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	Dr
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

(•) Chief Investigator

( ) Sponsor

○ Study co-ordinator
○ Student
○ Other – please give details
○ None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Joanne Jury on 11/04/2014 10:51.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancaster University
Email:	j.jury1@lancaster.ac.uk
Signature:	.....
Print Name:	
Date:	*(dd/mm/yyyy)*

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature: .....

Print Name:

Post:

Organisation:

Date: *(dd/mm/yyyy)*

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by jane simpson on 14/04/2014 12:09.

Job Title/Post:	Research Director/DCLINPSY
Organisation:	Lancaster University
Email:	j.simpson2@lancaster.ac.uk

REC Provisional Opinion Letter

23 April 2014

Miss Joanne Jury
Trainee Clinical Psychology
Lancashire Care NHS Foundation Trust
Doctorate in Clinical Psychology
C16 Furness College
Lancaster University
LANCASTER
LA1 4YG

Dear Miss Jury

Study title: **An exploration of the relationship between self-compassion and chronic pain.**
REC reference: [redacted]
IRAS project ID: **131410**

The Proportionate Review Sub-Committee of the NRES Committees - [redacted] reviewed by correspondence.

Provisional opinion

The Sub-Committee would be content to give a favourable ethical opinion of the research, subject to the following changes being made to the documentation for study participants:

1 The Proportionate Review Sub-Committee were unclear what would happen if a participant sent back the questionnaire without signing the Consent Form. The Proportionate Sub Committee advises that if the questionnaire is anonymous then Consent could be implied negating the requirement for a Consent Form. Please comment.

2 The Proportionate Review Sub-Committee noted in the thesis feedback form there were concerns about the limited variability reflected in the pain scores and wondered if this had been addressed. Please comment.

3 The Proportionate Review Sub-Committee asked if the participants completing the online questionnaire could have the contact details for support before they start completing the questionnaire as the paper copy has. Please address.

4 The Proportionate Review Sub-Committee requested sight of the wording of the tweet to be used for recruitment.

5 The Proportionate Review Sub-Committee wondered if it was possible for the Pain Clinic patients and the support group patients to be sent the link to the online Questionnaire alongside the invitation and Participant Invitation Sheet to give them the option of completing it online or on paper. Please comment.

6 The Proportionate Review Sub-Committee felt that the Participant Information Sheet was too long and suggest that this be shortened.

When submitting your response, please send the revised documentation underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

Authority to consider your response and to confirm the final opinion on behalf of the Committee has been delegated to Ms Sue Harrison.

Please let me know if you need any further clarification or would find it helpful to discuss the changes required with the lead reviewer.

The Committee will confirm the final ethical opinion within 7 days of receiving a full response.

Documents reviewed

The documents reviewed were:

Document	Version	Date
Covering Letter		
Evidence of insurance or indemnity		11 July 2013
Investigator CV – Miss Joanne Jury		08 September 2013
Letter from Sponsor		15 April 2014
CV - Dr Jane Simpson		26 March 2014
CV - Dr Alice Plummer		14 April 2014
Social Media Advert	1	08 September 2013
Invitation	1	08 September 2014
Debrief	1	08 September 2013
Questionnaire Pack Cover Letter	1	10 April 2014
Participant Consent Form	1	23 August 2013
Participant Information Sheet	1	08 September 2013
Protocol	1	08 September 2013
Questionnaire: PCS	1	10 April 2014
Questionnaire: CPAQ	1	10 April 2014
Questionnaire: Demographics	1	10 April 2014
Questionnaire: Pain-Related Questions	1	10 April 2014
Questionnaire: Pain Rating Scale	1	10 April 2014
Questionnaire: Pain Disability Index	1	10 April 2014
Questionnaire: Pain Self Efficacy	1	10 April 2014
Questionnaire: How I typically act towards myself in difficult times	1	10 April 2014

[redacted]

Questionnaire: HADS		*16 April 2014
REC application	131410/595801/1/729	16 April 2014
Referees or other scientific critique report		04 June 2013

*date received

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

[redacted] **Please quote this number on all correspondence**

Yours sincerely

[redacted]
Chair

Enclosures: List of names and professions of members who took part in the review

Copy to: Debbie Knight
[redacted]

[redacted]

[redacted]

Attendance at PRS Sub-Committee of the REC meeting on 23 April 2014

Committee Members:

Name	Profession	Present
[redacted]	Postdoctoral Research Fellow	Yes
[redacted]	ADP Strategic Development Analyst/Nurse	Yes
[redacted]	Trial Manager	Yes

Also in attendance:

Name	Position (or reason for attending)
[redacted]	Scientific Officer

My Response to Provisional Opinion Points

1. Changes have been made to the consent form to reflect the advice that returning of the paper questionnaire can imply consent. The consent form will be retained so that participants are aware of what they are consenting to by returning their questionnaire. However, participants will no longer need to tick and sign the form.
2. The limited variability in pain scores was addressed following thesis feedback by widening participation to support groups and social media, where it is expected a greater variation in scores will be observed.
3. All potential participants will have access to the Chief Investigator's contact details prior to completion of the questionnaire. This is provided in the information sheet, which all NHS and support group participants will be given prior to them opting in to the study. For those recruited online (via social media) will have access to contact details in an online version of the information sheet, which is available from a link contained within the social media advert.
4. The Tweet that will be sent out to relevant people on Twitter will read "Pls RT: Do you have chronic pain? I'm doing research into chronic pain & self-compassion. Please take a look http://bit.ly/1fVek26". This link will take Twitter users to an online version of the Social Media Advert v1.
5. The link for the online questionnaire is contained within the information sheet that all NHS and support group participants are given.
6. Changes have been made to the Participant Information Sheet in order to make it shorter. These changes have been tracked to highlight sections which have been removed.

REC Favourable Opinion Letter

[redacted]

30 April 2014

Miss Joanne Jury
Trainee Clinical Psychology
Lancashire Care NHS Foundation Trust
Doctorate in Clinical Psychology
C16 Furness College
Lancaster University
LANCASTER
LA1 4YG

Dear Miss Jury

Study title: **An exploration of the relationship between self-compassion and chronic pain.**
REC reference: [redacted]
IRAS project ID: **131410**

Thank you for your letter of 25 April 2014 responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Scientific Officer Dr[redacted]

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact [redacted] the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Covering Letter - Email	Email	25 April 2014
Evidence of insurance or indemnity		11 July 2013
Investigator CV – Miss Joanne Jury		08 September 2013
Letter from Sponsor		15 April 2014
CV - Dr Jane Simpson		26 March 2014
CV - [redacted]		14 April 2014
Social Media Advert	1	08 September 2013
Invitation	1	08 September 2014
Debrief	1	08 September 2013
Questionnaire Pack Cover Letter	1	10 April 2014
Response to Comments		25 April 2014
Participant Consent Form	2	25 April 2014
Participant Information Sheet	2	25 April 2014
Protocol	1	08 September 2013
Questionnaire: PCS	1	10 April 2014
Questionnaire: CPAQ	1	10 April 2014
Questionnaire: Demographics	1	10 April 2014
Questionnaire: Pain-Related Questions	1	10 April 2014
Questionnaire: Pain Rating Scale	1	10 April 2014
Questionnaire: Pain Disability Index	1	10 April 2014
Questionnaire: Pain Self Efficacy	1	10 April 2014
Questionnaire: How I typically act towards myself in difficult times	1	10 April 2014
Questionnaire: HADS		*16 April 2014
REC application	131410/595801/1/729	16 April 2014
Referees or other scientific critique report		04 June 2013
Response to Request for Further Information		

*date received

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

[redacted] **Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]
Chair

Enclosures: After ethical review – guidance for researchers

Copy to: Debbie Knight
[redacted]

IRAS Application for Substatial Amendment

Notice of Amendment IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Self-compassion and chronic pain

1. Is your project research?

◉ Yes ○ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
○ Basic science study involving procedures with human participants
◉ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
○ Study limited to working with data (specific project only)
○ Research tissue bank
○ Research database

If your work does not fit any of these categories, select the option below:

○ Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	◉ No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which review bodies are you applying to?

☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ National Information Governance Board for Health and Social Care (NIGB)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

○ Yes ◉ No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

○ Yes ◉ No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This study will form part of the award of Doctorate in Clinical Psychology.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title Forename/Initials Surname
	Miss Joanne Jury
Work Address	Doctorate in Clinical Psychology
	C16 Furness College
	Lancaster University
PostCode	LA1 4YG
Email	j.jury1@lancaster.ac.uk
Telephone	
Fax	

Full title of study:	An exploration of the relationship between self-compassion and chronic pain.
Lead sponsor:	Lancaster University
Name of REC:	[redacted]
REC reference number:	[redacted]
Name of lead R&D office:	[redacted]
Date study commenced:	03.05.2014
Protocol reference (if applicable), current version and date:	Protocol v2 27.07.14
Amendment number and date:	Amendment number 1 27.07.14

Type of amendment

(a) Amendment to information previously given in IRAS

(●) Yes ( ) No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

Changes to sections:
A6-2. Adverts will be sent out to promote this research via social media websites such as Twitter and Facebook. Adverts will also be placed on online chronic pain support forums. All forum rules pertaining to adverts for participants will be adhered to.
A13. Adverts will be sent out on social media websites and online support forums (expanding this beyond just Twitter).
A27-1. For recruitment via online forums and social media websites, adverts will be posted on relevant support groups or social media pages. Potential participants will be able to read the advert and then click through to an

online information sheet for more information.
A28. Recruitment will take place in online forums and on social media websites. Potential participants will be able to read the advert and click through to an online version of the information sheet.
A29. For online recruitment, participants will be self-identified and the researcher will not approach them. Support forums and relevant social media pages will be identified by the researcher and adverts will be posted as per forum regulations.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

A revised protocol (version 2, dated 27.07.14) has been submitted, and changes have been highlighted in bold.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

○ Yes ◉ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

In order to expand online recruitment beyond Twitter, the protocol has been changed to reflect the use of social media websites in general and online support forums. It is hoped this will lead to more participants, and thus achieving the required sample size.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Protocol v2 27.07.14	V2	27/07/2014

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Miss Joanne Jury on 27/07/2014 14:16.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancaster University
Email:	j.jury1@lancaster.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 07/08/2014 09:39.

Job Title/Post:	Research Support Officer
Organisation:	Lancaster University
Email:	s.c.taylor@lancaster.ac.uk

REC Favourable Opinion of Substantial Amendment

[redacted]

8 August 2014

Miss Joanne Jury
Trainee Clinical Psychology
Lancashire Care NHS Foundation Trust
Doctorate in Clinical Psychology
C16 Furness College
Lancaster University
LANCASTER
LA1 4YG

Dear Miss Jury

Study title: **An exploration of the relationship between self-compassion and chronic pain.**
REC reference: [redacted]
Amendment number: **AM01**
Amendment date: **07 August 2014**
IRAS project ID: **131410**

The above amendment was reviewed on 7 August 2014by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	AM01	07 August 2014
Research protocol or project proposal	2	27 July 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

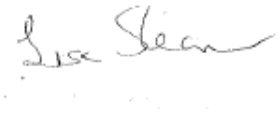
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

[redacted] **Please quote this number on all correspondence**

Yours sincerely



Pp'd on behalf of
[redacted]

Enclosures: List of names and professions of members who took part in the review

Copy to: [redacted]

[redacted]

Attendance at Sub-Committee of the REC meeting on 7 August 2014

Committee Members:

Name	Profession	Present	Notes
[redacted]	Clinical Property Advisor/Nurse	Yes	
[redacted]	Lay Member - Human Nutrition Manager	Yes	

Also in attendance:

Name	Position (or reason for attending)
[redacted]	Assistant Ethics Co-ordinator

Section One: Literature Review

The relationship between pain catastrophizing and pain intensity within a chronic pain population: A systematic review

Jo Jury

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

Word Count (excluding references, tables and appendices): 6835

Prepared in accordance with 'Author Information Pack' for the journal Pain [1]

All correspondence should be sent to:

Jo Jury
Doctorate in Clinical Psychology
Furness College
Lancaster University
Lancaster
LA1 4YT
j.jury1@lancaster.ac.uk

[1]**See Appendix A for 'Author Information Pack'**

Abstract

Psychological variables such as depression, anxiety and pain self-efficacy have been shown to be important in the experience of chronic pain. Another psychological variable, pain catastrophizing, has repeatedly been demonstrated to be a significant predictor of pain intensity. A number of reviews have been conducted, but no systematic review has been published which explores the relationship between pain catastrophizing and pain intensity on a cross-sectional basis.

Therefore this systematic review aimed to explore the cross-sectional relationship between pain catastrophizing and pain intensity in published empirical research. In April 2014 the following databases were searched: CINAHL, MEDLINE, Academic Search Complete, PsycInfo, PsycARTICLES and Web of Science. Studies were included that provided information on the cross-sectional relationship between the two variables in a chronic pain population (pain duration > 3 months).

The results suggested there was a significant relationship between pain intensity and pain catastrophizing on a cross-sectional basis within more simple bivariate designs. However this relationship became more complex when additional psychological factors were included in predictive models or considered as mediating or moderating variables. The limitations of the review and implications of findings are discussed.

Introduction

The physiological purpose of acute pain is to warn an individual that damage might be occurring somewhere in the body [47]. However, a person's experience of pain is not necessarily a reliable indicator of the severity of injury [19]. The role of psychological factors in the pain experience began to be considered 50 years ago [48] and since that time a number of different psychological models have been developed. Models such as the gate control theory proposed by Melzack and Wall in 1965 [71], the more recent neuromatrix model [52] and the fear-avoidance model [44] have attempted to give weight to the psychological processes underpinning the pain experience. A broadly consensual view across all theories argues that psychological processes take place throughout the pain experience, from noticing and attending to the pain, to interpreting it, coping and responding [45], and, through to how disabled people feel by their pain [20].

One example of a psychological process which takes place during the pain experience is pain catastrophizing. This is a cognitive thinking pattern involving thoughts about the pain being overwhelming and concerns that it will never get better [28]. For people experiencing pain, catastrophizing can feed into a cycle of physical deterioration and further pain [73] and can be seen as an integral part of the fear avoidance model [44]. In this model, it is pain catastrophizing and a fear response that differentiates those who adapt well to pain and those who enter an unhelpful cycle.

As part of a neuromatrix model of pain [52], which argues that pain is a response produced by the brain when it perceives that it needs to take action to avert damage or danger, catastrophizing could serve as a cognitive alert and thus result in pain being felt even at times where no stimulus is identified. Catastrophizing can also serve to draw attention to the pain which can increase the experienced intensity of the pain [16]. Indeed high levels of

catastrophizing have been shown to amplify pain processing [20] and activate areas of the brain responsible for anticipating, attending to, and emotionally processing pain [27].

Two recent reviews of the empirical research shows that catastrophic thinking influences people's recovery from injury or surgery and can cause a person to experience pain that persists beyond expected healing time [6,39]. This type of persistent pain is considered 'chronic' [3]. It has been shown that a person with chronic pain visits an emergency department in a hospital up to five times more than a person without chronic pain [2], which has direct implications on healthcare spending [50]. Chronic pain includes a number of dimensions such as disability and distress, but arguably the most clinically important facet is pain intensity [35] which is an individual's subjective evaluation of the strength of their pain [36]. A recent study [55] has suggested that pain intensity might be more important than psychological variables in predicting levels of disability and ill health. In a focus group study [72], researchers suggested that levels of pain and pain reduction were of great importance to participants as the intensity of the pain impacted on many aspects of their life, such as getting a restful night sleep and engaging in meaningful activity.

A systematic review has suggested that, for a person with chronic pain, their level of catastrophizing at one time point can predict their level of pain intensity at a future date [59]. Establishing this relationship is the only way to understand the predictive ability of catastrophizing however it can be useful to consider relationships using cross-sectional studies where both catastrophizing and intensity are measured at the same time point. Indeed for the individual experiencing pain, an understanding of what could be impacting on their current pain might offer some benefits. Additionally, evidence suggests that targeting pain catastrophizing using cognitive behavioural techniques can reduce the pain intensity a person experiences at the same time point [60].

Two reviews [20,60] have attempted to synthesise the cross-sectional research. Edwards et al. [20] argued that within an arthritis population the relationship between pain catastrophizing and pain intensity remained significant after controlling for depression and anxiety, although this conclusion was made based on two studies. This suggests that catastrophizing might play an important role in pain intensity irrespective of levels of anxiety or depression. However, no detail was given about the specific measures used in each of the five included studies. This means it is difficult to draw any substantial conclusions from these findings.

Additionally, the second review [60], which took a critical approach to pain catastrophizing across all pain conditions, suggested that catastrophizing is highly correlated with variables which are often not controlled for, such as pain-related fear and anxiety. The review authors conclude that these confounding variables can act as mediators between catastrophizing and pain, suggesting that consideration of potential confounding variables is important in research. Including a consideration of confounding variables into original research and subsequent reviews would also allow the shared variance between variables to be taken into account. Finally, neither of the aforementioned reviews adopted a systematic approach, exposing them to bias in how the papers were selected for inclusion [32].

Aims of the current review

As no previous reviews have systematically studied the strength and uniqueness of the statistical association between pain catastrophizing and pain intensity on a cross-sectional basis and across a heterogeneous population (i.e. people with chronic pain emerging from a number of different conditions), this review will attempt to address this in order to inform clinical practice and future research. This review will specifically focus on pain intensity in order to narrow the focus of the review.

The research question addressed within this review is to assess the strength of the relationship between pain catastrophizing and pain intensity, taking into consideration moderators and mediators which might impact upon this relationship.

Method

Eligibility Criteria

To be eligible for inclusion in this systematic review, studies had to be published in peer-reviewed academic journals. All participants had to be aged 18 or over to allow for an adult population. Therefore any papers which included participants aged under 18 were excluded. All studies had to state explicitly that the participants were from a chronic pain population, or they had to state that all participants had experienced pain for more than three months. If this was not clearly stated, the study was excluded.

In order to make the results as representative as possible no studies were excluded due to inclusion of participants who had chronic pain co-morbid with other physical or mental health diagnoses. Additionally, no exclusion criteria were placed regarding types of pain diagnosis in order to ensure results were as generalisable as possible [46]. Any measures of 'catastrophizing' and 'intensity' were considered, and these needed to be self-report in nature. Studies that took a measure of induced pain were excluded unless they also measured pain intensity as pertaining to the chronic pain. In order to address the research objective, both pain intensity and pain catastrophizing had to be measured at the same time point. This meant that prospective designs were considered as long as they measured both variables at baseline.

Literature Search

Searches for empirical studies took place using two main sources in April 2014. The first of these, ebsco, encompasses a number of different academic databases which allow access to a wide range of journals. Specifically selected for this search were: CINAHL,

MEDLINE, Academic Search Complete, PsycInfo and PsycARTICLES. The second database searched was Web of Science. The use of these databases was aided by the input from a specialist librarian.

The following search terms were used: (Subject= "chronic pain" OR "persistent pain") AND (Abstract=worry OR cop* OR cogniti* OR catastrophi*) AND (Abstract=intens* OR magnitude OR sever* OR depth OR feroc* OR experienc* OR sens* OR judg* OR exis* OR strength OR power OR quality OR aspect OR nature OR factor) AND (Abstract=correla* OR interac* OR connec* OR relat* OR allianc* OR depen* OR simila* OR link OR part OR predic*OR foretell OR infer OR presume* OR associa* OR identif* OR relat*), with *denoting a wildcard symbol so that any derivatives of the truncated word were included in the results. In Web of Science the limiters were adjusted slightly to allow for the database's variation in search strategy. For example, searches could not be limited to abstract only and so instead were limited to 'topic' for all search terms.

Further searches were made of the included studies' reference lists in order to identify additional studies not included in the databases. This was then repeated for any further studies included until all reference lists had been searched.

Literature Search Results

A total of 3,383 results were returned (1,328 from Ebsco, and 2,055 from Web of Science). The process can be seen in Figure 1. The titles of all these papers were scanned to see if they should be excluded based on the eligibility criteria. This resulted in retention of 49 articles from Ebsco, and 33 from Web of Science. Once duplicates were removed (N = 19), a total of 63 abstracts were inspected further. Forty-seven were retained in this process for full-text retrieval and the reference lists of these primary papers were scanned for further titles which might be of interest. Reference lists of all secondary papers were also scanned. Once all reference lists were scanned, a total of 85 papers were included for retrieval of full-text

articles. The author read through all full-text articles to determine if the study could be included in the final sample. Where inclusion criteria could not be met because statistical data were unclear, further data needed to be obtained, or clarification of study overlaps needed seeking, authors of the studies were contacted. The paper was retained if authors responded and sufficient details such as effect sizes, beta values or data to allow these tests to be calculated were provided. If the author did not respond within 4 weeks, the study was excluded. A final total of 29 studies were retained for full data extraction and quality assessment.

Insert Figure 1 here

Data Extraction

The author extracted all relevant data from each study included in this review and inputted this into a bespoke database. This database included columns for data that would aid in quality assessment (e.g., any funding sources, where participants were recruited from, types of measures used) and statistics which would aid in answering the research question (e.g., the correlation coefficient, sample size). Once all relevant data were extracted, quality assessment was undertaken.

Quality Assessment

The final papers that were included in the review were assessed for quality of reporting based on the Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE) checklist [21]. This checklist includes 32 items which assess the quality of reporting of the title and abstract, introduction, method, results, discussion and other information. It includes items such as ‘explain the scientific background and rationale

for the investigation being reported', 'describe any efforts to address potential sources of bias' and 'summarise key results with reference to study objectives'.

This checklist has been used in previous systematic reviews (e.g. [31]) and was chosen above other quality checklists such as the Quality Checklist [17] due to its applicability to the studies used in this review. The specific checklist chosen was for cross-sectional studies. Although three of the studies included were prospective studies, for the purposes of this review only the cross-sectional data from these studies was included.

Across published systematic reviews, variation exists on whether a study is excluded based on the quality of the reporting of the results. For example a previous review [79] chose to exclude studies with a 'low-quality'. Moreover, the original guidelines serve as a guide to quality of the reporting of data, rather than the methodological quality [21], with this latter specification influenced by specific journals' publishing requirements. Therefore excluding studies based on quality score could introduce bias into the systematic review process [11]. Additionally, Pincus et al. [59] highlight that assessment of quality can be a subjective decision and by retaining lower quality studies, a wider view of the evidence can be taken.

In order to improve the reliability of ratings given by the lead researcher, a second rater trained in quantitative methods separately scored each study included. Both raters were blind to the other's ratings until this task was complete. To score each study, every checklist item was either given a score of 1 for 'yes', or, 0 for 'no' or 'unclear'. Two items on the checklist, 16b and 16c, were excluded as during the process they were found to not be applicable to the studies included. Item 16b required studies to "report category boundaries when continuous variables were categorized" (p.1625) [21]. This was removed from the checklist as it was felt that studies which chose not to categorise variables would not obtain a point for this item and thus be disadvantaged when compared to studies which did categorise. Item 16c was removed because it involved risk estimates which were not of interest to the

current review. Removal of this item did not result in any study being disadvantaged as none of the included studies reported relative or absolute risk estimates.

Once all papers had been rated and scored, discussions over any discrepant items took place. The inter-rater reliability prior to discussion was found to be kappa = 0.59 ($p < 0.001$), which is considered moderate agreement [42]. This was then followed by a detailed discussion where the interpretation of each STROBE item was clarified and a final quality rating score for each study was assigned by the lead researcher, with only minimal discrepancies remaining. The scores from each paper led to a ranking of reporting quality, with a maximum obtainable score of 30 with items 16b and c excluded. Based on previous research [58], a study was considered to be of high quality if it scored at least 60 per cent of the maximum points (18+ points). If it scored 50 to 60 per cent of the maximum it was deemed of moderate quality (15 to 17 points) and if it scored below 50 per cent (14 points and below), it was considered low quality.

Insert Table 1 here

Results

Quality Assessment

Quality assessment scores ranged from eight [75] to 22 [56] with a mean score of 14.6 (*SD* = 3.1). See Table 1 for scores assigned to each study. Seven of the studies were deemed high quality in terms of their reporting of the study [14,15,26,40,54,56,82]. Eight of the studies were of moderate quality [13,29,49,62,63,65,69,77] and the remaining 14 studies were considered low quality [4,12,23–25,34,37,43,51,64,66,75,80,81].

One of the items on the quality checklist involved how studies addressed potential bias. Only four papers explicitly stated steps they had taken to reduce some form of bias in their study [25,62,63,65]. For example, one study [25] attempted to address order bias by randomising all participant questionnaires and another study [63] explicitly stated they had used statistical techniques in order to address bias arising from multiple analyses.

Additionally, only six studies reported how they handled missing data. These studies used a range of techniques, from excluding participants' full data set if one question was missing [34] to using an algorithm to replace missing items [15].

General Study Characteristics

Twenty-nine papers were included for review. Relevant details of all studies can be seen in Table 2. Some studies investigated only one type of chronic pain; for example, five studies focused on chronic low back pain (CLBP) [25,54,56,75,80], two on spinal cord injury [26,81], and seven studies on other pain conditions such as arthritis [37] or temporomandibular disorder [4]. Six studies included more than one type of pain condition, for example fibromyalgia alongside CLBP [12] and nine of the studies had a sample drawn from a heterogeneous pain population [14,15,24,62,64,65,69,77,82]. Sample sizes ranged from 31 [13] to 874 [64] (mean = 171.1), with a total sample size across all studies of 4962. Although not explicitly stated in almost half the studies [14,15,34,37,43,54,56,62–64,77,80,82], across all other 16 studies age ranged from 18 to 93 years. Five studies had more men than women, ranging from 50.9 per cent [43] to 81 per cent [26], and 3 studies included only a female population [14,29,66]. Most studies were conducted in the US (N = 12). Mean pain duration ranged from 26 months [43] to 16 years [40], and eight studies either did not report mean or median duration at all or did not provide data in order to calculate this. One study recruited just from support groups [40] and another from within a prison population [14]. The remainder recruited from either pain clinics or ongoing research

trials, with seven of these seeking additional recruitment outside of these settings [4,12,29,34,63,65,77].

Insert Table 2 here

Conceptualisation of 'Chronic' Pain

Studies conceptualised 'chronic' pain differently, with nine studies including pain that persisted beyond three months [4,14,26,43,51,54,56,80,82] and ten included anyone with pain lasting longer than six months (N = 9) [24,40,49,62–65,69,75,81]. The remaining ten did not state the minimum amount of time they considered 'chronic' [12,13,15,23,25,29,34,37,66,77].

Measurement of Pain Intensity

A wide range of pain intensity measures were used with variation also evident in their administration. Some studies used more than one pain intensity measure. The most commonly cited measure (N = 9) was Melzack's (1987) McGill Pain Questionnaire [23,24,26,29,49,64,66,69,75], and six studies used variations on a visual analogue scale (VAS) [13,43,51,56,77,80]. One study [51] measured intensity using the bodily pain index of the Short-Form Health Survey (SF-36) [78]. Other measures used included the Chronic Pain Grade Scale (CPGS; Von Korff, Ormel, Keefe, & Dworkin, 1992), which was utilised by two studies [40,81], the Brief Pain Inventory (BPI; Cleeland & Ryan, 1994), which was used by one study [4] and the Multidimensional Pain Inventory (MPI) [38] which was used in four studies [12,23,62,65].

Only six studies explicitly reported their own internal consistency statistics [15,37,40,62,63,81], although ten studies were unable to calculate this as pain intensity was

measured using a one-item scale [4,13,34,43,54,56,65,77,80,82]. Cronbach alphas in studies which provided these data ranged from .75 [37] to .95 [81].

Four studies looked at sub-components of pain intensity scales [24,26,29,49], investigating sensory and affective components. Two of these 4 also included an evaluative dimension [24,29].

Measurement of Catastrophizing

Two measures of catastrophizing were generally employed, with 12 studies [4,12–15,25,51,54,62,69,75,77] using the Pain Catastrophizing Scale (PCS) [67] which incorporates three subscales, namely helplessness, rumination and magnification [60]. Fourteen studies [24,26,29,34,37,40,43,49,56,63–66,80] used the catastrophizing subscale of the Coping Strategies Questionnaire (CSQ-CAT) [61]. Two studies [23,82] used the Pain Related Self-Statements Scale (PRSS) [22], and one [81] used the catastrophizing scale of the Pain Coping and Cognition List developed by Stomp-van den Berg et al. (cited in [81]). Two studies examined the magnification, rumination and helplessness subscales of the PCS [51,69]. Additionally, another study looked at the magnification and helplessness aspects of the PRSS [82].

Sixteen studies did not report internal consistency statistics for the catastrophizing measure for their present study [4,12,24–26,29,34,37,51,54,56,64,66,69,75,80], and for the studies that did report it Cronbach alphas ranged from .61 [65] to .95 [14].

Design

All studies employed a questionnaire design and were self-report in nature. Two studies asked participants to complete measures in an interview situation, either face-to-face [15] or via telephone [26]. Most studies (N = 26) were cross-sectional in design, in that participant measures were all taken at the same time point. Only three employed a prospective design [23,51,66] so that measures were taken at different time points. However,

within these three studies pain catastrophizing and pain intensity were measured at baseline so that the cross-sectional nature of the relationship could be extracted for the purpose of the current review.

For most studies (N = 17), catastrophizing was an independent variable, with intensity as a dependent or outcome variable [4,14,23,25,26,29,34,49,51,54,62,63,65,66,77,80,81]. Two undertook only a bivariate correlation analysis and so no dependent or independent variables were identified [56,75]. For the remaining studies, a variety of dependent variables were conceptualised, consisting of vigilance to pain [12], disability [13,40,56,69] and depression [43,82], with pain catastrophizing and pain intensity as independent variables.

Statistical Analysis

Regarding the type of analysis undertaken, most studies reported the unadjusted Pearson's or Spearman's correlation coefficient (N = 25) [4,12–15,23–26,29,40,43,49,51,54,56,62–64,66,69,75,77,80,81]. Of the studies that did not report a Pearson's or Spearman's correlation coefficient, three reported linear regression betas [34,65,82] and one reported path analysis coefficients [37].

The Relationship between Pain Catastrophizing and Pain Intensity

All 29 papers found a significant cross-sectional relationship between self-report measures of pain catastrophizing and pain intensity so that as a participant's level of catastrophizing increased so did the reported intensity of their pain. Correlation coefficients for the bivariate relationship between catastrophizing total score and pain intensity ranged from small/moderate (r = .24, N = 65) [66] to large (r = .615, N = 70) [23], using Cohen's effect size criteria [10].

For a number of studies the relationship between pain catastrophizing and pain intensity did not form part of the aims and so no further analysis of this relationship beyond a bivariate correlation was undertaken [13,40,43,56]. However, for those studies which did

analyse the relationship beyond Pearson's or Spearman's correlations, pain catastrophizing was found to be a predictor of pain intensity, explaining 20.2 and 22.6 per cent of the variance in VAS pain and the bodily pain subscale of the SF-36 respectively [51], and 27 per cent of the variance in pain as measured by the MPQ [29].

The relationship between the two variables can be seen as bi-directional, particularly as this review considers the relationship on a cross-sectional basis. For example, in one study, which analysed the relationship within a mediation model, pain intensity was a significant unique variable, explaining 10.2 percent of the variance in the magnification subscale of the PRSS and 7.4 per cent of the variance in the helplessness subscale [82].

Controlling for Confounding Variables

Demographics.

A number of studies (N = 18) controlled for confounding variables in a variety of ways with a wide range of variables being selected. For example, one study controlled only for age within a Pearson's correlation analysis [64], and others (e.g. [49]) chose to control for several variables within a linear regression.

Seven studies chose to control only for demographic variables such as age and gender, or physiological variables such as pain duration [15,23,34,49,62,64,77]. For all seven studies, catastrophizing appeared to remain an important variable, and in five of these it remained significant [34,49,62,64,77]. However one of these studies did not provide significance levels [15] and another only provided a significance level for a block which included catastrophizing along with other cognitive variables [23]. Therefore it is unclear if the relationship in these two studies remained significant once controlling for demographic and physiological variables.

Psychological variables.

In 11 studies, the impact of other psychological variables besides catastrophizing were controlled for in the relationship between catastrophizing and pain intensity [4,14,24–26,37,54,63,65,80,81]. In three of these studies, no demographic or physiological variables were accounted for [4,24,63] and in another study, the impact of depression on the relationship between catastrophizing and intensity was partialled out but depression was not included in the regression model [26].

In total, six studies controlled for the effects of depression among other variables [14,24,26,37,54,80]. The results of these varied. In four of these studies catastrophizing remained a significant predictor [14,26,37,80], in one study catastrophizing became a non-significant predictor [54], and in the remaining study catastrophizing was a non-significant predictor of the sensory aspect of pain intensity, but a significant predictor of the affective and evaluative dimensions [24]. In four of these studies [14,37,54,80], as well as in the affective and evaluative aspects of pain intensity within one study [24], depression was a non-significant predictor of pain intensity, suggesting that it did not add any significant variance above and beyond pain catastrophizing. This finding is also be supported by another study [49] which, while it did not control for depression, substituted depression for catastrophizing in separate regression models. This study found that the standardised betas were very similar, suggesting that they both play similar roles in pain intensity, although shared variance cannot be established in the latter study.

Within the five studies that controlled for depression, three included other psychological variables in a regression model [14,54,80]. Depression was a non-significant predictor in all three studies, while other psychological variables such as fear-avoidance, which involves anxious thoughts about the impact of physical activity on pain levels [76], and self-efficacy, which relates to a person’s confidence in their ability to perform particular tasks

despite their pain [57], were significant [54,80]. This suggests that other psychological variables might play more of a role in the relationship between pain catastrophizing and pain intensity than depression.

Finding fear-avoidance to be a significant predictor within a regression model suggests that anxiety could play a significant role in pain intensity. Three of the studies that controlled for depression also controlled either for measures of anxiety [14,80] or fear-avoidance [54]. The latter study also controlled for awareness of the physical sensations often experienced when anxious. Additionally two studies controlled for anxiety, namely pain-related fear [65] and fear-avoidance for physical activity [25], without controlling for depression. These five studies showed mixed results; in the two studies that did not control for depression [25,65], both catastrophizing and the conceptualisation of anxiety were significant predictors. In the former study, the standardised beta was higher for pain catastrophizing than for pain-related fear, suggesting that catastrophizing was a stronger predictor; in the latter study the opposite was observed. In another study [54], catastrophizing was not a significant predictor while fear-avoidance beliefs around work and awareness of physical sensations were significant. Finally, two studies [14,80] showed that catastrophizing was a significant predictor but anxiety was not.

Other psychological variables were controlled for within multiple regression models. One study entered a number of psychological variables into a regression model, i.e. anger, helplessness, acceptance, coping and perceived pain control [81]. Two studies chose control for 'cognitive' variables, with one study measuring body vigilance, negative self-statements and optimism[65], and another study measuring perceived pain control and ability to decrease pain along with self-efficacy [80]. In all of these studies catastrophizing was a unique significant predictor of pain intensity, although it was the most important predictor in just one

study [65]. In the other two studies it was second to perception of having internal control over one's pain [81] and functional self-efficacy [80].

Moderator and mediator variables.

Only four of the 29 studies chose to analyse variables that mediated or moderated the relationship between pain catastrophizing and pain intensity. A mediator acts as an explanatory variable of the relationship between two variables, whereas a moderator variable acts as a 'buffer' between two variables, causing the effect to be seen only at particular levels of the moderating variable [1].

Two studies chose to investigate moderating variables. One study chose psychosocial variables, i.e. living with a partner and levels of perceived solicitousness in that partner [26]. The other study considered gender and pain diagnoses as moderators [34]. The only variable found to be a significant moderator was living with a partner. This meant that for a person not living with a partner, no amount of catastrophizing increased pain intensity, whereas for a person living with a partner, greater catastrophizing led to increased sensory pain.

Two studies considered mediating variables, i.e. self-efficacy for pain control [63] and sleep disturbance [4]. Self-efficacy was found to be a significant mediator between total pain catastrophizing score and pain intensity. However, sleep disturbance only acted as a significant mediator between the rumination subscale of the PCS and pain intensity. Sleep disturbance did not mediate the significant relationship observed between the magnification and helplessness subscales and pain intensity. Therefore the relationship between pain catastrophizing and pain intensity can be explained by the impact that catastrophizing has on sleep disturbance and a person's propensity to ruminate about their pain.

Conceptualisation of Variables

As previously highlighted, there was a wide range of pain intensity measures used across the 29 studies. Some studies chose to use more than one measure of pain intensity,

and one study [66] found differing results between measures so that the relationship between catastrophizing and the MPQ reached significance, but the relationship with the AIMS pain score did not reach significance. This suggests that the two scales might have conceptualised pain intensity differently.

This issue of conceptualisation can be seen in the studies which chose to analyse sub-components of pain intensity. For example, within an arthritis population, only the evaluative and affective subscales of the MPQ were significantly correlated with pain catastrophizing, while the sensory subscale was not [29]. In another study [24], while they showed that all three subscales significantly correlated with catastrophizing, the differences between subscales could be seen once depression was partialled out; again the relationship only remained significant for the evaluative and affective components.

There was little difference observed between different measures of catastrophizing. As previously noted, use of the two main measures was nearly evenly split across the studies, with the CSQ-CAT being used in two more studies than the PCS. The PCS was the only measure with available subscales and only two of the 12 studies which utilised this measure chose to analyse the subscales statistically [4,69]. These two studies had slightly different results, with one study finding significant positive relationships between all PCS subscales and pain intensity [4] and the other finding a significant relationship only between the magnification subscale and intensity [69].

Discussion

Summary of Findings

This systematic review shows that all 29 of the studies included found a significant relationship between pain catastrophizing and pain intensity. This suggests that, at a superficial level at least, pain catastrophizing does play a role in the experience of pain

intensity. Moreover, all studies' results showed the same direction in the relationship; as catastrophizing increased, so did pain intensity.

However, further inspection of the results of these studies highlights the more complex nature of the relationship between the two variables. For example, considering psychological variables alongside each other within a regression model shows that there might be considerable overlap between catastrophizing and factors such as anxiety and depression. In both of the studies which controlled for a measure of anxiety but not depression, both catastrophizing and anxiety were found to be significant independent predictors of pain intensity. However in the three studies that did control for depression, only one of either anxiety or catastrophizing was significant. This suggests that pain catastrophizing shares similar characteristics with some measures of anxiety and that there might be shared variance between anxiety, catastrophizing and depression. Indeed this suggestion is supported by the studies which controlled for depression; in five of the six studies which included both depression and catastrophizing in a regression model, depression was not a unique significant predictor of pain intensity.

The impact of moderating or mediating variables must also be considered, albeit tentatively given the small number of studies which included mediating or moderating variables. Results from the small number of studies which used mediating and moderating designs suggest that factors such as living with a partner, pain self-efficacy and sleep disturbance might act as mediators or moderators to the relationship between pain catastrophizing and pain intensity. However replication and further research would be of benefit in order to draw firm conclusions.

The studies which analysed the subscales of the MPQ suggest that, while pain intensity as a global measure might be significantly related to catastrophizing, once the different facets of intensity are studied this relationship, again, becomes more complex. It

appears that the evaluative and affective subscales are significantly correlated with pain catastrophizing, even when the effect of depression on the relationship is partialled out. However the sensory subscale might not be significantly correlated with catastrophizing. Due to the small number of studies that have investigated facets of pain intensity in this manner, it is difficult to draw conclusions. However it might be that how a person evaluates their pain and how it impacts upon their emotional wellbeing can be affected by the level of catastrophizing, whereas the actual level of their pain felt physiologically might not be altered regardless of level of catastrophizing. This might be explained by previously discussed results from brain scans of people with chronic pain [27] which has seen activation in the pain anticipating, attending and emotional processing areas of the brain. While it might be that people report greater pain intensity when they catastrophize about their pain more, this could be a product of attending to their pain more closely rather than physically experiencing more pain. However, these hypotheses are based on small numbers of participants and very few studies so would need further exploration.

Similarly, because only two studies investigated the subscales of the PCS no conclusion can be drawn from the current review. However this does highlight the need for further research into the relationship between particular aspects of catastrophizing and pain intensity.

Methodological Issues

Methodological issues in some studies led to a number of studies being excluded from the current review. For example, one study [8] chose to exclude the catastrophizing subscale of the CSQ prior to data collection due to a debate around the conceptualisation of catastrophizing. Additionally, one study [5] was excluded due to pooling the catastrophizing measure into a higher order construct of ‘pain control and rational thinking’, meaning that the bivariate relationship between intensity and catastrophizing was not provided.

Conceptualisation of both catastrophizing and pain intensity differed across studies. This made comparison of studies difficult, and has been noted in a previous review [6]. While the current review found similar results between studies that had used measured catastrophizing with the CSQ and those that used the PCS, there was no way of assessing whether these were accounting for similar variance in pain intensity. Another previous review has highlighted the difference in conceptualisation between the two measures [60]. It would be beneficial to investigate further the differences between the two, perhaps utilising a regression model to explore the unique variance in pain outcomes explained by both measures.

There was also variation within studies, with one study [23] finding different results across two different pain intensity measures. This variation between studies extended to conceptualisation of the diagnosis of 'chronic pain'. Many did not state the minimum duration of pain a person needed to experience to be considered 'chronic', and for those that did there was variation between minimum pain duration of three and six months. One study [74] set the limit below three months and was excluded for this reason as guidelines provided by a leading pain society state that to be considered 'chronic' a person had to experience pain for at least three months [3].

Limitations of the review

This review had a number of limitations. The first concerns the exclusion of potentially relevant studies. When full-text articles were obtained it became clear that two pairs of studies might have included overlapping samples. In order to clarify this, all authors were contacted but as no response was received a decision had to be made about excluding one study in each of the overlapping pairs. This decision was made based on sample size and generalisability of results. For example, one study [68] was excluded as the sample was smaller, which might have resulted in less statistical power [7], and the population was

specific to one particular type of injury, limiting its generalisability. It is acknowledged that these decisions might have introduced bias into the review.

Additionally, publication bias might have been a factor to consider. As this review only included published peer-reviewed articles it is likely that a number of studies which had not been published, or which had been published by other sources, i.e. in publications that are not peer-reviewed, were not included in this study. This could have led to the findings being influenced by publication bias as non-significant results are less likely to be published than significant ones [70]. It has been argued that this is a serious issue and can impact upon the validity of systematic reviews [46]. Indeed, all the studies included in the current review found a significant relationship between catastrophizing and pain intensity. Addressing this issue was felt to be outside of the scope of this review due to the timescales set. However, with more time and resources, a search for non-published data could be undertaken.

Implications

This review has implications for future research. As very few studies have investigated the relationship between subscales of the PCS and pain intensity, and between subscales of the MPQ and catastrophizing, firm conclusions cannot be drawn. However, the current review highlights that there might be differences between conceptualisations of the facets of both pain intensity and pain catastrophizing. This would warrant further investigation. Future research should also consider carefully how they measure 'pain intensity'. A number of published articles attempt to compare and make recommendations on the plethora of scales available and generally recommend simple numerical rating or visual analogue scales [18,30,33]. However, these do not allow for subscales such as the ones found in the MPQ, and thus could perhaps be too simplistic for the type of future research suggested by the current review.

A previous review [60] has suggested that research investigating the relationship between pain catastrophizing and pain outcomes should, as standard, control for depression. This was not the case in all studies included for the current review and this is therefore recommended for future research. As this review has highlighted the overlap between a range of psychological variables and pain catastrophizing, future research should also concentrate on examining which facets of pain catastrophizing are unique in the experience of pain. This would allow further tailoring of psychological interventions in order to reduce replication of interventions which target overlapping variables. For example, if only the magnification subscale of the PCS plays a significant role in pain intensity as suggested by one study in this review [69], then targeting helplessness and rumination aspects of catastrophizing might not be of benefit to the person with chronic pain.

Along with implications for future research, the results from this review also have clinical implications. The results suggest that pain catastrophizing could be an element of a wider presentation of anxiety and thus interventions designed to reduce anxiety more generally might also serve to reduce pain catastrophizing. Similarly, by reducing catastrophizing a person might find as a consequence that their mood improves. Pain catastrophizing is one psychological factor that is often addressed in pain management interventions, alongside depression and other aspects of anxiety [19]. Given the results of this review, it could be suggested that not all these factors need to be directly addressed in order to effect improvements in anxiety, catastrophizing and depression. This could potentially reduce burden on people seeking support from pain management services, as well as the services themselves.

Conclusions

In summary, the results from this review suggest that there is a significant relationship between pain catastrophizing and pain intensity, regardless of the method of measurement.

However, once other psychological variables are taken into account, this relationship becomes more complex. It might be that there is a considerable overlap between pain catastrophizing and other psychological variables. The wide variation in variables that have been controlled for, or considered as mediating or moderating variables, suggest that a significant proportion of the variance in pain intensity explained by pain catastrophizing can be explained by other variables.

Additionally, once the concepts of catastrophizing and intensity are considered using available subscales, the relationship between the two becomes more complex, although too few empirical studies have been published to allow firm conclusion about the nature of this relationship.

Future research would benefit from further analyses of these subscales in order to allow more specific conclusions to be drawn and to allow specific tailoring of psychological interventions to specific individuals. Limitations of the review and clinical implications were discussed.

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Figure 1: Flow chart of systematic literature search

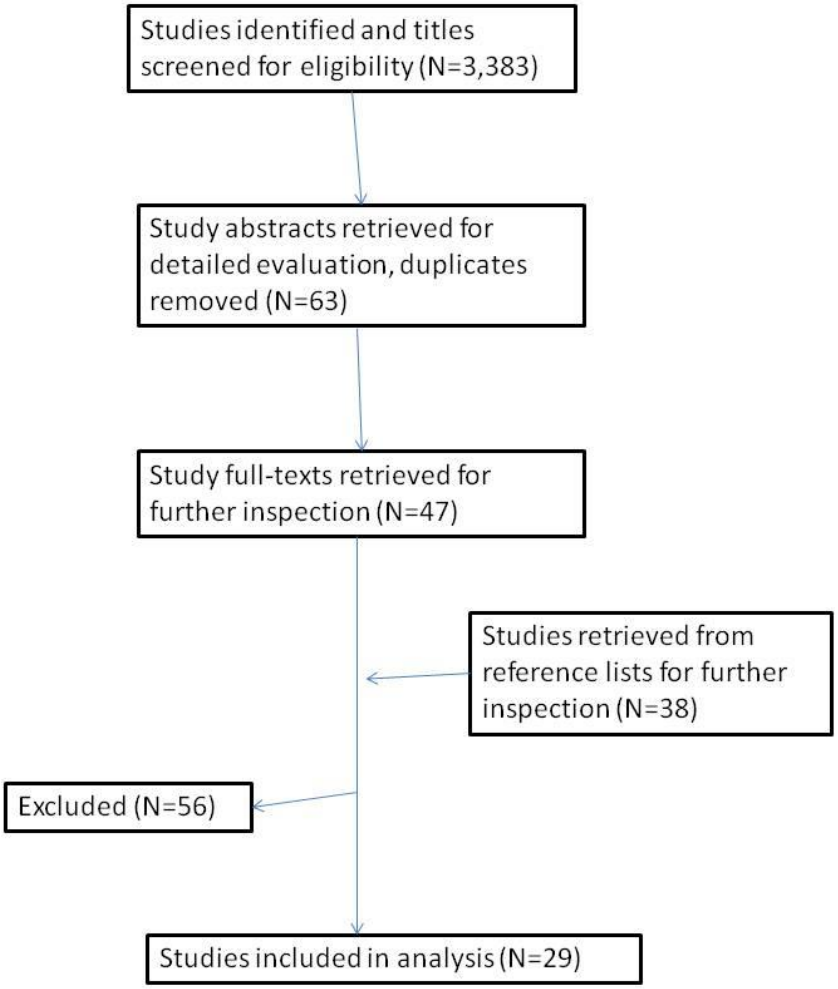

Table 1: Quality Assessment Total Scores

Authors (year)	**Quality assessment score**	Percentage
Vienneau et al. (1999)	8	27
Crombez et al. (2004)	11	37
Stewart & Knight, (1991)	11	37
Flor & Turk (1988)	12	40
Lee et al. (2008)	12	40
Woby et al. (2007)	13	43
Wollaars et al. (2007)	13	43
Buenaver et al. (2012)	14	47
Geisser et al. (1994)	14	47
George et al. (2011)	14	47
Hirsch et al. (2011)	14	47
Keefe et al. (2000)	14	47
Meeus et al. (2012)	14	47
Shipton et al. (2013)	14	47
Crombez et al. (1999)	15	50
Hassett et al. (2000)	15	50
Lumley et al. (2002)	15	50
Severeijns et al. (2001)	15	50
Shelby et al. (2008)	15	50
Sorbi et al. (2006)	15	50
De Vlieger et al. (2006)	16	53
Sullivan et al. (2002)	17	57
Darnall & Sazie (2012)	18	60
Giardino et al. (2003)	18	60
Knussen & McParland (2009)	18	60
Wood et al. (2013)	18	60
Day & Thorn (2010)	19	63
Meyer et al. (2009)	19	63
Moix et al. (2011)	22	73

Table 2: Study Characteristics

Authors (year), country	N	Mean age (years), range	Recruitment source	Pain population, minimum duration	Measures of interest		Method(s) of analysis	Variables controlled for	Results
					Pain catastrophizing	Pain intensity			
Buenaver et al. (2012) USA	214	34.3 (18-65)	Pain clinic & media adverts	Temporomandibular Disorder, duration >3 months	PCS & subscales	BPI	Correlation, bootstrapped mediation	Sleep disturbance	Relationship significant in correlations, mediation showed varying results for PCS subscales
Crombez et al. (2004) Belgium	110	41.7 (range not stated)	Pain services & self-help group	Fibromyalgia & chronic low back pain, duration not stated	PCS (adapted)	MPI	Correlation, mediation (PCS as mediator)	N/A	Relationship significant in correlation
Crombez et al. (1999), Netherlands	31	41.6 (range not stated)	Pain clinic waiting list	Chronic back pain, duration not stated	PCS	VAS for current pain	Correlation only	N/A	Relationship significant in correlation
Darnall & Sazie (2012), USA	159	Age not stated	Female prison population	Heterogeneous, duration >3months	PCS	BPI	Correlation, multiple regression	Age, depression, anxiety, substance use	Relationship significant in both correlation and regression
Day & Thorn (2010), USA	115	51.9 (range not stated)	Health clinics	Heterogeneous, duration not stated	PCS	BPI	Correlation, bootstrapped mediation	Reading ability, age	Relationship significant in correlation, mediator relationship unclear
De Vlieger et al. (2006), Belgium	185	54.1 (range not stated)	Pain clinic & community adverts	heterogeneous, duration not stated	PCS	Current pain VAS	Correlation, multiple regression	Age, gender, pain duration	Relationship significant in both correlation

									and regression
Flor & Turk (1988), USA	70	49.8 (24-79)	Pain clinics	Chronic back pain & rheumatoid arthritis, duration not stated	PRSS (catastrophizing subscale)	MPQ, MPI, daily 0-10 ratings	Correlation, multiple regression	Duration, change on x-rays, clinical activity, number of surgeries	Unclear if catastrophizing significant in correlation or regression
Geisser et al. (1994), USA	85	40.4 (21-76)	Pain and stress management clinics	Heterogeneous, duration >6 months	CSQ-CAT	MPQ subscales (sensory, affective, evaluative)	Correlation, path analysis (CSQ-CAT as mediator)	Depression	Bivariate correlations all significant, path analysis showed varying results for MPQ subscales
George et al. (2011), USA	80	46.6 (18-65)	Physical therapy clinics	Low back pain, duration not stated	PCS	NRS average of best, worst & current	Correlation, multiple regression	Age, gender, employment status, fear-avoidance	Relationship significant in both correlation and regression
Giardino et al. (2003), USA	74	41 (21-64)	Larger research trial	Spinal cord injury, duration >3 months	CSQ-CAT	MPQ subscales (sensory, affective)	Correlation, multiple regression	Age, gender, (depression but not in final model)	Relationship significant in both correlation and regression
Hassett et al. (2000), USA	96	46 (25-60)	Pain clinics, community adverts, support groups	Fibromyalgia and rheumatoid arthritis, duration not stated	CSQ-CAT,	MPQ total and subscales	Correlation, univariate regression (fibromyalgia participants only, MPQ total only)	N/A	Relationship significant in most correlations and within regression
Hirsh et al. (2011), USA	248	49.7 (range not stated)	Previous research, MS association	Spinal cord injury, multiple sclerosis, duration not stated	CSQ-CAT	NRS average over last week	Multiple regression	Gender, diagnosis	Relationship significant in regression model
Keefe et al. (2000), USA	168	61.1 (range not stated)	RCTs	Rheumatoid arthritis, duration not stated	CSQ-CAT	AIMS pain score	Structural equation model	Gender, depression	Relationship significant within model
Knussen & McParland	93	66 (43-93)	Support groups	Fibromyalgia, chronic back pain, arthritis,	CSQ-CAT	CPGS	Correlation	N/A	Relationship significant in

(2009), Scotland				duration >6 months					correlation
Lee et al. (2008), Canada	171	42.5 (range not stated)	Outpatient service	Musculoskeletal pain, duration >3 months	CSQ-CAT	VAS average over past week	Correlation	N/A	Relationship significant in correlation
Lumley et al. (2002), USA	80	48.7, (24-86)	Medical centre	Myofascial pain, duration >6 months	CSQ-CAT	MPQ subscales (sensory, affective). Total MPQ provided in correspondence	Correlation, multiple regression	Gender, age, marital status, pain duration	Relationship significant in correlation and regression
Meeus et al. (2012), Belgium	103	40.5 (18-65)	Chronic fatigue clinic	Chronic fatigue syndrome with chronic pain, duration >3 months	PCS	SF-36, VAS pain	Correlation, regression	none	Relationship significant in correlation and regression
Meyer et al. (2009), Switzerland	78	50 (range not stated)	Hospital clinics	Lower back pain, duration >3 months	PCS	GPRS	Correlation, multiple regression	Fear-avoidance, depression, somatic perception, age, gender	Relationship significant in correlation, non-significant in regression
Moix et al. (2011), Spain	123	50.4 (range not stated)	Pain clinics	Lower back pain, duration >3 months	CSQ-CAT	VAS pain	Correlation	N/A	Relationship significant in correlation
Severeijns et al. (2001), Netherlands	211	48 (range not stated)	Hospital clinics and research centre	Heterogeneous, duration >6 months	PCS	MPI	Correlation and multiple regression	Physical impairment, pain duration, age, gender	Relationship significant in correlation and regression
Shelby et al. (2008), USA	192	57 (range not stated)	Hospital clinics and community adverts	Osteoarthritis of the knee, duration >6 months	CSQ-CAT	AIMS pain score	Correlation, multiple mediator model	Self-efficacy	Relationship significant in correlation and mediator model
Shipton et al. (2013), New Zealand	874	50.3 (range not stated)	Pain management centre	Heterogeneous, duration >6 months	CSQ-CAT	MPQ	Correlation	Age	Relationship significant both when age controlled for and

									not
Sorbi et al. (2006), Netherlands	80	40.6 (18-60)	National sample, physiotherapy clinics, newspaper adverts	Heterogeneous, duration >6 months	CSQ-CAT	MPI (current pain only)	Multiple regression	Fear avoidance, cognitive responses, spousal responses	Relationship significant in regression model
Stewart & Knight, (1991), New Zealand	65	50.4 (30-65)	Rheumatology clinics	Rheumatoid & psoriatic arthritis, duration not stated	CSQ-CAT	MPQ, AIMS	Correlation, multiple regression	Not stated	Relationship between MPQ and catastrophizing significant, AIMS and CSQ-CAT non-significant. No significant relationship in regression model
Sullivan et al. (2002), Canada	150	36.1 (20-61)	Pain clinic	Heterogeneous, duration >6 months	PCS & subscales	MPQ-PRI	Correlation	N/A	Relationships in correlation differed according to chronicity and PCS subscales
Vienneau et al. (1999), Canada	40	44.8 (28-76)	Pain clinic	Chronic low back pain, duration >6 months	PCS	MPQ-PRI	Correlation	N/A	Relationship in correlation significant
Woby et al. (2007), UK	183	43.9 (range not stated)	Physiotherapy clinic	Chronic low back pain, duration >3 months	CSQ-CAT	VAS current pain	Correlation, multiple regression	Age, gender, other cognitive variables, depression, anxiety	Relationship significant in correlation and regression
Wollaars et al. (2007), Netherlands	215	51.5 (23-83)	Rehabilitation clinic	Spinal cord injury, duration >6 months	PCCL (catastrophizing subscale)	CPGS	Correlation, multiple regression	Various demographic variables, injury	Relationship significant in correlation and regression

								characteristics, anger, helplessness, acceptance, coping, pain control	
Wood et al. (2013), Australia	669	Not stated (age 61+)	Pain clinic & research centre	Heterogeneous, duration >3 months	PRSS-catastrophizing	NRS for past week	Regression for mediation model	N/A	Relationship significant in regression

PCS = Pain Catastrophizing Scale; BPI = Brief Pain Inventory; MPI = Multidimensional Pain Index; VAS = Visual Analogue Scale; PRSS = Pain-Related Self-Statements; MPQ = McGill Pain Questionnaire; PRI = Pain Rating Index; CSQ-CAT = Coping Strategies Questionnaire Catatrophizing subscale; NRS = Numerical Rating Scale; AIMS = Arthritis Impact Measurement Scale; CPGS = Chronic Pain Grade Scale; SF-36 = Short-Form Health Survey; GPRS = Graphic Pain Rating Scale; PCCL = Pain Coping and Cognition List

Appendix 1: Author Information Pack for the Journal 'Pain'

PAIN®
The Journal of the International Association for the Study of Pain

ELSEVIER

AUTHOR INFORMATION PACK

ISSN: 0304-3959

TABLE OF CONTENTS

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Section Two: Research Paper

An exploration of the relationship between self-compassion and chronic pain

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Abstract

A growing body of research suggests that self-compassion is an important factor in protecting against distress and enhancing wellbeing. More recently the concept of self-compassion has been applied to the experience of chronic pain. Previous research suggests that self-compassion could significantly predict pain-related disability and pain intensity within a chronic pain population. The aim of the current study was to investigate the relationship between self-compassion and chronic pain outcomes. The hypothesis was that self-compassion would explain a significant amount of additional variance in pain intensity and pain-related disability over and above previously established predictors. A total of 210 adult participants with chronic pain took part in this cross-sectional questionnaire-based study. Recruitment took place globally using a variety of sources including social media websites and NHS clinics. Results from multiple regression analyses did not support the hypothesis. Self-compassion was not a significant predictor of pain intensity or pain-related disability once demographic, condition-related and other psychological variables were included. Limitations of the study and clinical implications are discussed.

Introduction

Chronic pain is frequently defined as pain which continues beyond three months after normal healing would have been expected [13]. It affects between 10 and 25 percent of people globally [39], with a wide variation between countries [12]. Chronic pain can occur due to a number of reasons; these include progressive conditions such as arthritis [5] or persistent pain following acute tissue damage [11]. This acute pain serves as a warning sign for physiological injury or damage [55]. However it is argued that chronic pain serves no such function as further damage is no longer occurring [15].

It is unclear why some people continue to experience pain after the expected healing time. Although the severity of the original injury or condition has some explanatory value [46], Eccleston [26] has argued "pain is not a reliable indicator of tissue damage, and…tissue damage is not a reliable indicator of pain" (p.144). Additionally, physiological factors such as mobility restriction and low levels of activity [96], as well as demographic factors such as age [7] and gender [48] can offer some explanation as to why some people's pain persists.

Given the inability of either physiological or demographic variables to provide convincing explanations for a person's experience of chronic pain, psychological factors could address this gap. The role of psychological factors in chronic pain only emerged around 50 years ago [56,62] but the incorporation of individually measured psychological constructs has been argued to aid understanding of variation both in the development of chronic pain [47] and its maintenance [35], especially when individuals' physiological presentations are similar. Psychological variables have also been included in theoretical models of chronic pain (see [54] for a discussion) in an attempt to better understand pain outcomes such as pain-related disability [78], adjustment to chronic pain [44], pain behaviours [31], and pain intensity [75].

While it is important to understand all these aspects of the pain experience, from a clinical viewpoint, it is arguably beneficial to focus on pain intensity, which is a subjective perception of the strength of pain [43], and pain-related disability, which refers to the level at which the person feels able to participate fully in society. Indeed, a recent systematic review which included 54 published research papers concluded that pain intensity is "probably the most clinically relevant dimension of the pain experience" (p.1086) [41]. Research has shown that pain management programmes can lead to a reduction in pain intensity [101], suggesting that change in pain intensity is possible with psychological intervention. Pain intensity has been shown to play a significant role in disability [4], and both are related within a fear-avoidance model of chronic pain [50]. However the strength of this relationship is debated in the empirical research (e.g. [21]). Indeed effecting a change in intensity does not guarantee a change in perceived disability [28], and focusing interventions solely on reducing pain intensity is not recommended as there is no guarantee that this will impact on a person's level of disability [28]. Additionally research suggests that they are conceptually distinct aspects of the pain experience [86]. However, despite the debate, research suggests that similar psychological factors are involved in both. Indeed, much research has been done into psychological factors; the main factors shown repeatedly to predict individual variation in both intensity and disability are self-efficacy [6,20,33,51,63,100], anxiety [16,63,64,90,91], depression [1,3,30,34,38,52,68,69] and catastrophizing (e.g. [3,9,16,33,58,81,87,93,100]). This suggests that these factors will be important to consider when planning research in this field. Additionally, in recent years the importance of pain acceptance has been noted, with higher acceptance and willingness to experience pain being associated with less impaired functioning and less healthcare use (e.g. [60]).

Research has suggested that there might be overlap between psychological variables. For example, in one study where both self-efficacy and anxiety were significantly correlated

with pain intensity and disability, anxiety did not explain any unique variance in disability when entered into a regression model alongside self-efficacy [63]. In another study, the impact of catastrophizing on disability became non-significant when other psychological variables were entered into the model [100]. This suggests that there is shared variance between psychological variables, which must be taken into consideration.

Given that all these variables have been shown to explain variance in chronic pain outcomes it could be suggested that they share variance. This argument can be supported by research which shows that when anxiety is controlled for, other psychological variables such as depression and catastrophizing did not explain any unique variance in chronic pain disability, suggesting an overlap between psychological factors [64]. Therefore it would be good practice to include them in a psychological model of chronic pain in order to assess the unique contribution of each in pain outcomes.

In addition to already established psychological factors, recent research has suggested self-compassion might be an important factor in the experience of chronic pain (e.g. [18,19]). Self-compassion can be defined in a number of ways [37], although a commonly used definition [70] suggests that self-compassion involves three main elements: considering oneself non-judgementally, being mindful of one's own difficulties and seeing oneself as part of the collective human race. Gilbert [36] argues that behaving compassionately towards oneself is associated with greater wellbeing, and can activate the brain's soothing system, leading to a release of oxytocin and opiates. As oxytocin has an analgesic effect [89] it could be argued that self-compassion would have an impact on pain intensity due to oxytocin. Gilbert also argues for the role of self-compassion in the reduction of shame. As shame is often central to people's experiences of chronic pain [40,74], it can also be argued that increasing self-compassion in people with chronic pain could lead to significant clinical benefit.

Self-compassion could also be considered theoretically within existing psychological models of chronic pain. One example is the fear avoidance model, proposed by Leetham and colleagues in 1983 [50]. Self-compassion could act as a break to the cycle of avoidance, allowing a person to exit the cycle and take positive action in order to reduce their pain. Thus, even if an individual was a high catastrophizer, activating the self-soothing system could prevent that catastrophizing from impacting on their pain and disability levels. If the neuromatrix model of pain is considered [61], psychological factors such as self-compassion could theoretically influence pain intensity in two ways, firstly by impacting on how the brain perceives danger and thus how it responds, and secondly by making changes to an individual's pain 'neurosignature' over time.

While there seems to be good theoretical reason to consider the role of self-compassion in chronic pain, research in this field has only recently emerged in the past few years. Outside of a chronic pain population research suggests that self-compassion can predict depression scores in undergraduate students [88], and a recent meta-analysis has shown a significant relationship between self-compassion and various facets of mental health [57]. Within a chronic pain population similar findings have been demonstrated. A recently published study [19] showed that self-compassion explained a significant proportion of variance in distress, i.e. depression, anxiety and stress, within a heterogeneous chronic pain population, although for depression and anxiety this relationship became non-significant once experiential avoidance was entered into the regression model.

A slightly earlier study demonstrated that self-compassion is also significantly related to chronic pain specific outcomes [18]. This showed that self-compassion was significantly and positively correlated with acceptance of pain, so that the greater a person's self-compassion, the higher their level of acceptance. This research has begun to highlight the possible impact that self-compassion might have on the pain experience, although limited to

pain acceptance. However, these findings might be of little clinical relevance for the person experiencing high levels of pain, or for someone who feels disabled by their pain. Indeed, the lack of pain intensity or disability measures in the study was noted as a limitation by the authors [19].

These outcome measures were taken into account in a study by Wren et al. [102], who found that self-compassion was negatively and significantly associated with pain-related disability but explained only five percent of the variance once age, education and financial compensation were taken into account. The study also found that self-compassion was not a significant unique predictor of pain intensity. However, this study was conducted with an adult obese population and thus cannot be generalised to a more general chronic pain population. Additionally, the study only used the total score for self-compassion and did not take into account subscale scores.

In order to address the problems with lack of both generalisability and subscale scores in the aforementioned study [102], the current study aims to expand on previous research, identifying the unique predictive variance of self-compassion in measures of pain intensity and pain-related disability. Previous demographic, physiological and psychological factors have been demonstrated in published empirical research. There is a lack of evidence establishing the uniqueness of self-compassion in the variation of pain-related variables within a heterogeneous chronic pain population. It is a timely study because self-compassion and compassion-focused therapies are an emerging phenomenon in clinical psychology [37]. If research suggests there is a relationship between self-compassion and pain intensity or pain disability within a general chronic pain population, this could provide the beginnings of an evidence-base for using compassion-focussed therapies in the treatment of chronic pain.

Based on previous research the current study hypothesised that self-compassion, as a combined model of subscales, would explain a significant additional amount of variance in

two outcome measures (pain intensity and pain-related disability) over and above previously established predictors.

Method

Participants

To ascertain the minimum number of participants needed to carry out a hierarchical multiple regression an *a priori* power calculation was conducted using GPower 3.1. On the assumption that each regression model were to contain ten predictor variables, a minimum of 118 participants were needed in order to detect a medium effect size (r = .30) with 80% power. A total of 300 people took part online – of these, eight people reported that they did not have chronic pain that had persisted longer than three months, 20 responses were invalidated due to technological issues and a further 73 were invalid due to incompletion of measures. This left a total of 199 valid online responses which were included in this study. Additionally, 15 paper questionnaires were returned, of which four were invalid and therefore excluded due to incompletion of multiple measures. This resulted in a final sample size of 210 participants.

Potential participants were invited throughout the recruitment period of 5th May to 29th August 2014. A varied recruitment strategy was undertaken in order to ensure the results were generalisable to a wide chronic pain population. This also allowed for a wide variance in pain intensity as it was initially assumed that those recruited from NHS services would experience greater pain intensity and disability overall. Due to the variation in recruitment methods it is difficult to provide a response rate. For example, it is unknown how many people viewed online adverts pertaining to this study. Recruitment took place in the following ways:

NHS patients.

Patients seeking support from a number of NHS pain clinics across North England were invited to take part. They were given an invitation letter and information sheet as part of their routine care, either through the post alongside correspondence from the clinic, or face-to-face at an outpatient appointment. Twenty-five people (11.9% of the total sample size) recruited via NHS services took part in this study.

Support groups.

Four chronic pain community support groups across the British Isles agreed to circulate an invitation and information sheet to all attending members. In total 110 sheets were given to group leaders. It is unknown how many of these were passed onto group members. Only one participant was recruited via this method (0.5% of the sample).

Social media and online support forums.

Adverts were sent out to promote this research via social media websites, namely Twitter (www.twitter.com) and Facebook (www.facebook.com). Groups and individuals who promoted themselves as working within relevant fields were asked to share the advert with their friends and followers. Additionally, adverts were placed on well known chronic pain support forums online. Forty-four participants were recruited via Twitter directly, and 140 further participants were recruited from other online sources, including Facebook.

Inclusion/exclusion criteria.

Only participants who were aged 18 or over at the time of completing the questionnaire were included. No maximum age limit was set. All participants needed to consider themselves to have chronic pain, defined as pain that had persisted for 3 months or longer [29] and therefore were excluded if they answered ‘no’ to a screening question prior to consent-giving. Participants who could not read and understand English were unable to take part due to the included measures’ lack of validation in alternative languages.

Design

This study used a quantitative questionnaire design. As this was primarily an exploratory study, a cross-sectional design was chosen. All measures were completed at one time point by each participant.All measures were self-report in nature.

Measures.

Chronic Pain Intensity.

Pain intensity was measured using the Pain Rating Scale (PRS) [14]. This measure consists of six items, of which two measure pain intensity ('now' and 'on average last week'), two measure pain distress ('now' and 'on average last week'), one measures pain interference, and one measures relief felt by any treatment. The first five items use a 0 to 10 numerical rating scale, and the final item uses a 0-100 per cent rating scale, with higher scores indicating more pain, distress, interference or relief. For pain intensity and distress the two items in each scale are summed and the average taken for the total score, with a minimum score obtainable of zero and a maximum of 10.

This measure was chosen because 11-point numerical rating scales have been found to result in less error than a visual analogue scale [24] or a verbal rating scale [99]. A group of leading researchers in the field of chronic pain also recommend their use in research [25]. In the current study the Pain Intensity scale of the PRS was found to have adequate internal consistency ($\alpha = .75$).

Chronic Pain Disability.

The Pain Disability Index (PDI) [79] is a seven-item, 11-point Likert scale which measures the impact of pain on seven aspects of people's lives, such as recreation, occupation and self-care. Items are scaled from 0 ('no disability') to 10 ('worst disability'), with a

minimum total score obtainable of 0 and a maximum of 70. A higher score indicates greater disability.

The PDI is commonly used in research [103] and can be used with a heterogeneous pain population, unlike other common disability measures which are specific to particular areas of the body [84]. It has been shown to have good internal consistency both in previous research (α =.87) [95] and in the current study (α = .92).

Pain Catastrophizing.

The Pain Catastrophizing Scale (PCS) [92] is a 13-item, five-point Likert scale. It gives an overall score and consists of three subscales which measure rumination, magnification and helplessness. Scores for the overall scale can range from 0 to 52. Higher scores indicate greater levels of catastrophizing. The authors were able to demonstrate the scale's internal consistency (α = .87) [92]. In the current study these findings were supported (α = .95).

Self-Efficacy.

The Pain Self-Efficacy Questionnaire (PSEQ) [73] is a ten-item, seven-point Likert scale, which measures a person's perception of their ability to accomplish a number of things despite their pain. Scores can range from 0 to 60, and a higher score indicates greater self-efficacy. The author has suggested it has high internal consistency (α = .92). This was also shown in the current study (α = .93).

Pain Acceptance.

The Chronic Pain Acceptance Questionnaire (CPAQ) [59] is a 20-item, seven-point Likert scale which measures how willing and accepting a person is towards their pain. Scores can range from 0 to 120, with a higher score indicating greater acceptance of pain. It has been shown to have good psychometric properties [98], and internal consistency was found to be good in the current study (α = .91).

Anxiety and Depression.

The Hospital Anxiety and Depression Scale (HADS) [104] is a 14-item scale with four responses possible for each item. It incorporates two separate measures, i.e. anxiety and depression, with possible scores ranging from 0 to 21 on each measure. Higher scores indicate higher levels of anxiety or depression.

Originally designed for use within healthcare settings, it has also been used successfully in community populations [85]. It has been found to be an appropriate measure within a variety of pain populations (e.g. [77,97] and is commonly used in chronic pain research (e.g. [27]). Previous research [10] has shown that internal consistency can vary (anxiety α = .68 to .93, depression α = .67 to .90). In the current study internal consistency was acceptable (anxiety α = .85, depression α = .86).

Self-Compassion.

The Self-Compassion Scale (SCS) [70] is a 26-item, five-point Likert scale. It gives a global 'self-compassion' score, with possible scores ranging from 26 to 130. Higher scores indicate higher levels of self-compassion. It also includes six subscale scores, i.e. self-kindness, self-judgement, common humanity, isolation, mindfulness and over-identification.

In a chronic pain population, the whole-scale score has previously shown good consistency (α = .95) as have all the subscales (α = .83 to .93) [102]. In the current study the total scale showed good internal consistency (α = .94), and all subscales were adequate (self-kindness α = .88, self-judgement α = .87, common humanity α = .77, isolation α = .84, mindfulness = .76, over-identification α = .81).

Procedure

Ethical approval for this study was granted by an NHS ethics committee in May 2014 with a substantial amendment granted in August 2014. Individual Research and Development approval from four NHS trusts was given between May and June 2014.

Participants could choose to take part in this study in two ways, either online or by completing a paper questionnaire. The procedure differed slightly for each.

Online.

For participants choosing to take part online, a link was provided which took them to Qualtrics (www.Qualtrics.com), an online survey hosting website. Here they were asked to input a password due to copyright restrictions with one of the measures included. This password was provided in the information sheet. Once the password was entered participants were reminded of the study requirements, and asked to indicate if they had chronic pain. If they stated 'yes', they were then asked to read and complete the consent form. Participants had to tick all boxes in order to begin the survey. Prior to demographic questions, participants were asked to generate a 6 character code, made up of letters and numbers, which they could later use to exercise their right to withdraw their data from the study. Following demographic questions, participants were asked a number of questions about their pain, and then asked to complete the validated measures. Once they had completed the survey, participants had an option to enter their email address to receive an email version of the debrief sheet. This was also presented to them with an option to print once they had exited the survey.

Paper.

In order to remain inclusive to participants who might not want or be able to complete their questionnaire online, participants were able to request a paper copy of the questionnaires which they could return by post. Prior to posting questionnaires out, the lead researcher contacted the participant in order to screen them for the presence of chronic pain. This was done with one participant over the phone and the remaining participants were contacted by email. If participants indicated that they had chronic pain, they provided the researcher with their name and address in order for the questionnaire pack to be posted out. Consent for

those completing on paper was sought at the start of the questionnaire pack. Once participants had completed their questionnaire, they were asked to remove the debrief sheet, write their 6 character code on it, and return the questionnaire pack in a pre-paid envelope.

Analysis

Analysis was undertaken using SPSS versions 20 and 21 for Windows. Kolmogorov-Smirnov test results suggested that a number of variables were not normally distributed. However an inspection of Q-Q plots, histograms and consideration of the sample size meant that only the distribution of pain-related disability was of concern. The attempted transformation of this variable using a square root transformation [76] did not result in a normal distribution and so PDI scores were included in the analyses without transformation.

Categorical variables of interest were collapsed into two categories in order to inspect differences between groups using T-tests and, where applicable due to non-normal distributions, Mann-Whitney U tests. Where significant between-group differences were observed in the outcome variables, the categorical variable was selected for input into hierarchical regression models for further analysis. The exception to this collapsing of categories was with 'gender' which consisted of three categories, i.e. female, male, transgender. For the purpose of inspecting between group differences only, males and females were compared and the transgender category ($N = 1$) was excluded from this analysis.

In order to identify potential continuous predictors for the regression models, correlations were conducted (Pearson's and Spearman's: two-tailed). A *post hoc* Bonferroni correction was applied to significance levels to adjust for multiple correlations [32], and this resulted in a conservative significance level of $p \leq .0033$ being applied. Any correlations between the outcome variables and continuous potential predictors that reached this level of

significance were noted and these variables were retained for input into the regression models.

In total, two regression models were developed with predictor variables entered in theoretically driven blocks. Blocks were planned as follows:

Block 1: demographic variables

Block 2: condition-related variables

Block 3: psychological variables

Block 4: self-compassion total and subscale scores

Adding self-compassion variables in the final block of a regression model allowed a strict test of the ability of self-compassion to explain unique variance in pain outcome measures [82]. This meant that any variance explained by other variables entered into the model was already controlled before the entry of self-compassion into the model, and any overlap between variables as previously discussed could be accounted for. As there was potential for multicollinearity between variables entered into the regression models, inspection of tolerance and inflation statistics took place. Previous research suggests that tolerance levels of >.02 are acceptable, with a variance inflation factor (VIF) <10 (e.g. [83]). Results suggested that the multicollinearity assumption was not violated.

Missing data.

In order to ensure that enough data were provided by each participant, individual data sets were deemed invalid if three or more items were missing from the validated measures. For the two-item measures (pain intensity, pain distress), both items had to be missing for the individual data set to be deemed invalid. For measures in which one or two items were missing, the missing items were replaced with the personal mean score [42] for that scale.

For scales with subscales, the item was replaced with the mean of the relevant subscale. This was deemed appropriate given the large sample size and the small number of missing data points [32].

For the two-item measures, the missing item was replaced with a technique considered to share characteristics similar to 'hot deck' imputation [2]. For these measures, the mean of the other participants' data that had the same score for the non-missing item was used to replace the missing item. For example, if one participant was missing the item for 'average pain over the past week' and had scored six for 'current pain', the mean score for 'average pain over the past week' was taken from all other participants who had scored six for 'current pain'.

For categorical variables missing data were replaced with the mode from the entire data set. For gender, this resulted in two participants who had failed to complete this question being classified as 'female'. As one person indicated their gender as 'transgender', this was not recoded and this datum was not included in t-tests and Mann Whitney-U tests as variables needed to be dichotomous. The individual's data were retained for all other analyses.

Results

Insert Table 1 here

Demographics

The mean age of participants was 45.47 years (*SD* = 12.7, range = 18-77), and mean duration of pain was 144.65 months (*SD* = 117.9, range = 3-588). All participants provided

data on what type of chronic pain they had been diagnosed with. Participants were able to indicate more than one diagnostic category. The largest diagnostic category was fibromyalgia, with 30 percent (N = 63) of the sample having this diagnosis. 20.5 percent (N = 43) of the sample had a diagnosis of arthritis, and 39.5 percent (N = 83) of the sample had a diagnosis which was not captured by the questionnaire. Table 1 presents further demographic information, such as country of residence, ethnicity and working status. Mean scores, standard deviations as well as observed and possible ranges for pain-related and psychological variables can be found in Table 2.

Insert Table 2 here

Although the HADS was used as a continuous variable, the original authors suggested three groupings for the scales of anxiety and depression [104]. In the current study, based on the original authors' cut-off scores, 66 participants (31.4%) would be classed as no anxiety, 42 participants (20.0%) would be classed as possible anxiety and 102 participants (48.6%) would be considered probable anxiety. For the depression scale, 83 participants (39.5%) would be classed as non-depressed, 53 participants (25.2%) would be classed as possible depression and 74 (35.2%) would be classed as probable depression.

Between Group Differences

As this study recruited participants from both NHS and non-NHS sources it was important to assess the differences between the two recruitment streams on pain intensity and pain-related disability. As a number of the continuous variables were identified as showing non-normality, Mann Whitney-U tests were run. These revealed no significant differences (all $p \leq .05$) on either pain intensity or pain-related disability between recruitment source (NHS, non-NHS), gender (male, female), ethnicity (White British, non-White British),

relationship status (in a relationship, not in a relationship) and country of residence (UK, non-UK). A significant difference was observed between NHS and non-NHS participants on the self-kindness subscale of the self-compassion scale, and on the SCS total score (both $p \leq .05$), with no significant differences found on the remaining five subscales.

Correlation Analyses

Spearman rho values for relationships between all psychological variables and the outcome variables can be seen in Table 3. Results suggested that the isolation subscale of the SCS correlated positively and significantly with both pain intensity ($rs = .203$, $p \leq .0033$, Bonferroni adjustment) and pain-related disability ($rs = .243$, $p \leq .0033$), so that as a person's sense of being disconnected from others when distressed increased so too did the intensity and perceived disabling nature of their pain. The mindfulness subscale was negatively and significantly correlated with pain-related disability ($rs = -.273$, $p \leq .0033$) so that as a person was more mindful of their distress their sense of being disabled by their pain decreased.

Insert Table 3 here

Multiple Regression Analyses

Preliminary analyses were run to ensure no violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Across both regressions models, the lowest tolerance level for an individual variable was .395 and the highest VIF was 2.529. This suggests that multicollinearity was not a problem within this data set.

Outcome variable – pain intensity.

From the between-groups analyses and the correlation analyses, 9 variables were entered into four blocks in the regression model (see Table 4). Block 1 consisted of working

status and source of recruitment. Block 2 consisted of fibromyalgia diagnosis. Block 3 contained depression and anxiety, pain catastrophizing, pain self-efficacy and pain acceptance. Finally, block 4 consisted of the isolation subscale of the SCS. Block 1 on its own explained 7.7% of the variance in pain intensity. After entry of the variables in block 2, the variance explained increased to 11.4%. This increased again to 24.8% when psychological variables were entered in block 3. Finally, after entry of the self-compassion isolation subscale in block 4, the total variance explained by the model as a whole was significant, explaining 24.8% of the variance (R^2 = .248, $F(9, 200) = 7.343$, $p < .001$). The isolation subscale of the SCS did not explain any additional variance in pain intensity after controlling for demographics, condition-related variables and psychological variables, resulting in a non-significant change (R^2 change = .000, F change (9, 200) = .001, p = .978). In the final model (see table 4), only diagnosis of fibromyalgia and pain self-efficacy were statistically significant (respectively β = .135, $p < .05$, β = -.272, $p < .05$), so that a person diagnosed with fibromyalgia had significantly higher levels of pain intensity than a person not diagnosed with fibromyalgia, and as a person's pain self-efficacy increased, their level of pain intensity decreased.

Insert Table 4 here

Outcome variable - pain-related disability.

A total of 11 variables were selected for entry into four blocks in the regression model (see Table 5). Block 1 consisted of working status and source of recruitment. Block 2 consisted of fibromyalgia diagnosis. Block 3 contained depression and anxiety, pain

catastrophizing, pain self-efficacy and pain acceptance. Finally, block 4 consisted of the isolation and mindfulness subscales of the SCS as well as the SCS total score.

Block 1 on its own explained 14.5% of the variance in pain-related disability. After entry of the fibromyalgia diagnosis in block 2, the variance explained increased to 18.0%. This increased again to 58.6% when psychological variables were entered in block 3. Finally, after entry of the self-compassion measures in block 4, the total variance explained by the model as a whole was significant, explaining 59.5% of the variance (R^2 = .595, F(11, 198) = 26.47, p < .001). The SCS total score, isolation and mindfulness subscales together only explained an additional 0.9% of the variance in pain-related disability after controlling for demographics, condition-related variables and psychological variables, resulting in a non-significant change (R^2 change = .009, F change (11, 198) = 1.53, p = .208). In the final model (see table 5), pain acceptance, pain self-efficacy and self-compassion total score were statistically significant predictors (respectively β = -.175, p < .05, β = -.487, p < .001, β = .275, p < .05). As acceptance and self-efficacy increased, pain-related disability decreased, and as self-compassion increased, pain-related disability also increased.

Insert Table 5 here

Discussion

The aim of this study was to explore the relationship between self-compassion and chronic pain outcomes. Based on previous research, a hypothesis was made that self-compassion would explain a significant additional amount of variance in pain intensity and pain-related disability over and above previously established predictors.

Results suggested that some of the subscales of the SCS were significantly correlated with the two outcome measures. Only the isolation subscale was significantly correlated with pain intensity. However, when combined with other variables, the isolation subscale of the SCS was not able to predict any additional variance in pain intensity and was not a significant independent predictor. Therefore the results from the current study do not support the hypothesis. These results further expand on the findings of previous research by Wren et al. [102] who found that self-compassion, although only measured with the SCS total score, was not a significant predictor of pain intensity once demographic variables were included. In the current study, the only significant independent predictors were fibromyalgia diagnosis and pain self-efficacy. Interestingly, depression, catastrophizing and anxiety, which have been shown by previous research to be significant predictors of pain intensity (e.g. [38,63,100]), were all found to not be significant predictors in the current study.

Similarly, the isolation and mindfulness subscales, as well as the SCS total score, were significantly correlated with pain-related disability, however together they were able to explain only 0.9 per cent of the variance in pain-related disability. This was not statistically significant and thus these results did not support the hypothesis. The results contrast with previous research [102], in which the SCS total score was found to explain a significant amount of variance in pain-related disability. In this previous research, unlike the current study, no psychological variables were included in the model which raises the possibility that if the authors had considered other psychological factors, this significance might have disappeared.

Interestingly, when considering individual predictors, results suggest that SCS total score, pain acceptance and pain self-efficacy were significant independent predictors of pain-related disability. While both pain acceptance and pain self-efficacy showed a negative relationship with pain-related disability, in that increases in acceptance and self-efficacy were

associated with a significant increase in disability, the significance and direction of the relationship between self-compassion and disability was surprising. This relationship was positive, in that higher levels of self-compassion were associated with higher levels of disability. This contrasts with the observed bivariate correlation which was negative. This suggests that another variable might be acting as a suppressor variable, which could change the direction of the relationship between self-compassion and pain-related disability and inflate the size of the effect [94]. This might have lead to a Type 1 error and thus might not represent a true finding in the population [32]. Given this, as well as the observation that the block containing self-compassion measures was not able to explain a significant proportion of variance in disability, the finding that SCS total score was a significant predictor cannot lead to inference about the role of self-compassion in pain-related disability.

The results from the current study should be taken with caution as it was noted that the mean self-compassion scores were higher than expected, when compared to results found by the scale author [71], particularly among the non-NHS population. The high self-compassion scores in the sample might have had an impact upon the results of the current study. It is anticipated that high self-compassion scores might be found in subsequent studies, particularly where a non-clinical chronic pain population is sampled. Additionally, a significant difference was found between NHS and non-NHS participants on the self-compassion total score, as well as the self-kindness subscale score. This suggests variance between groups on these measures which could have influenced the findings.

The finding that self-compassion did not explain a significant amount of variance in pain disability might also be explained by the role that acceptance plays in the relationship. As previous research has found that self-compassion and chronic pain acceptance were significantly correlated [18], by controlling for acceptance in the current study variance that

self-compassion and acceptance shared was accounted for prior to entering self-compassion into the regression model.

Clinical Implications

The movement within positive psychology towards focusing on increasing wellbeing and acceptance rather than decreasing symptoms has in recent years led to a shift in how psychological services for people with chronic pain are provided. For example some pain management programmes focus exclusively on solution-focused techniques in order to effect change in people's relationship with their pain [23], while others take an acceptance and commitment approach [22]. Clinically, psychologists have moved towards using compassion-focused therapy within chronic pain services [17] which appears to have taken place outside of an evidence-based approach. Certainly, the results of the current study suggest that self-compassion explains no unique variance in people's perceived levels of pain or disability above and beyond other psychological variables which are already targeted areas for change in many pain management interventions (e.g. [66]).

Therefore if psychology services are already offering programmes which will allow a person to reduce the psychological factors which have been shown in the current study to be significant predictors of chronic pain outcomes, e.g. pain catastrophizing, acceptance, pain-related self-efficacy, anxiety and depression, adding compassion-focused approaches might not produce better outcomes for people with chronic pain. Additionally, it will add extra work for both the person with chronic pain and the clinician. Results from the current study suggest that further evidence of the role of self-compassion in chronic pain outcomes, or the impact of increasing self-compassion using psychological interventions, is needed before this type of approach is further adopted in clinical practice.

Strengths and Limitations

This study took a cross-sectional design in that all measures were taken at the same time point. This type of design was chosen as it offered a practical way to conduct this exploratory study. Cross-sectional studies can be open to criticism (e.g. [32]) and it is acknowledged that causation cannot be inferred from the results presented in the current study. For the individual experiencing pain, gaining an understanding of what might be associated with their experience of pain in the current moment could offer some value, however taking a prospective approach might have allowed causation to be more firmly established.

The limitations of the measures, particularly the pain intensity measure, must be noted. As this measure contained an item that was retrospective in nature, in that it asked people to rate their pain intensity for a period of time prior to the questionnaire completion, it could be open to recall bias [53]. In order to reduce the likelihood of this bias, participants were only asked to recall their pain over a short time frame of one week.

Criticism could also be levied at the measure of self-compassion used in the current study. The SCS has been criticised for being too cumbersome and therefore unsuitable when used with a number of other questionnaires [49]. In the current study, the SCS was one of the last measures presented on the questionnaire and by this point participants, particularly anyone experiencing fatigue or pain at that time, might have found it difficult to complete the items accurately. One solution to this would have been to have used the short-form version of the scale [80]. However, the authors of this scale acknowledge that when calculating subscale scores the longer version is more appropriate. Using the short-form version would have allowed less exploration of the concept of self-compassion, as it has been noted that each subscale combines to make a second-order concept of self-compassion rather than self-compassion being an entity in itself [72].

Furthermore, the use of online strategies to recruit participants might have led to exclusion of particular populations who for a variety of reasons might not have access to the internet. While some recruitment took place offline, this was only through NHS services and community support groups. Therefore people who did not access these forms of support would not have been able to take part unless they were actively online and had a certain level of computer ability. Additionally, for a person with severe chronic pain, using a computer for a prolonged period might have caused difficulties. While the online questionnaire was set up so that participants could return at a later date and thus complete measures over several sessions, this might not have been clear to people undertaking the questionnaire online. This resulted in a number of participants' data being excluded because they had not reached the end of the measures.

However, enabling participants to complete questionnaires online as well as on paper meant that this study was able to recruit participants from a wide range of sources and from a variety of countries. Recruiting only from health care services and community support groups would have resulted in a small sample size and results that could not be generalised outside of a treatment- and support-seeking population [8]. It is unclear why uptake from these sources was so low, but perhaps could be linked to possible low attendance at community groups. With the exception of one pain clinic, the lead researcher was not able to approach people personally. This meant less personal connection and potentially reduced motivation for people to partake. However, this strength of wide recruitment leads to a possible limitation of this study in terms of heterogeneity. T-tests and Mann Whitney-U tests revealed that while there were no significant differences between NHS and other recruitment sources on the proposed outcome variables, there were a number of significant differences on other measures. For example NHS participants were significantly older, more distressed and catastrophized more. They also showed significantly less self-kindness and lower levels of

self-compassion overall. This might be indicative of a treatment-seeking population but suggests that the two groups differ on some important variables. These observed differences on self-compassion scores might suggest that the relationship between self-compassion and chronic pain differs between the two groups. This indicates that those participants recruited through NHS services are a psychologically distinct group of individuals, with potentially higher levels of disability and catastrophizing, and lower levels of self-efficacy and pain acceptance. Further analysis would be required in order to test this hypothesis.

Future Research

The differences observed between the two groups, as discussed above, has implications, in that future researchers must consider recruitment carefully in all aspects of their study, considering the key differences in psychological measures between recruitment groups. Previous researchers prominent in the field of chronic pain have argued that groups of participants should be identified by psychological profiles rather than by diagnosis [65], and the current study seems to add to this argument.

Any potential future research would benefit from investigating the differences between the mindfulness subscale of the SCS and other measures of mindfulness. Previous research has suggested that mindfulness-based interventions are beneficial (e.g. [67]), although conversely in the current study the mindfulness subscale of the SCS was not a significant predictor of any of the chronic pain outcomes. This might be explained by the potential difference in definitions of mindfulness. For example, Kabat-Zinn [45] defines mindfulness as being non-judgementally and purposively present in the current moment. However, the mindfulness subscale of the SCS focuses more on the ability to be mindful at times of distress. This difference in conceptualisation needs to be explored further.

Future research could also take a prospective design which would allow researchers to investigate if the presence of high levels of pain intensity and pain-related disability erode a

person's capacity for self-compassion over time. This would deal with the limitation of the cross-sectional nature of the current study which leads to difficulties with establishing causation.

It would also be beneficial to investigate if the significant relationships observed between subscales of the self-compassion scale and chronic pain outcomes is mediated or moderated by other variables, such as chronic pain acceptance. Due to previously discussed research, there is suggestion that this could be the case, but no published study has undertaken this analysis as of yet.

Summary and Conclusion

In conclusion, the results from this study suggest that some aspects of self-compassion correlate with chronic pain outcomes. However once condition-related, demographic and previously established psychological predictors were taken into account no aspect of self-compassion significantly predicted chronic pain intensity, disability or distress. The findings of this study did not support the original hypothesis. Limitations of the research and some suggestions for future research have been considered.

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Table 1: Demographic Results

Characteristic	Total population N (%)	NHS population N (%)	Non-NHS population N (%)
Gender			
Female	175 (83.3)	22 (88.0)	153 (82.7)
Male	34 (16.2)	3 (12.0)	31 (16.8)
Transgender	1 (0.5)	0	1 (0.5)
Mode of completion			
Online	199 (94.8)	17 (68.0)	182 (98.4)
Paper	11 (5.2)	8 (32.0)	3 (1.6)
Country of residence			
UK	108 (51.4)	18 (72.0)	95 (51.4)
Australia	74 (35.2)	6 (24.0)	68 (36.8)
USA	11 (5.2)	0	11 (5.9)
Canada	3 (1.4)	0	3 (1.6)
Republic of Ireland	3 (1.4)	0	3 (1.6)
Belgium	1 (0.5)	0	1 (0.5)
Not provided	5 (2.4)	1 (4.0)	4 (2.2)
Recruitment source			
Facebook / online forums	140 (66.7)	0	140 (75.7)
Twitter	44 (21.0)	0	44 (23.8)
NHS pain clinics	25 (11.9)	25 (100)	0
Community support group	1 (0.5)	0	1 (0.5)
Relationship status			
Married / civil partnership	111 (52.9)	8 (32.0)	103 (55.7)
Single	32 (15.2)	3 (12.0)	29 (15.7)
Divorced / separated	26 (12.4)	7 (28.0)	19 (10.3)
Cohabiting with partner	20 (9.5)	1 (4.0)	19 (10.3)
In a relationship, not cohabiting	13 (6.2)	2 (8.0)	11 (5.9)
Widowed	7 (3.3)	4 (16.0)	3 (1.6)
Not provided	1 (0.5)	0	1 (0.5)
Employment status			
Not able to work	79 (37.6)	13 (52.0)	66 (35.7)
Employed full time	42 (30.0)	3 (12.0)	39 (21.1)
Employed part time	29 (13.8)	0	29 (15.7)
Retired	20 (9.5)	7 (28.0)	13 (7.0)
Self-employed	14 (6.7)	0	14 (7.6)
Homemaker or parent	9 (4.3)	1 (4.0)	8 (4.3)
Not employed, looking for work	6 (2.9)	1 (4.0)	5 (2.7)
Not employed, not looking for work	6 (2.9)	0	6 (3.2)
Student	5 (2.4)	0	5 (2.7)
Ethnicity			
White British	139 (66.2)	19 (76.0)	120 (64.9)
Other White background	48 (22.9)	5 (20.0)	43 (23.2)
White Irish	8 (3.8)	0	8 (4.3)
Mixed ethnicity	5 (2.4)	0	5 (2.7)
Any other background	2 (1.0)	0	2 (1.1)

Not provided	8 (3.8)	1 (4.0)	7 (3.8)
Diagnosis			
Fibromyalgia	63 (30.0)	10 (40.0)	53 (28.6)
Arthritis	43 (20.5)	4 (16.0)	39 (21.1)
Chronic Regional Pain Syndrome	20 (9.5)	4 (16.0)	16 (8.6)
Joint Hypermobility	18 (8.6)	0	18 (9.7)
Chronic Headaches	16 (7.6)	1 (4.0)	15 (8.1)
Chronic Back Pain	5 (2.4)	0	5 (2.7)
Post Herpetic Neuralgia	4 (1.9)	0	4 (2.2)
Multiple Sclerosis	4 (1.9)	0	4 (2.2)
Ankylosing Spondylitis	3 (1.4)	0	3(1.6)
SUNA syndrome	2 (1.0)	0	2 (1.1)
Spinal Stenosis	1 (0.5)	0	1 (0.5)
Other	83 (39.5)	13 (52.0)	70 (37.8)

Table 2: Summary Statistics for Variables

Variable (all *N* = 210)	Observed Range (Possible Range)	Total population (N=210) Mean Score (*SD*)	NHS population (N=25) Mean Score (SD)	Non-NHS population (N=185) Mean Score (SD)
Total pain locations	1-12 (1-12)	5.61 (3.5)	5.36 (3.5)	5.65 (3.5)
Chronicity (months)	3-588 (3+)	144.64 (117.9)	163.60 (144.5)	142.08 (114.1)
Pain Intensity	1-10 (0-10)	6.21 (1.8)	7.00 (1.6)	6.10 (1.8)
PDI	3-70 (0-70)	43.34 (15.4)	50.72 (10.6)	42.35 (15.6)
PSEQ	0-57 (0-60)	24.92 (13.6)	15.08 (9.2)	26.25 (14.0)
PCS	0-51 (0-52)	23.37 (13.5)	33.88 (14.0)	21.95 (12.9)
CPAQ	2-112 (0-120)	56.30 (20.7)	38.28 (14.7)	58.74 (20.2)
HADS anxiety	0-21 (0-21)	10.24 (4.5)	12.24 (4.4)	9.97 (4.5)
HADS depression	1-20 (0-21)	8.89 (4.5)	11.52 (3.8)	8.53 (4.4)
SCS self-kindness	5-25 (5-25)	13.8 (4.9)	11.92 (4.3)	14.05 (4.9)
SCS self-judgement	5-25 (5-25)	16.54 (5.2)	17.84 (4.5)	16.36 (5.3)
SCS common humanity	4-20 (4-20)	12.49 (3.8)	11.36 (3.7)	12.64 (3.8)
SCS isolation	4-20 (4-20)	13.17 (4.3)	14.08 (3.8)	13.04 (4.4)
SCS mindfulness	4-20 (4-20)	12.89 (3.3)	11.68 (3.6)	13.05 (3.3)
SCS over-identification	4-20 (4-20)	12.27 (4.1)	13.36 (3.3)	12.12 (4.1)
SCS total	31-130 (26-130)	75.21 (20.3)	67.68 (17.1)	76.23 (20.6)

PDI=Pain Disability Index, HADS=Hospital Anxiety and Depression Scale, PCS=Pain Catastrophizing Scale, PSEQ=Pain Self-Efficacy Questionnaire, CPAQ=Chronic Pain Acceptance Questionnaire, SCS=Self-Compassion Scale, SK=Self-kindness subscale, SJ=Self-judgment subscale, CH=Common humanity subscale, IS=Isolation subscale, MF=Mindfulness subscale, OI=Over identification subscale

Table 3. Zero-order Correlations between Outcome Measures and all Psychological Variables

Variable	Pain Intensity	PDI
CPAQ total	-.325*	-.609*
PSEQ	-.408*	-.712*
PCS total	.333*	.470*
HADS A	.267*	.368*
HADS D	.354*	.525*
SCS SK	-.138	-.125
SCS SJ	.181	.169
SCS CH	-.081	-.163
SCS IS	.203*	.243*
SCS MF	-.154	-.242*
SCS OI	.125	.167
SCS tot	-.188	-.227*

PDI=Pain Disability Index, HADS=Hospital Anxiety and Depression Scale, PCS=Pain Catastrophizing Scale, PSEQ=Pain Self-Efficacy Questionnaire, CPAQ=Chronic Pain Acceptance Questionnaire, SCS=Self-Compassion Scale, SK=Self-kindness subscale, SJ=Self-judgment subscale, CH=Common humanity subscale, IS=Isolation subscale, MF=Mindfulness subscale, OI=Over identification subscale

* $p \leq .0033$ (Bonferroni adjustment), all figures reported are Spearman's rho

Table 4. Results of multiple regression analysis, with Pain Intensity as the dependent variable (*N* = 210)

Model	Predictor variable	*β* (final model)	R^2 for the model	R^2 change
1	Working status	.111		
	Source of recruitment	-.011	.077***	.077***
2	Diagnosis fibromyalgia	.134*	.114***	.037**
3	HADS-Depression	.109		
	HADS-Anxiety	.042		
	PCS total	.110		
	PSEQ total	-.272*		
	CPAQ total	.063	.248***	.135
4	SCS IS	-.002	.248***	.000

HADS=Hospital Anxiety and Depression Scale, PCS=Pain Catastrophizing Scale, PSEQ=Pain Self-Efficacy Questionnaire, CPAQ=Chronic Pain Acceptance Questionnaire, SCS IS=Self-Compassion Scale Isolation Subscale

*** $p < .001$, ** $p < .01$ * $p < .05$

Table 5. Results of multiple regression analysis, with Pain Disability Index (PDI) as the dependent variable (*N* = 210)

Model	Predictor variable	*β* Final model	R^2 for the model	R^2 change
1	Working status	.091		
	Source of recruitment	.049	.145***	.145***
2	Diagnosis fibromyalgia	.038	.180***	.035**
3	CPAQ total	-.175*		
	HADS-Anxiety	.093		
	HADS-Depression	.140		
	PSEQ total	-.487***		
	PCS total	-.059	.586***	.406***
4	SCS IS	.121		
	SCS MF	-.128		
	SCS total	.275*	.595***	.009

HADS=Hospital Anxiety and Depression Scale, PCS=Pain Catastrophizing Scale, PSEQ=Pain Self-Efficacy Questionnaire, CPAQ=Chronic Pain Acceptance Questionnaire, SCS=Self-Compassion Scale, IS=Isolation subscale, MF=Mindfulness subscale,

*** $p < .001$, ** $p < .01$, *$p < .05$

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Appendix 2: Participant Questionnaire

Self-Compassion and Chronic Pain: A Research Project

Thank you for requesting a questionnaire pack and for agreeing to take part in my research.

Once you have completed the questionnaire, please detach the back page and return the questionnaire in the pre-paid envelope.

Please answer all questions, and answer them as honestly as you can. There are no right or wrong answers.

Yours Sincerely

Miss Jo Jury, Trainee Clinical Psychologist, Lancaster University

Instructions:

Before beginning, please choose a 6 character code. Because your data is anonymous, this code will be the only way to identify your data should you wish to withdraw it at a later date. This code should also be quoted in all future correspondence with the researcher.

Your code should be made up of 2 letters and 4 numbers. For example, you might choose a significant others' initials and a memorable date to make the code JS2512.

Please write your 6 character code here _____

Once you have completed the questionnaire, please remove the back page (the debrief), write your 6 digit code on it and keep it for future reference.

Demographics

Your Age:

_____ years

Gender:

Male / Female / Transgender (please circle)

Relationship Status:

Which of the following best describes your current relationship status?

___Married or civil partnership ___Widowed ___Divorced or separated

___Cohabiting with partner ___In a relationship, not cohabiting

___Single, never married or civil partnership

Which of the following categories best describes your employment status?

___Employed, working 30 hours or more per week ___Employed, working 1-29 hours per week

___Self-employed ___Not employed, looking for work ___Not employed, not looking for work

___Full-time student ___Homemaker or stay at home parent ___Retired ___Not able to work

Ethnicity:

How would you describe your ethnic group?

Please tick **ONE** option that best fits from the list below:

____White ____Mixed / Multiple ethnic groups ____Asian / Asian British ____Black / African / Caribbean / Black British

____Other ethnic group **(please indicate here _____)**

Please tell us how you found out about this research project (please tick one):

____Through an NHS pain clinic ____Through XXXXXXXXX support group

____Through Twitter ____Other (please state) _____

Pain –related questions

How long (approximately) have you experienced chronic pain for?

____Years _____Months

Where do you experience pain?

(tick all that apply)

__Head __Face __Back __Neck __Shoulders __Arms

__Hands__Torso__Hips__Pelvis__Legs __Feet

If you have been given a diagnosis related to your pain (e.g. Fibromyalgia, Complex Regional Pain Syndrome etc), please record it here:

Have you ever undergone any psychological therapy for yor pain (e.g. Pain Management Group, individual counselling, psychotherapy etc.)?

Y / N * (please circle)

If you answered yes, please give details here:

_____

PAIN RATING SCALE

Please mark the scale below to show how intense your pain is.

A zero (0) means no pain, and ten (10) means extreme pain.

How **intense** is your pain **now**?

0	1	2	3	4	5	6	7	8	9	10
no pain										extreme pain

How **intense** was your pain **on average last week**?

0	1	2	3	4	5	6	7	8	9	10
no pain										extreme pain

Now please use the same method to describe how **distressing** your pain is.
How **distressing** is your pain **now**?

0	1	2	3	4	5	6	7	8	9	10
not at all distressing										extremely distressing

How **distressing** was your pain **on average last week**?

0	1	2	3	4	5	6	7	8	9	10
not at all distressing										extremely distressing

Now please use the same method to describe **how much your pain interferes** with your normal everyday activities.

0	1	2	3	4	5	6	7	8	9	10
does not interfere										interferes completely

If you have had treatment for your pain, how much has this relieved (taken away) the pain?

no relief										complete relief
0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

Pain Disability Index

The rating scales below are designed to measure the degree to which aspects of your life are disrupted by chronic pain. In other words, we would like to know how much pain is preventing you from doing what you would normally do or from doing it as well as you normally would. Respond to each category indicating the overall impact of pain in your life, not just when pain is at its worst.

For each of the 7 categories of life activity listed, please circle the number on the scale that describes the level of disability you typically experience. A score of 0 means no disability at all, and a score of 10 signifies that all of the activities in which you would normally be involved have been totally disrupted or prevented by your pain.

Family/Home Responsibilities: This category refers to activities of the home or family. It includes chores or duties performed around the house (e.g. yard work) and errands or favours for other family members (e.g. driving the children to school).

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Recreation: This disability includes hobbies, sports, and other similar leisure time activities.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Social Activity: This category refers to activities, which involve participation with friends and acquaintances other than family members. It includes parties, theater, concerts, dining out, and other social functions.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Occupation: This category refers to activities that are part of or directly related to one's job.

This includes non-paying jobs as well, such as that of a housewife or volunteer.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Sexual Behaviour: This category refers to the frequency and quality of one's sex life.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Self Care: This category includes activities, which involve personal maintenance and independent daily living (e.g. taking a shower, driving, getting dressed, etc.)

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Life-Support Activities: This category refers to basic life supporting behaviors such as eating, sleeping and breathing.

No Disability 0 1 2 3 4 5 6 7 8 9 10 Worst Disability

Source: Pollard, C. A. (1984). Preliminary validity study of the pain disability index. *Perceptual and Motor Skills*, *59*(3), 974-974.

PAIN SELF EFFICACY QUESTIONNAIRE (PSEQ)

M.K.Nicholas (1989)

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle **one** of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

0 1 2 3 4 5 6

Not at all ***Completely***
Confident **confident**

Remember, this questionnaire is **not** asking whether of not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

1. I can enjoy things, despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

4. I can cope with my pain in most situations.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

7. I can cope with my pain without medication.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

8. I can still accomplish most of my goals in life, despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

9. I can live a normal lifestyle, despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

10. I can gradually become more active, despite the pain.

0 1 2 3 4 5 6

Not at all ***Completely***
Confident confident

Source: Nicholas M.K. Self-efficacy and chronic pain. Paper presented at the annual conference of the British Psychological Society. St. Andrews, 1989.

PCS

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

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

When I'm in pain …

1__ I worry all the time about whether the pain will end.

2__ I feel I can't go on.

3__ It's terrible and I think it's never going to get any better.

4__ It's awful and I feel that it overwhelms me.

5__I feel I can't stand it anymore.

6__I become afraid that the pain will get worse.

7__ I keep thinking of other painful events.

8__ I anxiously want the pain to go away.

9__ I can't seem to keep it out of my mind.

10__ I keep thinking about how much it hurts.

11__ I keep thinking about how badly I want the pain to stop.

12__ There's nothing I can do to reduce the intensity of the pain.

13__ I wonder whether something serious may happen.

CPAQ

Directions:

Below you will find a list of statements. Please rate the truth of each statement as it applies to you.

Use the following rating scale to make your choices. For instance, if you believe a statement is 'Always True,' you would write a 6 in the blank next to that statement

0	1	2	3	4	5	6
Never True	**Very Rarely True**	**Seldom True**	**Sometimes True**	**Often True**	**Almost Always True**	**Always True**

1. I am getting on with the business of living no matter what my level of pain is ……

2. My life is going well, even though I have chronic pain ……

3. It's OK to experience pain ……

4. I would gladly sacrifice important things in my life to control this pain better ……

5. It's not necessary for me to control my pain in order to handle my life well ……

6. Although things have changed, I am living a normal life despite my chronic pain ……

7. I need to concentrate on getting rid of my pain ……

8. There are many activities I do when I feel pain ……

9. I lead a full life even though I have chronic pain……

10. Controlling pain is less important than any other goals in my life ……

11. My thoughts and feelings about pain must change before I can take important steps in my life ……

12. Despite the pain, I am now sticking to a certain course in my life ……

13. Keeping my pain level under control takes first priority whenever I'm doing something ……

14. Before I can make any serious plans, I have to get some control over my pain ……

15. When my pain increases, I can still take care of my responsibilities ……

16. I will have better control over my life if I can control my negative thoughts about pain ……

17. I avoid putting myself in situations where my pain might increase ……

18. My worries and fears about what pain will do to me are true ……

19. It's a relief to realize that I don't have to change my pain to get on with my life ……

20. I have to struggle to do things when I have pain……

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				Almost always
1	2	3	4	5

_____ 1. I'm disapproving and judgmental about my own flaws and inadequacies.

_____ 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____ 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.

_____ 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.

_____ 5. I try to be loving towards myself when I'm feeling emotional pain.

_____ 6. When I fail at something important to me I become consumed by feelings of inadequacy.

_____ 7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.

_____ 8. When times are really difficult, I tend to be tough on myself.

_____ 9. When something upsets me I try to keep my emotions in balance.

_____ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____ 11. I'm intolerant and impatient towards those aspects of my personality I don't like.

_____ 12. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____ 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____ 14. When something painful happens I try to take a balanced view of the situation.

_____ 15. I try to see my failings as part of the human condition.

_____ 16. When I see aspects of myself that I don't like, I get down on myself.

_____ 17. When I fail at something important to me I try to keep things in perspective.

_____ 18. When I’m really struggling, I tend to feel like other people must be having an easier time of it.

____ 19. I’m kind to myself when I’m experiencing suffering.

_____ 20. When something upsets me I get carried away with my feelings.

_____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.

_____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.

_____ 23. I’m tolerant of my own flaws and inadequacies.

_____ 24. When something painful happens I tend to blow the incident out of proportion.

_____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.

_____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Source: Neff, K. D. (2003). Development and validation of a scale to measure self-compassion. *Self and Identity, 2, 223-250.*

Hospital Anxiety and Depression Scale removed for copyright reasons

This is the end of the questionnaire, thank you for taking part.

Please detach the back page (debrief), write your 6 character code on it and store it somewhere safe.

Please return this part of the questionnaire, along with the consent form, in the pre-paid envelope provided.

If you misplace your pre-paid envelope, questionnaires can be posted to:

Jo Jury, Trainee Clinical Psychologist

Faculty of Health & Medicine

Clinical Psychology - Division of Health Research

C16, Furness College

Lancaster University

Lancaster

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