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Individual experiences of an acceptance-based pain management programme: An interpretative phenomenological analysis

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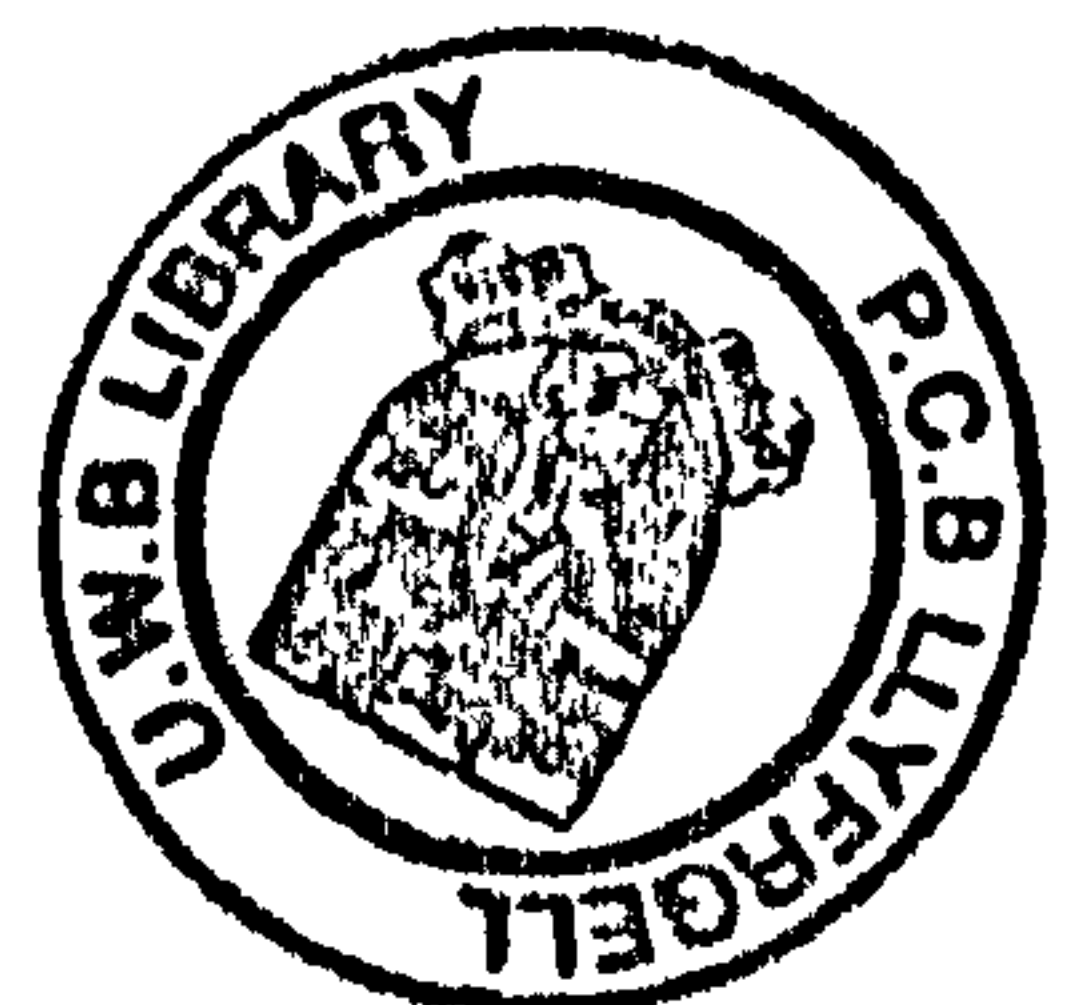
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Individual Experiences of an Acceptance-Based Pain Management Programme: An Interpretative Phenomenological Analysis.

Beth Mathias

**Presented in part fulfillment of a Doctor of Clinical Psychology
June 2010**

Bangor University



The following material (personal details) has been **excluded** from the digitised copy due to confidentiality:

Appendix 7 page 2

Appendix 8 first page

Appendix 9 page 4, 19, 20

Appendix 10 first page

Appendix 11 first page

Appendix 15 first page

Appendix 16 page 4

Appendix 17 page 3, 4, 21, 22

Appendix 18 first page

Appendix 19

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Acknowledgements

I would like to initially thank the six individuals who took part in this study. Without their active participation and openness this research would not have been possible. I am most grateful for the valuable time they gave up for interviews and feedback regarding the findings.

I am indebted to Beth for the help and support she has provided with this project. I really appreciate the fact that you have given up some evenings and time at weekends to read through ethics applications and drafts. I am thankful for the long telephone calls (in-between supervision sessions) and that you were happy for me to call at your house to sign ethics forms etc. Thank you to Shiona and Sue, who ran the programme along with Beth, and to all the staff associated with the pain management centre that were happy for me to interview on site.

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Mike I have saved you until last as words fail me, thanks does not do the support and help you have given me during this project and clinical training justice. Thanks for understanding that I had to spend a year living near the university two months after we got married. Thanks for our beautiful boy Shay and for looking after him during the weeks I was away on block and collecting data. The only reason I could leave was because I know you are such a fantastic dad. I can't imagine having done it without you the children and our beautiful boy Shay who helped keep this all in perspective.

CONTENTS

	Page
Abstract.....	i-ii
 Section 1: Ethics	
Protocol.....	1-7
References.....	8-9
Appendix 1: Description of the Chronic Pain Management Service.....	10
Appendix 2: Suggested Interview Questions	11
Appendix 3: The Four Stage Process.....	12
Appendix 4: Examples of Journals in Psychology & Health.....	13
Appendix 5: Participant Information Sheet.....	14
Appendix 6: Consent Form.....	15
Appendix 7: School of Psychology Ethics Form.....	16
Appendix 8: School of Psychology Ethics Approval	17
Appendix 9: Integrated Research Application System (IRAS) Research Ethics Committee (REC) Application and Letter from Sponsor.....	18
Appendix 10: REC Provisional Opinion Letter	19
Appendix 11: Amendments Letter	20
Appendix 12: Amended Participant Information Sheet (English & Welsh).....	21
Appendix 13: Amended Consent Form (Eng & Welsh).....	22
Appendix 14: GP Letter.....	23
Appendix 15: REC Approval Letter.....	24
Appendix 16: IRAS Site Specific Information Form.....	25
Appendix 17: IRAS Research & Development Application Form.....	26
Appendix 18: IRAS Research & Development Approval Letter.....	27
Appendix 19: Amendment email regarding site change. Ethical and Research & Development Approval Letters.....	28
 Section 2: Reflective Commentary	
Title page.....	1
Reflective Commentary.....	2-4
 Section 3: Literature Review	
Author guidelines for the Clinical Journal of Pain.....	i
Title Page.....	1
Abstract.....	2
Introduction.....	3-5
Review Method.....	5-6
Results.....	6-19
Goal directed behaviour and attention models.....	6-9
Coping models.....	10-12
Identity models.....	13-16
Psychological flexibility.....	17-19

Discussion.....19-23
References.....24-29
Figure 1A: Adaptation to Chronic Pain (ACP) Model.....30
Tables 1-4 Summary of Identified studies.....31-34

Section 4: Empirical Paper

Author Guidelines for Psychology & Health.....i
Title Page.....1
Abstract.....2
Introduction.....3-7
Method.....8-11
Results.....11-19
Discussion.....19-25
References.....26-29
Appendix 1: Interview Schedule.....30
Appendix 2: [For examination purposes only] Sample Extract of transcript and
Theme extraction.....31

Section 5: Extended discussion: Contributions to theory and clinical practice.

Title page.....1
Abstract.....2
Introduction.....3
Theoretical and clinical implications.....3-8
Service development.....9-11
Implications for future research.....11-12
Concluding remarks.....13
References.....14-16

Section 6: Word Counts.....1

Individual Experiences of an Acceptance-Based Pain Management Programme: An Interpretative Phenomenological Analysis.

Abstract

Although there is evidence of a positive relationship between acceptance of pain and healthy adaptation to chronic pain, such research appears to be devoid of a guiding theoretical framework. The review paper aims to investigate how 'acceptance' fits with models of adaptation to chronic pain. Fourteen-studies were reviewed and categorised into four-sections in accordance with the models of adaptation they cited. Exploration of the underlying components of the models illuminated five-key unifying concepts or 'elements' that appear to be important for adaptation: goal-setting, attention to pain, coping strategies, identity and psychological flexibility. A unifying model is proposed and the findings of the review suggest that acceptance-based interventions such as Mindfulness, Acceptance and Commitment Therapy and Contextual Cognitive Behavioural Therapy would be beneficial in enabling healthy adaptation to chronic pain.

Despite the growing evidence-base with regards to the effectiveness of acceptance-based interventions for chronic pain, previous research has focused on quantitative outcome measures. The processes that occur during such interventions, however, remain unknown. The research paper therefore qualitatively explores six-individual's experiences of an acceptance-based pain-management programme and the constituents they felt facilitated change. Findings highlighted the importance of pain-relevant social support,

psychoeducation, self-identity, positive acceptance of pain and proactive coping strategies such as pacing activity and mindfulness.

The discussion paper explores links between research findings and models of adaptation, the proposed model within the literature review, the contribution to clinical practice, and implications for future research. By unifying these components, a unique in-depth insight into people's experiences of the processes of chronic pain management has been gleaned. Especially into the experiential accounts of people using acceptance-based pain-management approaches, and highlights a need for further qualitative and mixed-methodology studies in the area of pain-management interventions.

LSRP Proposal

1. Project Title

Individual experiences of an acceptance-based Pain Management Programme: An interpretative phenomenological analysis

2. Who will supervise

Dr Beth Parry-Jones (Clinical Psychologist within NWW Trust) will supervise all aspects of the project including data analysis. Suzanne Skevington (Professor of Health Psychology at the University of Bath) is also happy to read through drafts and provide advice. Additional qualitative supervision from UWB would be helpful as I have never done a qualitative piece of work before.

3. Background

Chronic Pain

Chronic pain (CP) is costly to the National Health Service and Society due to the increased number of sick days (Latham & Davis, 1994) and the restricting consequences it can have on day to day life. CP is defined as "Pain or discomfort that persists continually or intermittently for longer than 3 months" (Elliot, et al., 1999) and despite subjective reports of pain, the absence of underlying pathology makes ongoing clinical assessment extremely difficult for health care professionals.

Pain Management Programmes (PMPs) for CP

Although CBT has documented efficacy for adults with CP, and is the treatment of choice, the processes underlying treatment effects remain unclear (Keefe et al., 2004; Morley, 2004). This has resulted in an increased interest into how thoughts beliefs and other psychological experiences impact upon behaviour. Longmore & Worrell (2007) reviewed the literature and found that cognitive components were neither superior to behavioural ones in the achievement of successful treatment outcomes. It has been argued that treatment may not need to focus on the logic or semantic meaning of thoughts and beliefs in order to be effective, but rather may focus on ways in which thoughts and beliefs have their impact on functioning (e.g. Hayes et al., 1999). This highlights the importance of looking at context (historical and situational) where distressing or discouraging psychological experiences occur as a way to understand "functions" or interrelations with behaviour (Hayes, 2004).

Recently there has been a move towards acceptance or the willingness to experience pain or other distressing events without attempts to control them. This has been reflected in the development of 'third wave' approaches to treatment such as Acceptance and Commitment Therapy (ACT) (Hayes et al., 1999) and Mindfulness (e.g. Kabat-Zinn et al 1985). ACT also focuses on value-based action, or the aligning of actions with desired personally meaningful purposes rather than the elimination of unwanted experiences (Hayes et al., 1999; 2004).

Acceptance-based approaches

There is growing evidence for the effectiveness of acceptance-based approaches for individuals with CP (Dahl et al., 2004; Wicksell et al., 2007; McCracken, 2005; Vowles et al., 2007a; Geiser, 1999; Vowles & McCracken, 2008). Acceptance-based PMPs have been linked to improvements on a range of outcome measures. McCracken et al (2005) examined an acceptance-based approach to CP within an inter-disciplinary treatment program and found significant improvements in emotional, social, physical functioning and healthcare-use following treatment. The majority of improvements continued at 3 months post-treatment. Vowles et al (2008) investigated the effectiveness of ACT (Hayes et al., 1999) in the treatment of CP and found significant improvements for pain, depression, pain related anxiety, disability, medical visits, work status and physical performance.

Improved outcomes have also been found for individuals with CP following mindfulness meditation training. Those being, statistically significant reductions in measures of present-moment pain, negative body image, inhibition of activity by pain, symptoms, mood disturbance and psychological symptomology (anxiety and depression) (Kabat-Zinn et al, 1985). These improvements were maintained up to 15 months post-training for all measures except present-moment pain. McCracken et al (2007) found mindfulness to account for significant variance in measures of depression, pain-related anxiety, physical, psychosocial and 'other' disability. In each instance greater mindfulness was associated with better functioning. Acceptance of pain and mindfulness combined accounted for a moderate degree of variance and appeared potentially meaningful. This view is supported by Seigel (2005) who has illustrated how mindfulness practice can be fruitfully combined with other psychotherapeutic interventions to treat psychophysiological difficulties.

An acceptance-based PMP in North West Wales (NWW)

The PMP in NWW uses a combination of components from CBT, Mindfulness and ACT. The PMP is delivered by a multidisciplinary team including Clinical Psychologists, an Assistant Psychologist, a Physiotherapist and a Clinical Nurse specialist. The programme started in 1995 and focuses on relevant pain-based education, activity, stress reduction and mood management. Following an initial introductory day, patients who decide to 'opt -in' (max 12 patients) participate in group sessions run one day a week for eight weeks, incorporating education, exercise and skills training components. Follow-up sessions are then held 3-months, 6-months and finally 12-months later. The follow-up sessions allow for further support, progress monitoring and feedback. Further information on the service in a wider context can be found in Appendix 1.

Together with the growing body of evidence that supports the use of ACT and mindfulness with people who have CP, a recent SRRP audit provides support for the effectiveness of this NWW PMP. The audit looked at 77 participants who completed the PMP and 12 month follow-up between 2004 and 2006. It concluded that this PMP is effective in improving participants' experience of pain, reducing emotional distress and increasing physical mobility. These improvements were maintained over a 12 month follow-up period.

Rationale for the study

It has been suggested that the next generation of research into therapies for CP will focus on the specific processes involved during treatment (McCracken et al., 2005) and the way in which treatments work to achieve adaptive behaviour change (Vowles et al., 2007b).

Acceptance, when defined functionally and contextually, appears to be a key process in treatment outcome and behaviour change in individuals with CP (Vowles et al., 2007b). Changes in acceptance during an acceptance-based PMP have also been found to be related to changes in depression, pain-related anxiety, physical and psychosocial disability, physical task persistence (McCracken et al., 2005). Changes in acceptance during such PMPs accounted for greater variance in outcome than changes in pain intensity and frequency of catastrophic thinking (Vowles et al., 2007b). Vowles et al (2008) found that acceptance and values-based action have also been associated with improvements in outcome measures. However, previous studies in the area have all been quantitative and there may be a number of other processes that facilitate change within acceptance-based PMPs.

Vowles et al (2007a) argue that processes such as acceptance need to be perused empirically, both in terms of its veracity and how best to address it in the clinic. Evaluation studies (high in ecological validity) that confirm the particular treatment components that lead to success and address the processes by which patients improve are missing from the evidence base (McCracken et al, 2005). Vowles et al (2007b) feel that the challenge for future treatment development is to refine the most effective, flexible, and durable behaviour change. An acceptance-based approach with its particular view of private experiences provides a promising base for further therapy development (McCracken et al., 2005).

The proposed study aims to add to previous research in the area by qualitatively exploring individual experiences during the acceptance-based PMP and look at the specific constituents of the programme that individuals feel may have facilitated change in any way.

4. Research Questions

There are 2 main research questions which are as follows:

- What are the experiences of individuals on an acceptance-based PMP?
- What constituents of the PMP do individuals regard as facilitating change?

5. Overlap with previous assessments

The proposed project has no overlap with previous assessments:

- Essay 1 (AMH): Transference and CBT
- RCA 1 (AMH) PTSD and Depression
- Essay 2 (OA): Person Centered Dementia Care
- RCA 2 (OA): Anxiety and Memory difficulties
- MAP: Evidence for the efficacy of Psychotherapy for Anorexia Nervosa

- SRRP (AMH): Reliability of measures for Psychosis at identifying individuals 'at risk' and the care they receive.
- Essay 3 (CA): CBT and children below the formal operational stage of development.

6. Participant recruitment

Participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of chronic pain. They also need to be able to attend a 10 am to 4 pm day at the pain clinic over an 8 week period. Although not direct inclusion criteria, the programme often advises individuals who are 'cure-seeking' to finish this process before starting the PMP. Similarly, those who have on-going medical investigations or treatments are generally advised to complete these before attending the PMP. Additional inclusion criteria would be the ability to attend an interview at the Pain Clinic 1 to 2 weeks after the PMP has finished, however individuals will not be discriminated against if they do not have access to transport as home visits will be considered.

Although the Clinical Psychologist running the PMP (my supervisor Dr Beth Parry-Jones) will mention that there may be some research attached to the PMP, potential participants will be approached by the researcher who will attend the 8th and final week of the PMP. Here the researcher will explain the rationale behind the research (i.e. to obtain a better understanding of the experiences of people attending the PMP and the key constituents that they feel may have facilitated change), provide an information sheet and obtain the informed consent of individuals willing to participate using a consent form. The researcher is hoping to recruit $n = 6$ from one PMP (usually the groups range from between 6 to 10). An 'n' of 5 or 6 is felt to be a reasonable sample size for IPA research (e.g. Smith & Osborn, 2003).

There is a possibility to recruit participants from PMPs that finish in November 2009 or potentially August 2009 (if ethical approval was granted in time).

Dr Beth Parry-Jones has obtained initial approval for the researcher to access potential participants from other PMP staff (Specialist Nurse & Physiotherapist).

Design and procedures

DESIGN: A qualitative approach to add to past quantitative research in the area by exploring individual experiences of an acceptance-based PMP (within NWW) together with the key constituents of the programme that they feel facilitated change.

PROCEDURE: After the participant recruitment and consent seeking process outlined above. Six participants will be invited along to semi-structured interviews at the pain clinic 1-2 weeks after the program has finished. The reason for this being that the last day of the PMP includes individual feedback on pre- and post program evaluation measures and an extra week or two would give participants time to reflect/consider what the PMP meant to them. It is anticipated that the length of the interviews may range from 20

minutes to 1 hour depending on how much information participants would like to discuss. However, no participant will be cut short should their time exceed 1hr.

Participants will then be told (at the end of the interview) that they are welcome to meet with a member of the PMP team should they wish to discuss anything upsetting that may have come up as a result of the interview process (even though this is not anticipated). They will also be asked if they would like to receive a 'Summary of Findings-Sheet' and telephone call in April 2010 to discuss views of the results. Contact details on the consent forms of those who would like to receive this sheet will be checked at this point. All participants will be provided with the researcher's contact details in case they would like to discuss anything further in relation to the group or if they have any worries or concerns which arise. Participants are welcome to contact the researcher on this number anytime after the interviews have finished until April 2010.

Measures

Semi-structured interview to explore both research questions see Appendix 2 for some suggested questions.

NB// direct questions about acceptance and other mindfulness related concepts will not be asked. However, if mentioned by participants, the researcher would like to ask them to elaborate further.

7. Data management and analysis

The data gained during individual interviews will be recorded (using a tape recorder), transcribed by the researcher and personally analysed using Interpretative Phenomenological Analysis (IPA) the objective of the study:

To explore individual experiences of an acceptance-based PMP and the key constituents that participants' felt facilitated change in any way.

The analysis will follow the four-stage process described in detail by Smith & Osborn (2003) (Appendix 3). IPA was chosen as the best method of analysis to address the research questions as it explores how participants make sense of their personal and social world by looking at the meanings of particular experiences, events, and states (Smith & Osborn, 2003).

Participants who wish to have a 'summary of findings sheet' will also be contacted by telephone to ask their opinion with regards to the findings. This should serve to validate the findings and will be included in the final write-up of the project.

8. Proposed Journals

- The Clinical Journal of Pain - This journal has published a previous paper I was involved with entitled 'accepting low back pain: Is it related to a good quality of life?'. Acceptance was found to play an important role in the QoL of people with

CP and had positive implications for the role of acceptance-based treatments for individuals with CP.

9. Psychology & Health – This journal has published several qualitative studies on the experiences of people with chronic pain and a related condition, chronic fatigue syndrome (CFS) (see Appendix 4 for examples).

10. Ethical/Registration Issues

At the time of writing this proposal, potential participants are patients of North West Wales NHS Trust, but from October 2009 they will be patients of North Wales NHS Trust. I would be grateful if the research panel at UWB could provide advice as to who the researcher would need to contact.

Informed consent will be gained from all participants in the study and ethical approval will be sought before any potential participants are approached.

11. Feedback

At the end of the interview, participants will be asked if they would like to have feedback regarding the research findings. If so, they will be sent a 'summary of findings sheet' by post after the results section has been approved by my supervisor. A follow-up telephone call to ask for their opinion as to whether they felt the correct themes have been identified would help them confirm or add to the findings. This will help with validating the analysis.

12. Risk Assessment

Although no risks are anticipated, if discussing individual experiences in relation to the PMP causes people to become upset, then, if they give permission, a member of the PMP team can contact them after the interview. Clients continue to be monitored at 3, 6, and 12 month follow-up post-PMP, and they are encouraged to contact the PMP Team in-between if they have any pain related distress that they cannot resolve themselves.

13. Data Storage

Data (audio-taped individual interviews, typed transcripts and any interpretations made) will be coded anonymously and stored in a lockable filing cabinet at the researcher's clinical placement.

At the end of the research, the anonymous data will be passed to my supervisor Dr Beth Parry-Jones for informative and evaluative purposes. It is hoped that that data may aid the delivery of future PMPs.

14. Financial information

Travel costs of participants for interviews and the trainee's travel costs should be met by the trust.

The anticipated costs for the study have been based on the potential maximum no. of participants in the PMP i.e. 10 (to account for 'drop out' etc) – even though the target sample size for the study is n=6.

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Wicksell, R. K., Melin, L. & Olsson, G. L. (2007) Exposure and acceptance in the rehabilitation of adolescents with idiopathic chronic pain: A pilot study, *European Journal of Pain*, 11, 267-274.

Appendix 1: Description of the Chronic Pain Management Service

Appendix 1

The PMP resides within a broader Chronic Pain Management Service (CPMS) which offers patients medical, physical and psychological interventions on an individual basis. The CPMS is additionally staffed by a multidisciplinary team including Consultant Anaesthetists, a physiotherapist and specialist nurse. Referral to the CPMS is restricted to GP's or hospital consultants. Referrals to the PMP are only accepted from CPMS team members. Prior to referral to the PMP, patients receive a number of traditional and alternative treatment regimes, such as medication, surgery, anaesthetic- blocks, TENS, physiotherapy, acupuncture or other alternative pain relief procedures, none of which have provided the patient with sufficient pain reduction.

Once a referral to the PMP is deemed appropriate, patients are invited to attend for an assessment which includes addressing their suitability for group therapy. If appropriate, patients are then invited to attend an 'opt-in' (or taster) day, before deciding whether to proceed with the group programme.

Appendix 2: Suggested Interview Questions

Appendix 2: Suggestions of questions that could be included in the semi-structured interview

- 1) *What are the experiences of individuals on an acceptance-based PMP?***
 - **What did the programme mean to participants?**
 - **What experiences were helpful/unhelpful?**
 - **How they think change happened (or didn't happen). E.g. was there a key turning point during the PMP?**
 - **Transfer of changes into daily life and what they are able to do, how they feel (emotionally and physiologically), what they believe about their pain, their view of 'self' and 'others'?**

- 2) *What constituents of the PMP do individuals regard as facilitating change?***
 - **What changes do individuals report as occurring as a result of attending an acceptance-based PMP?**
 - **Whether individuals were clear that there were different constituents happening (e.g. CBT, mindfulness, acceptance) and how they understood them e.g. 'mood management' is the term used in the group for work that focuses on thoughts feelings and behaviours.**
 - **What seemed to work for them, did they find any part of the programme more useful than others?**

Appendix 3: The Four Stage Process

Appendix 3 - The four-stage process (Smith & Osborn, 2003)

Analysis begins with a close interpretative reading of the first case where initial responses to the text are annotated in one margin. These initial notes are translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes are then interrogated in order to make connections between them. This then results in a table of subordinate themes with identifying information – that is, where the instances supporting the theme can be found within the interview transcript.

This process is repeated for each case. After analysis has been conducted on each case, patterns can be established cross-case and documented in a master table of themes for the group. Another researcher is then recommended to review and audit the themes to ensure that they are grounded and well-represented in the transcripts. The master table can be transformed into a narrative account; the analytic account is then supported by verbatim extracts from each participant.

Appendix 4: Examples of Journals in Psychology and Health

Appendix 4 – Examples of journals in Psychology & Health

Arroll, M. A. & Senior, V. (2007). Individuals experience of Chronic Fatigue Syndrome (CFS): An interpretative phenomenological analysis, *Psychology & Health*, 23(4), 443-458.

Dickson, A., Knussen, C. & Flowers, P. (2007). 'That was my old life: It's almost like a past-life now': Identity crisis, loss & adjustment amongst people living with CFS, *Psychology & Health*, 34(4), 459-476.

Smith, J. A. & Osborn, M. (2007). Pain as an assault on the self: An interpretative phenomenological of chronic benign low back pain, *Psychology & Health*, 22(5), 517-534.

Appendix 5: Participant Information Sheet

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Individual Experiences of a Pain Management Programme **PARTICIPANT INFORMATION SHEET**

Researchers: Beth Mathias, Trainee Clinical Psychologist, North Wales Clinical Psychology Programme, and Dr Beth Parry-Jones, Clinical Psychologist, NW Wales NHS Trust.

Invitation

We hope that you will be able to help with Beth Mathias' Doctoral Research Project, by agreeing to be interviewed one – two weeks after the end of the Pain Management Programme (PMP) about what being on the programme was like for you.

What is the purpose of the study?

Talking to individuals about their experiences is an important way to inform practice in health care. The next generation of research into Pain Management Programmes for chronic pain intends to look at the way in which programmes work to achieve change, exploring how people think, feel or act differently. Previous research has looked at change using questionnaire scores and physical measures before and after the programme. This study aims to go one step further by talking to you individually about your experience of being on the North West Wales Pain Management Programme and explore what parts of the programme you felt may have brought about change in any way.

Do I have to take part?

It is up to you whether or not you decide to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at anytime, or a decision not to take part, will not affect your future health care in anyway.

What does it involve?

You will be asked to arrange an appointment with Beth Mathias at the Pain Clinic 1-2 weeks after the end of the PMP at a convenient time for you. This appointment will take the form of an interview to explore what being on the programme was like for you and what parts of the programme you feel may have contributed to change in any way. The interview will last roughly 20 minutes to 1 hour, depending on how much you would like to talk about. It will be audio-taped so that Beth Mathias can type it up, pick out key themes and use non-identifiable direct quotes when she writes up the research. You also have the option of having a 'Summary of Findings' sheet posted to you at home in April 2010 and, if you agree, a follow-up telephone call from Beth Mathias to ask your opinion about the findings.

What are the possible benefits of taking part?

Previous PMP patients often miss the PMP after it has finished. Therefore the opportunity of coming back to the Pain Clinic a week or two after the programme has finished for an interview may create a more gradual end to the programme. All participants who would like to receive the 'Summary of Findings Sheet' will have additional telephone contact from the researcher in April 2010 to ask their opinion of the findings. Participants are also welcome to contact the researcher at

any point in-between with any questions, worries or concerns. This information will then be fed back to the PMP team who can arrange to meet and discuss this further, if necessary. Your participation in the study has the potential to benefit others in chronic pain and may serve to educate other professionals working with individuals who have similar difficulties.

What are the disadvantages or risks of taking part?

You will be asked to give some of your time to having an interview with the researcher which may range from 20 minutes to 1 hour. Although no risks are anticipated, if discussing individual experiences in relation to the PMP causes people to become upset, then, if they give permission, a member of the PMP team can contact them after the interview. However, the researcher is a Trainee Clinical Psychologist and, therefore, is trained to respond to distress.

What if something goes wrong?

The risks involved in taking part in the study are very small; however, the study does have full insurance cover in the unlikely event that you think you have been harmed in some way.

Will my taking part in the study be kept confidential?

All personal identifiable information will be removed from the typed-up interview transcripts and tapes will either be destroyed or returned to you (whatever you wish) at the end of the research. All information collected during the course of the research will be kept strictly confidential unless you tell Beth Mathias something that makes her concerned that there might be serious risk to you or another person. If this was the case, then she will have to inform the Pain Management Team and possibly others involved in your care.

What will happen to the results of the research study?

The intention is that the results will be published in a scientific journal and shared with health care professionals working with individuals who are in chronic pain. Although direct quotes from interviews may be used, you will not be identified in any report or potential publication.

Further information

If you would like longer to think about whether you would like to take part in the study, or if you require any further information please contact Beth Mathias (Trainee Clinical Psychologist), North Wales Clinical Psychology Programme, Bangor University, 43 College Road, Bangor, Gwynedd, LL57 2DG, telephone 07947 656 312 or via email: beth.mathias@yahoo.co.uk. Alternatively you can contact Dr Beth Parry-Jones (Clinical Psychologist), Pain Management Service, , telephone or via email: beth.parry-jones@nww-tr.wales.nhs.uk

If you decide to take part please complete the consent form and keep this information sheet so that you can refer to it in future. You will also be given a signed copy of the consent form to keep for your information

If you have any complaints about the conduct of this study, these should be addressed to:
Professor Oliver Turnbull, Head of School of Psychology, Bangor University, Bangor, Gwynedd, LL57 2DG.

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

Appendix 6: Consent Form



Patient identification Number:

CONSENT FORM:

Individual Experiences of a Pain Management Programme

Researchers: Beth Mathias, Trainee Clinical Psychologist, North Wales Clinical Psychology Programme, and Dr Beth Parry-Jones, Clinical Psychologist, NW Wales NHS Trust.

- Please Initial box
1. I confirm that I have read and understand the information sheet dated
(version) for the above study and have had the opportunity to ask questions.
 2. 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.
 3. I understand that sections of any of my medical notes may be looked at by responsible
individuals from the University of Wales Bangor and from regulatory authorities where it is
relevant to my taking part in research. I give permission for these individuals to have access
to my records.
 4. I am happy for my interview to be audio-taped so that Beth Mathias can type it up, pick out
key themes and use non-identifiable quotes when she writes up the research.
 5. I understand that if I tell Beth Mathias something that makes her concerned that I or
someone else may be at serious risk, then she will have to inform the Pain Management
Team and possibly others involved in my care.
 6. I agree to take part in the above study by attending an interview with Beth Mathias during
the next 1-2 weeks.

Name of Patient

Date

Signature

Address of Patient: _____

Telephone Number _____

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

Copies: 1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 7: School of Psychology Ethics Form

1399

SCHOOL OF PSYCHOLOGY ETHICAL APPROVAL FORM

Please complete all parts to this form.

Please attach consent and information/debriefing sheets to all applications.

RECEIVED
24 JUN 2009

Date: ~~23/06/09~~ version 2 : 16/07/09

Tick one box: STAFF PROJECT MASTERS PROJECT PHD PROJECT

CLINICAL PSYCHOLOGY PROJECT UNDERGRADUATE PROJECT
 CLASS DEMONSTRATION

What is the broad research area? Vision and the Brain Clinical & Health
 Language and Development Other

Who is the funder of the research? The school of Psychology on behalf of the University of Wales Bangor. Professor Oliver Turnbull.
Title of project: Individual experiences of an acceptance-based Pain management Programme.
Name and email address(es) of all researcher(s): hannah.martin@uw.ac.uk

	YES	NO
Is your project in the area of Health and Social Care requiring sponsorship by the University of Wales, Bangor? If yes, please complete your ethics application in NRES format and submit an NHS R&D form alongside it. You should still complete all sections to this form, but do not need to supply the additional information requested in boxes A or B of Part 1.	✓	
Does your project require scrutiny from an outside body that has its own forms? If yes, please complete your ethics application using the forms required by that outside body. You should still complete all sections to this form, but do not need to supply the additional information requested in boxes A or B of Part 1.		✓
If a student project, is this part of the supervisor's ongoing research that has been previously reviewed and approved? If yes, please give the proposal number of the approved research project, and complete all sections of this form.	Proposal no.	✓

PART ONE: ETHICAL CONSIDERATIONS

	YES	NO	N/A
1 Will you describe the main experimental procedures to participants ¹ in advance, so that they are informed about what to expect?	✓		
2 Will you tell participants that their participation is voluntary?	✓		
3 Will you obtain written consent for participation?	✓		
4 If the research is observational, will you ask participants for their consent to being observed?			✓
5 Will you tell participants that they may withdraw from the research at any time and for any reason?	✓		
6 With questionnaires, will you give participants the option of omitting questions they do not want to answer?	✓		✓
7 Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	✓		
8 Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)?	✓		

¹ In questions 1-9, if participants are children, please consider the information that you will supply to the legal guardian in each case.

~~Version NO. 1 23/06/09.~~
Version NO. 2 16/07/09

If you have ticked No to any of Q1-8, but have ticked box A overleaf, please give an explanation on a separate sheet.

[Note: N/A = not applicable]

		YES	NO	N/A
9	Will your project involve deliberately misleading participants in any way?		✓	
10a	Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? If Yes, give details on a separate sheet and state what you will tell them to do if they should experience any problems (e.g., who they can contact for help)	✓		
10b	Is there any realistic risk of any participants experiencing discomfort or risk to health, subsequent illness or injury that might require medical or psychological treatment as a result of the procedures?		✓	

If you have ticked Yes to 9 or 10 you should normally tick box B overleaf; if not, please give a full explanation on a separate sheet.

11	Does your project involve work with animals? If yes, please tick box B overleaf.		✓		
12	Does your project involve payment of participants that differs from the standard rates? Is there a significant concern that the levels of payment you offer for this study will unduly influence participants to agree to procedures that they may otherwise find unacceptable? If yes to either, please tick box B and explain in point 5 of the full protocol.		✓		
13	Do participants fall into any of the following special groups? If they do, please refer to BPS guidelines, and tick box B overleaf. Note that you may also need to obtain satisfactory CRB clearance.	Children (under 18 years of age) N.B. You must ensure that you have made adequate provision for child protection issues in your protocol		✓	
	People with learning or communication difficulties N.B. You must ensure that you have provided adequate provision to manage distress		✓		
	Participants covered by the Mental Capacity Act: i.e. Adults over 16 years of age who lack the mental capacity to make specific decisions for themselves. You must ensure that you have appropriate consent procedures in place (See guidance notes below) Some research involving participants who lack capacity will require review by an NHS REC. If you are unsure about whether this applies to your study, please contact the Ethics Administrator in the first instance		✓		
	Patients N.B. You must ensure that you have provided adequate provision to manage distress.	✓			
	People in custody		✓		

		People engaged in illegal activities (e.g. drug-taking)		✓	
		Participants recruited from one of the Neurology Patient Panels or the Psychiatry Patient Panel and, if so, has the protocol been reviewed by the appropriate expert/safety panel?			✓
		Physically vulnerable adults N.B. You must ensure that there is a person trained in CPR and seizure management on hand at all times during testing.		✓	
14 Does your project require use of any of the following facilities and, if so, has the protocol been reviewed by the appropriate expert/safety panel? If yes, tick Box B overleaf.		MRI		✓	
		TMS		✓	

Mental Capacity Act 2005

The act provides a comprehensive legal framework for decision making adults, aged 16 or over, when, because of specific mental disability (defined as an impairment of or disturbance in the functioning of a person's mind or brain), they lack the mental capacity to make specific decisions for themselves.

The Act enshrines several key principles:

- A person must be assumed to have capacity unless it is established that he/she lacks capacity.
- A person is not to be treated as unable to make a decision unless all practicable steps to help him/her do so have been taken without success.
- A person is not to be treated as unable to make a decision merely because he/she makes an unwise decision.
- Any decision made under this Act on behalf of a person who lacks capacity must be made in her/his best interests.

Intrusive research on people lacking capacity to consent is unlawful unless:

- The research is approved by specified body (LREC/MREC etc)
- It relates to the person's condition or treatment, and has negligible risks
- It cannot be done as effectively on people who have capacity to consent
- Stringent safeguards are put in place, including consultation with carers.

Researchers conducting studies involving individuals lacking capacity must familiarise themselves with their responsibilities under the law and ensure proper approval mechanisms and appropriate consent procedures are in place.

There is an obligation on the lead researcher to bring to the attention of the Departmental Ethics Committee any ethical implications not clearly covered by the above checklist.

PLEASE TICK EITHER BOX A OR BOX B OVERLEAF AND PROVIDE THE DETAILS REQUIRED IN SUPPORT OF YOUR APPLICATION.

Please tick

A. I consider that this project has no significant ethical implications to be brought before the Departmental Ethics Committee.

..

Give a brief description of participants and procedure, including information on (1) hypotheses, (2) participants & recruitment, (3) research methodology, and (4) Estimated start date and duration of the study. Please attach consent and debrief forms.(5) For studies recruiting via SONA please provide the summary of the study that will appear in SONA to inform participants about the study. N.B. This should be a brief factual description of the study and what participants will be required to do.

Please tick

B. I consider that this project may have ethical implications that should be brought before the Departmental Ethics Committee, and/or it will be carried out with children or other vulnerable populations.



Please provide all the further information listed below in a separate attachment, in this order.

1. Title of project
2. The potential value of addressing this issue
3. Brief background to the study
4. The hypotheses
5. Participants: recruitment methods, age, gender, exclusion/inclusion criteria
6. Research design
7. Procedures employed
8. Measures employed
9. Qualifications of the investigators to use the measures (Where working with children or vulnerable adults, please include information on investigators' CRB disclosures here.)
10. Venue for investigation
11. Estimated start date and duration of the study (N.B. If you know that the research is likely to continue for more than three years, please indicate this here).
12. Data analysis
13. Potential offence/distress to participants
14. Procedures to ensure confidentiality and data protection
15. *How consent is to be obtained (see BPS Guidelines and ensure consent forms are expressed bilingually where appropriate. The University has its own Welsh translations facilities on extension 2036)
16. Information for participants (provide actual consent forms and information sheets) including if appropriate, the summary of the study that will appear on SONA to inform participants about the study. N.B. This should be a brief factual description of the study and what participants will be required to do.
17. Approval of relevant professionals (e.g., GPs, Consultants, Teachers, parents etc.)
18. Payment to: participants, investigators, departments/institutions
19. Equipment required and its availability
20. If students will be engaged a project involving children, vulnerable adults, one of the neurology patient panels or the psychiatric patient panel, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)
21. If students will be engaged in a project involving use of MRI or TMS, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)
22. What arrangements are you making to give feedback to participants? The responsibility is yours to provide it, not participants' to request it.
23. Finally, check your proposal conforms to BPS Guidelines on Ethical Standards in research and sign the declaration. If you have any doubts about this, please outline them.

PLEASE COMPLETE PART TWO OVERLEAF.

PART TWO: RISK ASSESSMENT

If you tick "yes" to any of the questions in the table below, please outline on a separate sheet the probability and significance of the risks involved and the means proposed for the management of those risks. Where relevant, please also describe the procedures to be followed in the event of an adverse event or emergency.

		YES	NO	N/A
1	Is there significant potential risk to participants in any of the following ways?	Potential adverse effects		✓
		Potential distress Potential for persisting or subsequent illness or injury that might require medical or psychological treatment	✓	
2	Is there significant potential risk to investigator(s) in any of the following ways?	Potential risk of violence or other harm to the investigator(s) (e.g., through work with particular populations or through context of research).		✓
		Potential risk of allegations being made against the investigator(s). (e.g., through work with vulnerable populations or context of research).		✓
3	Is there significant potential risk to the institution in any way? (e.g., controversiality or potential for misuse of research findings.)		✓	
4	Is there significant potential risk to other members of staff or students at the institution? (e.g., reception or other staff required to deal with violent or vulnerable populations.)		✓	

The following questions address specific situations that can carry risks to the investigators and/or participants. If you tick "yes" to any of the questions below, please refer to the guidance given (see *Ethics Guidance and Procedures*) on procedures for dealing with these risks and, on a separate sheet, outline how these risks will be dealt with in your project.

5	Does the research involve the investigator(s) working under any of the following conditions: alone; away from the School; after-hours; or on weekends?	✓		
6	Does the experimental procedure involve touching participants?		✓	
7	Does the research involve disabled participants or children visiting the School?		✓	

There is an obligation on the lead researcher to bring to the attention of the Departmental Ethics Committee any risk implications of the research not clearly covered by the above checklist.

PLEASE COMPLETE PART THREE OVERLEAF.

PART THREE: RESEARCH INSURANCE

The purpose of this section is to decide whether the University requires additional insurance cover for a research project. In the case of student research, this section should be completed by the supervisor.

		YES	NO	N/A
1	Is the research to be conducted in the UK?	✓		
2	Is the research based solely upon the following methodologies? <ul style="list-style-type: none"> ▪ Psychological activity ▪ Questionnaires ▪ Measurements of physiological processes ▪ Venepuncture ▪ Collections of body secretions by non-invasive methods ▪ The administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements 	✓		

If you have ticked "Yes" to the questions above, then insurance cover is automatic for your research and there is no need to do anything further.

If the answer to either of the above questions is "No," we will supply you with a further questionnaire to complete and return to the Insurance Officer; in these cases the research should not commence until it has been established that appropriate insurance cover is in place.

PLEASE SIGN AND DATE THE DECLARATIONS ON THE FINAL PAGE OF THIS FORM OVERLEAF.

August 2008

Declaration of ethical compliance

This research project will be carried out in accordance with the guidelines laid down by the British Psychological Society and the procedures determined by the School of Psychology at Bangor. I understand that I am responsible for the ethical conduct of the research. I confirm that I am aware of the requirements of the Data Protection Act and the University's Data Protection Handbook, and that this research will comply with them.

Declaration of risk assessment

The potential risks to the investigator(s) for this research project have been fully reviewed and discussed. As an investigator, I understand that I am responsible for managing my safety and that of participants throughout this research. I will immediately report any adverse events that occur as a consequence of this research.

Declaration of conflicts of interest

To my knowledge, there is no conflict of interest on my part in carrying out this research.

Declaration of data ownership and IPR (for students)

I understand that any data produced through this project are owned by the University and must be made available to my supervisor on request or at the end of the project. I confirm that I am aware of the University's Intellectual Property Policy and that this research will comply with it.

For Undergraduate and Masters projects, I understand that in signing this form I am certifying that the study described meets appropriate scientific standards AND that I have reviewed the procedures described to ensure that they comply with ethical guidelines as published by the BPS and described in the School of Psychology's Ethical Guidance Procedures.

(Chief investigator/supervisor)

Signed: *P. Mathias*

supervisor: *[Signature]*

Date: *16/07/09*

(Associate investigator(s)/student(s))

Signed:

Date:

Appendix 8: School of Psychology Ethics Approval

Ethics proposal 1399

Thursday, 23 July, 2009 7:47 PM

Dear Colleagues

Individual experiences of an acceptance based Pain Management Programme Ethics proposal 1399

Your research proposal referred to above has been reviewed by the School of Psychology Research Ethics Committee and they are satisfied:

- (i) That the research proposed accords with the relevant ethical guidelines.
- (ii) That the research proposed is appropriate for sponsorship by Bangor University.

Approval is granted subject to you submitting Welsh translations of your information/consent and debrief forms to me.

If you wish to make any non-trivial modifications to the research project please inform the committee in writing before proceeding. Please also inform the committee as soon as possible if research participants experience any unanticipated harm as a result of participating in your research.

You should now forward the application to NRES and to the appropriate Local Research Ethics Committee (LREC). If you need a signature on the form regarding research sponsorship by the University, and/or a letter confirming this sponsorship, please send the final version of your NRES form to me and I will make arrangements for this.

The NHS Research Ethics Committee expect one of the investigators to make an oral presentation in support of the proposal at their meeting. You will be contacted by their committee with details as to the date and place of the meeting at which your proposal will be considered.

You may not proceed with the research project until you are notified of the approval of the Local Research Ethics Committee and have R&D approval from the relevant NHS Trusts.

The approval for this project is given on the understanding that you will

complete a review form on the project when requested; to this end I would be grateful if you could complete the form below and return it to me.

Yours sincerely

Everil

UWB-SPONSORED RESEARCH PROJECTS

MONITORING ARRANGEMENTS FORM

Principal Investigator:

Project Title:

Because Bangor University has agreed to act as research sponsor for the research project named above, we are required to ensure that arrangements are in place to monitor the progress of the project. Please read through the information below, tick the box that applies to this project, and return to the ethics coordinator.

This research is funded by an external agency that requires regular progress reports.
In this case, please copy all such progress reports to the ethics coordinator for review.

This is student research under your supervision.
It is the responsibility of the supervisor to monitor the progress of research conducted by students and to report any significant changes or issues arising to the ethics coordinator.

Progress reports are not required for this research by the external funder, or this is non-funded research conducted by you as a staff member.

The ethics coordinator will contact you at regular intervals for a short progress report.

Everil McQuarrie
Research & PhD Administrator,
School of Psychology,
Bangor University,
Room 109
Brigantia Building,
Penrallt Road,
Bangor,
Gwynedd.
LL57 2AS

Tel: 01248 383671

-- Gall y neges e-bost hon, ac unrhyw atodiadau a anfonwyd gyda hi, gynnwys deunydd cyfrinachol ac wedi eu bwriadu i'w defnyddio'n unig gan y sawl y cawsant eu cyfeirio ato (atynt). Os ydych wedi derbyn y neges e-bost hon trwy gamgymeriad, rhowch wybod i'r anfonwr ar unwaith a dilëwch y neges. Os na fwriadwyd anfon y neges atoch chi, rhaid i chi beidio â defnyddio, cadw neu ddatgelu unrhyw wybodaeth a gynhwysir ynddi. Mae unrhyw farn neu safbwynt yn eiddo i'r sawl a'i hanfonodd yn unig ac nid yw o anghenraid yn cynrychioli barn Prifysgol Bangor. Nid yw Prifysgol Bangor yn gwarantu bod y neges e-bost hon neu unrhyw atodiadau yn rhydd rhag frysau neu 100% yn ddiogel. Oni bai fod hyn wedi ei ddatgan yn uniongyrchol yn nhestun yr e-bost, nid bwriad y neges e-bost hon yw ffurfio contract rhwymol - mae rhestr o lofnodwyr awdurdodedig ar gael o Swyddfa Cyllid Prifysgol Bangor. www.bangor.ac.uk

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**Appendix 9: Integrated Research Application System (IRAS)
Research Ethics Committee (REC) application and letter
from sponsor**

[Redacted]

[Redacted]

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)
Individual experiences of an acceptance-based PMP

1. Is your project an audit or service evaluation?
 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 or clinical investigation
- 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, other human biological samples and/or 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 R&D office be located?

- England
- Scotland

- Wales
 Northern Ireland

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)

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

- Yes No

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

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

- Yes No

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

- Yes No

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

- Yes No

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

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

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

- Yes No

Integrated Research Application System
Application Form for Research involving qualitative methods only



National Patient Safety Agency
National Research Ethics Service

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](#).

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Individual experiences of an acceptance-based PMP

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

REC Name:
North West Wales REC

REC Reference Number:
09/WNo01/35

Submission date:
29/07/2009

A1. Full title of the research:

Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.

A2-1. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate of Clinical Psychology (D.ClinPsy)

Name of educational establishment:
North Wales Clinical Psychology Programme, Bangor University.

Name and contact details of academic supervisor:

Title Forename/Initials Surname
Dr Beth Pamy-Jones

Address

Post Code

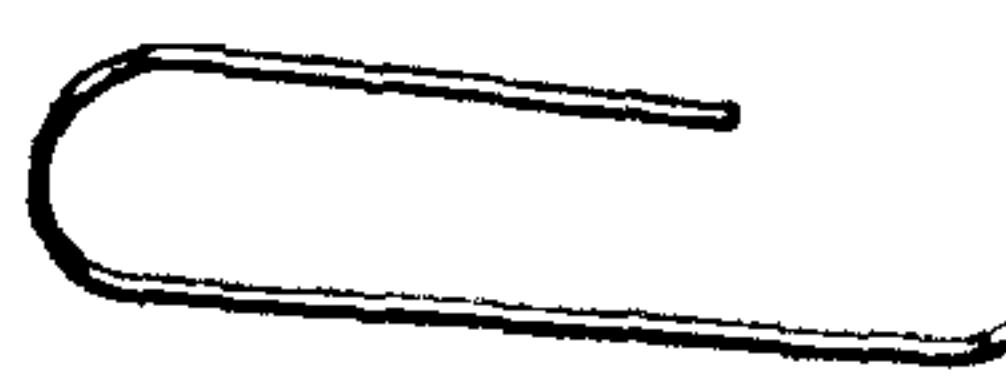
removed for confidentiality

E-mail beth.parry-jones@nww-tr.wales.nhs.uk

Telephone

Fax

Name and contact details of student:



A copy of a current CV for the student (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. Chief Investigator:

Post

Qualifications

Employer

Work Address

Post Code

Work E-mail

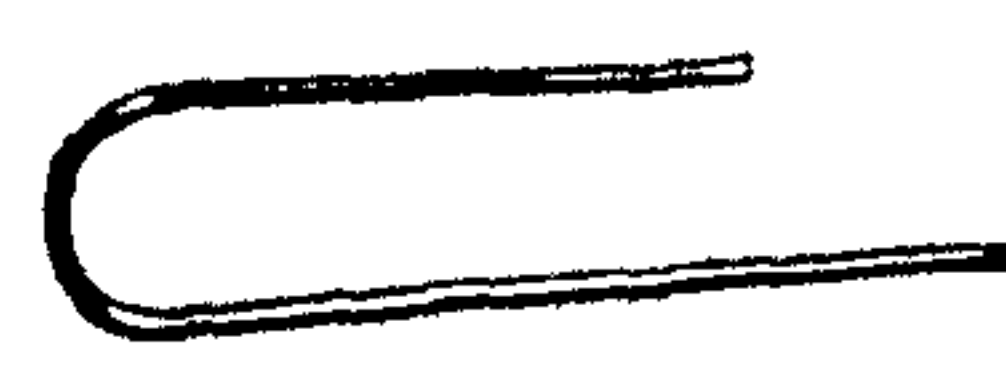
* Personal E-mail

Work Telephone

* Personal Telephone/Mo

Fax

** This information is option
prior consent.*



A copy of a current CV (max.

A4. Is there a central study co-ordinator for this research?

- Yes
- No

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:
- International Standard Randomised Controlled Trial Number (ISRCTN):
- ClinicalTrials.gov Identifier (NCT number):
- European Clinical Trials Database (EudraCT) number:
- Project website:

Ref.Number Description	Reference Number
------------------------	------------------

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

Yes No

Please give brief details and reference numbers.

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. This summary will be published on the website of the National Research Ethics Service following the ethical review.

Chronic pain patients who attend pain management programmes (PMPs) do so to help develop ways of coping with, and reduce, their pain-related distress. PMPs that contain ideas about 'accepting pain' have been found to improve patients' general well-being such as their mood, daily activity level and social relationships. Most research that has investigated PMPs has compared self-report questionnaires and physical measures before and after PMP (e.g. measures of pain interference, physical activity and mood). It has been suggested that future research in this area should not just look at what has changed for patients before and after the PMP, but explore how changes have come about. This study, therefore, aims to explore the experiences of patients who have attended an acceptance-based PMP, in particular the aspects they think may have brought about change. Patients will be approached on the 8th (final) week of the PMP to see who would like to take part. Six patients will then be invited to participate in individual semi-structured interviews with the researcher 1 - 2 weeks following the end of PMP to discuss their experiences of attending the PMP. Interviews will be audio-taped, typed-up and interpreted by the researcher using Interpretive Phenomenological Analysis (IPA) to pick out key themes from what participants have said. Participants who would like to know the results of the study will be posted a 'summary of findings sheet' and receive a follow-up telephone call from the researcher to ask their opinion, to help validate the findings.

A6-2. Summary of main issues. Please summarise the main ethical and design issues arising from the study and say how you have addressed them.

PURPOSE AND DESIGN:

The research has 2 main objectives which as yet have not been addressed in the literature:

- 1) To explore individual experiences of an acceptance-based PMP
- 2) To look at which constituents of the programme individuals regard as facilitating change.

Previous research into acceptance-based PMPs has looked primarily at quantitative outcome measures. The present

study aims to add to research in this area by being the first study to qualitatively explore individuals' experiences during this kind of PMP, including identifying the key consistents that they felt contributed to change. The researcher is hopeful that n=6 will be recruited from one PMP as the groups usually contain between 6 and 10 patients. An 'n' of 5 or 6 is considered a reasonable sample size for IPA research (e.g. Smith & Osborne, 2003).

My supervisor, Dr Beth Parry-Jones (Clinical Psychologist), has been involved in developing the research proposal. Dr Parry-Jones is the Clinical Psychologist who runs the acceptance-based PMP being researched (at NW Wales NHS Trust) and has provided advice, support and guidance with the design and more practical aspects of the research. Dr Dave Daley (Senior Research Tutor, NWCPP, University of Wales, Bangor) will provide additional support throughout the project. Professor Suzanne Skevington (Professor of Health Psychology at the University of Bath) is also happy to read through drafts and provide advice.

The proposed research has the potential to inform and shape future acceptance-based PMPs and, consequently, to improve the well-being of chronic pain patients who attend future PMPs. Taking individual experiences into account is an important way of informing practice in health care. In so doing, the study has the potential to make acceptance-based PMPs more patient-centred, throughout the UK and elsewhere. If the findings can be successfully applied to other PMPs, they may contribute to a reduction in the total financial expenditure by the NHS as a result of chronic pain. Findings could therefore be used for educational purposes with other professionals working with individuals who have chronic pain. Above all, the study has the potential to benefit the large number of individuals who live with chronic pain.

RECRUITMENT: (INCLUSION/EXCLUSION)

Participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of chronic pain. They also need to be able to attend a 10am to 4pm day at an outpatient clinic over an 8 week period. Although not direct inclusion criteria, the programme often advises those who are 'cure-seeking' to finish this process before starting the PMP. Similarly those who have on-going medical investigations or treatments are generally advised to complete these before attending the PMP. Additional inclusion criteria would be the ability to attend an interview with the researcher at the Pain Clinic post-PMP. However, potential participants will not be discriminated against if they do not have access to transport as home visits are possible.

There are no exclusion criteria.

CONSENT:

All participants will have the capacity to consent to the study as certain complex cognitive skills are required in order for participants to understand the material covered in the programme sessions e.g. links between thoughts, feelings and behaviour. Participants will therefore:

- understand the purpose and nature of the research
- understand what the research involves, its benefits, risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision
- be able to make a free choice
- be capable of providing informed consent during the time frame in which it needs to be made (1-2 weeks).

The researcher fully understands the ethical principles that underpin informed consent.

Potential participants will initially be approached by the Clinical Psychologist running the group (my supervisor, Dr Beth Parry-Jones). She will outline that there will be some research attached to this particular PMP (looking at patients' experiences of attending the PMP) and that the researcher will be attending the final session to explain more about it and see who would like to be involved.

The researcher will be introduced to potential participants during the final PMP day (week 8) by Dr Beth Parry-Jones. The researcher will explain the research in detail, provide an information sheet and give participants the opportunity to ask as many questions as they wish. The researcher will also explain to participants that they do not have to decide whether they would like to take part the same day. They are welcome to 'mull it over' during the next 1-2 weeks and will be provided with the researcher's, and research supervisor's, contact details on the information sheet. It will be explained to participants that if the researcher or research supervisor has not had any contact from them during the next 1-2 weeks they will assume that the individual does not wish to participate in the study. Potential participants will be made aware that a decision 'not to take part' in the study will not effect their future health care in anyway, as they are under no obligation, and that if they decide to take part they are welcome to withdraw at any time without explanation. Consent forms will be given to individuals who wish to consent immediately and the researcher will be on hand during the rest of this final PMP day (10am until 4pm) for all participants who wish to ask any further questions during the breaks.

RISK/BURDENS AND BENEFITS:

Although no risks are anticipated for participants, if dicussing individual experiences in relation to the PMP causes

people to become upset then, if they give permission, a member of the PMP team can contact them after the interview. However, the researcher is a Trainee Clinical Psychologist and, therefore, is trained to respond to distress. PMP participants continue to be monitored at 3, 6 and 12 month follow-up appointments post-PMP, and they are encouraged to contact the PMP team in-between if they have any pain-related distress that they cannot resolve themselves.

No burdens for research participants are anticipated as interviews will be scheduled at times that are convenient for participants. The length of interview will also be participant-led, that is, it will be dependent upon how much or little they would like to discuss. Participants will be made aware that they can draw the interview to a close at anytime and are also free to withdraw from the research at anytime.

Although, again, not anticipated, it is useful to be aware of potential situations that may arise. Discussing personal experiences of the PMP has the potential to draw upon sensitive, embarrassing or upsetting past experiences of living with chronic pain - even though there are no interview questions in these areas. For this reason, the researcher decided that individual semi-structured interviews would be the most appropriate method of qualitatively exploring people's experiences of the PMP rather than using focus groups. Participants will also be made aware that they can disclose as much or as little as they like about their own experiences.

Benefits to participants - After talking to my supervisor Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP) it appears that the general feedback of previous patients involved in the PMP is that they often experience a void during the weeks after the PMP has finished, as they miss the sense of purpose and socialisation that the PMP provides. Therefore the opportunity of coming back to the Pain Clinic a week after it has finished for a semi-structured interview may serve as a more gradual end to the programme. The interview may also provide a sense of closure, as participants will have the unique opportunity to express their experiences about the whole process after having a week (or two) to reflect about what it meant to them. Although the PMP team monitor individuals who have been on the programme, at 3,6 and 12 monthly intervals, all participants who would like to receive the 'summary of findings sheet' will have additional contact from the researcher in April 2010 to ask their opinion of the findings. Participants are also welcome to contact the researcher at any point after the interview until April 2010 with any questions, worries or concerns. This information will then be fed back to the PMP team who can arrange to meet and discuss this further, if relevant. Research participants may also benefit from being involved in the research process due to a knowledge that their collective experiences may benefit others with similar difficulties.

The only minimal risk to the researcher would be being alone with individual participants during the semi-structured interviews. However, all patients are risk assessed before starting the programme. Interviews are also intended to be carried out at the Pain Clinic which has policies in place to reduce risk when seeing patients in this setting. Home visits will be kept to a minimum and only used in circumstances when a participant does not have transport. On any potential home visits that may arise the researcher will act in accordance with the North West Wales NHS Trust and Bangor University Lone Worker Policies.

CONFIDENTIALITY:

All identifiable information will be anonymised using pseudonyms. All data including transcripts and audio recording devices will be stored in a lockable filing cabinet at the researcher's NHS clinical placement. The office is shared by a clinical psychologist and an assistant psychologist, but the researcher will be the only person who has a key to access the specific door of the cabinet in which the transcripts will be held. Transcripts will be saved on the researcher's designated NHS computer within her placement office, in anonymised form, and will be password protected. Any transfer of transcripts will be done using a pin code protected USB stick.

The researcher intends to respect the confidentiality of personal data and meet the requirements of the Data Protection Act. The researcher also intends to treat data in a manner that is concordant with best practice. That is, to adhere to the NHS code of confidentiality and the professional practice guidelines set out by the British Psychological Society (1995) for confidentiality (Section 6). The researcher also intends to adhere to the ethical framework set out by the 'Caldicott Principles' with regards to the use of identifiable data. As in all clinical work, there may be rare occasions that confidentiality has to be broken. That is, if participants or others are at serious risk. This will be clearly outlined during informed consent seeking and managed in accordance with the BPS guidelines and my clinical training from Bangor University.

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

The proposed research aims to add to previous research in the area by adopting a qualitative approach to explore individual experiences of an acceptance-based PMP including the specific constituents of the programme that individuals feel may have facilitated change.

A Qualitative approach gathers non numerical data (Coolican, 1999) and aims to gather an in-depth understanding of human behaviour and the reasons that govern such behaviour (Denzin & Lincoln, 2005). It investigates why and how -

not just what, where, when. Therefore, small but focused samples are often needed rather than large random samples. This approach takes the stance that information about human events and experience, if reduced to numerical form, loses most of its important meaning and value (Coolican, 1999).

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

The research has 2 main objectives which are as follows:

- To explore individual experiences of an acceptance-based PMP.
- To look at the key constituents of the programme that individuals regard as facilitating change.

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

It has been suggested that the next generation of research into therapies for chronic pain will focus on the specific processes involved during treatment (McCracken et al., 2005) and the way in which treatments work to achieve adaptive behaviour change (Vowles et al., 2007b).

Acceptance appears to be a key process in treatment outcome and behaviour change in individuals with chronic pain (Vowles et al., 2007b). Changes in acceptance during an acceptance-based Pain Management Programme have also been found to be related to changes in depression, pain-related anxiety, physical and psychosocial disability and persistence with physical tasks (McCracken et al., 2005). Vowles et al (2008) found that acceptance and values-based action have also been associated with improvements on such outcome measures. However, previous studies in the area have all been quantitative and there may be a number of other processes that facilitate change within acceptance-based Pain Management Programmes that questionnaire measures alone fail to capture.

Vowles et al (2007a) argue that processes (such as acceptance) that operate during Pain Management need to be investigated in more detail so that they can be better addressed in clinic. Evaluation studies that confirm the particular treatment components that lead to success and address the processes by which individuals with chronic pain improve are missing from the evidence base (McCracken et al., 2005). Vowles et al (2007) feel that the challenge for future treatment development is to refine the most effective methods for behaviour change. The best way to access this kind of information is to actually ask the individuals who have participated in an acceptance-based Pain Management Programme. An acceptance-based approach with its particular view of private experiences provides a promising base for further therapy development (McCracken et al., 2005).

A13. Please give a full summary of 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.

DESIGN AND METHODOLOGICAL OVERVIEW:

A qualitative approach to add to past quantitative research in the area by exploring individual experiences of an acceptance-based PMP (at _____ Hospital in _____) together with the key constituents of the programme that they feel facilitated change.

PREPARATION: Dr Beth-Parry Jones (Clinical Psychologist of the PMP and supervisor of the proposed project) will explain that there will be some research attached to this particular PMP during the first day of the programme (1 of 8). She will also inform patients that the researcher will attend the final session to explain more about it, provide some information and see who would like to be involved.

INTRODUCTIONS, INFORMATION AND CONSENT:

Potential participants will be introduced to the researcher by Dr Beth Parry-Jones during the 8th and final session of the PMP. Here the researcher will explain the rationale behind the research (i.e. to obtain a better understanding of the experiences of people attending the PMP and the key constituents that they feel may have facilitated change in any way - positive or negative) and provide a concise information sheet outlining the project. Participants will be given the opportunity to ask as many questions as they like as the researcher will be 'on hand' during this final session.

The PMP runs from 10am to 4pm with regular breaks for participants. Individuals can decide if they would like to take part in the project whenever they like e.g. straight away, at the end of the day or during the next week using the (researcher's and/or research supervisor's) contact numbers provided on the information sheet. The researcher will explain to participants that if the researcher or research supervisor has not heard anything over the next 2 weeks it will be assumed that they do not want to be involved in the study. The researcher will inform participants that a decision not to take part will not affect their future health care in any way and that they are free to withdraw from the study at any time

- without reason. A consent form will be signed by those willing to participate in the study which will outline that they have read the information sheet and understand what the study involves:
- An interview with the researcher at the pain clinic 1-2 weeks after the PMP has finished.
- Consideration of whether they would like to receive a summary of findings sheet and be contacted by the researcher in April 2010 to discuss these findings.

SEMI-STRUCTURED INTERVIEWS:

The researcher and each individual participant (n=6) will then arrange a convenient time to meet at the Pain Clinic to conduct individual semi-structured interviews during the 2 weeks after the the programme has finished. The reason for this being that an extra week (or potentially fortnight) would give participants time to reflect/consider what the PMP meant to them. The semi-structured interview will explore both research objectives, see proposed suggestions for interview questions included within the proposal. Direct questions about acceptance and other mindfulness related concepts will not be asked. However, if mentioned by participants, the researcher would like to ask them to elaborate further. It is anticipated that the length of the interviews may range from 20 minutes to 1 hour depending upon how much information participants would like to discuss. However, no participant will be 'cut short' should their time exceed 1 hour.

Participants will then be told that they are welcome to meet with a member of the PMP team should they wish to discuss anything upsetting that may have come up as a result of the interview process (even though this is not anticipated). Participants will then be asked if they would like to receive a 'summary of findings sheet' and telephone call in April 2010 to discuss their views of the results. Contact details on the consent forms of those who do will be clarified. All participants will be provided with the researcher's contact details in case they would like to discuss anything further in relation to the group or if they have any worries or concerns which arise during time that the research is taking place (post-interview to April 2010).

INTERPRETING AND ANALYSING FINDINGS:

Qualitative Analysis

Each individual interview will be transcribed and anonymised by the researcher. Data within the transcripts will be analysed using Interpretative Phenomenological Analysis (IPA) by the researcher in order to meet the study's objective:

To explore individual experiences of an acceptance-based PMP and the key constituents that participants' felt facilitated change in any way.

This interpretative phenomenological analysis will follow the 4-stage process outlined by Smith & Osborne (2003):

Analysis begins with a close interpretative reading of the first case where initial responses to the text are annotated in one margin. These initial notes are translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes are then interrogated in order to make connections between them. This then results in a table of subordinate themes with identifying information - that is, where the instances supporting the theme can be found within the interview transcript.

This process is repeated for each case. After analysis has been conducted on each case, patterns can be established cross-case and documented in a master table of themes for the group. Another researcher is then recommended to review the audit themes to ensure that they are grounded and well-represented in the transcripts. The mastertable can be transformed into a narrative account; the analytic account is then supported by verbatim extracts from each participant.

Participants who wish to have a 'summary of findings sheet' will also be contacted by telephone to ask their opinion with regards to the findings. This should serve to validate the findings and will be included in the final write-up of the project.

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?

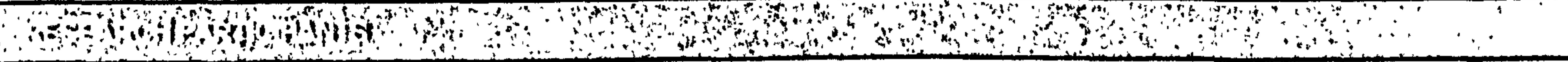
- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

Participants will be introduced to the researcher during the final week (wk8) of the PMP by the Clinical Psychologist running the group (the researcher's supervisor Dr Beth Parry-Jones). Participants who would like to be involved in the study will read an information sheet and complete a consent form. Participants will be made aware that in consenting to being involved in the study means that they are willing to:

- Attend an interview with the researcher 1-2 weeks after the programme has finished.
- Consider whether they would like to be contacted again (in April 2010) to discuss the findings of the study.

Those who have provided consent will be invited along for a semi-structured interview at a convenient time for them during the following week. The interview will last for between 20 minutes to 1 hour depending on how much participants would like to discuss. Participants who would like to have feedback regarding the findings will be sent a 'summary of findings sheet' by post after the results section has been approved by my supervisor Dr Beth-Parry Jones (Clinical Psychologist) and Dr Dave Daley (Senior Research Tutor). A follow-up telephone call from the researcher to ask for participants' opinion as to whether they felt the correct themes have been identified, would help them confirm, or add to the findings. This would help with validating the analysis and will be added to the write-up.



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

Participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of chronic pain. They also need to be able to attend a 10am to 4pm day at _____ in _____ over an 8 week period. Although not direct inclusion criteria, the programme often advises those who are 'cure-seeking' to finish this process before starting the PMP. Similarly those who have on-going medical investigations or treatments are generally advised to complete these before attending the PMP. Additional inclusion criteria would be the ability to attend an interview at _____ Pain Clinic, however individuals will not be discriminated against if they do not have access to transport as home visits are possible.

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

There are no exclusion criteria.



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
- Informed Consent	2	0	30	The researcher will provide informed consent and will conduct individual semi-structured interviews with participants at _____ in _____
- Semi-structured interview to explore participants' experiences of being in the PMP and the key constituents of the programme that they feel may have brought about change.			minutes	

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

Since meeting participants on the final week of the PMP and gaining consent to being contacted regarding their opinions about the 'summary of findings sheet', I estimate that each participant will be in the study for either a total of 6 months (November 2009 to April 2010) or 9 months (August 2009 to April 2010 - if ethical approval was obtained by August) as there will be the opportunity to recruit from PMPs that finish in either August or November 09. Semi-structured interviews will be carried out approximately 1-2 weeks after the final PMP session and participants are welcome to contact the researcher at anytime during this period if they have any questions.

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.

RISK

Although no risks are anticipated, if discussing individual experiences in relation to the PMP causes people to become upset, then if they give permission, a member of the PMP team can contact them after the interview. Clients of the PMP continue to be monitored at 3, 6 and 12 month follow-up post-PMP, and they are encouraged to contact the PMP team in-between if they have any pain related distress that they cannot resolve themselves. The researcher will also provide a contact number, should participants wish to discuss anything further.

BURDENS

No burdens for research participants are anticipated as interviews will be scheduled at times that are convenient for participants and home visits will be considered for those unable to access transport. The length of interview will also be participant led, that is, it will be totally dependent upon how much or little they would like to discuss. Participants will be made aware that they can draw the interview to a close at anytime and are also free to withdraw from the research at any point - without reason.

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:

Although again, not anticipated, it is useful to be aware of potential situations that may arise. Discussing personal experiences of the PMP has the potential to draw upon sensitive, embarrassing or upsetting past experiences of living with chronic pain - even though there are no direct interview questions in these areas. For this reason, the researcher decided that individual semi-structured interviews would be the most appropriate method of qualitatively exploring people's experiences of the PMP rather than through focus groups. Participants will also be made aware that they can disclose as much or as little as they like about their own experiences. Although all individuals who have taken part in the PMP at [redacted] are monitored at 3, 6 and 12 monthly intervals, the researcher will also provide a contact number should participants wish to discuss any worries or concerns throughout the 6 (or potentially 9) months that the research is taking place.

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

Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP) explained that the general feedback of previous clients involved in the PMP is that they often experience a void during the weeks that follow the end of the programme as they miss the sense of purpose and socialisation that the PMP provides. Therefore the opportunity of coming back to the Pain Clinic during the first or second week after the programme finishes, may serve to act as a more gradual end to the programme. The interview may also provide a sense of closure to the group as participants will have the unique opportunity to express their experiences about the whole process after having a week to reflect about what it meant to them. Although the PMP team monitor individuals who have been on the programme, at 3, 6 and 12 monthly intervals, the researcher will also provide a contact number should participants wish to discuss any worries or concerns throughout the 6-months (or 9 months) that the research is taking place. All participants who would like to receive the 'summary of findings sheet' will have additional contact from the researcher approximately 5 months after the end of the group that ends in November (or potentially 8 months if it was possible to recruit from the group that ends in August), to ask their opinion and hence discuss the group further. This information will then be fed back to the PMP team who can arrange to meet and discuss this further if necessary.

Research participants may also benefit from being involved in the research process due to a knowledge that their collective experiences may benefit others with similar difficulties.

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

The only minimal risk to the researcher would be being alone with individual participants during the semi-structured interview. However, interviews are intended to be carried out at Pain Clinic which has policies in place to reduce risk during clinic appointments. Home visits will be kept to a minimum and only used in circumstances when a participant does not have transport. On any potential home visits that may arise the researcher will make sure she is familiar with the trust's lone worker policies. All participants are risk assessed when they attend the PMP.

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).

Potential participants will be identified by their attendance of the PMP at the outpatients Pain Clinic, NW Wales NHS Trust. Their attendance (and potential inclusion in the study) will be dependent upon the PMP's inclusion criteria (See A16 for more information).

Although my supervisor Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP under investigation) will mention that there is a possibility that some research may be attached to their PMP, the researcher will formally introduce patients to the study. This will occur during the 8th and final week of the PMP when the researcher will outline the aim of the research 'to explore individual experiences of the PMP' and what it will entail. Information sheets will also be provided together with consent forms. Semi-structured interviews will be arranged at times during the following 1-2 weeks that are convenient for those who have given consent to participate in the study. The researcher will be on hand for the whole of this final session at .f patients would like to give it further consideration throughout the day and ask additional questions. The researcher will explain to patients who would like more time, that they can contact the researcher or research supervisor using the numbers on the information sheet. Patients will also be made aware that it is hoped that interviews will take place during the following 1-2 weeks and that if the researcher or research supervisor does not hear from them during this time it will be assumed that they do not wish to take part in the study. It will also be made clear to patients that a decision not to take part in the study will not effect their future receipt of health care in anyway and that they can withdraw from the study at anytime without reason.

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:

The identification of potential participants will not involve reviewing or screening the personal information of patients.

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

Yes No

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

Potential participants will initially be approached by the Clinical Psychologist running the group (my supervisor Dr Beth Parry-Jones) who will outline that there will be some research attached to this particular PMP (looking at people's experiences of being in the group) and that the researcher will be attending the final session to explain more about it and see who would like to be involved.

The researcher will be introduced to potential participants during the final PMP session (wk 8) by Dr Beth Parry-Jones.

The researcher will take up a short section of the start of this final session and explain the research in detail, provide an information sheet and give potential participants the opportunity to ask as many questions as they like. The researcher will also explain to participants that they do not need to decide whether they would like to take part straight away as the study is due to take place the following week. Consent forms will be provided to individuals who wish to consent immediately and the researcher will be on hand during the rest of this session (10am until 4pm) for all participants who wish to give it further consideration during the breaks. Alternatively the researcher will provide a contact number at the end for anyone who would like additional time (over the next week) to consider being involved in the study. Potential participants will be made aware that a decision not to consent to the study will not affect their future receipt of healthcare in anyway as they are under no obligation.

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.

I the researcher will be obtaining informed consent from adult participants as outlined above using an information sheet and consent form. Both forms and a full explanation about the research will occur during the final session of the PMP. All participants who would like to give it further consideration during the following 1-2 weeks will be provided with a contact number for the researcher and research supervisor.

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?

Potential participants will have a 1-2 weeks to decide whether they wish to take part. The reason for this being that due to the nature of the research exploring people's experiences of being in the PMP, recall may be affected with increasing time. My supervisor Dr Beth Parry-Jones felt that this should give participants time to reflect on their experiences and what the PMP meant to them.

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)

The policy of North West Wales NHS trust is to provide written information in both English and Welsh. However, the PMP is in English and part of the initial assessment, conducted by the PMP team would be ensuring individuals understand English sufficiently. If not, not that this has happened yet within the PMPs, it would be possible to have a translator. Unfortunately the researcher is unable to speak Welsh and would have to conduct the semi-structured interviews in English. However, if needed, a translator could be arranged if participants would prefer to speak Welsh during the interviews. My supervisor Dr Beth Parry-Jones has informed me that it is possible to include a BSL translator if a participant has a hearing impairment (even though the PMP has not had to do this as yet). The PMP has not yet had anyone who has been partially sighted, but it is always possible to have written documents such as the information sheet and consent form in large print. The programme has also never had an individual who is blind, although braille could be a possibility.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

The researcher is aware that the provision of information is governed by the Welsh Language Act (1993) and that English and Welsh languages should be treated equally. Potential participants will therefore have the right to choose which language they would prefer during the process of informed consent, all other aspects and correspondence

involved in the research together with future NHS correspondence and provision of care. Information sheets and consent forms will be written in both English and Welsh in accordance with the Welsh Language Act and Policies within the North West Wales Trust. The researcher recognises that participants can express their views and needs better in their preferred language and is aware of the ethical importance of this during informed consent seeking.

Advice from the NHS R & D office about the language requirements of the local population and the Welsh language policies in place at this site has been sought from Dr Rossela Roberts (Clinical Governance Officer) and Dr Beth Pary-Jones (Clinical Psychologist within NWW Trust).

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.

Further details:

As the participant would have already given consent to participate in the study, identifiable data already collected would be retained in anonymised form and used in the study. However, it clearly would not be appropriate to try to conduct an interview with someone who did not understand what was happening. Potential participants will be made fully aware of this during consent seeking.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.



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:

USE OF PERSONAL ADDRESSES AND TELEPHONE NUMBERS:

Personal addresses and telephone numbers of those who have provided consent (to be involved in the study) and wish to receive the 'summary of findings sheet' by post will be used to validate the research findings. The provision of a personal address and telephone number is required on the consent form.

PUBLICATION OF DIRECT QUOTATIONS FROM RESPONDENTS:

Should the study be worthy of publication, there is a possibility that direct quotations from participants may be published if they fall under particular themes identified during qualitative analysis (IPA). Participants will be made aware of this during 'consent seeking' and this will be clearly stated in the information sheet and consent form. It will also be made clear that all identifiable information will be removed from interview transcripts as they are transcribed.

USE OF AN AUDIO RECORDING DEVICE:

An Audio recording device will be used to record individual semi-structured interviews. No identifiable information will be written on the tapes which will be stored in a lockable filing cabinet at the researcher's NHS placement. The only person who will have access to this part of the filing cabinet is the researcher who has her own key. Participants will be made aware of the use of an audio recording device at the consent seeking stage - see information sheet.

STORAGE OF DATA ON NHS COMPUTERS AND LAPTOP COMPUTERS:

As all identifiable information that occurs during transcription will be anonymised, transcripts will be saved on an NHS computer in this format. This computer is password protected with the researcher being the only person who will be able to access this information.

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.

Pseudonyms will be used throughout transcripts and care will be taken to anonymise any other identifiable information that may emerge.

The researcher intends to respect the confidentiality of personal data and meet the requirements of the Data Protection Act. The researcher also intends to treat data in a manner that is concordant with best practice. That is, to adhere to the NHS code of confidentiality and the professional practice guidelines set out by the British Psychological Society (1995) for confidentiality (Section 6)

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 researcher, and research supervisor alone.

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

If longer than 12 months, please justify:

This would give the researcher ample time to publish/amend anything.

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

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.

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

Yes No

Please give details, or justify if not registering the research.

I will not be registering the research as it is not a clinical trial and so there are no legal requirements for registration. There is also no suitable register on which the research could be placed.

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)

Feedback of results to participants using the 'summary of findings sheet' and later telephone call to ask whether they feel these findings are valid.

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.

Results will be fed back to all participants who would like them by post using the 'summary of findings sheet'. The researcher will then contact these individuals by telephone to ask whether they feel these findings are valid. Their opinions will be used to validate the study and added to the findings section during the final write-up.

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:

The scientific quality of the research has been verified via an internal peer review by my supervisors (Dr Beth Parry-Jones and Dr Dave Daley) and will be submitted to the School of Psychology Ethics and Research Governance committee for approval which involves a dual review.

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.

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: 6
 Total international sample size (including UK):
 Total in European Economic Area:

Further details:

The PMP group contains between 6 and 10 individuals who will be invited to participate in the study as they have undergone the acceptance-based PMP at in An n of 6 was chosen as the sample size for the present project an n of 5 or 6 is felt to be a reasonable sample size for IPA research (e.g. Smith & Osborne, 2003). An n of 6 should therefore result in data saturation as the very nature of qualitative research means that rich informative data about participant experiences of being in an acceptance-based PMP and the key constituents that facilitated change should emerge.

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.

An n of 6 should therefore result in data saturation as the very nature of qualitative research means that rich informative data about participant experiences of being in an acceptance-based PMP and the key constituents that facilitated change should emerge. See A59 (Smith & Osborne, 2003).

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.

Qualitative Analysis

Data within the transcripts will be analysed using IPA by the researcher in order to meet the objectives of the study. That is, to answer the following research question:

What are the experiences of individuals on an acceptance-based Pain Management Programme- including the key constituents of the programme that they regard as facilitating change?

This interpretative phenomenological analysis will follow the 4-stage process outlined by Smith & Osborne (2003):

Analysis begins with a close interpretative reading of the first case where initial responses to the text are annotated in one margin. These initial notes are translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes are then interrogated in order to make connections between them. This then results in a table of subordinate themes with identifying information - that is, where the instances supporting the theme can be found within the interview transcript.

This process is repeated for each case. After analysis has been conducted on each case, patterns can be established cross-case and documented in a master table of themes for the group. Another researcher is then recommended to review the audit themes to ensure that they are grounded and well-represented in the transcripts. The mastertable can be transformed into a narrative account; the analytic account is then supported by verbatim extracts from each participant.

The validity of the findings will then be examined through follow up telephone calls to participants who wished to receive a summary of findings sheet by post. Their responses will also be included in the results section of the final write up.

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
Post		
Qualifications		
Employer		
Work Address		
Post Code		
Telephone		
Fax		
Mobile		
Work Email		

A64-1. Sponsor

Lead Sponsor

Status: NHS or HSC care organisation
 Academic
 Pharmaceutical industry

Commercial status:

- Medical device industry
- Local Authority
- Other social care provider (including voluntary sector or private organisation)
- Other

If Other, please specify:

Contact person

Name of organisation The School of Psychology Bangor University

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

Is the sponsor based outside the UK?

- Yes
- No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

Legal representative of the sponsor

Contact person

Name of organisation

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

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.

- Medical device industry
- Local Authority
- Other social care provider (including voluntary sector or private organisation)
- Other

If Other, please specify:

Contact person

Name of organisation The School of Psychology Bangor University

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

Is the sponsor based outside the UK?

- Yes
- No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

Legal representative of the sponsor

Contact person

Name of organisation

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

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

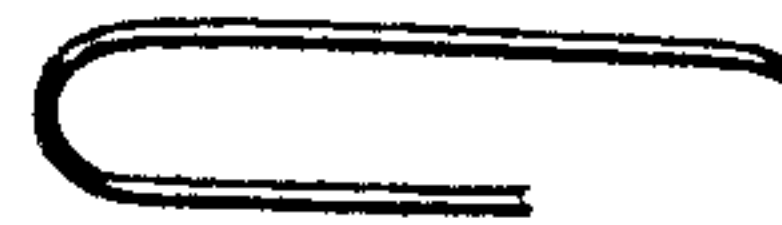
- Yes
- No

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

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile



Details can be obt

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

Planned start date: 11/08/2009
Planned end date: 04/05/2010
Total duration:
Years: 0 Months: 8 Days: 23

A71-1. Is this study?

- Single centre
- Multicentre

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 1

Does this trial involve countries outside the EU?

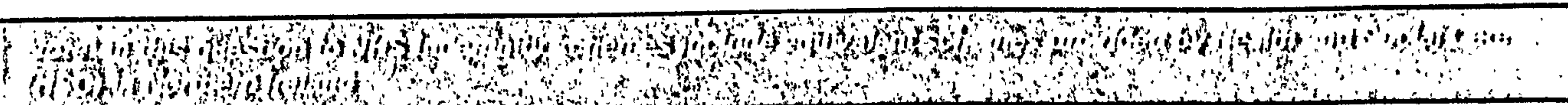
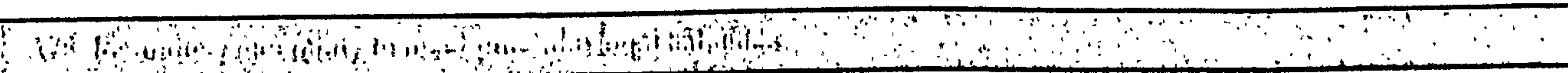
- Yes
- No

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
- NHS organisations in Wales 1
- 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)

Total UK sites in study: 1



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)

The University of Bangor's indemnity insurance policy. See certificate.

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)

The University of Bangor's indemnity insurance policy. See certificate.

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)

The University of Bangor's indemnity insurance policy, which covers non-negligent harm. See certificate.

Please enclose a copy of relevant documents.

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	Pain Management Service,	Title	Mrs
Department name		First name/ Initials	Beth
Street address		Surname	Mathias
Town/city			
Post Code			

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 main REC or the GTAC (as 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 main REC, 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.
 - 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.
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. 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

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's UK contact point
 Study co-ordinator

- Student
- Other – please give details
- None

Title:
Forename / Initials:
Surname:
Post:
Work address:
Work email:
Work telephone:

Access to application for training purposes

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.

Signature:

Print Name: Beth Gemma Mathias

Date: 29/07/2009 (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. 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: Oliver Turnbull

Date: 27/07/2009 (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor

- 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 Chief Investigator and 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.

Signature:

Print Name: Beth Parry-Jones

Date: 29/07/2009 (dd/mm/yyyy)

Post: Clinical Psychologist

Organisation: North West Wales NHS Trust

**Ysgol Seicoleg
Prifysgol Bangor**

Adeilad Brigantia, Ffordd Penrallt
Bangor, Gwynedd LL57 2AS

Ffôn: (01248) 382211 - Ffacs: (01248) 382599
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www.psychology.bangor.ac.uk

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e-mail: psychology@bangor.ac.uk
www.psychology.bangor.ac.uk

23rd July 2009

Dear Sir or Madam,

I confirm that Bangor University, has agreed to act as research sponsor for the following project:

**Individual experiences of an acceptance-based pain management system.
Ethics proposal 1399**

This project will be conducted by Dr Beth Parry-Jones and Mrs Beth Mathias.

Please contact me should you require any further details.

Yours faithfully,

Professor. Oliver Turnbull
Head, School of Psychology
Bangor University

Appendix 10: REC Provisional Opinion Letter

PRIVATE & CONFIDENTIAL

Dear Mrs Mathias

Study Title: Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.**REC reference number:** 09/WNo01/35**Protocol number:** 2

The Research Ethics Committee reviewed the above application at the meeting held on 20 August 2009. Thank you for attending to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	-	29 July 2009
Application	22381/52815/1/1	29 July 2009
Protocol	2	16 July 2009
Participant Information Sheet	2	16 July 2009
Participant Consent Form	2	16 July 2009
Letter from Sponsor	-	23 July 2009
Insurance / Indemnity Arrangements	UMAL	01 August 2008
Investigator CV	-	23 June 2009
Supervisor CV	-	

Provisional opinion

All members and deputy members present at the meeting were present for the review of this application. No written comments were sent by absent members in relation to this application. No conflicts of interest were declared in relation to this application.

The Chief Investigator, Mrs Beth Mathias and her Educational/Clinical Supervisor, Dr Beth Parry-Jones attended to speak to this submission.

The Chairman welcomed the investigators, introduced the Committee members and the observer; the Chairman explained that the observer will have no input in the ethical review or the decision making process and gave the applicant the opportunity to raise an objection to the observer being present for the review of this application. The applicant did not raise an objection to the observer being present.

The Chairman invited the applicant to give an overview of the project. The applicant presented the project as an exploration of the experiences of patients who have attended an acceptance-based PMP, in particular the aspects they think may have brought that change. Patients will be approached on the final week of the PMP and six patients will be invited to participate in individual semi-structured interviews with the researcher to discuss their experiences of attending the PMP.

The Committee raised the following issues with the applicant:

Scientific design and conduct of the study

The Committee recognised the merits of the application, as an important qualitative study into the patients' experiences of the PMP and an evaluation of this programme's input into the management of their condition.

The committee queried if six participants would be sufficient to reach theme saturation.

The CI clarified that in existing literature on interpretative phenomenological analysis six participants are often mentioned as the required/sufficient number to reach saturation.

A further question was raised on the conduct of the semi-structured interview: the Committee requested clarification on how the researcher will prevent asking leading questions. The CI clarified that the questions are listed on the interview guide and her experience in clinical practice will guide her during the interview. The interviews will be recorded and transcribed; the transcript will serve as verification means to avoid leading questions.

The Committee concluded that research design and the proposed analysis were deemed suitable for answering the research question.

It was noted that in the application form the inclusion criteria described in Q A17-1 is in fact the inclusion criteria for the Pain Management Programme, not for the research project and no exclusion criteria have been identified.

No further ethical issues were raised.

Suitability of the applicant and facilities; community considerations

The Committee concluded that the Chief Investigator is sufficiently qualified and adequately supervised to carry out this research. The local facilities and arrangements are suitable, and community issues have been considered. The CI clarified that the venue might need to change in view of the changes in the NHS "B" should this be the case an amendment will be submitted. No further ethical issues were raised.

Anticipated benefits/risks for research participants

The Committee discussed the anticipated benefits and potential risks to participants and was satisfied that the applicant has suitably identified the risks and benefits and highlighted them in the information given to participants.

No further ethical issues were raised

Care and protection of research participants (welfare and dignity)

The Committee was satisfied that the welfare and dignity of potential participants has been taken into account in a professional manner; the Lone Worker Policy will be applicable to the person who does the interviews in the participants' homes.

No further ethical issues were raised.

Adequacy and completeness of Participant Information

The Committee agreed that generally the language used is clear and understandable and all the procedures described in the protocol have been addressed in the Information Sheet, but felt that some minor corrections are needed:

In paragraph 'Further Information' an office telephone number should be provided, rather than a personal mobile number. The CI agreed to rectify.

Informed Consent process

The Committee noted that written informed consent is taken as part of a process - with participants having adequate time to consider the information, and opportunity to ask questions. The information is clear to what the participant consents. The committee queried a possible element of coercion, as the person leading the PMP is also supervisor for this research and patients might feel obliged to consent. The supervisor clarified that she will only be acting as point of contact and therefore participants will not feel coerced. Also, the PIS clarifies that refusal to take part or withdrawal will not affect the care they receive. The requirements of the Mental Capacity Act are followed for participants who lack capacity /lose capacity to consent. No other ethical issues were raised.

Data protection and participant's confidentiality

The Committee discussed where and for how long will data be stored, and clarified who will have access to the data. Participants are informed that access to their records may be required for monitoring and audit purposes. The committee queried why access to medical notes is required. The CI clarified that is not the medical record but only the PMP programme notes and agreed to clarify this on the CF. The Committee requested that the CF is explicit with regards to who will have access to the notes: not ' individuals from Bangor University' but more appropriately 'the research team' The Committee felt that the participant's GP needs to be informed. The CI agreed: a template GP information letter will be submitted for the Committee's perusal. The PIS will inform and the CF will request participants' consent to inform the GP. No further ethical issues were raised

General comments/ missing information/ typographical errors/ application errors

No comments were made

The Chairman thanked the investigators for attending and gave an opportunity to the applicant to ask questions. The applicant did not raise any issues. The Chairman confirmed that the Committee will deliberate and will be in touch shortly with the result.

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

Further information or clarification required

Following deliberations, the Committee requested the following amendments:

Participant Information and Consent (PIS and CF):

The committee requested amendments to be made to the PIS and CF, as follows:

The Participant Information Sheet should inform patients that the research team would like to notify their GP about their participation in this research and would seek consent to do so. In paragraph 'Further Information' an office telephone number should be provided, rather than a personal mobile number.

The Consent form should be re-phrased to clarify who will have access to the medical notes ('the research team', rather than 'individuals from Bangor University') and which notes in particular ('PMP notes' rather than 'medical record')

Consent should be sought to inform the GP.

A template GP information letter should be submitted for the Committee's perusal.

Other:

Insurance certificate: an up-to-date insurance certificate is required (professional indemnity, employer's liability) is required as soon as this becomes available.

Welsh translations:

The amended Participant Information Sheet and Consent Form need translating and the Welsh language version made available to participants.

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

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 19 December 2009.

Membership of the Committee

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

No conflicts of interest were declared in relation to this application.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/WNo01/35

Please quote this number on all correspondence

Yours sincerely



 Mr David Owen, CBE, QPM
Chairman

Email: Rossella.Roberts@nww-tr.wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"*

Copy to: Sponsor's Representative: Prof Oliver Turnbull, School of Psychology Bangor University
R&D office, Lead site, R&D Manager, North West Wales NHS Trust

North West Wales Research Ethics Committee
Attendance at Committee meeting on 20 August 2009

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Dr Swapna Alexander	Expert member, Consultant Physician	Yes
Mr J K Blomeley	Lay member +, Retired teacher	Yes
Mrs Rebecca Mary Burns	Expert member, Research Nurse	No
Mrs K Chester	Expert member, Research Nurse (deputy for Mrs R Burns)	No
Dr Christine Clark	Expert member, Consultant Obstetrician & Gynaecologist	No
Mr Derek James Crawford	Expert member, Consultant Surgeon	Yes
Mrs Gwen Dale-Jones	Lay member +, Personal Secretary	No
Mr Hywel Lloyd Davies	Lay member +, Solicitor	Yes
Mr Henry Alan Owen Hughes	Expert member, Pharmacist	Yes
Dr Mike C Jackson	Expert member, Clinical Psychologist	No
Mr Clive Robert Mackie Jenkins	Lay member - Clinical Research Auditor	No
Ms Gillian Jones	Lay member - Information Governance Officer	Yes
Mr David Owen	Lay member +, retired Chief Constable	No
Mr Paramasivan Sathyamoorthy	Expert member, Consultant Orthopaedic Surgeon	Yes
Dr T Vasu	Expert member, Consultant Anaesthetist	Yes
Mr Christopher Whitaker	Lay member, Statistician	Yes
Dr Philip W White	Expert member, General Practitioner	Yes

In Attendance:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Miss Angela Filippi	Assistant Committee Co-ordinator	Yes
Dr Rossela Roberts	Committee Co-ordinator	Yes

Observer:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Miss Lowri Pritchard	Student	Yes

Appendix 11: Amendments Letter

**Ysgol Seicoleg
Prifysgol Cymru, Bangor**

Adeilad Brigantia, Ffordd Penrallt
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Mr. D. Owen,
(Chairman)
North West Wales NHS Trust,
Clinical Academic Office,
Clinical School,
Ysbyty Gwynedd,
Bangor.
LL57 2PW

Dear Mr Owen,

**Re: Research Project– Individual experiences of an
acceptance-based Pain Management Programme: An
Interpretative Phenomenological analysis.
(09/WNo01/35)**

Thank you for your letter outlining the feedback from the Research Ethics Committee meeting on 20th August 2009. In light of this feedback I have made the following amendments:

Patient Information sheet

- The patient information sheet now informs patients that the research team would like to notify their GP about their participation and intend to seek consent to do so.
- In the paragraph entitled 'further information' an office telephone number has been provided instead of a mobile number. It was felt that the Chief Investigator's (CI's) clinical placement telephone number was the best office number to give as this is where the CI will be spending the majority of her time throughout the third and final year of clinical training. This would mean that the CI would be easily accessible to participants who required any further information or had any questions about the research.

Consent Form

- This form now clarifies who will have access to the specific kind of patient notes. That is, the form seeks consent for 'the research team' (rather than 'individuals from Bangor University') to access 'the Pain Management Programme notes' (rather than 'medical records').
- Consent to inform the GP of their involvement of the study has also been included in this form.

GP Information letter

- A GP information letter has been constructed and has been submitted for the committee's perusal.

Insurance certificates

- A copy of the Employer's Liability and Professional Indemnity for the current year have also been enclosed.

Welsh Translations

- The amended participant information sheet and consent form are in the process of being translated and once amendments are approved will be sent to the translation Department within Bangor University.

All revised documentation enclosed has been underlined to indicate the changes that have been made. Revised Version numbers have also been added to these documents.

Yours Sincerely,

**Mrs Beth Mathias
(Trainee Clinical Psychologist)**

**Appendix 12: Amended Participant Information Sheet
(English and Welsh)**

Ysgol Seicoleg
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Individual Experiences of a Pain Management Programme **PARTICIPANT INFORMATION SHEET**

Researchers: Beth Mathias, Trainee Clinical Psychologist, North Wales Clinical Psychology Programme, and Dr Beth Parry-Jones, Clinical Psychologist, NW Wales NHS Trust.

Invitation

We hope that you will be able to help with Beth Mathias' Doctoral Research Project, by agreeing to be interviewed one – two weeks after the end of the Pain Management Programme (PMP) about what being on the programme was like for you.

What is the purpose of the study?

Talking to individuals about their experiences is an important way to inform practice in health care. The next generation of research into Pain Management Programmes for chronic pain intends to look at the way in which programmes work to achieve change, exploring how people think, feel or act differently. Previous research has looked at change using questionnaire scores and physical measures before and after the programme. This study aims to go one step further by talking to you individually about your experience of being on the North West Wales Pain Management Programme and explore what parts of the programme you felt may have brought about change in any way.

Do I have to take part?

It is up to you whether or not you decide to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at anytime, or a decision not to take part, will not affect your future health care in anyway.

What does it involve?

You will be asked to arrange an appointment with Beth Mathias at the Pain Clinic 1-2 weeks after the end of the PMP at a convenient time for you. This appointment will take the form of an interview to explore what being on the programme was like for you and what parts of the programme you feel may have contributed to change in any way. The interview will last roughly 20 minutes to 1 hour, depending on how much you would like to talk about. It will be audio-taped so that Beth Mathias can type it up, pick out key themes and use non-identifiable direct quotes when she writes up the research. You also have the option of having a 'Summary of Findings' sheet posted to you at home in April 2010 and, if you agree, a follow-up telephone call from Beth Mathias to ask your opinion about the findings. The research team would also like to notify your GP about your participation in the study and will seek your consent to do so.

What are the possible benefits of taking part?

Previous PMP patients often miss the PMP after it has finished. Therefore the opportunity of coming back to the Pain Clinic a week or two after the programme has finished for an interview may create a more gradual end to the programme. All participants who would like to receive the

'Summary of Findings Sheet' will have additional telephone contact from the researcher in April 2010 to ask their opinion of the findings. Participants are also welcome to contact the researcher at any point in-between with any questions, worries or concerns. This information will then be fed back to the PMP team who can arrange to meet and discuss this further, if necessary. Your participation in the study has the potential to benefit others in chronic pain and may serve to educate other professionals working with individuals who have similar difficulties.

What are the disadvantages or risks of taking part?

You will be asked to give some of your time to having an interview with the researcher which may range from 20 minutes to 1 hour. Although no risks are anticipated, if discussing individual experiences in relation to the PMP causes people to become upset, then, if they give permission, a member of the PMP team can contact them after the interview. However, the researcher is a Trainee Clinical Psychologist and, therefore, is trained to respond to distress.

What if something goes wrong?

The risks involved in taking part in the study are very small; however, the study does have full insurance cover in the unlikely event that you think you have been harmed in some way.

Will my taking part in the study be kept confidential?

All personal identifiable information will be removed from the typed-up interview transcripts and tapes will either be destroyed or returned to you (whatever you wish) at the end of the research. All information collected during the course of the research will be kept strictly confidential unless you tell Beth Mathias something that makes her concerned that there might be serious risk to you or another person. If this was the case, then she will have to inform the Pain Management Team and possibly others involved in your care.

What will happen to the results of the research study?

The intention is that the results will be published in a scientific journal and shared with health care professionals working with individuals who are in chronic pain. Although direct quotes from interviews may be used, you will not be identified in any report or potential publication.

Further information

If you would like longer to think about whether you would like to take part in the study, or if you require any further information please contact Beth Mathias (Trainee Clinical Psychologist), North Wales Clinical Psychology Programme, Bangor University, 43 College Road, Bangor, Gwynedd, LL57 2DG, telephone Beth Mathias' clinical placement office 01437 776409 (Secretary 01437 776404) or email: beth.mathias@yahoo.co.uk. Alternatively you can contact Dr Beth Parry-Jones (Clinical Psychologist), Pain Management Service, or via email: beth.parry-jones@nww-tr.wales.nhs.uk, telephone

If you decide to take part please complete the consent form and keep this information sheet so that you can refer to it in future. You will also be given a signed copy of the consent form to keep for your information

If you have any complaints about the conduct of this study, these should be addressed to:
Professor Oliver Turnbull, Head of School of Psychology, Bangor University, Bangor, Gwynedd, LL57 2DG.

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

Ysgol Seicoleg
Prifysgol Cymru, Bangor

Adeilad Brigantia, Ffordd Penrallt
Bangor, Gwynedd LL57 2AS

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www.psychology.bangor.ac.uk

Profiadau unigol o raglen reoli poen **TAFLEN WYBODAETH I GYFRANOGWYR**

Ymchwilwyr: Beth Mathias, Seicolegydd clinigol dan hyfforddiant, Rhaglen Seicoleg Glinigol Gogledd Cymru a Dr Beth Parry-Jones, Seicolegydd clinigol, Ymddiriedolaeth GIG Gogledd Cymru.

Gwahoddiad

Rydym yn gobeithio y byddwch yn gallu helpu gyda phroject ymchwil PhD Beth Mathias trwy gytuno i gael eich cyfweld wythnos neu bythefnos wedi diwedd y rhaglen reoli poen ynglŷn â'ch profiad gyda'r rhaglen.

Beth yw pwrpas yr astudiaeth hon?

Mae siarad gydag unigolion am eu profiadau yn ffordd bwysig iawn o wella ymarfer ym maes gofal iechyd. Nod y genhedlaeth nesaf o ymchwil i raglenni rheoli poen ar gyfer poen cronig yw ystyried y ffyrdd y mae'r rhaglenni hyn yn ceisio newid sefyllfa unigolion, ac ystyried pa newidiadau sy'n digwydd i agwedd, i deimladau neu i ymddygiad pobl. Mae ymchwil blaenorol wedi astudio newid trwy ddefnyddio sgoriau holiaduron a mesurau corfforol cyn y rhaglen ac wedi'r rhaglen. Nod yr astudiaeth hon yw mynd cam ymhellach trwy siarad gyda chi'n unigol ynglŷn â'ch profiad o fod ar raglen reoli poen gogledd orllewin Cymru a thrafod pa rannau o'r rhaglen sydd wedi achosi unrhyw fath o newid yn eich barn chi.

Oes rhaid i mi gymryd rhan?

Chi sydd i benderfynu a ydych am gymryd rhan ai peidio. Os penderfynwch gymryd rhan, cewch y daflen wybodaeth hon i'w chadw, a bydd gofyn i chi lofnodi ffurflen gydsynio. Os byddwch yn penderfynu cymryd rhan, mae gennych hawl i dynnu allan unrhyw bryd heb roi rheswm. Ni fydd eich penderfyniad i gymryd rhan yn gwneud unrhyw wahaniaeth i'r gofal iechyd a dderbyniwch yn y dyfodol.

Beth mae'n ei olygu?

Byddwn yn gofyn i chi drefnu apwyntiad gyda Beth Mathias yn y clinig poen wythnos i bythefnos ar ôl diwedd y rhaglen rheoli poen ar amser sy'n gyfleus i chi. Bydd yr apwyntiad ar ffurf cyfweiliad i drafod sut brofiad oedd bod ar y rhaglen a pha rannau o'r rhaglen sydd wedi cyfrannu at unrhyw newidiadau, yn eich barn chi. Bydd y cyfweiliad yn para rhwng 20 munud ac awr, yn dibynnu ar faint o bethau y byddwch eisiau eu trafod. Caiff ei recordio ar dâp sain er mwyn i Beth Mathias allu ei deipio, nodi'r themâu allweddol a defnyddio dyfyniadau uniongyrchol dienw wrth ysgrifennu am ei hymchwil. Mae gennych hefyd y dewis o gael taflen 'crynodeb o'r casgliadau' wedi ei hanfon atoch ym mis Ebrill 2010, ac os byddwch yn cytuno, galwad ffôn gan Beth Mathias yn gofyn eich barn am y casgliadau. Hoffai'r tîm ymchwil hefyd roi gwybod i'ch meddyg teulu eich bod yn cymryd rhan yn yr astudiaeth a byddent yn gofyn eich caniatâd i wneud hynny.

Beth yw manteision posibl cymryd rhan?

Mae cyn gleifion ar y rhaglen reoli poen yn aml yn gweld ei heisiau wedi i'r rhaglen ddod i ben. Felly gallai'r cyfle i ddod yn ôl i'r clinig poen wythnos neu bythefnos wedi diwedd y rhaglen am

Fersiwn: 3 Dyddiad: 25/08/09

gyfweliad ddod â'r rhaglen i ben yn fwy graddol. Bydd yr ymchwilydd yn ffonio pob cyfranogwr sy'n dymuno cael copi o'r daflen 'crynodeb o'r casgliadau' ym mis Ebrill 2010 i ofyn eu barn ar y casgliadau. Mae croeso hefyd i'r cyfranogwyr gysylltu â'r ymchwilydd ar unrhyw adeg i ofyn cwestiynau neu drafod pryderon. Caiff y wybodaeth hon ei bwydo'n ôl i dîm y rhaglen reoli poen a gallent drefnu i gyfarfod â thrafod y mater ymhellach os oes angen. Gallai eich cyfraniad at yr astudiaeth fod o fudd i bobl eraill gyda phoen cronig a gallai wella dealltwriaeth pobl sy'n gweithio gydag unigolion gyda phroblemau tebyg.

Beth yw'r anfanteision neu'r risgiau o gymryd rhan?

Gofynnir i chi roi rhwng 20 munud ac awr o'ch amser ar gyfer cyfweliad gyda'r ymchwilydd. Er nad ydym yn rhagweld unrhyw risgiau, os bydd trafod eich profiad o ran y rhaglen reoli poen yn creu gofid i chi yna gall aelod o dîm y rhaglen reoli poen gysylltu â chi ar ôl y cyfweliad, os byddwch yn cytuno. Ond gan fod yr ymchwilydd yn seicolegydd clinigol dan hyfforddiant, mae wedi ei hyfforddi i ymdrin â gofid.

Beth os aiff rhywbeth o'i le?

Mae'r risgiau sy'n ymwneud â chymryd rhan yn yr astudiaeth hon yn fychan iawn; fodd bynnag, mae'r astudiaeth wedi ei hyswiro'n llawn yn yr achos annhebygol eich bod yn meddwl i chi gael eich niweidio mewn rhyw ffordd.

A fydd y ffaith fy mod yn cymryd rhan yn yr astudiaeth yn cael ei gadw'n gyfrinachol?

Caiff pob gwybodaeth a ellir ei defnyddio i'ch adnabod ei hepgor o drawsgrifiadau'r cyfweliadau a byddwn naill ai'n dinistrio'r tapiau neu'n eu hanfon yn ôl atoch, yn unol â'ch dymuniad, ar ddiwedd yr ymchwil.

Bydd yr holl wybodaeth a gesglir yn ystod yr ymchwil yn cael ei chadw'n hollol gyfrinachol, oni bai eich bod yn dweud rhywbeth wrth Beth Mathias sy'n gwneud iddi feddwl bod risg ddifrifol i chi neu berson arall. Os byddai hynny'n digwydd, yna byddai'n rhaid iddi roi gwybod i'r tîm rheoli poen ac efallai pobl eraill sy'n cyfrannu at eich gofal.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth ymchwil?

Rydym yn bwriadu cyhoeddi canlyniadau'r astudiaeth mewn cylchgrawn gwyddonol, a'u rhannu â gweithwyr proffesiynol ym maes gofal iechyd sy'n gweithio gydag unigolion sydd mewn poen cronig. Er y caiff dyfyniadau uniongyrchol o gyfweliadau eu defnyddio, ni chewch eich enwi mewn unrhyw adroddiad na chyhoeddiad.

Rhagor o wybodaeth

Os hoffech fwy o amser i ystyried a ydych am gymryd rhan yn yr astudiaeth hon, neu os oes arnoch angen rhagor o wybodaeth, cysylltwch â Beth Mathias (Seicolegydd clinigol dan hyfforddiant), Rhaglen Seicoleg Glinigol Gogledd Cymru, Prifysgol Bangor, 43 Ffordd y Coleg, Bangor, Gwynedd LL57 2DG, neu ffoniwch swyddfa lleoliad clinigol Beth Mathias ar 01437 776409 (ysgrifenyddes 01437 776404) neu drwy e-bost: beth.mathias@yahoo.co.uk. Gallwch hefyd gysylltu â Dr Beth Parry-Jones (Seicolegydd clinigol),

beth.parry-jones@nww-tr.wales.nhs.uk, ffôn . . . neu drwy e-bost:

Os penderfynwch gymryd rhan, llenwch y daflen gydsynio a chadwch y daflen wybodaeth hon fel y gallwch gyfeirio ati yn y dyfodol. Byddwch hefyd yn cael copi wedi'i lofnodi o'r ffurflen gydsynio, er gwybodaeth i chi.

Dylech gyfeirio unrhyw gwynion sydd gennych am y modd y cynhaliwyd yr astudiaeth hon at:
Yr Athro Oliver Turnbull, Pennaeth yr Ysgol Seicoleg, Prifysgol Bangor, Bangor, Gwynedd,
LL57 2DG

Diolch i chi am gymryd amser i ddarllen y wybodaeth hon.

Fersiwn: 3 Dyddiad: 25/08/09

**Appendix 13: Amended Consent Form
(English & Welsh)**

Ysgol Seicoleg
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Patient identification Number:

CONSENT FORM:

Individual Experiences of a Pain Management Programme

Researchers: Beth Mathias, Trainee Clinical Psychologist, North Wales Clinical Psychology Programme, and Dr Beth Parry-Jones, Clinical Psychologist, NW Wales NHS Trust.

- Please initial box
1. I confirm that I have read and understand the information sheet dated
(version) for the above study and have had the opportunity to ask questions.
 2. 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.
 3. I understand that sections of my Pain Management Program notes may be looked at by
responsible individuals within the research team and regulatory authorities where it is
relevant to my taking part in research. I give permission for these individuals to have access
to my records.
 4. I am happy for my interview to be audio-taped so that Beth Mathias can type it up, pick out
key themes and use non-identifiable quotes when she writes up the research.
 5. I understand that if I tell Beth Mathias something that makes her concerned that I or
someone else may be at serious risk, then she will have to inform the Pain Management
Team and possibly others involved in my care.
 6. I agree to take part in the above study by attending an interview with Beth Mathias during
the next 1-2 weeks.
 7. I give consent for Beth Mathias to inform my GP of my involvement in the research.

Name of Patient

Date

Signature

Address of Patient: _____

Telephone Number _____

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

Copies: 1 for patient; 1 for researcher; 1 to be kept with hospital notes

Version: 3 Date: 25/08/09

Ysgol Seicoleg
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Rhif adnabod y claf:

FFURFLEN GYDSYNIO:

Profiadau unigol o raglen reoli poen

Ymchwilydd: Beth Mathias, Seicolegydd clinigol dan hyfforddiant, Rhaglen Seicoleg Glinigol Gogledd Cymru a Dr Beth Parry-Jones, Seicolegydd clinigol, Ymddiriedolaeth GIG Gogledd Cymru.

Llofnodwch y blwch

1. Rwy'n cadarnhau fy mod wedi darllen a deall y daflen wybodaeth dyddiedig (fersiwn.....) ar gyfer yr astudiaeth uchod ac fy mod wedi cael cyfle i ofyn cwestiynau.
2. Deallaf fy mod yn cymryd rhan o'm gwirfodd a'm bod yn rhydd i dynnu'n ôl ar unrhyw adeg heb roi reswm a heb i hynny effeithio ar fy ngofal meddygol neu hawliau cyfreithiol.
3. Deallaf y gallai unigolion cyfrifol o'r tîm ymchwil neu'r awdurdodau rheoliadol edrych ar adrannau o unrhyw rai o'm nodiadau o'r rhaglen reoli poen, lle mae fy rhan i yn yr ymchwil yn berthnasol. Rhoddaf ganiatâd i'r unigolion hyn weld fy nghofnodion.
4. Rwy'n hapus i'm cyfweiliad gael ei recordio ar dâp sain er mwyn i Beth Mathias allu ei deipio, nodi'r themâu allweddol a defnyddio dyfyniadau uniongyrchol dienw wrth ysgrifennu am ei hymchwil.
5. Deallaf os y byddaf yn dweud rhywbeth wrth Beth Mathias sy'n gwneud iddi feddwl bod risg ddifrifol i mi neu unigolyn arall y bydd yn rhaid iddi roi gwybod i'r tîm rheoli poen ac efallai pobl eraill sy'n cyfrannu at fy ngofal.
6. Cytunaf i gymryd rhan yn yr astudiaeth uchod a chael fy nghyfweld gan Beth Mathias yn ystod yr wythnos neu'r bythefnos nesaf.
7. Rwy'n rhoi caniatâd i Beth Mathias roi gwybod i fy meddyg teulu fy mod yn cymryd rhan yn yr ymchwil hwn

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Enw'r claf _____ Dyddiad _____ Llofnod _____

Cyfeiriad y claf: _____

Rhif ffôn: _____

Enw'r sawl sy'n derbyn y caniatâd _____ Dyddiad _____ Llofnod _____
(os yw'n wahanol i'r ymchwilydd)

Ymchwilydd _____ Dyddiad _____ Llofnod _____

Copïau: 1 i'r claf; 1 i'r ymchwilydd; 1 i'w chadw gyda nodiadau'r ysbyty

Appendix 14: GP Letter

**Ysgol Seicoleg
Prifysgol Cymru, Bangor**

Adeilad Brigantia, Ffordd Penrallt
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e-mail: psychology@bangor.ac.uk
www.psychology.bangor.ac.uk

Pain Management Service.

Email: beth.mathias@yahoo.co.uk
(date of letter)

GP (name),
GP (address).

.....
.....
.....
.....

Dear (GP name),

**Re: Research Project– Individual experiences of an
acceptance-based Pain Management Programme: An
Interpretative Phenomenological analysis.**

I am writing to inform you that your patienthas expressed an
interest in the above named research project.

The project will involve your patient attending an appointment with myself at
Pain Clinic 1-2 weeks after the end of their Pain Management
Programme. This appointment will take the form of an interview to explore what
being on the programme was like for them and what parts of the programme they
feel may have contributed to change in any way. The interview will last roughly
20 minutes to 1 hour, depending on how much patients would like to talk about. It
will be audio-taped so that I can type it up, pick out key themes and use non-
identifiable direct quotes when I write up the research as part of my Doctorate in
Clinical Psychology. Participants also have the option of having a 'Summary of
Findings' sheet posted to their homes in April 2010 and, if they agree, a follow-up
telephone call to ask their opinion about the findings.

Please do not hesitate to contact me or my supervisor Dr Beth Parry-Jones (Clinical Psychologist) on the above number if you require any further information.

Yours Sincerely,

**Mrs Beth Mathias
(Trainee Clinical Psychologist)**

Appendix 15: REC Approval Letter

07 September 2009

Dear Mrs Mathias

Study Title: Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.

REC reference number: 09/WNo01/35

Protocol number: 2

Thank you for your letter of 25 August 2009, responding to the Committee's request for further information on the above research and submitting revised documentation. The further information has been considered on behalf of the Committee by the Chair.

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, subject to the conditions specified below.

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.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) 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>. Sponsors are not required to notify the Committee of approvals from host organisations.

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 final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
REC application	22381/52815/1/1	29 July 2009
Protocol	2	16 July 2009
Participant Information Sheet	3	25 August 2009
Participant Information Sheet Superseded	2	16 July 2009
Participant Consent Form	3	25 August 2009
Participant Consent Form Superseded	2	16 July 2009
GP/Consultant Information Sheets	1	25 August 2009
Letter from Sponsor	No version	23 July 2009
Covering Letter	No version	29 July 2009
Compensation Arrangements	UMAL	01 August 2008
Evidence of insurance or indemnity	No version	01 August 2009
Response to Request for Further Information	No version	25 August 2009
Supervisor CV	No version	No date
Investigator CV	No version	23 June 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/WNo01/35

Please quote this number on all correspondence

Yours sincerely


pp Mr David Owen
Chair

Enclosures: "After ethical review – guidance for researchers"

Copy to: Sponsor's Representative: Professor Oliver Turnbull, Bangor University
R&D office lead site - North West Wales NHS Trust

Appendix 16: IRAS Site Specific Information Form

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)
 Individual experiences of an acceptance-based PMP

1. Is your project an audit or service evaluation?

- 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 or clinical investigation
- 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, other human biological samples and/or 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 R&D office be located?

- England
- Scotland

- Wales
- Northern Ireland

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- Ministry of Justice (MoJ)

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

- Yes
- No

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

- Yes
- No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.

- Yes
- No

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

- Yes
- No

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

- Yes
- No

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

- Yes
- No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes
- No

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

- Yes
- No

Is the site hosting this research a NHS site or a non-NHS site? NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.

- NHS site
- Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.

Short title: Individual experiences of an acceptance-based PMP

Chief Investigator:	<table border="0"> <tr> <td style="text-align: right;">Title</td> <td style="text-align: right;">Forename/Initials</td> <td style="text-align: right;">Surname</td> </tr> <tr> <td style="text-align: right;">Mrs</td> <td style="text-align: right;">Beth</td> <td style="text-align: right;">Mathias</td> </tr> </table>	Title	Forename/Initials	Surname	Mrs	Beth	Mathias
Title	Forename/Initials	Surname					
Mrs	Beth	Mathias					

Name of NHS Research Ethics Committee to which application for ethical review is being made:
North West Wales REC

Project reference number from above REC: 09/WNo01/35

1-1. Give the name of the NHS organisation responsible for this research site

1-2. In which country is the research site located?

- England
- Wales
- Scotland
- Northern Ireland

1-3. Is the research site a GP practice or other Primary Care Organisation?

- Yes
- No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: Principal Investigator
 Local Collaborator

Title Forename/Initials Surname

Post

Qualifications

Organisation

Work Address

PostCode

Work E-mail

Work Telephone

Mobile

Fax

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*

Beth Mathias will allocate either a total of 6 months (Novemebr 2009 to April 2010) or 8 months (August to April 2010 - if ethical approval was obtained by August) as their will be the opportunity to recruit from PMPs that finish in either August or Novemebr 2009. Semi-structured interviews will be carried out approximately 1-2 weeks after the final PMP session and participants are welcome to contact the researcher at anytime during this period if they have any questions.

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? Yes No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

Location	Activity/facilities
1 removed for confidentiality	Informed consent seeking and semi-structured interviews.
2 Possibly the homes of potential participants.	Potential semi-structured interviews for those who do not have transport to enable them to attend the Pain Management Service 1-2 weeks after the PMP has finished.

5. Please give details of all other members of the research team at this site.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement

(e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No

7. What is the proposed local start and end date for the research at this site?

Start date: 25/08/2009
 End date: 04/05/2010
 Duration (Months): 9

8-1. 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.)

Columns 1-4 have been completed with information from A18 as below:

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

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
- Informed Consent- Semi-structured interview to explore participants' experiences of being in the PMP and the key constituents of the programme that they feel may have brought about change.	2	0	30 minutes	The researcher will provide informed consent and will conduct individual semi-structured interviews with participants at in	Dr Beth Parry-Jones will inform potential participants that there will be some research attached to their particular PMP. However, Beth Mathias (Trainee Clinical Psychologist) will conduct the informed consent seeking and semi-structured interviews at this site.

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

Yes No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

It is hoped that six research participants will be recruited from this site.

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Potential participants will be identified through their attendance of the 8 week (10am to 4pm) acceptance-based PMP at Therefore participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self management of chronic pain. Although not direct inclusion criteria, the programme often advises those who are 'cure-seeking' to finish this process before starting the PMP. Similarly those who have on-going medical investigations or treatments are generally advised

to complete these before attending the PMP. However, potential participants will not be discriminated against if they do not have access to transport as home visits are possible.

Potential participants will initially be approached by the Clinical Psychologist running the group (my supervisor, Dr Beth Parry-Jones). She will outline that there will be some research attached to this particular PMP (looking at Patients' experiences of attending the PMP) and that the researcher will be attending the final session to explain more about it and see who would like to be involved.

The researcher will be introduced to potential participants during the final PMP day (week 8) by Dr Beth Parry-Jones. The researcher will explain the research in detail, provide an information sheet and give participants the opportunity to ask as many questions as they wish. The researcher will also explain to participants that they do not have to decide whether they would like to take part the same day. They are welcome to 'mull it over' during the next 1-2 weeks and will be provided with the researcher's and research supervisor's contact details on the information sheet. It will be explained to participants that if the researcher or research supervisor has not had any contact from them during the next 1-2 weeks they will assume that the individual does not wish to participate in the study. Potential participants will be made aware that a decision 'not to take part' in the study will not effect their future health care in any way, as they are under no obligation, and that if they decide to take part they are welcome to withdraw at anytime without explanation. Consent forms will be given to individuals who wish to consent immediately and the researcher will be on hand during the rest of this final PMP day (10am until 4pm) for all participants who wish to ask any further questions during the breaks.

12. Who will be responsible for obtaining Informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Mrs Beth Mathias	<ul style="list-style-type: none"> - Currently training to be a Clinical Psychologist at the University of Bangor and therefore is aware of the ethcial prnciples that underpin informed consent seeking. - MSc. in Health Psychology which involved a 4 month placement within a pain clinic at the Royal United Hospital in Bath. Informed consent was sought during this placement for my Msc research into the relationship between acceptance of pain and quality of life. - BSc.(Hons) Psychology, which also involved gaining informed consent as part of my dissertation.

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Participants are welcome to ask staff within the pain clinic for advice about taking part in the research.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

Potential participants are welcome to contact the researcher Mrs Beth Mathias (Trainee Clinical Psychologist) throughout the potential 9 months that the research is taking place. Potential participants are also welcome to contact Dr Beth Parry-Jones also at anytime throughout this period and longer (as pateints are followed up at regular intervals by the PMP - often up to 12 months). The attention of potential participants will be drawn to the contact details for Mrs Beth Mathias and Dr Beth Parry-Jones which appear on the participant information sheet.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants 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 etc.)

The policy of the North West Wales Trust NHS trust is to provide written information in both English and Welsh. However, the PMP is in English and part of the assessment conducted by the PMP team would be ensuring individuals understand English sufficiently. If not, not that this has happened yet within the PMPs, it would be possible to have a translator. Unfortunately, the researcher is unable to speak Welsh and would have to conduct the semi-structured interviews in English. However, if needed, a translator could be arranged if participants would prefer to speak Welsh during interviews. My supervisor Dr Beth Parry-Jones has informed me that it is possible to include a BSL translator if a participant has a hearing impairment (even though the PMP has not had to do this yet). The PMP has not yet had anyone who has been partially sighted, but it is always possible to have written documents such as the information sheet and consent form in large print. The programme has also never had an individual who is blind, although braille could be a possibility.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

It was not felt that there was a need for the participants' GPs to be informed of their involvement in the study. If discussing individual experiences in relation to the PMP causes people to become upset, then if they give permission, a member of the PMP team can contact them after the interview. As in all clinical work, there may be occasions whereby confidentiality has to be broken. That is, if participants or others are at serious risk. This will be clearly outlined during informed consent seeking and all relevant health care professionals will be informed in light of such information.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

As touched upon above, although not anticipated, if discussing individual experiences in relation to the PMP causes individuals to become upset, (if they give permission) a member of the PMP team can contact them after the interview. However, the researcher is a Trainee Clinical Psychologist, and therefore, is trained to respond to distress. PMP participants continue to be monitored at 3, 6 and 12 month follow-up appointments post-PMP, and they are encouraged to contact the PMP team in-between if they have pain related distress that they cannot resolve themselves.

No burdens for research participants are anticipated as interviews will be scheduled at times that are convenient for participants. The length of the interview will also be participant-led, that is, it will be dependent upon how much or little they would like to discuss. Participants will be made aware that they can draw the interview to a close at anytime and are also free to withdraw from the research at anytime.

The researcher decided that individual semi-structured interviews would be the most appropriate method of qualitatively exploring people's experiences of the PMP rather than using focus groups. This decision was made as discussing personal experiences of the PMP has the potential to draw upon sensitive, embarrassing or upsetting past experiences of living with chronic pain - even though there are no interview questions in these areas. Participants will also be made aware that they can disclose as much or as little as they like about their own experiences.

The researcher intends to respect the confidentiality of personal data and meet the requirement of the Data Protection Act. The researcher also intends to treat data in a manner that is concordant with best practice. That is to adhere to the NHS code of confidentiality and the professional practice guidelines set out by the British Psychological Society (1995) for confidentiality (Section 6). The researcher also intends to adhere to the ethical framework set out by the 'Caldicott Principles' with regards to the use of identifiable data. As mentioned above, in clinical work confidentiality has to be broken in circumstances whereby participants or others are at serious risk. This will be clearly outlined during informed consent seeking and managed in accordance with the BPS guidelines and my clinical training from Bangor University.

The only minimal risk to the researcher would be being alone with individual participants during the semi-structured interviews. However, all patients are risk assessed before starting the programme. Interviews are also intended to be carried out at the pain clinic which has policies in place to reduce risk when seeing patients in this setting. Home visits will be kept to a minimum and only used in circumstances when a participant does not have transport. On any potential home visits that do arise the researcher will act in accordance with the North West Wales NHS Trust and Bangor University Lone Worker Policies.

20. What are the arrangements for the supervision of the conduct of the research at this site? Please give the name and contact details of any supervisor not already listed in the application.

The conduct of the research will be supervised at _____ Hospital in Caernarfon by my supervisor Dr Beth Parry-Jones (Clinical Psychologist within the Pain Management Service at this site). Dr Beth Parry-Jones will be present during the informed consent seeking which will occur during the 8th and final PMP session at _____. Although Dr Parry-Jones will not be present during the individual semi-structured interviews she will provide supervision for the

analysis of typed anonymised transcripts, and in so doing will oversee the information that is shared with participants within the 'summary of findings sheet'.

21. What external funding will be provided for the research at this site?

- Funded by commercial sponsor
- Other funding
- No external funding

How will the costs of the research be covered?
The costs of the research will be covered by the University of Bangor. Due to the use of administrative resources. These costs have already been approved by the School of Psychology at the University and are outlined in the project proposal.

23. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:
Authorisation to undertake the study on behalf of the Pain Management Service at Bryn Seiont has been gained by my Clinical Supervisor.

Title	Forename/Initials	Surname
	Dr Beth	Parry-Jones
Post	Clinical Psychologist	
Qualifications	DClinPsy, PhD Social Psychology, MSc Applied Psychology, BSc(Hons) Psychology.	
Organisation		
Work Address	<i>removed for confidentiality</i>	
PostCode		
Work E-mail	beth.parry-jones@nww-tr.wales.nhs.uk	
Work Telephone		
Mobile		
Fax		

Signature:

Date:

2. Type of authorisation:
Authorisation has been granted from Professor Oliver Turnbull, Head of the School of Psychology at Bangor University who has agreed to act as as research sponsor for the study. This was obtained following ethical approval from the School of Psychology Ethics Panel.

	Title	Forename/Initials	Surname
	Professor	Oliver	Turnbull
Post	Head of the School of Psychology		
Qualifications			
Organisation	The school of Psychology Bangor University		
Work Address	Bangor University, Adeilad Brigantia, Penrallt Rd, Bangor		
PostCode	LL57 2AS		
Work E-mail	o.turnbull@bangor.ac.uk		
Work Telephone			
Mobile			
Fax			
Signature:		
Date:		

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

- 12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and 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.
- 13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application 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.

Signature of Principal Investigator
or Local Collaborator:

Print Name: Beth Mathias

Date: 12/08/2009

Appendix 17: IRAS Research and Development Application Form

[Redacted]

[Redacted]

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)
 Individual experiences of an acceptance-based PMP

1. Is your project an audit or service evaluation?

- 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 or clinical investigation
- 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, other human biological samples and/or 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 R&D office be located?

- England
- Scotland

- Wales
 Northern Ireland

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)

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

- Yes No

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

- Yes No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.

- Yes No

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

- Yes No

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

- Yes No

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

- Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

- Yes No

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

- Yes No

**Integrated Research Application System
Application Form for Research Involving qualitative methods only**

NHS/HSC R&D Form (project information)

Please refer to the Submission and Checklist tabs for instructions on submitting R&D applications.

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](#).

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Individual experiences of an acceptance-based PMP

Project Information

ADMINISTRATIVE DETAILS

A1. Full title of the research:
Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.

A2-1. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate of Clinical Psychology (D.ClinPsy)

Name of educational establishment:
North Wales Clinical Psychology Programme, Bangor University.

Name and contact details of academic supervisor:

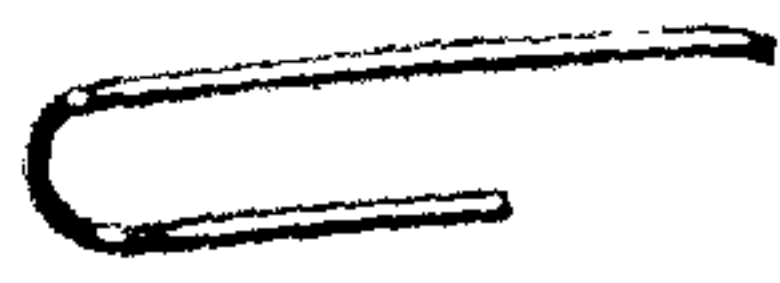
	Title	Forename/Initials	Surname
	Dr	Beth	Parry-Jones

Address

Post Code

E-mail beth.parry-jones@nww-tr.wales.nhs.uk

Telephone



Post Code	SA61 1HX
E-mail	beth.mathias@yahoo.co.uk
Telephone	07947656312
Fax	

A copy of a current CV for the student (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. Chief Investigator:

Post
 Qualifications
 Employer
 Work Address

Post Code
 Work E-mail
 * Personal E-mail
 Work Telephone
 * Personal Telephone/Mc
 Fax

** This information is optional. It should 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. Is there a central study co-ordinator for this research?

Yes No

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): mathias 09/35
 Sponsor's/protocol number:
 Protocol Version:
 Protocol Date:
 Funder's reference number:
 International Standard Randomised Controlled Trial Number (ISRCTN):
 ClinicalTrials.gov Identifier (NCT number):

European Clinical Trials Database (EudraCT) number:

Project website:

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

Yes No

Please give brief details and reference numbers.

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. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

Chronic pain patients who attend pain management programmes (PMPs) do so to help develop ways of coping with, and reduce, their pain-related distress. PMPs that contain ideas about 'accepting pain' have been found to improve patients' general well-being such as their mood, daily activity level and social relationships. Most research that has investigated PMPs has compared self-report questionnaires and physical measures before and after PMP (e.g. measures of pain interference, physical activity and mood). It has been suggested that future research in this area should not just look at what has changed for patients before and after the PMP, but explore how changes have come about. This study, therefore, aims to explore the experiences of patients who have attended an acceptance-based PMP, in particular the aspects they think may have brought about change. Patients will be approached on the 8th (final) week of the PMP to see who would like to take part. Six patients will then be invited to participate in individual semi-structured interviews with the researcher 1 - 2 weeks following the end of PMP to discuss their experiences of attending the PMP. Interviews will be audio-taped, typed-up and interpreted by the researcher using Interpretive Phenomenological Analysis (IPA) to pick out key themes from what participants have said. Participants who would like to know the results of the study will be posted a 'summary of findings sheet' and receive a follow-up telephone call from the researcher to ask their opinion, to help validate the findings.

A6-2. Summary of main issues. *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

PURPOSE AND DESIGN:

The research has 2 main objectives which as yet have not been addressed in the literature:

- 1) To explore individual experiences of an acceptance-based PMP
- 2) To look at which constituents of the programme individuals regard as facilitating change.

Previous research into acceptance-based PMPs has looked primarily at quantitative outcome measures. The present study aims to add to research in this area by being the first study to qualitatively explore individuals' experiences during this kind of PMP, including identifying the key constituents that they felt contributed to change. The researcher is hopeful that n=6 will be recruited from one PMP as the groups usually contain between 6 and 10 patients. An 'n' of 5 or 6 is considered a reasonable sample size for IPA research (e.g. Smith & Osborne, 2003).

My supervisor, Dr Beth Parry-Jones (Clinical Psychologist), has been involved in developing the research proposal. Dr Parry-Jones is the Clinical Psychologist who runs the acceptance-based PMP being researched (at NW Wales NHS Trust) and has provided advice, support and guidance with the design and more practical aspects of the research. Dr Dave Daley (Senior Research Tutor, NWCPP, University of Wales, Bangor) will provide additional support throughout the project. Professor Suzanne Skevington (Professor of Health Psychology at the University of Bath) is also happy to read through drafts and provide advice.

The proposed research has the potential to inform and shape future acceptance-based PMPs and, consequently, to improve the well-being of chronic pain patients who attend future PMPs. Taking individual experiences into account is

an important way of informing practice in health care. In so doing, the study has the potential to make acceptance-based PMPs more patient-centred, throughout the UK and elsewhere. If the findings can be successfully applied to other PMPs, they may contribute to a reduction in the total financial expenditure by the NHS as a result of chronic pain. Findings could therefore be used for educational purposes with other professionals working with individuals who have chronic pain. Above all, the study has the potential to benefit the large number of individuals who live with chronic pain.

RECRUITMENT: (INCLUSION/EXCLUSION)

Participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of chronic pain. They also need to be able to attend a 10am to 4pm day at an outpatient clinic over an 8 week period. Although not direct inclusion criteria, the programme often advises those who are 'cure-seeking' to finish this process before starting the PMP. Similarly those who have on-going medical investigations or treatments are generally advised to complete these before attending the PMP. Additional inclusion criteria would be the ability to attend an interview with the researcher at the Pain Clinic post-PMP. However, potential participants will not be discriminated against if they do not have access to transport as home visits are possible.

There are no exclusion criteria.

CONSENT:

All participants will have the capacity to consent to the study as certain complex cognitive skills are required in order for participants to understand the material covered in the programme sessions e.g. links between thoughts, feelings and behaviour. Participants will therefore:

- understand the purpose and nature of the research
- understand what the research involves, its benefits, risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision
- be able to make a free choice
- be capable of providing informed consent during the time frame in which it needs to be made (1-2 weeks).

The researcher fully understands the ethical principles that underpin informed consent.

Potential participants will initially be approached by the Clinical Psychologist running the group (my supervisor, Dr Beth Parry-Jones). She will outline that there will be some research attached to this particular PMP (looking at patients' experiences of attending the PMP) and that the researcher will be attending the final session to explain more about it and see who would like to be involved.

The researcher will be introduced to potential participants during the final PMP day (week 8) by Dr Beth Parry-Jones. The researcher will explain the research in detail, provide an information sheet and give participants the opportunity to ask as many questions as they wish. The researcher will also explain to participants that they do not have to decide whether they would like to take part the same day. They are welcome to 'mull it over' during the next 1-2 weeks and will be provided with the researcher's, and research supervisor's, contact details on the information sheet. It will be explained to participants that if the researcher or research supervisor has not had any contact from them during the next 1-2 weeks they will assume that the individual does not wish to participate in the study. Potential participants will be made aware that a decision 'not to take part' in the study will not affect their future health care in anyway, as they are under no obligation, and that if they decide to take part they are welcome to withdraw at any time without explanation. Consent forms will be given to individuals who wish to consent immediately and the researcher will be on hand during the rest of this final PMP day (10am until 4pm) for all participants who wish to ask any further questions during the breaks.

RISK/BURDENS AND BENEFITS:

Although no risks are anticipated for participants, if discussing individual experiences in relation to the PMP causes people to become upset then, if they give permission, a member of the PMP team can contact them after the interview. However, the researcher is a Trainee Clinical Psychologist and, therefore, is trained to respond to distress. PMP participants continue to be monitored at 3, 6 and 12 month follow-up appointments post-PMP, and they are encouraged to contact the PMP team in-between if they have any pain-related distress that they cannot resolve themselves.

No burdens for research participants are anticipated as interviews will be scheduled at times that are convenient for participants. The length of interview will also be participant-led, that is, it will be dependent upon how much or little they would like to discuss. Participants will be made aware that they can draw the interview to a close at anytime and are also free to withdraw from the research at anytime.

Although, again, not anticipated, it is useful to be aware of potential situations that may arise. Discussing personal experiences of the PMP has the potential to draw upon sensitive, embarrassing or upsetting past experiences of living with chronic pain - even though there are no interview questions in these areas. For this reason, the researcher

decided that individual semi-structured interviews would be the most appropriate method of qualitatively exploring people's experiences of the PMP rather than using focus groups. Participants will also be made aware that they can disclose as much or as little as they like about their own experiences.

Benefits to participants - After talking to my supervisor Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP) it appears that the general feedback of previous patients involved in the PMP is that they often experience a void during the weeks after the PMP has finished, as they miss the sense of purpose and socialisation that the PMP provides. Therefore the opportunity of coming back to the Pain Clinic a week after it has finished for a semi-structured interview may serve as a more gradual end to the programme. The interview may also provide a sense of closure, as participants will have the unique opportunity to express their experiences about the whole process after having a week (or two) to reflect about what it meant to them. Although the PMP team monitor individuals who have been on the programme, at 3,6 and 12 monthly intervals, all participants who would like to receive the 'summary of findings sheet' will have additional contact from the researcher in April 2010 to ask their opinion of the findings. Participants are also welcome to contact the researcher at any point after the interview until April 2010 with any questions, worries or concerns. This information will then be fed back to the PMP team who can arrange to meet and discuss this further, if relevant. Research participants may also benefit from being involved in the research process due to a knowledge that their collective experiences may benefit others with similar difficulties.

The only minimal risk to the researcher would be being alone with individual participants during the semi-structured interviews. However, all patients are risk assessed before starting the programme. Interviews are also intended to be carried out at the Pain Clinic which has policies in place to reduce risk when seeing patients in this setting. Home visits will be kept to a minimum and only used in circumstances when a participant does not have transport. On any potential home visits that may arise the researcher will act in accordance with the North West Wales NHS Trust and Bangor University Lone Worker Policies.

CONFIDENTIALITY:

All identifiable information will be anonymised using pseudonyms. All data including transcripts and audio recording devices will be stored in a lockable filing cabinet at the researcher's NHS clinical placement. The office is shared by a clinical psychologist and an assistant psychologist, but the researcher will be the only person who has a key to access the specific door of the cabinet in which the transcripts will be held. Transcripts will be saved on the researcher's designated NHS computer within her placement office, in anonymised form, and will be password protected. Any transfer of transcripts will be done using a pin code protected USB stick.

The researcher intends to respect the confidentiality of personal data and meet the requirements of the Data Protection Act. The researcher also intends to treat data in a manner that is concordant with best practice. That is, to adhere to the NHS code of confidentiality and the professional practice guidelines set out by the British Psychological Society (1995) for confidentiality (Section 6). The researcher also intends to adhere to the ethical framework set out by the 'Caldicott Principles' with regards to the use of identifiable data. As in all clinical work, there may be rare occasions that confidentiality has to be broken. That is, if participants or others are at serious risk. This will be clearly outlined during informed consent seeking and managed in accordance with the BPS guidelines and my clinical training from Bangor University.

7. PURPOSE AND SCOPE OF 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
- 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.

The proposed research aims to add to previous research in the area by adopting a qualitative approach to explore individual experiences of an acceptance-based PMP including the specific constituents of the programme that individuals feel may have facilitated change.

A Qualitative approach gathers non numerical data (Coolican, 1999) and aims to gather an in-depth understanding of human behaviour and the reasons that govern such behaviour (Denzin & Lincoln, 2005). It investigates why and how - not just what, where, when. Therefore, small but focused samples are often needed rather than large random samples. This approach takes the stance that information about human events and experience, if reduced to numerical form, loses most of its important meaning and value (Coolican, 1999).

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

The research has 2 main objectives which are as follows:

- To explore individual experiences of an acceptance-based PMP.
- To look at the key constituents of the programme that individuals regard as facilitating change.

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

It has been suggested that the next generation of research into therapies for chronic pain will focus on the specific processes involved during treatment (McCracken et al., 2005) and the way in which treatments work to achieve adaptive behaviour change (Vowles et al., 2007b).

Acceptance appears to be a key process in treatment outcome and behaviour change in individuals with chronic pain (Vowles et al., 2007b). Changes in acceptance during an acceptance-based Pain Management Programme have also been found to be related to changes in depression, pain-related anxiety, physical and psychosocial disability and persistence with physical tasks (McCracken et al., 2005). Vowles et al (2008) found that acceptance and values-based action have also been associated with improvements on such outcome measures. However, previous studies in the area have all been quantitative and there may be a number of other processes that facilitate change within acceptance-based Pain Management Programmes that questionnaire measures alone fail to capture.

Vowles et al (2007a) argue that processes (such as acceptance) that operate during Pain Management need to be investigated in more detail so that they can be better addressed in clinic. Evaluation studies that confirm the particular treatment components that lead to success and address the processes by which individuals with chronic pain improve are missing from the evidence base (McCracken et al., 2005). Vowles et al (2007) feel that the challenge for future treatment development is to refine the most effective methods for behaviour change. The best way to access this kind of information is to actually ask the individuals who have participated in an acceptance-based Pain Management Programme. An acceptance-based approach with its particular view of private experiences provides a promising base for further therapy development (McCracken et al., 2005).

A13. Please give a full summary of 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.

DESIGN AND METHODOLOGICAL OVERVIEW:

A qualitative approach to add to past quantitative research in the area by exploring individual experiences of an acceptance-based PMP (at _____ Hospital _____) together with the key constituents of the programme that they feel facilitated change.

PREPARATION: Dr Beth-Parry Jones (Clinical Psychologist of the PMP and supervisor of the proposed project) will explain that there will be some research attached to this particular PMP during the first day of the programme (1 of 8). She will also inform patients that the researcher will attend the final session to explain more about it, provide some information and see who would like to be involved.

INTRODUCTIONS, INFORMATION AND CONSENT:

Potential participants will be introduced to the researcher by Dr Beth Parry-Jones during the 8th and final session of the PMP. Here the researcher will explain the rationale behind the research (i.e. to obtain a better understanding of the experiences of people attending the PMP and the key constituents that they feel may have facilitated change in any way - positive or negative) and provide a concise information sheet outlining the project. Participants will be given the opportunity to ask as many questions as they like as the researcher will be 'on hand' during this final session.

The PMP runs from 10am to 4pm with regular breaks for participants. Individuals can decide if they would like to take part in the project whenever they like e.g. straight away, at the end of the day or during the next week using the (researcher's and/or research supervisor's) contact numbers provided on the information sheet. The researcher will explain to participants that if the researcher or research supervisor has not heard anything over the next 2 weeks it will be assumed that they do not want to be involved in the study. The researcher will inform participants that a decision not to take part will not affect their future health care in any way and that they are free to withdraw from the study at any time - without reason. A consent form will be signed by those willing to participate in the study which will outline that they have read the information sheet and understand what the study involves:

- An interview with the researcher at the pain clinic 1-2 weeks after the PMP has finished.
- Consideration of whether they would like to receive a summary of findings sheet and be contacted by the researcher in April 2010 to discuss these findings.

SEMI-STRUCTURED INTERVIEWS:

The researcher and each individual participant (n=6) will then arrange a convenient time to meet at the Pain Clinic to conduct individual semi-structured interviews during the 2 weeks after the programme has finished. The reason for this being that an extra week (or potentially fortnight) would give participants time to reflect/consider what the PMP meant to them. The semi-structured interview will explore both research objectives, see proposed suggestions for interview questions included within the proposal. Direct questions about acceptance and other mindfulness related concepts will not be asked. However, if mentioned by participants, the researcher would like to ask them to elaborate further. It is anticipated that the length of the interviews may range from 20 minutes to 1 hour depending upon how much information participants would like to discuss. However, no participant will be 'cut short' should their time exceed 1 hour.

Participants will then be told that they are welcome to meet with a member of the PMP team should they wish to discuss anything upsetting that may have come up as a result of the interview process (even though this is not anticipated). Participants will then be asked if they would like to receive a 'summary of findings sheet' and telephone call in April 2010 to discuss their views of the results. Contact details on the consent forms of those who do will be clarified. All participants will be provided with the researcher's contact details in case they would like to discuss anything further in relation to the group or if they have any worries or concerns which arise during time that the research is taking place (post-interview to April 2010).

INTERPRETING AND ANALYSING FINDINGS:**Qualitative Analysis**

Each individual interview will be transcribed and anonymised by the researcher. Data within the transcripts will be analysed using Interpretative Phenomenological Analysis (IPA) by the researcher in order to meet the study's objective:

To explore individual experiences of an acceptance-based PMP and the key constituents that participants' felt facilitated change in any way.

This interpretative phenomenological analysis will follow the 4-stage process outlined by Smith & Osborne (2003):

Analysis begins with a close interpretative reading of the first case where initial responses to the text are annotated in one margin. These initial notes are translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes are then interrogated in order to make connections between them. This then results in a table of subordinate themes with identifying information - that is, where the instances supporting the theme can be found within the interview transcript.

This process is repeated for each case. After analysis has been conducted on each case, patterns can be established cross-case and documented in a master table of themes for the group. Another researcher is then recommended to review the audit themes to ensure that they are grounded and well-represented in the transcripts. The mastertable can be transformed into a narrative account; the analytic account is then supported by verbatim extracts from each participant.

Participants who wish to have a 'summary of findings sheet' will also be contacted by telephone to ask their opinion with regards to the findings. This should serve to validate the findings and will be included in the final write-up of the project.

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?

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

Give details of involvement, or if none please justify the absence of involvement.

Participants will be introduced to the researcher during the final week (wk8) of the PMP by the Clinical Psychologist running the group (the researcher's supervisor Dr Beth Parry-Jones). Participants who would like to be involved in the study will read an information sheet and complete a consent form. Participants will be made aware that in consenting to being involved in the study means that they are willing to:

- Attend an interview with the researcher 1-2 weeks after the programme has finished.
- Consider whether they would like to be contacted again (in April 2010) to discuss the findings of the study.

Those who have provided consent will be invited along for a semi-structured interview at a convenient time for them during the following week. The interview will last for between 20 minutes to 1 hour depending on how much participants would like to discuss. Participants who would like to have feedback regarding the findings will be sent a 'summary of findings sheet' by post after the results section has been approved by my supervisor Dr Beth-Parry Jones (Clinical Psychologist) and Dr Dave Daley (Senior Research Tutor). A follow-up telephone call from the researcher to ask for participants' opinion as to whether they felt the correct themes have been identified, would help them confirm, or add to the findings. This would help with validating the analysis and will be added to the write-up.



A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases
- Diabetes
- Ear
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological

Oral and Gastrointestinal
 Paediatrics
 Renal and Urogenital
 Reproductive Health and Childbirth
 Respiratory
 Skin
 Stroke

Gender: Male and female participants
 Lower age limit: 18 Years
 Upper age limit: 85 Years

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

Participants will be recruited using the same inclusion criteria used for the PMP. That is, adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of chronic pain. They also need to be able to attend a 10am to 4pm day at _____ in _____ over an 8 week period. Although not direct inclusion criteria, the programme often advises those who are 'cure-seeking' to finish this process before starting the PMP. Similarly those who have on-going medical investigations or treatments are generally advised to complete these before attending the PMP. Additional inclusion criteria would be the ability to attend an interview at _____ Pain Clinic, however individuals will not be discriminated against if they do not have access to transport as home visits are possible.

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

There are no exclusion criteria.

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:

- Total number of interventions/procedures to be received by each participant as part of the research protocol.
- 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?
- Average time taken per intervention/procedure (minutes, hours or days)
- Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
- Informed Consent	2	0	30	The researcher will provide Informed consent and will conduct individual semi-structured interviews with participants at _____ in _____
- Semi-structured interview to explore participants' experiences of being in the PMP and the key constituents of the programme that they feel may have brought about change.			minutes	

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

Since meeting participants on the final week of the PMP and gaining consent to being contacted regarding their opinions about the 'summary of findings sheet', I estimate that each participant will be in the study for either a total of 6 months (November 2009 to April 2010) or 9 months (August 2009 to April 2010 - if ethical approval was obtained by August) as there will be the opportunity to recruit from PMPs that finish in either August or November 09. Semi-structured interviews will be carried out approximately 1-2 weeks after the final PMP session and participants are

welcome to contact the researcher at anytime during this period if they have any questions.

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.

RISK

Although no risks are anticipated, if discussing individual experiences in relation to the PMP causes people to become upset, then if they give permission, a member of the PMP team can contact them after the interview. Clients of the PMP continue to be monitored at 3, 6 and 12 month follow-up post-PMP, and they are encouraged to contact the PMP team in-between if they have any pain related distress that they cannot resolve themselves. The researcher will also provide a contact number, should participants wish to discuss anything further.

BURDENS

No burdens for research participants are anticipated as interviews will be scheduled at times that are convenient for participants and home visits will be considered for those unable to access transport. The length of interview will also be participant led, that is, it will be totally dependent upon how much or little they would like to discuss. Participants will be made aware that they can draw the interview to a close at anytime and are also free to withdraw from the research at any point - without reason.

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:

Although again, not anticipated, it is useful to be aware of potential situations that may arise. Discussing personal experiences of the PMP has the potential to draw upon sensitive, embarrassing or upsetting past experiences of living with chronic pain - even though there are no direct interview questions in these areas. For this reason, the researcher decided that individual semi-structured interviews would be the most appropriate method of qualitatively exploring people's experiences of the PMP rather than through focus groups. Participants will also be made aware that they can disclose as much or as little as they like about their own experiences. Although all individuals who have taken part in the PMP at [redacted] are monitored at 3, 6 and 12 monthly intervals, the researcher will also provide a contact number should participants wish to discuss any worries or concerns throughout the 6 (or potentially 9) months that the research is taking place.

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

Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP) explained that the general feedback of previous clients involved in the PMP is that they often experience a void during the weeks that follow the end of the programme as they miss the sense of purpose and socialisation that the PMP provides. Therefore the opportunity of coming back to the Pain Clinic during the first or second week after the programme finishes, may serve to act as a more gradual end to the programme. The interview may also provide a sense of closure to the group as participants will have the unique opportunity to express their experiences about the whole process after having a week to reflect about what it meant to them. Although the PMP team monitor individuals who have been on the programme, at 3, 6 and 12 monthly intervals, the researcher will also provide a contact number should participants wish to discuss any worries or concerns throughout the 6-months (or 9 months) that the research is taking place. All participants who would like to receive the 'summary of findings sheet' will have additional contact from the researcher approximately 5 months after the end of the group that ends in November (or potentially 8 months if it was possible to recruit from the group that ends in August), to ask their opinion and hence discuss the group further. This information will then be fed back to the PMP team who can arrange to meet and discuss this further if necessary.

Research participants may also benefit from being involved in the research process due to a knowledge that their collective experiences may benefit others with similar difficulties.

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

The only minimal risk to the researcher would be being alone with individual participants during the semi-structured interview. However, interviews are intended to be carried out at [redacted] Pain Clinic which has policies in place to reduce risk during clinic appointments. Home visits will be kept to a minimum and only used in circumstances when

when a participant does not have transport. On any potential home visits that may arise the researcher will make sure she is familiar with the trust's lone worker policies. All participants are risk assessed when they attend the PMP.

REMOVED AND INFORMED CONSENT

REMOVED AND INFORMED CONSENT

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).

Potential participants will be identified by their attendance of the PMP at the outpatients Pain Clinic, NW Wales NHS Trust. Their attendance (and potential inclusion in the study) will be dependent upon the PMP's inclusion criteria (See A16 for more information).

Although my supervisor Dr Beth Parry-Jones (Clinical Psychologist who runs the PMP under investigation) will mention that there is a possibility that some research may be attached to their PMP, the researcher will formally introduce patients to the study. This will occur during the 8th and final week of the PMP when the researcher will outline the aim of the research 'to explore individual experiences of the PMP' and what it will entail. Information sheets will also be provided together with consent forms. Semi-structured interviews will be arranged at times during the following 1-2 weeks that are convenient for those who have given consent to participate in the study. The researcher will be on hand for the whole of this final session at [redacted] if patients would like to give it further consideration throughout the day and ask additional questions. The researcher will explain to patients who would like more time, that they can contact the researcher or research supervisor using the numbers on the information sheet. Patients will also be made aware that it is hoped that interviews will take place during the following 1-2 weeks and that if the researcher or research supervisor does not hear from them during this time it will be assumed that they do not wish to take part in the study. It will also be made clear to patients that a decision not to take part in the study will not effect their future receipt of health care in anyway and that they can withdraw from the study at anytime without reason.

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:

The identification of potential participants will not involve reviewing or screening the personal information of patients.

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

Yes No

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

Potential participants will initially be approached by the Clinical Psychologist running the group (my supervisor Dr Beth Parry-Jones) who will outline that there will be some research attached to this particular PMP (looking at people's experiences of being in the group) and that the researcher will be attending the final session to explain more about it and see who would like to be involved.

The researcher will be introduced to potential participants during the final PMP session (wk 8) by Dr Beth Parry-Jones. The researcher will take up a short section of the start of this final session and explain the research in detail, provide an information sheet and give potential participants the opportunity to ask as many questions as they like. The researcher will also explain to participants that they do not need to decide whether they would like to take part straight away as the study is due to take place the following week. Consent forms will be provided to individuals who wish to consent immediately and the researcher will be on hand during the rest of this session (10am until 4pm) for all participants who wish to give it further consideration during the breaks. Alternatively the researcher will provide a contact number at the end for anyone who would like additional time (over the next week) to consider being involved in

the study. Potential participants will be made aware that a decision not to consent to the study will not effect their future receipt of healthcare in anyway as they are under no obligation.

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.

I the researcher will be obtaining informed consent from adult participants as outlined above using an information sheet and consent form. Both forms and a full explanation about the research will occur during the final session of the PMP. All participants who would like to give it further consideration during the following 1-2 weeks will be provided with a contact number for the researcher and research supervisor.

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?

Potential participants will have a 1-2 weeks to decide whether they wish to take part. The reason for this being that due to the nature of the research exploring people's experiences of being in the PMP, recall may be affected with increasing time. My supervisor Dr Beth Parry-Jones felt that this should give participants time to reflect on their experiences and what the PMP meant to them.

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)

The policy of North West Wales NHS trust is to provide written information in both English and Welsh. However, the PMP is in English and part of the initial assessment, conducted by the PMP team would be ensuring individuals understand English sufficiently. If not, not that this has happened yet within the PMPs, it would be possible to have a translator. Unfortunately the researcher is unable to speak Welsh and would have to conduct the semi-structured interviews in English. However, if needed, a translator could be arranged if participants would prefer to speak Welsh during the interviews. My supervisor Dr Beth Parry-Jones has informed me that it is possible to include a BSL translator if a participant has a hearing impairment (even though the PMP has not had to do this as yet). The PMP has not yet had anyone who has been partially sighted, but it is always possible to have written documents such as the information sheet and consent form in large print. The programme has also never had an individual who is blind, although braille could be a possibility.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

The researcher is aware that the provision of information is governed by the Welsh Language Act (1993) and that English and Welsh languages should be treated equally. Potential participants will therefore have the right to choose which language they would prefer during the process of informed consent, all other aspects and correspondence involved in the research together with future NHS correspondence and provision of care. Information sheets and consent forms will be written in both English and Welsh in accordance with the Welsh Language Act and Policies within the North West Wales Trust. The researcher recognises that participants can express their views and needs better in their preferred language and is aware of the ethical importance of this during informed consent seeking.

Advice from the NHS R & D office about the language requirements of the local population and the Welsh language policies in place at this sight has been sought from Dr Rossela Roberts (Clinical Governance Officer) and Dr Beth

Parry-Jones (Clinical Psychologist within NWW Trust).

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.

Further details:

As the participant would have already given consent to participate in the study, identifiable data already collected would be retained in anonymised form and used in the study. However, it clearly would not be appropriate to try to conduct an interview with someone who did not understand what was happening. Potential participants will be made fully aware of this during consent seeking.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIAL

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:

USE OF PERSONAL ADDRESSES AND TELEPHONE NUMBERS:

Personal addresses and telephone numbers of those who have provided consent (to be involved in the study) and

wish to receive the 'summary of findings sheet' by post will be used to validate the research findings. The provision of a personal address and telephone number is required on the consent form.

PUBLICATION OF DIRECT QUOTATIONS FROM RESPONDENTS:

Should the study be worthy of publication, there is a possibility that direct quotations from participants may be published if they fall under particular themes identified during qualitative analysis (IPA). Participants will be made aware of this during 'consent seeking' and this will be clearly stated in the information sheet and consent form. It will also be made clear that all identifiable information will be removed from interview transcripts as they are transcribed.

USE OF AN AUDIO RECORDING DEVICE:

An Audio recording device will be used to record individual semi-structured interviews. No identifiable information will be written on the tapes which will be stored in a lockable filing cabinet at the researcher's NHS placement. The only person who will have access to this part of the filing cabinet is the researcher who has her own key. Participants will be made aware of the use of an audio recording device at the consent seeking stage - see information sheet.

STORAGE OF DATA ON NHS COMPUTERS AND LAPTOP COMPUTERS:

As all identifiable information that occurs during transcription will be anonymised, transcripts will be saved on an NHS computer in this format. This computer is password protected with the researcher being the only person who will be able to access this information.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Data (audio-taped individual interviews, typed transcripts and any interpretations made) will be coded anonymously (see A39 below) and stored in a lockable filing cabinet at the researcher's NHS clinical placement. The researcher has been allocated a drawer within this filing cabinet. The office that contains the filing cabinet is only used by 2 other members of the psychology team who have their own keys to the office.

Transcripts in anonymised form and any interpretations made during the analysis will be stored on an NHS computer which is password protected by the researcher.

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.

Pseudonyms will be used throughout transcripts and care will be taken to anonymise any other identifiable information that may emerge.

The researcher intends to respect the confidentiality of personal data and meet the requirements of the Data Protection Act. The researcher also intends to treat data in a manner that is concordant with best practice. That is, to adhere to the NHS code of confidentiality and the professional practice guidelines set out by the British Psychological Society (1995) for confidentiality (Section 6)

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 researcher, and research supervisor alone.

A41. Where will the data generated by the study be analysed and by whom?

The data generated by the study will be analysed by the researcher at the researcher's NHS clinical placement so that all the data is on hand for reference purposes. This will occur on the researcher's allocated study/research days. Anonymised transcripts will be shared between the researcher and research supervisor during the supervision of data analysis.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title Forename/Initials Surname Dr Beth Parry-Jones	
Post	Clinical Psychologist	
Qualifications	Academic Qualifications: BSc (Hons) in Psychology (1989); MSc in Applied Psychology (Occupational Psychology specialism; 1990); PhD in Social Policy (2002); DClinPsy (2004). BPS Chartered Psychologist (1992); BPS Chartered Occupational Psychologist (from 2000); BPS Chartered Clinical Psychologist (from 2004).	
Work Address	<i>removed for confidentiality</i>	
Post Code		
Work Email		beth.parry-jones@nww-tr.wales.nhs.uk
Work Telephone		
Fax		

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

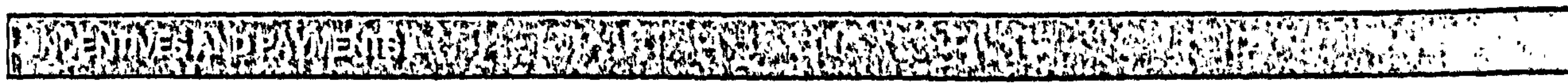
If longer than 12 months, please justify:
 This would give the researcher ample time to publish/amend anything.

A44. For how long will you store research data generated by the study?

Years: 5
 Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

At the end of the research, the anonymous data will be passed to my supervisor Dr Beth Parry-Jones (Clinical Psychologist) at the Pain Clinic, NW Wales NHS Trust. It will be stored with existing PMP evaluation data that dates back to 1995 when the PMP started. The data will be safe at the Pain Clinic and it is hoped that the data may aid/inform the delivery of future PMPs.



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.
 I will not be registering the research as it is not a clinical trial and so there are no legal requirements for registration. There is also no suitable register on which the research could be placed.

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)

Feedback of results to participants using the 'summary of findings sheet' and later telephone call to ask whether they feel these findings are valid.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Pseudonyms will be used throughout the results section and care will be taken that all identifiable information e.g. occupation, ethnicity etc will be removed from transcripts prior to the analysis of any results.

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.

Results will be fed back to all participants who would like them by post using the 'summary of findings sheet'. The researcher will then contact these individuals by telephone to ask whether they feel these findings are valid. Their opinions will be used to validate the study and added to the findings section during the final write-up.



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:

The scientific quality of the research has been verified via an internal peer review by my supervisors (Dr Beth Parry-Jones and Dr Dave Daley) and will be submitted to the School of Psychology Ethics and Research Governance committee for approval which involves a dual review.

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.

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: 6
 Total international sample size (including UK):
 Total in European Economic Area:

Further details:

The PMP group contains between 6 and 10 individuals who will be invited to participate in the study as they have undergone the acceptance-based PMP at [redacted] in [redacted]. An n of 6 was chosen as the sample size for the present project as an n of 5 or 6 is felt to be a reasonable sample size for IPA research (e.g. Smith & Osborne, 2003). An n of 6 should therefore result in data saturation as the very nature of qualitative research means that rich informative data about participant experiences of being in an acceptance-based PMP and the key constituents that facilitated change should emerge.

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.

An n of 6 should therefore result in data saturation as the very nature of qualitative research means that rich informative data about participant experiences of being in an acceptance-based PMP and the key constituents that facilitated change should emerge. See A59 (Smith & Osborne, 2003).

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.

Qualitative Analysis

Data within the transcripts will be analysed using IPA by the researcher in order to meet the objectives of the study. That is, to answer the following research question:

What are the experiences of individuals on an acceptance-based Pain Management Programme- including the key

constituents of the programme that they regard as facilitating change?

This interpretative phenomenological analysis will follow the 4-stage process outlined by Smith & Osborne (2003):

Analysis begins with a close interpretative reading of the first case where initial responses to the text are annotated in one margin. These initial notes are translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes are then interrogated in order to make connections between them. This then results in a table of subordinate themes with identifying information - that is, where the instances supporting the theme can be found within the interview transcript.

This process is repeated for each case. After analysis has been conducted on each case, patterns can be established cross-case and documented in a master table of themes for the group. Another researcher is then recommended to review the audit themes to ensure that they are grounded and well-represented in the transcripts. The mastertable can be transformed into a narrative account; the analytic account is then supported by verbatim extracts from each participant.

The validity of the findings will then be examined through follow up telephone calls to participants who wished to receive a summary of findings sheet by post. Their responses will also be included in the results section of the final write up.

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.

<p>Title Forename/Initials Surname</p>
<p>Post</p> <p>Qualifications</p> <p>Employer</p> <p>Work Address</p>
<p>Post Code</p> <p>Telephone</p> <p>Fax</p> <p>Mobile</p> <p>Work Email</p>

MANAGEMENT OF THE RESEARCH

A64-1. Sponsor

<p>Lead Sponsor</p>	
<p>Status: <input type="radio"/> NHS or HSC care organisation</p> <p><input checked="" type="radio"/> Academic</p> <p><input type="radio"/> Pharmaceutical industry</p> <p><input type="radio"/> Medical device industry</p> <p><input type="radio"/> Local Authority</p> <p><input type="radio"/> Other social care provider (including voluntary sector or private organisation)</p>	<p>Commercial status:</p>

Other

If Other, please specify:

Contact person

Name of organisa

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

Is the sponsor ba:

Yes No

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.

Legal representative of the sponsor

Contact person

Name of organisatio

Given name

Family name

Address

Town/city

Post code

Country

Telephone

Fax

E-mail

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

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1)? Please give details of subcontractors if applicable.

Yes No

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

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile

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

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

Planned start date: 11/08/2009
Planned end date: 04/05/2010
Total duration:
Years: 0 Months: 8 Days: 23

A71-1. Is this study?

Single centre
 Multicentre

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 1

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
- NHS organisations in Wales 1
- 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)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

Yes No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Monitoring the conduct of the research will occur through supervision with Dr Beth Parry-Jones (Clinical Psychologist who runs the acceptance-based PMP at .. The conduct of the research will be audited by North Wales Clinical Psychology Programme.

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)

The University of Bangor's indemnity insurance policy. See certificate.

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)

The University of Bangor's indemnity insurance policy. See certificate.

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)

The University of Bangor's indemnity insurance policy, which covers non-negligent harm. See certificate.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- Yes
- No
- Not sure

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	Title	Mrs
Department name	First name/	Beth
Street address	Initials	
Town/city	Surname	Mathias
Post Code		

Removed for confidentiality.


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 main REC or the GTAC (as 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 main REC, 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.
 - 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.
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. 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

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's UK contact point
- Study co-ordinator

- Student
- Other – please give details
- None

Title:
Forename / Initials:
Surname:
Post:
Work address:
Work email:
Work telephone:

Access to application for training purposes

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.

Signature:

Print Name: Beth Gemma Mathias

Date: 29/07/2009 (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. 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: Oliver Turnbull

Date: 27/07/2009 (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor

- 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 Chief Investigator and 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.

Signature:

Print Name: Beth Parry-Jones

Date: 29/07/2009 (dd/mm/yyyy)

Post: Clinical Psychologist

Organisation: North West Wales NHS Trust

Appendix 18: IRAS Research and Development Approval Letter



Review: Mathias 09/35 Individual experiences of an acceptance based pain management programme: an interpretative phenomenological analysis
Chief Investigator: Miss Bath Mathias

Documents reviewed: R&D Application form 29/07/2009; NHS SSI form 12/08/2009; Protocol v.2 16/07/2009; PIS v.3 25/08/2009; CF v.3 25/08/2009; GP Letter v.1 25/08/2009; Sponsor's Letter 23/07/2009; Indemnity 01/08/2009; CV of CI 23/06/2009; CV of Supervisor.

The above research project was reviewed at the meeting of the Trust Research Governance Committee / Internal Review Panel held on 10th September 2009. The Committee is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the revised application.

I have pleasure in confirming that the Internal Review Panel is pleased to grant Trust approval to proceed at the North West Wales NHS Trust sites.

The study should not commence until the Ethics Committee reviewing the research has confirmed final ethical approval - favourable opinion.

All research conducted at the North West Wales NHS Trust sites must comply with the Research Governance Framework for Health and Social Care in Wales (November 2001). An electronic link to this document is provided on the Trust's R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the North West Wales NHS Trust.

If you would like further information on any other points covered by this letter please do not hesitate to contact me. On behalf of the Committee, may I take this opportunity to wish you every success with your research.

Yours sincerely


Pl Dr K D Griffiths

Consultant Biochemist
R&D Director, Assistant to the Medical Director
Chairman Trust Research Governance Committee

**Appendix 19: Amendment e-mail regarding site change.
Ethical and Research and Development Approval
Letters.**



National Patient Safety Agency

National Research Ethics Service

**Pwyllgor Moeseg Ymchwil Gogledd Orllewin Cymru
North West Wales Research Ethics Committee**

PRIVATE & CONFIDENTIAL

Mrs Beth Mathias
Trainee Clinical Psychologist
NWCPP, School of Psychology,
Bangor University, 43 College Rd,
Gwynedd, North Wales.
LL57 2DG

North West Wales NHS Trust, Ysbyty Gwynedd
Clinical Academic Office

Bangor, Gwynedd
LL57 2PW

Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@nww-tr.wales.nhs.uk

18 December 2009

Dear Mrs Mathias

Study title: Individual experiences of an acceptance-based Pain Management Programme: An Interpretative Phenomenological Analysis.
REC reference: 09/WNo01/35
Protocol number: 2
Amendment number: AM01 - Minor
Amendment date: 16 December 2009

Thank you for your letter of 16 December 2009, notifying the Committee of the above amendment. The amendment has been considered by the Chair.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment		16 December 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/WNo01/35: Please quote this number on all correspondence

Yours sincerely

**Dr. Rossela Roberts
Committee Co-ordinator**

*Copy to: Sponsor Representative: Professor Oliver Turnbull, Bangor University
R&D office for Betsi Cadwalader University Health Board*



GIG
CYMRU
NHS
WALES

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R&D Internal Review Panel – West Division**

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7 January 2009

Dear Mrs Mathias,

Re: Minor Amendment Review: Mathias 09/35 Individual experiences of an acceptance based pain management programme

Documents enclosed: Notification of Minor Amendment 16/12/2009 (change of site)

Thank you for your letter of 7 December 2009, notifying the Betsi Cadwaladr University Health Board's Internal Review Panel () of the minor amendment to the above study.

The amendment was considered and acknowledged at the meeting of the Committee held on 7 January 2010. The Committee is satisfied with the risk assessment, the review of the NHS costs and resource implications and all other research management issues pertaining to the review of the amendment.

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (November 2001). An electronic link to this document is provided on the Trust's R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

If you would like further information on any other points covered by this letter please do not hesitate to contact me. On behalf of the Committee, may I take this opportunity to wish you every success with your research.

Yours sincerely

Rossela Roberts

DH

Professor David Healy
Consultant Psychiatrist, Professor of Psychological Medicine
Chairman Internal Review Panel

Section 3: Literature Review



Clinical Journal of Pain

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Journal article

1. Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: medical and behavioral assessment. *Clin J Pain* 2001; 17: 206-14.

Book chapter

2. Todd VR. Visual information analysis: frame of reference for visual perception. In: Kramer P, Hinojosa J, eds. *Frames of reference for pediatric occupational therapy*. Philadelphia: Lippincott Williams & Wilkins, 1999:205-56.

Entire book

3. Kellman RM, Marentette LJ. *Atlas of craniomaxillofacial fixation*. Philadelphia: Lippincott Williams & Wilkins, 1999.

Software

4. *Epi Info* [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention; 1994.

Online journals

5. Friedman SA. Preeclampsia: a review of the role of prostaglandins. *Obstet Gynecol* [serial online]. January 1988;71:22-37. Available from: BRS Information Technologies, McLean, VA. Accessed December 15, 1990.

Database

6. CANCERNET-PDQ [database online]. Bethesda, MD: National Cancer Institute; 1996. Updated March 29, 1996.

World Wide Web

7. Gostin LO. Drug use and HIV/AIDS [JAMA HIV/AIDS Web site]. June 1, 1996. Available at: <http://www.ama-assn.org/special/hiv/ethics>. Accessed June 26, 1997.

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**A review of how acceptance fits with models of adaptation to chronic
pain: Towards a unified model**

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Abstract

Objectives: Acceptance of pain has been found to play an important role in adaptation to a life with chronic pain. Although findings have been consistent in showing a positive relationship between acceptance of pain and healthy adaptation, research in this area has proceeded in the relative absence of a guiding theoretical framework in terms of how people adapt to their chronic pain. The main purpose of this article was to review the literature to investigate how acceptance fits with models of adaptation to chronic pain.

Method: An advanced search (earliest-2010) was performed within the 'Social Sciences-CSA' database. Fourteen studies were included as they were all peer reviewed and made reference to acceptance within a model or theory of adaptation to pain.

Results: Studies were split into four main sections in accordance with the models of adaptation that they referenced: 1) Goal-directed motivational models and attention 2) Models that centre around identity 3) Coping Models 4) a model of Psychological Flexibility.

Discussion: It is suggested that despite differing terminologies within the models identified, many similarities exist between five key concepts or 'elements' and their interplay with acceptance. Namely: goal-setting, attention to pain, coping strategies, identity or sense of self and psychological flexibility. A proposed model is presented which attempts to unify the main findings. Limitations are also identified and recommendations are made for future research.

Introduction

Pain has been referred to as 'chronic' if it has '*persisted continually or intermittently for longer than three months*'.^{1p1248} Statistics released in 2004 by the International Association in the Study of Pain (IASP) and the European Federation of the IASP Chapters (EFIC), indicate that one in five people suffer from moderate to severe chronic pain, and that one in three are unable or less able to maintain an independent lifestyle due to their pain². Half to two-thirds of people with chronic pain are less able or unable to exercise, enjoy normal sleep, perform household chores, attend social activities, drive a car, walk or have sexual relations². Although many people with chronic pain give up work, refrain from activity and adopt the 'sick-role', some continue to live an active and fulfilled life in spite of pain³. They remain mobile, continue to work and socialise as before. Attention has therefore turned to the ways in which people adapt to chronic pain.

Recent research into adaptation has highlighted vast individual variation in the strategies individuals use to cope with pain⁴⁻¹⁶. Some are more beneficial for adaptation whereas others have been deemed 'maladaptive' such as catastrophising, passivity and avoidance. The tendency to 'catastrophise' (make negative predictions) during painful stimulation contributes to more intense pain and increased emotional distress.^{4,5,6} Catastrophising and being passive have been shown to be linked with difficult adaptation.^{7,8} Avoiding pain has been found to amplify it and transform it into something traumatic⁹ often heightening anxiety¹⁰. Healthy adaptation has been associated with active coping strategies such as: problem-solving¹¹, emotional intelligence¹², perceived social support¹³, satisfaction with spouse responses¹⁴, reductions in perceived handicap and an internal locus of control (LOC).¹⁰ LOC refers to the extent to which individuals

believe that they can control events that affect them. Individuals with a high internal-LOC believe that events result primarily from their own behavior and actions whereas those with a high external-LOC believe that powerful others, fate, or chance primarily determine events¹⁵. Lower internal-LOC, greater avoidance and higher perceived handicap have been found to predict higher depression in people with chronic pain¹⁰. 'Ways of being' or psychological dispositions are also likely to promote adaptive coping such as optimism, hope and broader personality traits such as extraversion and openness to experience¹⁶.

In recent years acceptance of pain has been found to play a key role in adaptation. Greater acceptance of pain has been associated with reports of lower pain intensity, less pain-related anxiety and avoidance, less depression, less physical and psychosocial disability, more daily up-time and better work status¹⁷ and general good quality of life¹⁸. Although research consistently indicates a positive relationship between acceptance of pain and healthy adaptation, or living a positive life despite pain^{19,20}, research in this area appears to have proceeded in the relative absence of a theoretical model of adaptation to chronic pain. This review of the literature will therefore investigate how acceptance fits with current models of adaptation to chronic pain. However a thorough understanding of the multifaceted and elusive concept of acceptance is required first.

Acceptance of chronic pain has been defined as *"Acknowledging that one has pain, giving up unproductive attempts to control pain, acting as if pain does not necessarily imply disability, and being able to commit one's efforts towards living a satisfying life despite pain"*^{17p2}. It therefore involves a disengagement from struggling with pain, a realistic approach to pain and pain-related circumstances, and a positive

engagement in daily activities²¹. Patients do not need to try to change their pain, but possibly alter their relationship with pain to accept their pain, and thus 'get on with the business of living' by appreciating the good things in life²². This in itself can be a huge relief to patients, and can lead to positive outcomes (such as increased self-esteem^{23,24,25} and reductions in medication²⁶). However, negative connotations of 'acceptance' are illustrated through resigned acceptance (the realisation that the pain will not go) where the individual becomes passive in the face of their illness. It could be argued that such resigned acceptance borders on helplessness/hopelessness attributions²⁷ and depression²⁸.

Acceptance is both a 'state' (outcome) and part of a process of adjusting to chronic pain. It has been referred to as the fifth stage in the process of coming to terms with loss in the Grief Stages Model²⁹ after the earlier stages of denial, anger, bargaining and depression. Although these stages are not necessarily sequential, and are not all experienced by everyone, acceptance is generally considered as the ultimate-stage as it brings peace, and signifies the end of suffering. Although this model does not refer to chronic pain directly, it is concerned with issues of suffering (which infers the experiencing of emotional pain), catastrophic loss and coming to terms with an irrevocable change. The following review of the literature therefore aims to uncover other models that might aid understanding of how individuals accept and adapt to chronic pain.

Review-Method:

An advanced search was performed using the search engine 'Social Sciences-CSA' (earliest-2010) as CSA provides access to more than 100 full-text and bibliographic databases. The following search terms were entered: chronic pain; acceptance;

adjustment/adaptation; theory/model. Various combinations of these searches yielded 40 results when discounting duplications. Of these 40 results, 29 studies were excluded in total. These studies were excluded because either:

- They were the same article published in another journal (2)
- They were focused primarily on measures (7)
- Were not peer reviewed (7)
- Did not make any reference to a model/theory (and focused on Pain Management) (11)
- Were written in German (there was insufficient time for translation to English) (2)

Fourteen studies (3 qualitative and 11 quantitative) were included in total and details of these studies are summarised in Tables 1-4 (Appendix-1). They all made some attempt to include acceptance within a model of adjustment to chronic pain.

Results

The fourteen studies were organised in accordance with the models of adaptation they referenced. These fell within four main categories: 'Goal directed behaviour and attention' (2 studies), 'Coping Models' (5 studies), 'Models of Identity' (4 studies) and 'Psychological Flexibility' (3 studies), which will be considered in turn.

Goal-directed behaviour and attention

Although goal-directed behaviour and attention were the main focus of the two studies in this section^{30,31}, they continue as an important linking theme throughout other sub-sections and so they have been presented first. Both studies in this section explored

acceptance within goal-directed motivational models and made reference to Brantstadter and Renner's³² Dual Process Theory (DPT) of goal motivated behaviour. This theory postulates that individuals have two dominant modes of coping with adversity such as pain called *assimilative* and *accommodative* coping. *Assimilative* coping involves directing efforts at curing pain and *accommodative* coping involves relinquishing pain relief as the primary goal by reducing its importance.

Crombez et al³⁰ postulated that when faced with the problem of pain, individuals can attempt a solution aimed at relief (*assimilation*) or a solution aimed at acceptance (*accommodation*) and used the DPT to compare acute and chronic patients' approach to problem-solving. Patients (n=364), completed a battery of self report measures such as the Multi-dimensional Pain Inventory (MPI), the Pain Disability Index (PDI), the Hospital Anxiety and Depression Scale (HADS), Pain Vigilance and Awareness Questionnaire (PVAQ) and the Pain Catastrophising Scale (PCS). A Pain Solutions Questionnaire (PaSol) was also used to assess how adults frame problems of pain and how they attempt solutions, based on the DPT. Chronic pain patients (n=303) reported greater disability and catastrophic thinking about pain than acute pain patients (n=61). *Assimilative* coping was associated with greater disability, greater attention to pain and more catastrophic thinking about pain beyond the effects of demographic variables, pain severity and pain duration. For chronic pain patients, catastrophic thinking about pain was greater when *assimilative* coping was higher.

Viane et al³¹ focused on the Goal-Directed Motivation Model (GDMM^{33,34}) which views people as motivated by personal, value dependent goals that shift in and out of consciousness. The affective-motivational system was postulated to promote on-task

behaviour, and reduce interference from distracting off-task demands. Thought shifting off-task was considered as interference when the content focused upon (e.g. chronic pain) subverts the activity or goal a person is motivated to accomplish. Acceptance not only implies less attention to pain but also makes it more possible to re-engage attention to daily activities and personal goals. However, Viane et al³¹ thought that preserving a positive life despite the uncontrollable effects of pain may best be achieved through the flexible adjustment of personal goals to current limitations and acknowledged that this idea is integral to the DPT³².

Viane et al³¹ reported the results of two studies. The first study was cross-sectional and 501 patients with chronic pain completed self-report instruments of pain severity (MPI:Part-1), attention to pain (PVAQ) and acceptance (Illness Cognition Questionnaire ICQ). In a second diary study 62 patients rated pain intensity, attention to pain and characteristics of goal directed behaviour using a 7-point likert scale (not at all – very much). Participants recorded their pain 8-times a day on an electronic diary over a 2-week period. Goal-directed characteristics of daily activities within the diary were based on the ‘GDMM’^{33,34}. Correlational and hierarchical regressions were conducted using data from the above self-report measures within study 1 and using acceptance (ICQ) and diary data (comprising patient average scores over the 2-week period) within study 2. Acceptance was related to: less attention to pain (studies 1&2), more engagement with daily activities, a higher motivation to complete activities and a better efficacy to perform daily activities (study 2). Viane et al³¹ argued that when committed to striving for a particular goal (e.g. engagement in daily activities), our attentional system is sensitised to information or cues that are congruent with that goal, which serve as a naturally

occurring distracter that reduces attention to chronic pain. Likewise, processing information that is incompatible or incongruent with that goal (e.g. focusing on finding a cure or avoidance) is reduced or blocked due to reduced attention to pain.

Crombez et al³⁰ and Viane et al's³¹ first study are limited due to their cross-sectional designs using self-report measures. Therefore, findings cannot support any claims regarding the order of relationships or how patterns of problem solving develop. The longitudinal 2-week period used within Viane et al's³¹ second study attempts to bridge this gap. However averaging diary scores may mean that rich extreme (high or low) data is not captured. The self-report measures within these two studies^{30,31} were Dutch versions and despite good reliability and validity estimates, findings may not be generalisable to other populations. Crombez et al's³⁰ sample contained more chronic (n=303) than acute pain (n=61) participants which may have been responsible for the 'PaSols' heavily skewed pain attitude and solutions sub-scales, which made analysis of the separate sub-scales impossible.

Despite the above limitations, *assimilative* coping within the DPT³² seems to be linked to 'off-task attention to pain' within the GDMM^{33,34}. The studies in Table 1 suggest, in line with the DPT, that individuals can adapt to chronic pain in two predominant ways. One involves a direct focus on pain through attempts to control it, avoid it and/or find a cure ('*assimilation*' or 'non-acceptance'). This increases attention to pain and has been linked with catastrophising. The other involves acknowledging pain is real, relinquishing the importance of pain relief as the primary goal by reducing its importance ('*accommodation*' or 'acceptance'). This reduces attention to pain when congruent with an individual's goals.

Coping Models

Five studies looked at the role of acceptance within models of coping (see Table 2). Two studies found acceptance to be more advantageous in adapting to a life with chronic pain than coping variables^{21,35}. Three hinted that these aspects may be interlinked and complementary^{36,37,38}.

One hundred and twenty chronic pain patients completed the Brief Pain Coping Inventory (BPCI) to assess acceptance-oriented and control/avoidance oriented responses to pain³⁵. They also completed the Chronic Pain Acceptance Questionnaire (CPAQ), Sickness Impact Profile (SIP), Beck Depression Inventory (BDI), Pain Anxiety Symptoms Scale (PASS) and sit-to-stand performance (during a one-minute interval) at two time-points with an average of 3.7 months between them³⁵. A four-factor model emerged from the coping data (BPCI scores), with factor loadings labeled 'pain management', 'pain control', 'help seeking' and 'activity persistence'. 'Activity persistence' was associated with better functioning over time on the measures administered, while control-orientated responses were associated with greater difficulty.

McCracken & Eccleston²¹ compared a coping approach (using the Coping Strategies Questionnaire, CSQ) with an acceptance approach (CPAQ) in terms of their ability to predict distress and disability. Patients (n=230) completed the CSQ, CPAQ, BDI, SIP, and the PASS. Coping and acceptance were not highly associated with one another. Acceptance was associated with less pain, disability, depression and pain-related anxiety, higher daily uptime, better work status and repeatedly accounted for more variance (24%) than coping variables (4.6%) in models of adjustment indicators. Acceptance may therefore have more utility than coping for understanding adjustment to

chronic pain. However, its cross-sectional design meant that generalisability and causality could not be inferred.

The three following studies found coping and acceptance to be interlinked. McCracken et al³⁸ used the Multidimensional Pain Inventory (MPI) which classified a total of 190 participants into three categories. 'Dysfunctional' (n=41) patients reported that their pain affects a broad range of functioning; 'interpersonally distressed' (n=28) patients perceived their significant others as unsupportive and 'adaptive copers' (n=114) denied significant negative effects of pain. Accepting pain was the most powerful predictor of whether patients were classified as dysfunctional or adaptive copers, independent of pain intensity or depression scores. The dysfunctional group reported greater pain-related anxiety and less acceptance of pain than other sub-groups. Decreasing anxiety and increasing acceptance may 'move' patients with chronic pain from the dysfunctional to the adaptive copers category. However, the inter-personally distressed patients could not be distinguished from their dysfunctional or adaptive copers counterparts on the basis of acceptance or the other measures.

Esteve et al³⁶ used structural equation modeling after giving patients (n=117) a battery of questionnaire measures (comprising Spanish versions of the CPAQ, Pain-related self-statement scale, Pain-Related Control Scale, Vanderbilt Pain Management Inventory, HADS, The impairment and Functioning Inventory and Pain Intensity ratings) at one time point. Although acceptance of pain was found to determine functional status and functional impairment scores, active-coping scores had a significant positive influence on measures of emotional distress (e.g. catastrophising self-statements) and

resourcefulness beliefs had a significant negative influence on depression. However the reliability and validity coefficients of Spanish-equivalents were not provided.

Sofaer et al³⁷ used a qualitative grounded theory approach to ascertain the practical, physical and psychosocial limitations faced by older individuals with chronic pain (n=63; aged 60-83 years). Qualitative methods also have their limitations as small sample sizes make it difficult to generate causal mechanisms. However, the rich nature of data does enable key themes to be analysed from participant accounts (including similarities and differences between participants' perspectives) which can aid theoretical development. Two main themes emerged within this study, firstly the desire for independence and control and secondly adaptation to a life with chronic pain (containing acceptance/non-acceptance). A link was identified between the two themes and it was hypothesised that when independence and control are achieved, older people may adapt better to their chronic pain, which seemed to be the overarching theory grounded directly in the data. The authors suggested that acceptance may be the first step in understanding adaptation to chronic pain, followed by pacing, downward comparisons (viewing other people as worse-off than oneself), helping others, engaging in community activities, and socialisation as instrumental in distraction from pain and essential for well-being.

The evidence appears to favour an interconnection between acceptance and coping, whereby acceptance has been found to be predictive of an adaptive coping style³⁸ and related to more effective attempts towards independence/control³⁷. They may work together to determine the chronic pain experience; with acceptance maintaining functioning and control beliefs and active coping maintaining positive mood³⁶.

Identity models

Four studies within the review specifically looked at identity models (summarised in Table 3). Two were quantitative studies that used hierarchical regression analysis to investigate how acceptance related to enmeshment together with theories of self-discrepancy, self-regulation and hopelessness^{39,40}. The remaining two studies were qualitative and concerned with individual experiences^{41,42}.

Self-Discrepancy Theory⁴³ maintains that negative emotional consequences arise when an individual's *actual*-self is discrepant with strongly held aspirations (*ideal*-self) and obligations (*ought*-self), and that such negative emotions motivate individuals to change. Self-pain enmeshment may be construed as a measure of a person's identity: their sense of who they are and what they might become referred to as their '*possible-selves*' and the degree to which this self is conditional (enmeshed) on the absence of pain. Emotional adjustment (specifically depression) to chronic pain is partly determined by the extent to which aspects of the self are enmeshed with pain⁴⁴. Self-Regulatory Theory^{45,46} states that the affect generated by self-discrepancy should be dependent upon the rate at which discrepancies alter, with greater discrepancy resulting in greater affective distress. Hopelessness Theory⁴⁷ posits that Hopelessness comprises two core expectations: A negative expectation about the occurrence of highly valued outcomes (outcome expectation), and expectations of helplessness with respect to changing the likelihood of occurrence of these outcomes (helplessness expectation).

Morley et al³⁹ modified Higgins'^{43,48} self-discrepancy methodology using the '*possible-selves* interview'. This required participants (n=89) to generate sets of 10-characteristics describing three aspects of their self (as it is now), their *hoped-for* and

feared-for selves, judge whether each characteristic would be possible if they were in pain and rate their efficacy of accomplishing both *hoped-for* and *feared-for* selves (1=not capable, 7=definitely capable) and expectancy of them in the future (1=very unlikely, 7=very likely). Participants also completed standardised self-report measures of depression (BDI-II), acceptance (CPAQ), Pain Disability (PDI) and pain intensity (Visual Analogue Scales). The degree to which characteristics of the future *hoped-for* self were conditional (enmeshed) on the absence of pain, statistically predicted depression and acceptance scores. The more *hoped-for* characteristics that could be achieved in the absence of pain the higher the BDI-II score ($\beta=0.392$, $p<0.0001$) and less the degree of acceptance ($\beta=-0.254$, $p<0.02$). The 'possible-selves interview' may have been susceptible to biases such as verbal fluency, education and age. However, the generation of aspects of the *hoped-for* self may help patients consider that it is possible to retain both personal characteristics and develop new ones in the presence of continued pain. The Self Discrepancy Theory did not make predictions concerning the enmeshment of pain and self. The magnitude of experienced depression was due to the likelihood of achieving their *hoped-for* self. Where pain elimination was the primary but unobtainable goal, movement towards other goals (*future-selves*) was blocked and led to frustration, a sense of entrapment and depression. This goal compromised emotional adjustment and led to self-pain enmeshment. Enmeshment was felt to provide an alternative approach to the hopelessness theory³⁹.

Sutherland and Morley⁴⁰ used the same quantitative methodology as Morley et al³⁹. Eighty-two patients completed the same measures as the previous study but additionally completed the HADS and a 'Personal Style Inventory' (measuring two

motivational preferences *autonomy* and *sociotropy* i.e. high levels of dependence and excessive need to please others. Data supported Morley et al's³⁹ observation that discrepancies between a person's *actual* and *hoped-for* selves and the degree to which characteristics of the future *hoped-for* self was conditional (enmeshed) on the absence of pain, are related to depression and acceptance. Findings also confirmed that the relationship between the conditional selves (enmeshed-self) and measures of adjustment were not attributable to generalised hopelessness. When HADS-Anxiety was considered, there was no main effect for any of the self aspects (*hoped-for* or *feared-for* selves), but there were specific interactions between *hoped-for* selves and *autonomy* and *sociotrophy*. However only two forms of motivational preference were examined and findings cannot provide a causal account of the relationship between aspects of the self.

The remaining two studies were qualitative^{41,42}. Campbell and Cramb⁴² used semi-structured interviews to explore what it was like to live with chronic pain for 12 participants who had not accessed secondary or tertiary health services. Three main themes regarding adaptation emerged: 'dependence and social withdrawal', 'being normal in comparison to others' and 'striving for self-management', which contained aspects of coping and control. Rather than exhibiting pain behaviour, the participants in this study actively masked their pain to appear as the person they were before they experienced pain. However, this created tension and conflict within themselves, as they had to wrestle with a changed self. Such change produces feelings of loss for their previous self and former way of life. Coming to terms with pain represents accepting that they will never return to their old pre-pain self and way of life, but have gained the ability

and self confidence to move on or co-exist with their pain, which often takes years to achieve.

Miles et al⁴¹ employed a grounded theory methodology to offer insight into the experience of pain and provide a theory of how patients attempt to resolve its constraints. Adaptation was found to be more complex than *assimilation* and *accommodation* alone and these modes of 'coping categories' were presented in a model alongside two additional modes of coping (*confrontation* and *subversion*), with identity at its core. In *assimilation*, the constraints were absorbed and normal life maintained. In *accommodation*, the constraints were accepted and normal life re-defined. In *confrontation*, the constraints were rejected and pre-pain identities and activities pursued despite leading to increased pain levels. In *subversion*, attempts were made to retain pre-pain identities, and although pain levels were minimised, activities were altered to a significant degree. The four coping categories were dichotomised as two modes of acceptance (*assimilation* and *accommodation*) and two modes of resistance (*confrontation* and *subversion*). Interestingly, assimilation was felt to be a form of acceptance in instances whereby individuals accept support from others who absorb the constraints of pain by taking on their responsibilities/roles. Miles et al⁴¹ speculated that the limitations imposed by pain often form the focus of people's coping efforts, rather than pain per se. Studies in Table 3 support the notion that the desire to retain pre-pain normal lifestyles may underlie people's use of coping strategies that exacerbate pain intensity and pain related disability. Although Miles et al's⁴¹ model links the concepts of goal-directed motivational models, coping and identity, it did not include attention or another theory linked to acceptance known as '*psychological flexibility*'.

Psychological Flexibility

Three quantitative studies looked at the various components of *psychological flexibility* which comprises the processes of *acceptance, mindfulness, values and cognitive defusion*^{49,50,51}. *Mindfulness* involves directing attention to remain in contact with each present moment, in a way that is accepting, and free from the influences of interpretations and judgments; *values* represent influences from important long-term goals; and *cognitive defusion* refers to freedom from unhelpful response narrowing influences of thoughts or beliefs. All studies administered similar self-report measures (e.g. British Columbia Major Depression Inventory BC-MDI, CPAQ, Mindful Attention Awareness Scale, Pain Anxiety Symptoms Scale PASS-20, and SIP), conducted correlational/regression analysis and had a relatively homogenous mean age range across studies (46.6-48.1 years).

McCracken & Vowles⁴⁹ investigated aspects of *psychological flexibility* and functioning within patients seeking treatment for chronic pain. Patients (n=260) completed a battery comprising many of the above measures, including an expanded version of an instrument assessing responses to pain that reflect both *psychological flexibility* and traditionally conceived pain management strategies (i.e. pacing, relaxation, positive self-statements), the BPCI-2. '*Psychological flexibility*' accounted for significant variance in eight separate measures of functioning, whereas self-reported pain management strategies were significant in none. According to the model presented here, *psychological flexibility* occurs when behaviour patterns demonstrate processes of *acceptance, mindfulness, values and/or cognitive defusion*.

McCracken & Keogh⁵¹ considered a key process in psychological 'inflexibility' known as *experiential avoidance*: attempts to control or limit contact with emotional,

physical, and cognitive experiences evaluated as undesirable (e.g. pain, fatigue, depression, anxiety anger or painful memories) which has links to *Anxiety Sensitivity (AS)*. *AS* (or fear of anxiety⁵²) was associated with greater pain, disability and distress and *acceptance, mindfulness and values-based action* reduced the average variance accounted for by *AS* in patient functioning from $R^2 = .21$ to $R^2 = .048$. This suggests that when these three processes were taken into account statistically, *AS* alone retained relatively little association with patient functioning. *AS* may amplify the impact of emotional distress on patient functioning and that the combined processes of *acceptance, mindfulness and values-based action* may reduce this effect.

The studies by McCracken and Vowles⁴⁹ and McCracken and Keough⁵¹ were limited due to the cross-sectional design which meant that making inferences regarding causality were not possible. McCracken and Vowles⁵⁰ however, prospectively investigated the combined processes of *acceptance* and *values-based action* in 115 patients at their initial assessment and on their first day of treatment an average of 18.5 weeks later. Correlation analysis showed that *acceptance* of pain and *values-based action* measured at time-1 were significantly negatively correlated with pain, pain-related distress, pain-related anxiety and avoidance, depression, depression-related interference with functioning, and physical and psychosocial disability measured at time-2. Multiple regressions showed that combined *acceptance* and *values-based action* accounted for between 6.5% and 27.0% of the variance in the aforementioned areas later in time. However, waiting times were variable across patients (range 10.0-26.5 weeks), which may have affected the findings.

Although all three studies used quantitative self-report measures and maintain that further exploration is needed to establish whether their findings are replicable and generalisable to other settings, the studies suggest that *psychological flexibility*⁴⁹ and its various components^{50,51} contribute to reductions in pain, distress and disability.

Discussion

The review highlights how acceptance fits with a number of models of adaptation to chronic pain. Its links with the DPT³² and GDMM^{33,34} have furthered our understanding of how individuals move towards acceptance/*accommodation*³⁰ and how this may be influenced by less attention to pain, personal goals and greater engagement in daily activity³¹. However, acceptance's link with models of coping^{36,37,38} and identity^{39,40,41,42} highlighted that there was more to adaptation than *assimilation*, *accommodation* and attention alone. Identity, appeared central to acceptance, its role best explained by the Self Regulatory Model⁴⁵ and the Enmeshment Hypothesis⁴⁴, which linked adaptation with the degree to which one's future *hoped-for* self is enmeshed with pain^{39,40}. There also appeared to be an inter-play between identity and the coping strategies of *assimilation*, *accommodation*, *confrontation* and *subversion*⁴¹. Constituents of '*psychological flexibility*' also seemed to have a positive influence on adaptation^{49,50,51}. However, these were fragmented accounts and not combined in a unifying theory.

Reviewing the literature in terms of how acceptance fits with models of adaptation to chronic pain was clouded by the various terminology used to describe similar constructs within the models identified. The motivational goal aspect within the DPT appeared to be the same as the *values* component of *Psychological Flexibility* and

the degree to which attention is focused on pain, akin to *mindfulness*. Despite viewing *assimilation* as non-acceptance and *accommodation* as acceptance, Miles et al⁴¹ described *assimilation* and *accommodation* as forms of acceptance and so it may be more helpful to consider *assimilation* as non-acceptance and/or resigned acceptance and *accommodation* as positive acceptance. They could therefore exist on a continuum, similar to the Grief Stages Model²⁹ whereby in some instances resigned acceptance may be a necessary part of the process towards attaining full (positive) acceptance. Miles et al⁴¹ also used the term 'coping' to describe these two forms of acceptance (*assimilation* and *accommodation*) and two forms of resistance (*confrontation* and *subversion*). Other studies have found coping and acceptance to be separate entities^{21,35}. This highlights the confusion caused by the term 'coping', which is often used in two ways in the literature. Firstly, as behaviour(s) which successfully reduce the impact of pain and secondly as behaviour(s) exhibited in response to pain regardless of the result²¹.

Despite these terminological difficulties, the review uncovered five key elements within the various models of adaptation to chronic pain outlined above which may influence the way in which an individual accepts and adapts. These included: 1) goal setting³⁰; 2) attention³¹; 3) coping variables^{36,37,38}; 4) identity or sense of self^{39,40,41,42}; and 5) the interactive role of acceptance amongst other concepts of *psychological flexibility*^{49,50,51}. However, as there is no unifying study or theory that links these constructs, it is only possible to postulate that they may be interconnected in the following way by summarising the models and findings of the review:

Insert Figure 1A: ↓

Figure 1A, 'Adaptation to Chronic Pain' (ACP) Model illustrates that *accommodation* (positive acceptance) and *assimilation* (non-acceptance and or resigned acceptance) may exist upon a continuum, with *accommodation* being linked to more positive adaptation and *assimilation* to more negative adaptation. This is illustrated further through *assimilation's* link to increased attention to pain, emotional distress, increased pain severity and unhelpful coping strategies concerned with attempts to maintain *the old you* (i.e. *confrontation* and *subversion*). However, the continuum illustrates that there may be some instances whereby resigned acceptance may be a necessary part of the process towards attaining full positive acceptance (*Accommodation*). The movement along a continuum towards an outcome of positive acceptance echoes that described within the Grief Stages Model²⁹. The latter can additionally be influenced by one's attention to pain or *mindfulness* to the present moment and the degree of *cognitive defusion*. However, perhaps it is only when *values/goals/motivations* are adjusted in line with a new sense of self (*a new you*) that reengagement in daily activities can occur.

Additional methodological issues and future research

Although the ACP Model (*Fig. 1A*) highlights that acceptance is integral to adjustment to chronic pain and is linked to the aforementioned five constructs, no study has yet measured all five. The majority of the studies included in this review used quantitative cross-sectional designs, based on correlational analysis of self-report questionnaire

measures, thus making inferences about causality impossible. There is therefore, a need for more studies incorporating longitudinal designs. Such designs allow for greater consideration of causal factors (direction of relationships), and can investigate the effects of particular combinations of strategies that people use to accept and adapt to chronic pain over time. There is a particular need for studies to explore the interconnections within ACP Model (*Fig. 1A*) with the aim of furthering theory in this area. Given the central role of identity, future research into identity management may further our understanding of the factors which may promote pain acceptance⁴¹. Additional treatment outcome analysis is needed to strengthen the case for the particular processes that may aid acceptance⁵⁰. Further research is also needed to determine how (re)engagement with daily activities has been accomplished and whether acceptance can be achieved therapeutically⁴⁹. Qualitative research is likely to have an important part to play in uncovering the role of acceptance in the process of adapting to chronic pain and the contexts in which this can best be achieved.

Clinical implications

From the evidence, it is clear that clinicians must consider acceptance of pain as a primary aim for treatment to facilitate healthy adaptation to chronic pain. Sufferers should therefore be supported by care providers in order to come to terms with and accept their pain⁴². The generation of specific aspects of the *hoped-for* self within the 'possible-selves interview'^{39,40} may have clinical utility in that patients can appreciate that it may be possible for them to retain both personal characteristics and develop new ones even in the presence of continued pain. This may ensure that individuals not only retain their own identity but recover a sense of personal growth³⁹.

More recently, a number of related approaches have sought to foster acceptance-based means of managing difficult internal experiences. These approaches have come to be known as ‘third-wave cognitive behavioural therapies’. Examples of such therapies include: Dialectical Behaviour Therapy⁵³; Mindfulness-based Cognitive Therapy⁵⁴ and Acceptance and Commitment Therapy (ACT)⁵⁵. These third wave approaches build on more traditional ‘second wave’ cognitive behavioural approaches, such as Cognitive Behavioural Therapy⁵⁶ as they are more experiential, more focused on context, and less oriented towards directly altering the content of cognitions. However, the goal-setting and pacing and coping strategies included in most Cognitive Behavioural Therapy (CBT) pain management programmes (PMPs) probably enables people with CP to move towards re-engagement with daily activities and acceptance.

The five key elements identified within the present review support the use of acceptance-based approaches such as Mindfulness, ACT, and as applied to chronic pain Contextual Cognitive Behavioural Therapy (CCBT). These therapies take the majority of the elements included within the ACP Model into account. For example, ACT includes six-core therapeutic processes: *Acceptance* being present (e.g. an aspect of *mindfulness*), *values*, *cognitive defusion*, *committed action*, and *self-as-context*⁵⁶. Ten of the fourteen studies reviewed recommended the application of a functional contextual model of psychopathology, the model underlying ACT and related approaches such as CCBT to aid positive adaptation^{30,31,21,35,36,38,42,49,50,51}. Further clinically oriented research is required in this area.

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Fig 1A: Adaptation to Chronic Pain (ACP) Model

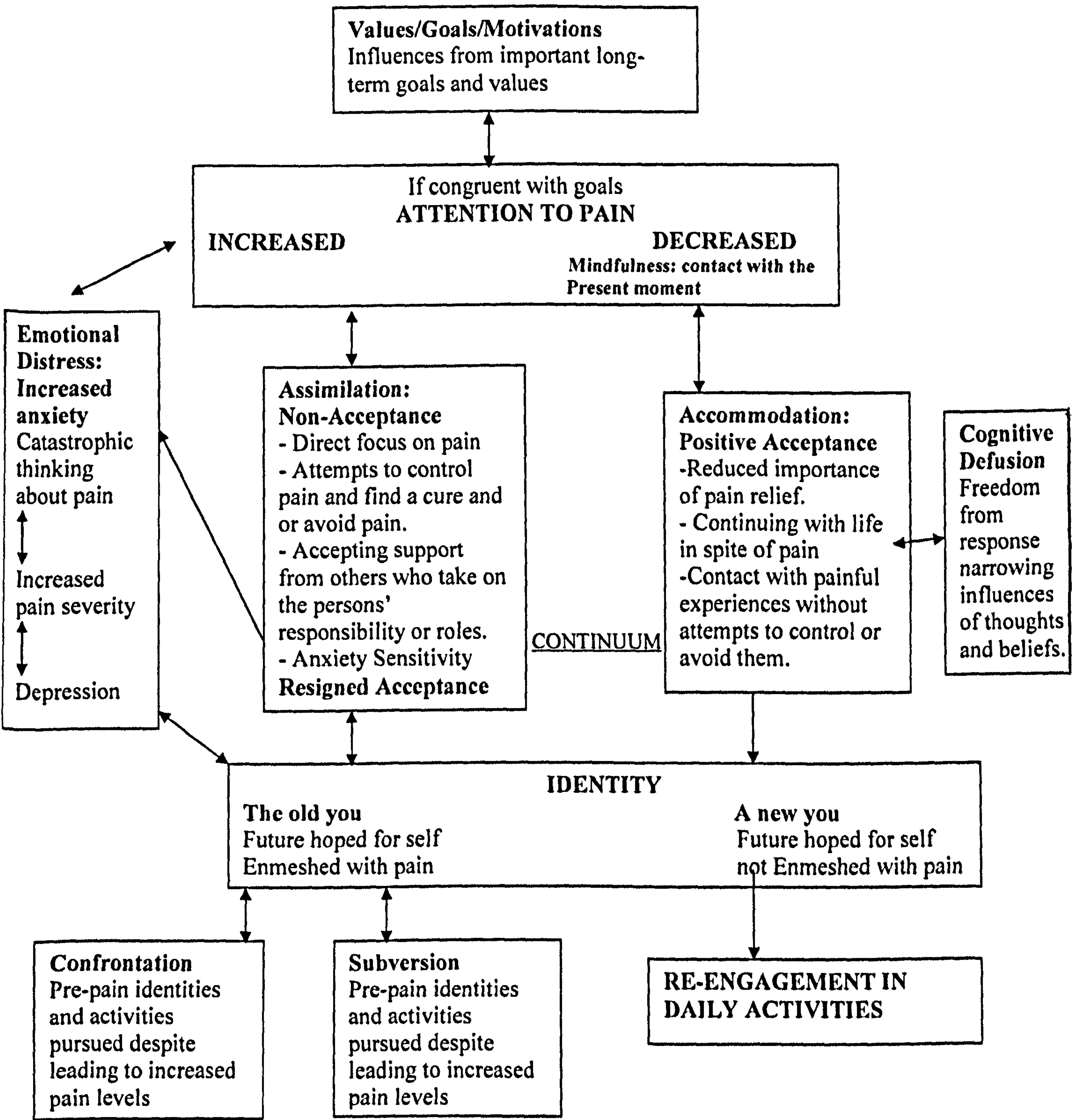


Table 1: Summary of studies that make reference to goal-directed motivational models and or attention.

Table 1: summary of studies that make reference to goal motivational models and or attention.

Author and Title	Age in Years	Methodology	Key Themes & Theories Mentioned
30] Crombez et al. (2008)*	Range:14-85 Mean: 48.30	<p>Participants: 364: 303 (chronic pain CP) 61 (acute pain AP)</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Correlations and regressions</p> <p>Measures:</p> <ul style="list-style-type: none"> • The Pain Solutions Questionnaire (PaSol) • Multi-dimensional Pain Inventory (MPI) • Dutch: Pain Disability Index (PDI) • Dutch: Hospital Anxiety and Depression Scale (HADS) • Dutch: Pain Vigilance and Awareness Questionnaire (PVAQ). • Dutch: Pain Catastrophising Scale (PCS) 	<p>Dual Process Model used to compare AP and CP patients' approach to problem-solving.</p> <p>CP patients reported greater disability and catastrophic thinking about pain than AP patients. Assimilative coping was associated with greater disability, greater attention to pain, and more catastrophic thinking about pain, beyond the effects of demographic variables and pain severity.</p> <p>Catastrophic thinking about pain was greater in CP Patients when assimilative coping was higher.</p> <p>Goal-Directed Motivational Model used to describe findings.</p>
31] Viane et al (2004)*	Range:25-92 Mean: 53.28	<p>STUDY 1: Participants: 501</p> <p>Design: Cross-sectional, Self report</p> <p>Quantitative Analysis: Hierarchical multiple regressions</p> <p>Measures:</p> <ul style="list-style-type: none"> • Dutch: Multidimensional Pain Inventory-part 1 (MPI-DLV) • Dutch: pain Vigilance and awareness questionnaire (PVAQ) • Illness Cognition Questionnaire (ICQ) <p>STUDY 2: Participants: 62</p> <p>Design: Longitudinal</p> <p>Measures: Diary data for each participant averaged over 2-wk period. Pain intensity, attention to pain and characteristics of goal directed behaviour reported 8-times a day on a 7-point likert scale (1='not at all' to 7='very much').</p> <ul style="list-style-type: none"> • ICQ <p>Quantitative Analysis: Hierarchical regression between ICQ acceptance and diary 'attention to pain' and 'goals'</p>	<p>Models of Goal-Directed Behaviour.</p> <p>Acceptance was related to less attention to pain (study 1 & 2), more engagement with daily activities, a higher motivation to complete activities and a better efficacy to perform daily activities (study 2). Results are discussed in terms of how a positive life despite pain may be preserved by a flexible adjustment of personal goals to current limitations and adversities</p>

Key: CP = Chronic Pain

* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

Table 2: Summary of studies that make reference to coping models

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Author and Title	Age in Years	Methodology	Key Themes & Theories Mentioned
35] McCracken et al (2007)*	Mean: 44.6	<p>Participants: 120</p> <p>Design: Longitudinal (two time points separated by an average of 3.7 months)</p> <p>Quantitative Analysis: Preliminary factor analyses, correlations and regressions</p> <p>Measures:</p> <ul style="list-style-type: none"> • Brief pain coping inventory (BPCI) • Chronic Pain Acceptance Questionnaire (CPAQ) • Sickness Impact Profile (SIP) • Beck Depression Inventory (BDI) • Pain Anxiety Symptoms Scale (PASS) • Sit-to-stand frequency during 1-minute interval 	<p>A 4 factor model emerged within the coping data: pain management, pain control, help seeking and activity persistence.</p> <p>Activity persistence was associated with better functioning over time (i.e. better adaptation on measures of pain, up-time, disabilities, depression, pain-related anxiety and avoidance and sit-to-stand) while control-orientated responses were associated with greater difficulty.</p> <p>The factor representing more or less traditional pain management methods showed surprisingly limited relations with aspects of patient functioning.</p>
21] McCracken & Eccleston (2003)*	Mean 46.4	<p>Participants: 230</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Correlations, Hierarchical Regressions.</p> <p>Measures:</p> <ul style="list-style-type: none"> • Chronic Pain Acceptance Questionnaire (CPAQ) • Coping Strategies Questionnaire (CSQ) • Beck Depression Inventory (BDI) • Sickness Impact Profile (SIP) • Pain Anxiety Symptoms Scale (PASS) 	<p>Models of coping and acceptance compared in terms of their ability to predict disability and distress in patients seeking treatment for CP.</p> <p>Coping variables were relatively weakly related to acceptance of pain and relatively unreliably related to pain adjustment variables.</p> <p>Acceptance of CP was associated with less pain, disability, depression and pain-related anxiety, higher daily up-time and better work status.</p> <p>Acceptance of pain repeatedly accounted for more variance in models of adjustment indicators in relation to CP.</p>

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38] McCracken et al. (1999)*	Mean: 47.1	<p>Participants: 190</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Discriminant function analysis</p> <p>Measures:</p> <ul style="list-style-type: none"> • Chronic Pain Acceptance Questionnaire (CPAQ) • Beck Depression Inventory (BDI) • Multidimensional Pain Inventory (MPI) • Pain Anxiety Symptoms Scale (PASS) 	<p>Examined the role of pain-related anxiety and acceptance of pain in differentiating patients classified as <i>adaptive, dysfunctional, or interpersonally distressed copers based on the empirically derived taxonomy of Turk & Rudy (1988)</i>. 'Interpersonally distressed' could not be distinguished from other groups This may be due to social environmental issues their label suggests and not their responses to pain.</p> <p>The dysfunctional group reported greater pain-related anxiety and less acceptance of pain than the other groups. Pain related anxiety and acceptance of pain appeared to be unique behavioural dimensions of adjustment to chronic pain. Decreasing anxiety and increasing acceptance may move patients with CP from the dysfunctional to the adaptive coper category.</p>
36] Esteve et al (2007)*	Mean: 54	<p>Participants: 117</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Structural equation modeling</p> <p>Measures:</p> <ul style="list-style-type: none"> • Interview for demographic information • Spanish: Chronic Pain Acceptance Questionnaire (CPAQ) • Spanish: Pain-related self-statement scale (PRSS) • Spanish: Pain-related control scale (PRCS) • Spanish: Vanderbilt Pain Management Inventory (VPMI) • Spanish: Hospital Anxiety and Depression Scale (HADS) • The impairment and functioning inventory (IFI) • Self-monitoring: pain intensity self-rated at home (1-10 where 10 is v intense) 3 times a day and an intensity score was calculated. 	<p><i>The final model (SEM)</i> showed that acceptance of pain determined functional status and functional impairment. However, coping measures had a significant influence on measures of emotional distress.</p> <p>Catastrophising self-statements significantly influenced reported pain intensity and anxiety.</p> <p>Acceptance may play a critical role in the maintenance of functioning and, with this aim, acceptance-based treatments are promising to avoid the development of disability. They also lend support to the role of control beliefs and of active coping to maintain a positive mood.</p> <p>Acceptance and coping are presented as complementary approaches.</p>

Key: CP = Chronic Pain

* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

37] Sofaer et al (2005).	60-87	<p>Participants: 63</p> <p>Design: Cross-sectional</p> <p>Qualitative Analysis: Grounded theory</p> <p>Measures: Unstructured interviews</p>	<p>Grounded theory showing that acceptance may be the first step in understanding adaptation to CP</p> <p>Two main themes emerged: 1) the desire for independence and control and 2) adaptation to a life with CP. Several sub-categories formed the theme of adaptation. These were acceptance and non-acceptance, pacing oneself, helping other people, the use of prayer and 'looking good and feeling good'.</p>
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* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

Table 3: Summary of studies that make reference to models of identity

Table 3: summary of studies that make reference to models of Identity

Author and Title	Age in Years	Methodology	Key Themes & Theories Mentioned
39] Morley et al (2005)	Mean: 45	<p>Participants: 89</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Hierarchical multiple regressions</p> <p>Measures:</p> <ul style="list-style-type: none"> • Visual Analogue Scales (VAS) to rate pain and feelings. • Pain Disability Index (PDI) • Word fluency-controlled oral word association test. • Chronic Pain Acceptance Questionnaire (CPAQ) • Beck Depression Inventory-II (BDI-II) • Possible-selves interview. 	<p>Enmeshment hypothesis and theories of self-discrepancy, self-regulation and hopelessness.</p> <p>Tested whether enmeshment of self and pain predicted adjustment (depression and acceptance) in a CP pop and found that the proportion of 'hoped-for' self-characteristics that could be achieved in the presence of pain predicted the magnitude of depression and acceptance scores. The findings are discussed with reference to the enmeshment hypothesis and theories of self-discrepancy, self-regulation and hopelessness.</p>
40] Sutherland & Morley (2008)	Mean: 45	<p>Participants: 82</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Hierarchical regressions</p> <p>Measures: Same as the above study including:</p> <ul style="list-style-type: none"> • Hospital Anxiety and Depression Scale (HADS). • Personal style inventory-II (PSI-II). 	<p>Aimed to replicate and extend the previous observations on the relationship between enmeshment of the self and pain and measures of adjustment (Morely et al., 2005) and to test the hypothesis that individual variation in motivation preferences interacts with enmeshment. The relationship between self-enmeshment and depression and acceptance was confirmed. When anxiety was considered there was no main effect for any of the self aspects but there were specific interactions between hoped-for (own) and (other) selves and two motivational preferences, autonomy and sociotropy. Self-regulatory theory</p>

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* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

42] Campbell & Cramb (2008)*	Range:33-66	<p>Participants: 12</p> <p>Design: Cross-sectional</p> <p>Qualitative Analysis: Thematic content analysis</p> <p>Measures: Qualitative Semi-structured Interviews</p>	<p>Three main themes regarding adaptation emerged: 'dependence and social withdrawal', 'being normal in comparison to others' and 'striving for self-management', which contained aspects of coping and control.</p> <p>Biomedical model, helplessness and hopelessness.</p> <p>-Rather than exhibiting pain behaviour, participants actively masked their pain to appear as the person they were before they experienced pain. However, this created tension and conflict within themselves, as they had to wrestle with a changed self. Such change produces feelings of loss for their previous self and former way of life.</p> <p>Coming to terms with pain represents accepting one will never return to their old pre-pain self and way of life, but have gained the ability and self confidence to move on or co-exist with their pain, which often takes years to achieve.</p>
41] Miles et al (2005).	Range:21-84 Mean: 55.6	<p>Participants: 29</p> <p>Design: Cross-sectional</p> <p>Qualitative Analysis: Grounded Theory</p> <p>Measures: Open-ended interview</p>	<p>A model depicting the basic social psychological process of maintaining a normal life through constraint was developed.</p> <p>Four coping categories: 2 modes of acceptance (assimilation and accommodation) and 2 modes of resistance (confrontation and subversion) to the limitations of pain. 'Relationship between constraint perceived impact and coping with CP'.</p> <p>The desire to retain pre-pain normal lifestyles my underlie people's use of coping strategies that exacerbate pain intensity and pain related disability.</p>

Key: CP = Chronic Pain

* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

Table 4: Summary of studies that make reference to psychological flexibility

Table 4: summary of studies that make reference to Psychological Flexibility

Author and Title	Age in Years	Methodology	Key Themes & Theories Mentioned
49] McCracken & Vowles (2007)*	Mean: 47.5	<p>Participants: 120</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Correlations</p> <p>Measures:</p> <ul style="list-style-type: none"> • Brief patient background inventory. • Brief Pain coping Inventory-2 (BPCI-2) • Chronic Pain Acceptance Questionnaire (CPAQ) • Pain anxiety symptoms scale (PASS-20) • Mindful attention awareness scale (MAAS) • British Columbia Major Depression Inventory (BC-MDI) • Sickness Impact Profile (SIP) 	<p>Psychological Flexibility (acceptance, mindfulness, values and cognitive diffusion) demonstrated significant positive relationships with eight measures of functioning whilst Pain Management strategies accounted for significant variance in none.</p> <p>This process (a blend of the above constructs within psychological flexibility) is significantly related to pain functioning in CP.</p>
51] McCracken & Keogh (2009)*	Mean: 46.6	<p>Participants: 125</p> <p>Design: Cross-sectional</p> <p>Quantitative Analysis: Correlations</p> <p>Measures:</p> <ul style="list-style-type: none"> • the Anxiety Sensitivity Index(ASI) • The British Columbia-major depression inventory (BC-MDI) • Chronic Pain Acceptance Questionnaire (CPAQ) • The chronic pain values inventory (CPVI) • The mindful attention awareness scale (MAAS) • The pain anxiety symptoms scale (PASS-20) • The sickness impact profile (SIP) 	<p>Results suggest that Anxiety Sensitivity (or fear of anxiety) may amplify the impact of emotional distress on patient functioning in CP and that processes of acceptance, mindfulness and values-based action (i.e. <i>psychological flexibility</i>) may reduce this effect.</p> <p>This paper also mentions <i>experiential avoidance</i> which is derived from the model of ACT</p>

Key: CP = Chronic Pain

* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

<p>50] McCracken & Vowles (2008)*</p>	<p>Mean:48.1</p>	<p>Participants: 155 Design: Longitudinal. Two time points averaging 18.5 weeks. Quantitative Analysis: Paired t-tests, Correlations and Regressions Measures:</p> <ul style="list-style-type: none"> • Chronic Pain Acceptance Questionnaire (CPAQ) • Chronic Pain Values Inventory (CPVI) • Pain Anxiety Symptoms Scale (PASS-20) • British Columbia Major Depression Inventory (BC-MDI) • Sickness Impact Profile (SIP) 	<p>Correlation analysis showed that acceptance of pain and values based action measured at time 1 were significantly correlated with pain, pain-related distress, pain-related anxiety and avoidance, depression, depression-related interference with functioning, and physical and psychosocial disability measured at time 2.</p> <p>Regression models showed that combined acceptance and values-based action accounted for between 6.5% and 27.0% of variance in 6 key measures of patient functioning later in time.</p> <p>Results also encourage continued applications of a functional contextual model of psychopathology, the model underlying ACT and related approaches such as CCBT.</p>
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Key: CP = Chronic Pain

* = Results of these studies support the notion of contextual acceptance-related approaches such as Acceptance and Commitment Therapy (ACT) or Contextual Cognitive Behavioural Therapeutic approaches in order to facilitate positive adaptation.

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Individual experiences of an acceptance-based pain management programme: An interpretative phenomenological analysis.

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Abstract

Acceptance of pain has been found to play an important role in adjusting to chronic pain and the evidence-base is growing with regards to the effectiveness of acceptance-based interventions such as Acceptance and Commitment Therapy, Mindfulness and Contextual Cognitive Behavioural Therapy within pain management settings. Despite the growing interest in such interventions, previous studies into acceptance-based pain management programmes are quantitative and the exact processes at work during such programmes remain unknown. This study aims to add to previous quantitative research in the area by qualitatively exploring individual experiences of attending an acceptance-based pain management programme and identifying the key constituents of the programme that participants felt facilitated change. Semi-structured interviews (n=6) were analysed using interpretative phenomenological analysis and five themes emerged: *'I'm not alone, others understand my pain'*, *'Freedom from pain taking over'*, *'A new self – one with pain'*, *'parts of the programme participants felt facilitated change'* and *'exercise is possible'*. These findings are then considered in relation to past research and relevant constructs in the literature. Implications for future research and clinical practice are also discussed alongside participant reflections and suggested areas for improvement.

Keywords: pain, acceptance, experiences, word, interpretative phenomenological analysis.

Introduction

Chronic Pain (CP) is recognised as sporadic or constant pain or discomfort lasting for more than 3-months (Elliot, Smith, Penny, Smith & Chambers 1999), and individuals invest considerable efforts searching for solutions that are predominantly pharmacological or involve avoidance of pain-provoking activities (Davies, Crombie, Macrae & Rogers 1992). These approaches are often unsuccessful and lead to further perseveration in these areas, which creates more distress, disability and preoccupation with pain (Aldrich, Eccleston & Crombez, 2000). Hayes & Smith (2005, p7) describe how *“attempts to ‘get rid of pain’ only amplifies it, entangles you further in it and transforms it into something traumatic”*. Acceptance of pain, defined as a willingness to experience pain without attempts to control or avoid it, appears to play an important role in adaptation to CP (e.g. McCracken, 1998). Its association with goals, attention-to-pain, coping, psychological flexibility (mindfulness, values and cognitive defusion) and identity, supports the use of acceptance-based approaches such as Acceptance and Commitment Therapy (ACT), Mindfulness or as applied to CP Contextual Cognitive Behavioural Therapy (CCBT) (Mathias & Parry-Jones, 2010).

Cognitive Behavioural Therapy (CBT) has efficacy for adults with CP, however, the processes underlying treatment effects remain unclear (Keefe, Rumble, Scipio, Giordano & Perri, 2004). This has generated interest into how thoughts, beliefs and other psychological experiences impact upon behaviour, as the cognitive model postulates that individuals' interpretation of events/situations can influence feelings and behaviour (Beck, 1976). For example, catastrophising is strongly correlated with depression and CP (Jensen, Turner & Romano, 2001). CBT's cognitive component aims to modify or replace cognitions, affective experiences, and behaviours that have become maladaptive (White, 2001). Thoughts, emotions and

behaviours are monitored to recognise and expose maladaptive cyclical relationships between emotion, pain, distress, environmental influences and psychosocial factors (Keefe, Dunsmore & Burnett, 1992). CBT's behavioural element can help replace maladaptive strategies with more adaptive 'well' behaviours (Sanders, 1996) via contingency management in areas such as sleep hygiene, medication use, graded exercise and pacing to increase activity. Pacing activity (higher activity levels with little avoidance) has been found to demonstrate better physical and emotional functioning and acceptance of pain (McCracken & Samuel, 2007).

A review by Longmore and Worrell (2007) found that cognitive-components were not superior to behavioural ones in the achievement of successful treatment outcomes. It has been argued that treatment may not need to focus on the logic or semantic meaning of thoughts and beliefs to be effective, but rather may focus on ways in which thoughts and beliefs have their impact on functioning (Hayes, Strosahl & Wilson, 1999). This highlights the importance of looking at context (historical and situational) where distressing or discouraging psychological experiences occur as a way to understand "functions" or interrelations with behaviour (Hayes, 2004). Recently there has been a move towards promoting acceptance or the willingness to experience pain or other distressing events without attempts to control them; reflected by the development of 'third wave' approaches such as ACT, Mindfulness and CCBT.

The ACT model includes six-core therapeutic processes: *Acceptance* being present (an aspect of *mindfulness*), *cognitive defusion*, *values*, *committed action* and *self-as-context* (Hayes et al., 1999). Within ACT, individuals with CP are encouraged to consider current modes of coping, and to evaluate their effectiveness. Unhelpful strategies are identified, particularly those that relate to avoidance (*i.e.* thought

suppression, social withdrawal, mind altering substances *etc*). *Mindfulness* skills are taught to facilitate the ability to be 'in the present moment', rather than dwelling on past experience or future scenarios. ACT also involves cognitive defusion, that is, reducing the focus on the 'content' of thoughts, and there is an acknowledgment that 'minds' will generate thoughts continually, although they are not necessarily reflective of objective reality (Hayes & Smith, 2005). *Values* represent chosen ways of living that are meaningful to the person, and provide a direction in life, not based on the reduction of psychological symptoms (Hayes & Smith, 2005). They are aligned with actions that have meaningful purposes to create *value-based action*, rather than the elimination of unwanted experiences (Hayes et al., 1999; 2004). '*Self-as-context*' (whereby the self is acknowledged as a conscious vessel that contains private experiences) is also essential as CP can have a negative impact on individuals' sense-of-self (Smith & Osborne, 2007).

Mindfulness has been found to have a beneficial role for individuals with CP when considered in its own right. Statistically significant reductions in measures of present-moment pain, negative body image, inhibition of activity by pain, symptoms, mood disturbance and psychological symptomology (anxiety and depression) have been found for individuals with CP following Mindfulness Meditation Training (Kabat-Zinn, Lipworth, & Burney, 1985). These improvements were maintained up to 15-months post-training for all measures except present-moment pain. McCracken, Gauntlett-Gilbert and Vowles (2007) also found mindfulness to account for significant variance in measures of depression, pain-related anxiety, physical, psychosocial and 'other' disability. In each instance greater mindfulness was associated with better functioning. This supports Seigel's (2005) findings that

mindfulness practice can be fruitfully combined with other psychotherapeutic interventions to treat psychophysiological difficulties.

There is growing evidence for the effectiveness of acceptance-based approaches for individuals with CP (*e.g.* Dahl, Wilson & Nilsson, 2004; McCracken, 2005; Wicksell, Melin & Olsson, 2007; Geiser, 1992). Changes in acceptance during an acceptance-based Pain Management Programme (PMP) have been related to changes in depression, pain-related anxiety, physical and psychosocial disability, physical task persistence, and these have been shown to persist at 3-months post-treatment (McCracken, Vowles & Eccleston, 2005). Changes in acceptance and catastrophising have also been found to account for significantly greater variance in these outcomes than that accounted for by changes in pain intensity alone (Vowles et al., 2007a). ACT interventions have also led to significant improvements in pain, depression, pain-related anxiety, disability, medical visits, work status and physical performance (Vowles & McCracken, 2008). Furthermore, Vowles, Wetherall, Loebach, and Sorrell (2009) report how the findings of two-pilot studies support the feasibility of acceptance-based treatment for individuals with CP and suggest that effectiveness rates compare favourably with CBT. Although the literature provides evidence for the effectiveness of ACT-consistent treatments for CP, Vowles et al. (2009) address the need for further research within pain-management settings, where treatment is generally time-limited, multi-disciplinary and outpatient.

Acceptance, when defined functionally and contextually, appears to be a key process in treatment outcome and behaviour change in individuals with CP (Vowles et al., 2007a). However previous studies have been quantitative, and there may be a number of other processes that facilitate change within acceptance-based PMPs. For example, acceptance and values-based action have been associated with improved

outcomes (Vowles & McCracken, 2008) and the inclusion of a values-component within an ACT-based intervention led to significantly greater pain tolerance than an acceptance-component alone (Bransetter-Rost, Cushing & Douleh, 2009). High levels of pain-relevant social support can also buffer the relationship between poorer self-appraised problem-solving competence, and depressive symptoms (Kerns, Rosenberg & Otis, 2002). Qualitative inquiry can facilitate further exploration into these processes and it has been suggested that the next generation of research into therapies for CP will focus on the specific processes involved during treatment (McCracken et al., 2005). Vowles, McCracken & Eccleston (2007b) argue that processes such as acceptance need to be perused empirically, both in terms of its veracity, and how best to address it in clinic. Studies that confirm the particular treatment components that lead to success and address the processes by which participants improve, appear to be absent from the evidence-base (McCracken et al, 2005). Vowles et al (2007a) feel that the challenge for future treatment development is to refine the most effective, flexible, and durable behaviour change. An acceptance-based approach with its particular view of private experiences provides a promising base for further therapy development (McCracken et al., 2005).

This study aims to qualitatively explore individual experiences during a Community Outpatient Acceptance-Based PMP and explore the specific constituents that individuals feel may have facilitated change in any way. Interpretative Phenomenological Analysis (IPA) (Smith & Osborne, 2003) was chosen to gain in-depth, ideographic accounts of participant's 'lived experiences' (Smith, Flowers & Larkin, 2009) as it enables key themes to be identified within participant accounts, including similarities and differences between perspectives.

Method

Methodology

IPA combines Phenomenology, based on Husserl's philosophy which is concerned with individual's perceptions rather than the development of objective accounts and Symbolic Interactionism, which proposes that meanings are the result of social interactions, and occur through a process of interpretation (Smith, et al., 2009). IPA involves ideographic inquiry, where each participant account is examined in great detail as a unique entity before a move to more general claims are made. IPA is more than a post-data collection analytic method and Smith et al's (2009) book influenced the development and supervised refinement of the interview schedule (*Appendix-1*).

IPA involves the researcher's reflections into their own biases, preconceptions, and values, and this interplay between participants' interpretation of their experiences, and the researcher's own interpretation of the accounts is known as the 'double hermeneutic' (Smith et al., 2009). With this in mind, the primary researcher (and interviewer) was a trainee clinical psychologist, who was supervised by a facilitator of the acceptance-based PMP in part-fulfilment of a doctorate in Clinical Psychology. The primary researcher had a particular interest in ACT and Mindfulness-based interventions for CP and acknowledged a pre-existing expectation of their merits.

The Acceptance-Based PMP

The acceptance-based PMP contained a combination of CBT, Mindfulness and ACT-components that focused on pain-based education, pacing, goal-setting and values, exercise/movement, mood management and mindfulness (as a core component). It was co-ordinated by a multidisciplinary team (which comprised a Clinical Psychologist, Physiotherapist and Clinical Nurse Specialist) following an individual multidisciplinary assessment process. After an introductory day, individuals who

'opt-in' (maximum n=12) attend weekly (6-hour) group sessions for a total of 8-weeks. Follow-up monitoring/support sessions are held 3, 6 and 12-months later.

Participants

Participants (n=6) were white British females in middle-adulthood, aged 46-64 and had been experiencing pain over a range of 1.5-10 years. This was the intended sample size as it is normative for IPA due to the detailed analysis of each case (Smith & Osborne, 2003). These participants were adults with chronic non-malignant pain and a willingness/interest in learning about the self-management of CP. All participants had stopped paid employment due to their pain except one who worked a day a week. Participants had no previous experience of psychological interventions for pain except one who attended 5-individual psychological pain-management sessions before the PMP. All participants were not felt by staff to have significant psychological co-morbidity that would affect their ability to attend the PMP. Participants' pain ranged from previous trauma and lifting to ongoing disease processes. Two-participants were awaiting further medical interventions and investigations. All participants were considered by staff to have CP associated with high levels of distress and disability.

After local ethical approval had been secured, research was carried out in accordance with universal ethical principles (Emanuel, Wendler & Grady, 2000). Participants were approached by the first author during the final week of the PMP, informed about the study and asked if they would consider participating. Information sheets and consent forms were administered and appointment times for semi-structured interviews during the next 1-2 weeks were scheduled at participants' convenience. The 6-participants in the study represent the 6-individuals (out of an initial 10 who started the PMP) who were present during its final day. All 6-

participants provided informed consent had attended the majority of the 8-programme sessions (range 7-8). With consent, participants' General Practitioners were informed of their involvement in the study as requested by Ethics.

Data Collection

Data were collected through semi-structured interviews using the interview schedule (*Appendix-1*) as a guide. Participants were encouraged to talk as widely as possible about their experiences of the PMP and the constituents that they felt facilitated change in any way. The interviews were semi-structured and although direct questions about acceptance and other mindfulness related concepts were not posed, they were explored when raised by participants. At the end of the interview, participants declined the offer of meeting with a member of the PMP-team, as they did not feel that anything potentially distressing had arisen. Nevertheless, participants were provided with the researcher's contact details should they wish to discuss anything further in relation to the PMP, the research or any worries or concerns. Participants were also asked if they would like to receive a 'summary of findings sheet' and telephone call in 4-months time to provide feedback regarding the findings. Interviews were audio-taped, transcribed by the researcher and served as raw data for the study (*Appendix-2*).

Analysis

Data were analysed using IPA and followed the four-stage process described in detail in Smith & Osborne (2003). Analysis began with a close interpretative reading of the first case where the researcher's initial responses to the text were annotated in one margin. These initial notes were translated into emergent themes at one higher level of abstraction and recorded in the other margin. The themes were then interrogated in order to make connections between them. This then resulted in an arrangement of

subordinate themes with identifying information – that is, where the instances supporting the theme can be found within the interview transcript. This process was repeated for each case (*Appendix-2*). After the analysis of each case, patterns were established cross-case and documented in a master-table of themes for the group. Two-research supervisors then reviewed and audited the themes to ensure they were well-grounded within the transcripts. The master-table was then transformed into a narrative account: the analytic account supported by verbatim extracts from each participant. All six-participants felt that a summary of the findings provided a true representation of their experience of the PMP. They were pleased that their suggested areas for improvement had been noted.

Results

Five themes emerged from the analysis of participant experiences, which will be considered in turn below. Participant's reflections and suggested areas of improvement have also been noted at the end of this section. Identifiable information has been changed to protect anonymity.

'I'm not alone others understand my pain'

Despite initial apprehension about meeting others, the support, normality and validation that listening to other people's experiences provided was invaluable. Participants described how they no longer felt that they were alone and experienced a sense of relief that others understood what it was like to have CP:

Helen: 'it's wasn't just you it was everybody in the group, they've all experienced the same um feelings at some time or another'..... 'it was good because for once, for one day a week you got somebody who understood what you were going through' 'the best thing for the lot of us was finding that [...] there was somebody else going through it, you weren't just on your own'.

Prior to attending the PMP, such validation, and being believed, appeared to have been absent:

Melany: 'I've often said, particularly to the family...I just wish you could feel it for 5-minutes because you can't explain it to anybody'

Helen: 'people sort of tutted and looked at you as if you've got two heads because you look healthy, and [...]you haven't got an arm missing, or um a leg missing'

The feeling of others understanding pain extended to PMP facilitators through their provision of psycho-education regarding pain and mood cycles:

Ester: 'I'm understanding what it [pain] is and it's not damage, and um when you don't understand what something is you worry about it more'.....'there was a cycle and um catastrophising just brings more stress which brings more pain which brings you back to catastrophising you know, how um it's a vicious circle, the same with mood and anxiety brings on stress, brings on pain[...]it [the PMP] gets you out of that way of thinking'.

Bronwyn: 'I understood what [...] chronic pain was, which I'd taken in my own mind was something to do that how you weren't right upstairs'

Melany: ' I haven't linked my anxiety with pain before'..... 'the word catastrophising came up and keeps coming into my head when I get a little bit panicky'

Psychoeducation appeared to increase participants' understanding of themselves and facilitate the revision of core-beliefs about pain '*as damage*' and '*that you weren't right upstairs*'. Participants related to the concept '*catastrophising*' and its association with unwanted/distressing ('*stress*' and '*panicky*') feelings. Perhaps learning the term '*catastrophising*' further deepened participants' understanding of themselves.

'Freedom from pain taking over'

'Freedom from pain taking over' emerged post-PMP via positive acceptance of pain:

Bronwyn: 'you can do things that you like, still be in pain and still enjoy it'.

Melany: 'It's [the PMP] helped me mentally more than anything I think. I've just accepted that this is pain, this is chronic pain and I don't get too sort of built up about the thought of it, it would be great if it was relieved, that would be fantastic, that would be the best thing ever but I'm not banking on that anymore and I'm quite happy to feel that way now'.

Ester: 'these sessions having given me a sort of freedom from that really [pain taking over] I mean it's still there [pain], um but...'

Positive acceptance of pain appeared to be associated with an ability to co-exist with pain by being able to '*do things that you like, still be in pain and enjoy*' (Bronwyn). Ester's reference to sessions as providing a '*freedom from pain taking over*' implies a degree of empowerment which was echoed by other participants. Such empowerment appeared strengthened by an increased ability to control/cope with pain.

Bronwyn: 'you realise maybe it won't go away but you know you're happier with it, like you can sort of sort yourself out, you know cope with it'... 'I can sort of control it rather than the pain be there all the time, you know controlling me'.. 'because you could control it a little bit it was a good feeling, yes, something I wouldn't have been able to do before, well I hadn't been able to do it for 6 years'.

Here the focus is on the '*control*' or management of pain rather than attempts at the '*elimination of pain*' pre-PMP. The latter was illustrated through the multiple medical interventions participants described prior to their PMP-referral and their experience of powerlessness whilst searching for a solution:

Helen: 'they [reference to Health Care Professionals HCPs] didn't seem particularly bothered about it so they sent me to a physio[....]she said I'm not particularly bothered about your neck' 'I feel that nobody [reference to HCPs] is bothered'

Being passed around in the system (*'they sent me'*) appeared invalidating for participants (*'nobody [reference to HCPs] is bothered'*) and tied to difficult emotions such as self-blame and even questioning their own sanity.

Melany: 'I blamed myself'; 'when your pain's worse that you've done something more to make it worse'

Bronwyn: 'nobody believed me';.. 'are you actually telling me it is all in my mind?'; 'its been said I've been making it up and it's been awful' ... 'I think they [HCPs] thought it was all in my head'; 'the pain just took over, it had completely taken over'

Bronwyn's use of the word 'had' or past tense in relation to *'pain taking over'* highlights her experience of living with pain pre-PMP. It implies that pain was dominating her life before the PMP.

'A new self – one with pain'

There seemed to be a change in the way participants viewed themselves and their pain-situation after attending the PMP. This 'new self' appeared linked in some way with increased confidence and self-esteem:

Bronwyn: 'I can actually look forward to things now that before I used to think, oh I'll never be the same person again but I know that, but it 's made you a different type of person'.....'the biggest thing really is that it [the PMP] has given me the confidence that I'd lost[...], the confidence has made me a lot happier in myself'.

Brenda: 'its [the PMP] given me more confidence and self-esteem to manage to get things moving forward for myself, it makes me feel like I'm not crippled, I can do this'... 'I've got more confidence in myself to get up and get things moving[...] forward instead of sitting back thinking I can't do this'.

Bronwyn talked of being '*a different type of person*' since the PMP, and described how the PMP had helped her regain a confidence that had been lost (due to pain) and generated a more positive sense of self. Brenda also felt that the PMP helped her develop confidence in getting '*things moving*', and she compared this with her pre-PMP self that she portrayed as '*sitting back thinking, I can't do this*'. Participants' different outlook post-PMP is highlighted by Brenda's view of herself as '*not crippled*' and Melany's sense of '*peace with herself*' below:

'I'm patting myself on the back for coping with it [pain] because[...], I'd rather beat myself up and blame myself for things'... 'I don't keep up with others and I don't care about that anymore and if they don't quite understand why then that doesn't matter either and I don't worry and the pain management course has helped me to appreciate that too'... 'rather than think what I haven't been able to do, it's what I have been able to do, more content and satisfied, um at peace with myself'.

'Parts of the programme that facilitated change'

There were no negative changes reported as a result of attending the PMP and overall participants felt that change in the above areas was a direct result of attending the PMP. Bronwyn felt that change occurred early on, during a mood and pain psychoeducation session:

'when she [facilitator] said for the first [...] introductory day or the first session, you know the pain isn't going to go away but they can show us how to embrace it and deal with it'... 'I think initially

it's a disappointment but you know[.....]she went into [..] the pain circle, you know that um when the circle is there you know you sort of think oh yes that makes sense, um even if you can't get rid of the pain you can learn how to manage it you know how to stop before getting the pain, so in a way my pain has lessened because I've learned how to stop before it kicks in'.

Participants' sense of control over pain was enhanced by learning strategies such as 'relaxed breathing and meditation', which they adapted to suit their individual needs. The following example shows how meditation can be adapted to be more congruent with religious beliefs and how breathing and meditation can be applied within different contexts (*i.e.* to aid sleep, or during a pain 'flare-up').

Melany: 'I don't do the emptying the mind bit [.....] because of my religious beliefs I feel that can be quite a dangerous thing so I'd rather have other thoughts and ideas going on rather than having an empty space there'

Bronwyn: 'the relaxed breathing and the meditation and that sort of calmed it [panic attack] down in the middle of the night when you feel panicky'

Ester: 'the relaxation um breathing helps to cope with the pain, you know when it flares up'

'Exercise is possible'

Participants talked about the impact being able to exercise again had on their lives, which was a direct contrast to the avoidance of activity pre-PMP.

Ester: 'it was such a relief that [.....] exercise is possible' ... 'whatever I tried I seemed to make things worse, so I just gave up on exercise, and I knew that I was, with this deconditioning I knew, that I could tell that I was you know disintegrating'

Ester's analogy of 'disintegrating' is representative of more than just physical deconditioning due to avoidance and seems to fit with the disintegration of self. The term 'deconditioning' infers that Ester has identified with the PMP's terminology as it is not everyday language. Exercises within the PMP helped participants through their emphasis on the gradual execution of movement without '*overdoing it*'.

Brenda: 'some of the movements they were teaching us[.....]actually freed up the areas that had been in spasm for such a long time, she [Physio] was actually getting them to move without telling me to overdo it'

Melany: 'exercises where you're breathing in and out and stretching and cos it's good for your circulation and deep breathing at the same time'...'if you can't do it then you just[.....]visualise yourself doing the exercises, and that helps to break you in'

Helen: 'I found a lot of the Chinese exercises were good because you were doing stretching and things but you weren't doing it so it hurt, you did it slowly and gently'... 'I've now started putting the same principle of getting out of the chair of coming up from the sink, of coming up steadily'

Combining movement with breathing, or 'moving mindfully', was important for Melany and Helen. For example, the Chinese exercises (Qi Gong) work in conjunction with inhalation and exhalation. Helen's generalisation of '*coming up steadily*' from the chair to the sink highlights her ability to adapt in conjunction with pain. Participants found the concept of pacing an essential part of living with CP and it appeared to require some adjustments to the self:

Melany: 'the pain management course has helped me to...pace and be satisfied with less, not be a perfectionist which I tend to be'

A note relating to participants' reflections and their suggested areas for improvement:

Helen's quote highlights her changed relationship with pain after attending the PMP:

Helen: 'I know it [the PMP] doesn't, didn't do a lot with the pain, but it gave you a different look at things.'

Melany: 'through being interviewed I suppose I've been able to realise even more the positive effects and that I have improved[...] I have come forward'

Overall participants were pleased with the way the group was run and its content.

However they did make suggestions about the ways in which it could be improved.

Unfortunately some of these came down to funding issues such as reducing waiting times and making the group more widely accessible:

Bronwyn: 'It [the PMP] has been a great help, you know I think everybody should go on it, I don't think they should have to wait so long'....'if I could have done this 4-years ago I think, you know I would be in a different place today'....'they said that they're not going to get rid of the pain for you but you know the way they bring it over how different ways that you can cope with it in your everyday life, you know that's invaluable, I think everybody who is in pain should be able to get that information' .

Helen made a suggestion about increasing others awareness of CP:

'it's a pity that we can't somehow through the course make other people aware, a sort of sheet[...] to take home and give 'em that to read, um because they don't appreciate what it is because if you haven't had it, you can't'.

The PMP's supportive value was reflected by participants' lack of motivation to go out or continue with the exercises when the group stopped and suggestions were made about how to overcome this by combining exercise and socialisation:

Brenda: 'They'll come back and do it [exercise sessions] but they won't do it on their own, they feel like they've lost something, because all the sessions have stopped they've got no purpose to go out'.

Helen: 'we [fellow participants] could perhaps meet once every so often[...], like a little social gathering, if even for a quarter of a mile, or you know, cos I know some of them couldn't walk more than that'.

Discussion

Participants in this study provided a unique insight into the experience of being part of an acceptance-based PMP and therefore satisfied the aim of this IPA study. The five-themes will be considered in turn, to examine their links with theory and research. It is interesting that within each theme, participants placed their experiences of the PMP 'in context' (Hayes et al., 2004).

'I'm not alone others understand my pain'

The validation and support provided by meeting people who 'understood' CP was magnified by participant descriptions of how alone and different from others they felt pre-PMP; captured by Helen's analogy of having '*two heads*'. Social support was valued within every interview and supports the importance of interventions aimed at increasing adaptive pain-relevant social support (Kerns et al., 2002). The extension of this feeling towards PMP-facilitators through developing an awareness of the cycles of pain highlights the role psychoeducation and meeting others with similar experiences can play in increasing participant's understanding of themselves. The

revision of core-beliefs directly links to the cognitive component of CBT, however Melany's description of the way *'the word catastrophising'* comes into her head when feeling panicky implies the use of *cognitive defusion*; reduced focus on the 'content' of thoughts, an acknowledgment that 'minds' will generate thoughts continually, yet they are not necessarily reflective of objective reality (Hayes & Smith, 2005). Perhaps language used within the PMP (e.g. catastrophising) helped individuals distance themselves further from distressing thoughts. Links participants made between 'catastrophising' and distressing emotions such as stress and panic compliment the findings of Jensen et al. (2001) who found that 'catastrophising' was strongly correlated with depression and CP.

'Freedom from pain taking over'

Acceptance of pain during the PMP and the *'freedom'* this provided *'from pain taking over'* fits with the acceptance literature, whereby *'trying to get rid of your pain only amplifies it and transforms it into something traumatic'* (Hayes & Smith, 2005). Participants spent considerable time and effort pre-PMP searching for a solution highlighted through the multiple medical interventions they described (Davies, et al., 2002) and the distress emotions this evoked (Aldrich et al., 2000). Their search for a cure was associated with emotions such as self-blame and even questioning their sanity. Discussing concepts such as acceptance of pain alongside issues of control over pain was particularly interesting as acceptance implies 'a willingness to experience pain without attempts to control it'. Perhaps acceptance of pain does not mean substituting control for no control, but rather changing the focus of control from uncontrollable events (pain itself) to controllable factors (Hayes et al., 1999). Or perhaps lay people use the word 'control' when they actually mean acceptance or coping.

'A new sense of self – one with pain'

This theme supported the *'self-as-context'* therapeutic process of ACT (Hayes et al., 1999) as participants compared themselves with their pre-PMP selves. Brenda viewed herself as *'not crippled now'* and Melany as *'at peace'*, which demonstrates the connection between physical disability, state of mind/beliefs and acceptance of pain. This also implies living life in accordance with *values* (Hayes & Smith, 2005) and supports the inclusion of *values*-components within ACT (Vowles et al., 2008; Bransetter-Rost, 2009). Such positive changes to the self are encouraging given the potential detrimental effects CP can have in this area (Smith & Osborne, 2007). Changes to 'the self' were also related to increased confidence and self-esteem which compliments a dearth of literature which implies changes in these areas associated with acceptance of pain, even though 'self-esteem' was not measured directly. For example, acceptance of pain has been associated with reductions in depression, pain-related anxiety, physical and psychosocial disability and increased physical task persistence (e.g. McCracken et al., 2005; Vowles et al., 2008).

Participants view of what promoted change

Bronwyn's example of how change came about during a session on psychoeducation regarding mood and pain provides an excellent example of how ACT and CBT can work hand in hand. Acceptance of pain was discussed from the outset:

'when she [facilitator] said for the first, I think the introductory day or the first session, said you know the pain isn't going to go away but they can show us how to embrace it and deal with it'.

Although this was *'initially a disappointment'*, Bronwyn described the impact learning about the pain cycle had for her:

'that makes sense, um even if you can't get rid of the pain you can learn how to manage it you know how to stop before getting the pain, so in a way my pain has lessened because I've learned how to stop before it kicks in'.

Bonwyn's description of 'pain cycle' epitomises CBT's (Beck 1976) identification of maladaptive cyclical relationships that exist between emotion, pain, environmental influences and psychosocial factors (Keefe et al., 1992). Relaxed breathing and meditation were also felt to facilitate change by increasing individuals' ability to manage or control their pain. Although relaxed breathing is also used within CBT, its combination with meditation is used frequently in mindfulness-based interventions (Kabat-Zinn et al., 1985; McCracken et al 2007; Seigel, 2005). Mindfulness was a core PMP-component: as well as meditation practice, it was integrated into exercise and movement sessions and discussions of how people get 'stuck' with focusing negatively on the past or predicting the future in a way that entraps the individual in pain-mood cycles.

'Exercise is possible'

All participants felt exercise was responsible for positive post-PMP change. The ability to exercise contrasted greatly with participants' tendency to avoid pain-provoking activity before the PMP (as found elsewhere, Davies et al., 1992). Participants valued the slow and gentle execution of movement delivered in a non-pressured manner '*without over-doing it*'. ACT formally recognises the importance of language, such as '*deconditioning*' in facilitating change (or stuckness). References to Chinese exercises and the importance of 'mindful movement' provides further support for mindfulness-based approaches for individuals with CP (e.g. Kabat-Zinn et al., 1985). The idea of pacing to increase activity fits with the behavioural component of CBT (Beck, 1976; Sanders, 1996) and its links with better physical and emotional

functioning and acceptance of pain (McCracken & Samuel, 2007). The ability to pace and be satisfied with what was achieved was also tied to some adjustments to the self as stated by Melany (e.g. *'not being such a perfectionist'*) which highlights the importance of the self in adjustment to CP (Hayes et al., 1999; Mathias et al. 2010).

A note relating to participants' reflections and their suggested areas for improvement

Although the PMP *'didn't do a lot with the pain'* (Helen), it did bring about a changed relationship with pain captured by the above themes. Comments regarding areas for improvement, namely, availability and increasing others awareness of CP deserve thorough consideration. The motivational element the group provided is also important for future service provision:

'They'll come back and do it [exercise sessions] but they won't do it on their own, they feel like they've lost something, because all the sessions have stopped they've got no purpose to go out'.

The PMP appears to have filled a hole in participants' lives created by pain, and when it ends they are left with a sense of vacancy/emptiness. Meeting up to socialise and exercise post-PMP could possibly be incorporated into the end of the PMP.

Limitations and suggestions for further research and interventions

It is possible that participants may have viewed the main researcher as being in some way allied to the programme, due to supervisory links with one of the facilitators (second author). This may have influenced reports of their experiences. However, their *'suggested areas for improvement'* suggests that participants were not impeded in their accounts.

Caution should be taken in any claims made from the study. The sample size was small, contained only white British females with a limited age range. However, as participants spoke similarly about the PMP and with such intensity, its impact is suggestive of wider applicability. It would be useful to repeat the study with a different acceptance-based PMP and to conduct a subsequent study with purposively sampled participants (in terms of age, class, ethnicity and geographical region) to test the breadth of possible applicability.

Although the qualitative IPA methodology yielded rich data regarding participants' experiences of the PMP, findings were not intended as an evaluation of the efficacy of the programme. In particular, it is not possible to accurately chart changes over time. Participants' subjective experiences within the present study could be extended to incorporate PMP facilitators' views of what promotes positive change, or through participant observation whereby the researcher could become part of the PMP and its processes.

This study could also be expanded by doing interviews, pre, during, post and possibly follow-up to further explore the processes of change. It could also be triangulated by collecting quantitative data to measure acceptance, control/coping, psychological distress, self-esteem, physical ability and quality-of-life. It would be beneficial if such measures were taken at start, finish and follow-up. Such longitudinal designs would allow deeper consideration into the mechanism of change and how this develops over time. The addition of a control group (such as a waiting-list-control) would also enable more solid conclusions to be made.

The findings of this study can be used to inform the future development of PMPs. The importance of pacing activity which involves goal-setting, mindfulness (breathing and movement) which involves focusing attention in the present moment,

acceptance of pain, proactive coping strategies and self-identity provides support for Mathias & Parry-Jones (2010). Additional clinically relevant findings were the importance of pain-relevant social support (Kerns et al, 2002), psychoeducation about cycles of pain and mood (Beck, 1976), pain language/terminology in reducing distress (Hayes et al., 1999) and the 'self' experiencing pain.

Conclusions

Exploring participant experience of attending an outpatient acceptance-based PMP and their view of what enabled change provided a unique insight into the multifaceted construct of acceptance. Participants felt that the PMP fostered the positive acceptance of a 'self with pain', an increased understanding of themselves and the ability to cope with pain through the provision of strategies such as, mindful movement, meditation, relaxed-breathing and pacing activity. Findings support the use of qualitative methodology in further understanding the processes involved in promoting positive change and acceptance and, thus, aid the development of clinical interventions for pain

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Appendix 1: Interview Schedule

1) Tell me what it was like to be in the group?

- a. What did being on the programme mean to you?
- b. What was your best/worst experience?

2) Do you feel that there have been any changes since starting the programme (e.g. in terms of the way you feel about yourself your mood your ability to get around)?

- a. Transfer of changes into daily life and what they are able to do, how they feel (emotionally and physiologically), what they believe about their pain, their view of 'self' and 'others'?
- b. Positive and negative change

3) How much of this change do you feel was a direct result of attending the PMP?

- a. attributable to other factors
- b. changes in other areas not mentioned or not thought relevant.
- c. If there were no changes ask why they think there weren't any

4) How do you think this change/these changes happened (or didn't happen).

- a. Was there are key turning point during the PMP
- b. Beginning, middle, end.

5) Did you find any part(s) of the programme more useful than others?

- a. What worked for them.
- b. large small elements

6) What will you take away from your journey through the group? a. key constituents in the programme e.g. mood management, pacing, mindful movement etc.

- b. Do they view themselves any differently since starting?

8) Is there anything about the interview that you would like to reflect on?

Appendix 2: [For examination purposes only] Sample Extract from Transcript and Initial Theme Extraction

The following extract is taken from the transcript of Bronwyn's interview. It is included in order to provide an example of (part of) the process of analysis. Only part of the interview is included in order to maintain participant confidentiality (with regards to possible identifiable information discussed towards the beginning of the interview).

The theme extraction for Bronwyn is also included under broad headings. Verbatim quotes that fall under theme headings can be traced back to the original transcript. The following notation is used to identify the placement of extracts in the original transcript:

(Page number, e.g. 1): (Line on the page, e.g. 1 refers to the first line etc)

i.e. 1:1.

A selection of the direct quotes that have been used throughout the results section have been highlighted within the transcript extract and underlined within the theme extraction document for ease of reference.

EXTRACT FROM
BRONWYN'S TRANSCRIPT

ATNR = Quotes used
in results section.

KEY:
NON-ITALICS = BRONWYN
ITALICS = THE RESEARCHER.

That's lovely, and um my next question is how much of this change do you feel was a direct result of attending the pain management programme here?

Um I think it's because I know now what it is, you know how why the pain's there, I think that was a great help but you know there were little changes I made myself but I think it's given me more of an insight really so that I know now that I'm doing right or, you know and also learning as a group, you know hearing other people say what they've done and how they cope, you know it's sort of suggestions really that you adapt for yourself. It has been a

Understanding of
- understanding

- Adapt to

- confidence

- Normalise

- Accept

~~should go on it, I don't think they should have to wait so long.~~

difficulties of source, practitioner

No that's the only downside isn't it, the waiting yeah.

I was saying, you know I ~~should have done this 4 years ago~~ I think, you know I would be in a ~~different place~~

+PC

Yes, isn't it amazing when you know when we do find something then that everything does really click?

Yes, I'm not saying the pain, you know that ~~it's not going to get rid of the pain for you~~ but you know the way they bring it every day, you know that you can cope with it, you know ~~everybody else you know that's inevitable, I think everybody who is in pain should be able to get that~~

Accepted
in it
if here
isn't

Um, that's as you say because knowing then that maybe it is going to be with you, the pain, you know I suppose you reach a sense of ok, what can I do?

Repetition
about it's awful
to every
before
searching for a
answer

Yes, yeah, because deep down we all think there must be something somebody can do, you know to help, um well you obviously think of getting rid of the pain but when ~~you realise maybe it won't go~~

Accepted

~~away but you know you're happier with it, and you can sort of sort yourself out, you know or cope with it~~ because I think judging from what everybody else said, you know the pain does actually make you feel very, very low in yourself, you know you've got no confidence, like I know that when I

Med
didn't
cope
with
it

go out I'm going to suffer, you know so it tends to make me not want to go out, but uh B suggested, you know go out for an hour or 2 hours and then you know gradually build it up, padding.

accept

And did the group help with that process at all, that process of maybe thinking about, ok this is with me and oh I suppose maybe embracing it in anyway, did it help with embracing your pain at all as well as controlling it?

Yes, yeah because you know when she said for the first, I think the introductory day or the first ~~session~~ you know the pain isn't going to go away but they can show us how to embrace it and ~~deal with it~~

naming pain
early on in
the program
the concept
of pain
not going
away was
introduced

How did that feel when they said that to you?

Um I think initially it's a disappointment but you know you then go, she went into the, you know the pain, the pain circle, you know that um when the circle is there you know you sort of think oh yes that makes sense, um even if you can't get rid of the pain you can learn how to manage it you know how to stop before getting the pain, so in a way my pain has lessened because I've learned how to stop before it kicks in.

disappoint
before
understand
acceptance
as learn
how to
cope with
pain

Empowerment

at least
in imp.

all
wanted
any
for
pain
circle

~~XXXXXXXXXX~~

~~XXXXXXXXXX~~

Mm, mm, that certainly sounds like that's been very helpful for you as well to enable you to do things. How do you think these changes happened, was there any key turning point during the pain management programme?

4
5
6
7
understand
relief
addition

4 Um I think from the very beginning you know it was such a relief to know that I wasn't making it up and other people felt the same, other people had the same symptoms as I did, you know and you think, oh you know I'm not on my own which was a nice feeling you know because then you can ask advice or they put a problem up and you can see yes that's like I feel you know that problem I've had many a time, and then she was working out you know how to get out of the cycle really, so I found it very, very helpful.

validation
normalisation
not isolated
can relate

techniques

And were there, were there - so it was from the very beginning and did it build at all during the programme?

Yes, yeah.

Um and then or did you find it just tapering off a bit or did you feel that it was...

13
14
17
18
19
dance
MP

13 No, no it was building up all the time because to start off with you thought, oh I wonder if that would work you know, and then you try it and then you realise yes it does work and then you get knocked down again, you know you have a pain flare up or whatever, um but you've always got that knowledge or information that if you try it again, you know, so it did get better as the programme developed, you know every session really I used to love the exercise because I had stopped exercising because before the accident I used to go to the gym twice a week, I used to go swimming, I've tried going to swimming but it just aggravated the pain, but you know B has mentioned that if you go in and not do as much or I think it might be to just, you know relax in the water even, and then build it up slowly, so that's something I want to try but not in this cold weather.

skeptical
discover
before P
before
gym
pacing

Yes, wait 'til it warms up a bit! And were there parts of the programme, you've mentioned a few already, that were more useful than others, you mentioned um the (?) exercise, that was particularly...

25
26
dance
MP

25 Yes I found that very helpful because like I said I had actually stopped doing everything, you know and gradually I've been going for walks you know just down the road a little bit and uh even though I'm in pain when I actually do walk, um I've gradually been able to build up how long I can go out for a walk for.

pacing

That's great.

31 Because before you used to know it was all in your mind that bit I'll go for a walk but I've got to come back and I'm going to be in pain, but you know now you can sort of gradually build it up even though you're in pain you enjoy it, that's another lesson we learnt you know.

walking
present
pacing
even though you're in pain you enjoy it
acceptance + more

Um that's interesting.

34
dance
MP

34 Yeah you can learn about, you can do things that you like, still be in pain and still enjoy it, yeah.

on
repeating
in daily
activity

Mm and that seems to have made a real difference for you.

Yes, yea, yea.

And were there any other elements of the programme, your mentioning changes about mood and I wondered if there were parts of the programme that maybe looked at that in any way?

4
5 Um, just understanding why you know the pain used to make me feel miserable you know, and then understanding the cycle of the pain making you, your mood down, your down mood making the pain worse sort of thing you know, and just trying it was quite interesting to know that it was normal you know, to feel like that so you know understanding something gives you confidence which boosts your mood really.

Understand by pain effects of mood - normal
- capture in one sentence

And were there anything else, any other aspects within the programme that you felt were maybe more useful than others, whether there was maybe large bits of the programme or even small elements within the programme?

12 I think meeting people as well you know every week, um and sharing your experiences and knowing that other people are coping with it as well.

sexualisation
- normal

Mm.

15 It makes you, I don't know I don't want to sound morbid really but it makes you glad that you're not the only one that's suffering you know...

- Normal
- soc. compa

Yes absolutely, and it seems that you all get on very well and you've all swapped numbers too I believe, yeah.

17 And I think you know the suggestion with the goals as well you know, for that's a good idea for something to work or look forward to, helps you cope when the pain is bad, you know it helps you cope knowing that you know you've got your little goal time to wait for and you're one step closer to it.

goals

To the goal setting as well, that's great. And now the programme is finished what will you take away from your journey with the group?

25 Um I don't know really it's just how it changed my life, the people that you meet and how I can actually look forward to things now that before I used to think on it it never be the same person again but I know that but you know it's made you a different type of person.

changes
my
life
-
uh
uh

new sense of self

-So it seems that you view yourself um quite differently then from starting.

30 Yes I don't think of myself as much of a failure anymore you know, because you do think you've failed, but uh you know, and also knowing that it's normal not to want the same amount of sleep as I used to, you know before I used to sleep for about 7 or 8 hours undisturbed sleep, but now you know I'm lucky if I get 2 or 3 hours, but um to be told that's normal you know.

adjusted sense of self
adjustable
action
eg sleep

So it seems that you're not comparing yourself then against what you believed to be, what you used to be. So do you have a new sense of who you are now?

35 Um different, I'm a different person, everybody says I'm a different person anyway but um you know to what I was, because I always used to work, work, work you know but now that's one of the nice

A different person repeats

things I think about having had the accident, I now have more time with my family, you know with my children and my grandchildren, because before I used to be working all the time.

Positives of having had the accident

And what is it that other people say they see differently in you now?

relationships changed?

Um what after the pain programme my husband says I'm a lot happier which I am, I feel happier you know, I just feel I understand what's happened, you know and I can't change it but there are things that I could change and I have tried you know to change things round, and yes I'm more confident in a way probably that's one of the most, the biggest thing really is that it's given me this confidence

5
6
7

in the end

and the confidence has made me a lot happier in myself.

That's lovely! Well um thank you for all your time and the very last thing to ask you is whether there's anything about the interview you'd like to reflect on, whether anything maybe came out that you thought, oh I didn't realise I felt that.

No, not really.

Or whether there was anything about the process of it?

I think I learnt how to relax as well, you know I was always wanting to do things and couldn't, you know that led to frustration because you couldn't do it as well as you could before, but I've learnt to relax a lot, again it makes you happier.

striving to do it led to frustration

That's great, and to ask you whether you still consent to take part in the study?

Yes.

And whether you wish to receive a summary of findings sheet in the post in April?

Yes, that would be interesting.

Brilliant, and what I'll do then is pop it in the post and it's whether you wish then to receive a follow up telephone call from me to see what you think of it really to get your final views.

Yes fine.

So I presume your number will be the same as the one I have I'm sure I have it there yes, 0000000

That's right.

And whether you wish to speak to any member of the pain management team now, ok. And yeah just to let you know that you can contact me or B on the numbers provided on the consent form if anything comes up for you between now and when I call you in April about the research, or anything, any general questions, and to just say a very big thank you for taking part.

~ Theme Extraction ~

Bronwyn's Themes:

The experience of being in the PMP

PAIN RELEVANT SOCIAL SUPPORT: 'very supportive' 3;17/ 'we um most of us actually you know uh supported each other you know uh with the symptoms as well' 3;25/

Normality and validation: 'it was nice to know that other people was experiencing the same symptoms as yourself' 3;19. 8;5. 'it was comforting to know that other people felt the same....depressed' 3;24/ 'I think the main boost was knowing that, you know the pain was real because I felt most people used to think it was all made up' 5;6/ 'it was such a relief to know that I wasn't making it up' 8;4/ 'I'm not on my own which was a nice feeling' 8;6./ 'sharing your experiences and knowing that other people are coping with it as well' 9;12./ 'knowing that it's normal not to want the same amount of sleep as I used to, you know before I used to sleep for about 7 or 8 hours undisturbed sleep, but now you know I'm lucky if I get 2 or 3 hours, but um to be told that's normal you know' 9;30./ 'glad that you're not the only one that's suffering you know...' 9;15

Socialisation: 'meeting people as well you know every week,' 9;12.

Understanding my pain psychologically: 'I understood what my pain was, you know I understood what chronic pain was, which I'd taken in my own mind it was something to do that how you weren't right upstairs' 3;17/ 'going through the stress and what causes the pain, and the pain flare ups and things like that it set your mind at ease' 3;27/

'knowing that there was such a thing as chronic pain and how it came about, and you know what triggers it off and things like that it gives you confidence' 4;7.

Psychological explanations and equating stress with pain flare up. 'the worrying about it (pain) makes it worse, yes, so you know it makes you bad tempered, it makes you um you know tired all the time' 5;7.

Something to look forward to every week: A goal: 'I think it was something it gave me something to look forward to every week' 3;35/ 'it gave you a goal each week to come to the clinic' 4;1/

Positive changes since the PMP

Acceptance: 'they said that they're not going to get rid of the pain for you but you know the way they bring it over how different ways that you can cope with it in your everyday life, you know that's invaluable, I think everybody who is in pain should be able to get that information' 7; 13. Repetitions about the PMP being available to everyone 7;7/ 'but when you realise maybe it won't go away but you know you're happier with it, like you can sort of sort yourself out, you know or cope with it' 7;20./ 'but you know now you can sort of gradually build it up (walking) even though you're in pain you enjoy it, that's another lesson we learnt you know' 8;31/ 'you can do things that you like, still be in pain and still enjoy it, yeah' 8;34./ 'I can't change it but there are things that I could change and I have tried you know to change things round' 10;5.

Changes to the self – a new self: 'I feel a lot better in myself now you know after the, after the pain clinic' 3;13./ 'it built up my confidence' 3;20 and 4;1 and 4;20 and 10;6/ 'the biggest thing really is that's it's given me this confidence that I'd lost, you know and the confidence has made me a lot happier in myself' 10; 7./ 'we were depressed' 3.25 said in past tense/ 'I feel confident now you know to go out' 3;33/ 'I'm a lot happier I'm a lot calmer' 5;6./ 'when I worked I couldn't do it (go for a lie down) and that's when I was in constant pain, it was day and night you know, but since I've been home I've been able to do something feel the pain coming on and then just have a, a break really and so I can cope with it a lot better' 6;34./ 'I've learnt to relax a lot, again it makes you happier' 10;15./ 'I feel happier you know, I just feel I understand what's happened' 10;4./ 'I'm a different person anyway but um you know to what I was, because I always used to work, work, work you know but now that's one of the nice things I think about having had the accident, I now have more time with my family, you know with my children and my grandchildren, because before I used to be working all the time' 9; 35./ 'I don't think of myself as much of a failure anymore you know' 9;29./ 'I can actually look forward to things now that before I used to think, oh I'll never be the same person again but I know that, but you know it's made you a different type of person' 9;25.

Increased sense of control: 'more in control' 4;20/ 'I can sort of control it rather than the pain be there all the time, you know controlling me' 4;20. 'It was a relief that you know, I could control it, yeah before I would have you know maybe just got up and worried about it, and, you know took a few tablets, you know, but because I could control it, it felt uh I had achieved something, you know sort of sense of achievement really' 5;1./ 'you know when you can do something to control it (pain) then obviously it makes you a happier person' 5;13./ 'now I sort of work it out, you know the different ways of doing things and I'm a lot calmer' 6;1./ 'the best thing to do when I am in pain is just to lie down you know just to lie down on the sofa and just uh not do anything for about half an hour or whatever, and then the pain goes as well as if you took tablets for it you know' 6;27/ 'because you could control it a little bit it was a good feeling, yes, something I wouldn't have been able to do before, well I hadn't been able to do for 6 years' 5;8.

Impact on other family members: 'my husband even said you know I'm a lot happier since I've been on the course' 4;5. 10;4/

How much of this positive change was a direct results of attending the PMP: 'it changed my life' 9.25./ 'I think it's because I know now what it is, you know how why the pain's there' 7;3./ 'I think that was a great help (knowing why the pain was there) but you know there were little changes I made myself but I think it's given me more of an insight really so that I know now that I'm doing right' 7;4./ 'suggestions really that you adapt for yourself' 7;7.

How did change come about on the programme?/helpful parts of the programme

Goals: 'the suggestion with the goals' 9;19./ 'it helps you cope knowing that you know you've got your little goal time to wait for and you're one step closer to it' 9;20/.

Relaxed breathing, meditation and exercise: 'the relaxed breathing I've found very helpful, the meditation and the little exercises' 4;23 / 'the relaxed breathing and the meditation and that sort of calmed it (panic attack) down in the middle of the night when you feel panicky' 4;27/ 'I used to love the exercise because I had stopped exercising' 8;18

The vicious cycle: 'working out you know how to get out of the cycle really, so I found it very, very helpful' 8;7./ 'just understanding why you know the pain used to make me feel miserable' 9;4./ 'understanding the cycle of the pain making you, your mood down, your down mood making the pain worse sort of thing you know, and just trying it was quite interesting to know that it was normal you know, to feel like that so you know understanding something gives you confidence which boosts your mood really' 9;5.

Pacing: 'The pacing, you know that seems to work, before I used to try, I used to carry on (e.g. of ironing) I would do it in one big bulk and that would result in a lot of pain' 5;17/ 'before I would have, you know carried on finished the windows but I did one or two, well I did two one day and stopped before the pain kicked in and you know I was able to carry on for a few more times you know like that and I didn't get the usual pain that I do' 5;21./ 'go out for an hour or 2 hours and then you know gradually build it up' 7;25. 'I had actually worked out before coming to the pain clinic I had had to um, you know cut my housework into um, spread it out over the week rather than have one day doing it' 5;26/ 'but then they went into more detail in pain management, you know about what pacing is, how you can stop before you actually go into a pain, so I think that was quite a valuable thing' 5;30./ 'I've tried going to swimming but it just aggravated the pain, but you know B has mentioned that if you go in and not do as much or I think it might be to just, you know relax in the water even, and then build it up slowly, so that's something I want to try' 8;19./ 'gradually I've been going for walks you know just down the road a little bit and uh even though I'm in pain when I actually do walk, um I've gradually been able to build up how long I can go out for a walk for' 8;26.

Change occurred early on: 'when she said (facilitator) for the first, I think the introductory day or the first session, said you know the pain isn't going to go away but they can show us how to embrace it and deal with it' 7;29. 'I think initially it's a disappointment but you know you then go, she went into the, you know the pain, the pain circle, you know that um when the circle is there you know you sort of think oh yes that makes sense, um even if you can't get rid of the pain you can learn how to manage it you know how to stop before getting the pain, so in a way my pain has lessened because I've learned how to stop before it kicks in' 7;33./ 'from the very beginning' 8;4./

Negative changes since starting the PMP

No negative changes: 'I can't really say there have been any negative' 6;6.

Areas for improvement: 'It has been a great help, you know I think everybody should go on it, I don't think they should have to wait so long' 7;7/ 'if I could have done this 4 years ago I think, you know I would be in a different place today 7;10.

Extended Discussion: Contributions to theory and clinical practice

Beth Mathias

Abstract

Findings from the Interpretative Phenomenological Analysis (IPA) study are considered in greater detail in terms of the contributions they make to theory and clinical practice. Each of the five themes ('I'm not alone others understand my pain', 'Freedom from pain taking over', 'A new self – one with pain', 'parts of the programme that facilitated change' and 'exercise is possible') will be examined to determine their theoretical fit with models of adaptation to chronic pain and their clinical implications. Findings and participant reflections will then inform service development and implications for future pain management research.

Introduction

Although IPA research cannot, and is not intended to be generalisable to the wider population, this 'phenomenological' approach provided a unique insight into individual 'lived experiences' of attending an acceptance-based Pain Management Programme (PMP). Therefore, although the aim was to explore a small number of individual experiences in detail (n=6), consideration of the thesis as a whole makes it possible to ponder how findings may link with previous research, models of adaptation and clinical practice.

Theoretical and clinical implications

I'm not alone others understand my pain

The importance of social support from others who understood chronic pain (from fellow group members to facilitators) was repeatedly mentioned by participants due to the sense of validation and relief that 'no longer feeling alone' provided. The emergence of this theme is especially important as the semi-structured interview did not ask any questions about peer support. Its importance is consistent within the wider literature regarding the beneficial effects of perceived social support which can enhance adjustment to chronic pain in chronic back pain patients (Li & Moore, 1998; Holtzman & DeLongis, 2007). The importance of social support for adaptation to chronic pain was not evident within the models uncovered by the literature review (Section-3) and was therefore not included in the proposed 'Adaptation to Chronic Pain' (ACP) model. However, it is important to

remember that this model summarises adaptation in the absence of psychological interventions such as PMPs. The findings here would suggest that social support plays an integral role in terms of adaptation within an acceptance-based PMP. The social aspect of the group appeared to provide more than just validation and support for participants. Sofaer, et al. (2005) recognised how socialisation can be instrumental in distraction from pain and essential for well-being. Clinically, being with similar others may go deeper than just the revision of core-beliefs (*e.g. it's not damage*) and may help in a process of redefining the self in relation to others. That is, an individual may view themselves as acceptable to others even though they have pain and all the limitations and emotions that go with a life of chronic pain.

Freedom from pain taking over

Participants described a 'freedom from pain taking over' by being able to accept their pain or '*do things that you like, still be in pain and still enjoy it*' and an increased ability to control/cope with pain: '*I can sort of control it rather than the pain be there all the time, controlling me*'. This finding provides support for studies identified in the literature review which found acceptance and control to be interlinked/complementary (McCracken, Spertus, Janeck, Sinclair & Wetzel, 1999; Esteve, Ramirez-Maestre & Lopez-Martinez, 2007; Sofaer et al., 2005) and challenged those that found acceptance to be more advantageous to control responses (McCracken & Eccleston, 2003; McCracken, Vowles & Gauntlett-Gilbert, 2007). However, as identified in the empirical discussion, this may be more to do with language and terminology used by lay individuals. The term 'control' may be used because it is more common than talking in terms of coping or acceptance, for individuals who have not developed the sophistication of academics in their use of language.

Acceptance may not mean substituting control for no control, but rather changing the focus of control from uncontrollable events (pain itself) to controllable factors (Hayes, Strosahal & Wilson, 1999). Participants' shift in focus from the 'elimination of pain' pre-PMP, to the 'control or management of pain' post-PMP may have been akin to a 'shift' along the ACP Model's continuum from *assimilation* to *accommodation* (positive acceptance); which concords with the Dual Process Theory (DPT, Brantstader & Renner, 1990). This shift may have reduced participants' attention to pain and subsequently their catastrophic thinking about pain (Crombez, Eccleston, Van Hamme & De Vlieger, 2008). The Goal Directed Motivational Model (Klinger, 1996; Klinger, Barta & Maxeiner, 1981) highlights how *acceptance* not only implies less attention to pain, but also makes it more possible to re-engage attention to daily activities and personal goals. This conceptualisation is supported by Viane, Crombez, Eccleston, Devulder & De Corte (2004) who found acceptance to be related to less attention to pain, more engagement with daily activities, higher motivation to complete activities and a better efficacy to perform daily activities. Support for the finding that preserving a positive life, despite the uncontrollable effects of pain, may best be achieved through the flexible adjustment of personal goals to current limitations (Viane, et al., 2004) is very important for clinical practice. It supports the inclusion of pacing and goal-setting sessions within PMPs and therefore may mediate the relationship between positive acceptance and management of pain.

A new self – one with pain

Changed goals from *assimilation* to *accommodation* may have also stemmed from deeper changes with 'the self'. Miles, Curran, Pearce & Allen (2005) discussed how an

individual's choice of coping mode (*assimilation, accommodation, confrontation or subversion*) depended on attempts to maintain 'normal' (pre-pain) identities and actions, or alter them. Retaining pain elimination as a primary goal has also been found to compromise emotional adjustment and eventually lead to self-pain enmeshment (Morley, Davies & Barton, 2005).

Participants within the IPA study described a 'new self – one with pain' (e.g. Bronwyn talked of being '*a different type of person*' since the PMP. This 'new self' was associated with increased confidence and self-esteem for many participants. It seems that the PMP facilitated an acceptance of not returning to the old pre-pain self and way of life and fostered the ability and confidence to move on or co-exist with pain, which often takes years to achieve. The PMP may therefore have enabled participants to become less enmeshed with pain (Pincus & Morley, 2001), reduced discrepancies between *actual* and *ideal* or *ought* selves (Higgins, 1987) and subsequently lessened affective distress (Carver & Sheier, 1998; Carver, Lawrence & Sheier, 1999).

Participants reflected on their pre-PMP and the post-PMP selves (e.g. '*no longer crippled*'). These comparisons provide support for 'the old you' and 'new you' identity elements of the ACP Model, identity's central inclusion and the four reviewed studies which outlined the importance of identity during adaptation (Morley, et al., 2005; Sutherland & Morley, 2008; Miles et al., 2005; Campbell & Cramb, 2008). Changes to the self appear essential in order for proactive goal-setting to begin. Both goals and identity were integral parts of the ACP Model (Mathias & Parry-Jones, 2010). Therefore

the importance of 'the self' during acceptance of pain supports the inclusion of PMP-sessions that look at the effects of pain on the person, in terms of effects on their activities, emotional world and thoughts/beliefs. It is essential that the 'self experiencing pain' as well as 'the pain itself' is addressed. Consideration of the self and ones relationship with pain could be enhanced through the completion of the possible-selves interview (Morley, et al., 2005; Sutherland & Morley, 2008).

Parts of the programme that facilitated change

The way acceptance and psychoeducation worked hand in hand (*e.g. its not going to go away, but this is how you deal with it*) and *'learning how to stop before pain kicks in'*) provides support for ACT and CBT as complementary approaches within PMPs. Relaxed-breathing and meditation appeared to facilitate a sense of control or management of pain, which supports the importance of including *mindfulness* components in interventions for individuals with chronic pain (*e.g. Kabat-Zinn, Lipworth & Burney, 1985*). Relaxed-breathing and meditation calmed Bronwyn's panic attack down in the middle of the night, which supports the role mindfulness can play (with *acceptance* and *values-based action*) in reducing the effects of *anxiety sensitivity* (McCracken & Keough, 2009). Participants' descriptions of how they adapted the strategies provided to suit their individual needs (*e.g. religious beliefs and context*) are already actively encouraged through regular reflection within the PMP. However, perhaps they could possibly be included within the programme after the presentation of a new technique.

Exercise is possible

Participants were relieved that 'exercise is possible' due to their prior tendency to avoid pain-provoking activity (e.g. Hayes & Smith, 2005; Arraras, et al, 2002). This tendency is captured within the *assimilation* part of the ACP Model, derived from the DPT (Brantstadter & Renner, 1990). The shift towards *accommodation* during individual's 'freedom from pain taking over' is evident through participants' ability to exercise even though they had pain. The 'mindful movement element' of the exercises discussed (e.g. Qi Gong) provides further support for the importance of mindfulness for individuals in chronic pain (e.g. Kabat-Zinn et al, 1985). The CBT notion of pacing (Beck, 1976) was particularly important for participants and requires the adjustment of goals. As outlined in the literature review, goals are very similar to *values* captured within the ACT model (Hayes et al., 1999) and *psychological flexibility* (McCracken & Vowles, 2007; McCracken & Vowles, 2008; McCracken & Keogh, 2009). That is, 'influences from important long-term goals as they are chosen ways of living that are meaningful to the person, and provide direction not based on the reduction of psychological symptoms' (Hayes & Smith, 2005). This link between *goals* and *values* fits with participant accounts as the goal-setting act of pacing seemed strongly linked with adjustments within the self (e.g. '*pace and be satisfied with less, not be a perfectionist which I tend to be*'). The association between an adjusted or 'new self' and re-engagement in daily activities is captured by the ACP Model. Clinically, this finding provides support for the PMP's inclusion of values-based exercises within goal-setting sessions. It also support the PMP's discussions about the role perfectionism can play in maintaining unrealistic expectations of the self, with inevitable lowering of mood and self-efficacy.

Service Development

The IPA study, and the studies within the literature review provide support for the utility of acceptance-based interventions, such as ACT, CCBT and Mindfulness, for helping people adapt to CP. The studied PMP's unique blend of constituents used from each of these orientations appeared clinically helpful for participants.

Bronwyn: 'they said that they're not going to get rid of the pain for you but you know the way they bring it over how different ways that you can cope with it in your everyday life, you know that's invaluable, I think everybody who is in pain should be able to get that information'

Unfortunately making the group more widely accessible and reducing waiting times are complicated by funding issues within the NHS. However, it may be possible to trial PMPs with a similar protocol in other locations throughout the UK and/or begin a number of groups run by different clinicians at the current Pain Management centre.

Helen's suggestion of increasing others awareness about chronic pain could be incorporated into the initial sessions of the PMP due to the important validating influence of social support. Perhaps a leaflet could be devised within PMP-sessions to aid discussion with family and friends outside of sessions. Discussions could then be fed back to the PMP whereby the facilitator could help with any issues that may have arisen. PMP facilitators currently give participants space to reflect on how family and friends have been following discussions about aspects of the PMP and CP. However, perhaps having a session within the PMP to specifically address issues regarding family and friends would be helpful. Alternatively, a group for friends and family of individuals in chronic pain could be run alongside the PMP. This could consist of 3-4 weekly sessions comprising,

psychoeducation regarding the vicious cycle of pain, an outline of the PMP's content that their friend/family member is undertaking and helpful ways of responding during 'pain flare-ups'. This 'friends and family group' could occur at the same time as the PMP and sessions could compliment each other with the aim of stimulating conversation at home about chronic pain.

The supportive and motivational value that the PMP provided was highlighted by participant descriptions of how they stopped exercising and socialising when the group stopped.

'They won't do it [exercise] on their own, they feel like they've lost something, because all the sessions have stopped they've got no purpose to go out'

This dependency on the PMP team, as well as on the group was apparent clinically. Facilitators could therefore incorporate additional sessions towards the middle to end of the PMP, aimed at preparing people for its end and create more independence rather than dependency. This could involve a structured arrangement for the 'first post-PMP get-together' and then a written plan/agreement for continuing with weekly exercises. This arrangement could therefore generate a continual support group for participants with the hope that this would continue long after the PMP has ended. Participants could be in charge of managing the focus and direction of this group. Regular follow-up sessions run by the Pain Management centre (at 3, 6, 12 months) could help manage issues that may arise within this support group. Follow-up sessions could possibly be brought forward so that they fall nearer to the end of the PMP (e.g. 4-6 weeks post-PMP). Perhaps a pain

service facilitated by a regular support group post-PMP that graduates of any PMP can attend would be the best way forward for optimal service development.

Implications for future research

The IPA study illustrates how qualitative methodology can further the PMP knowledge-base. Accessing the 'lived experiences' of participants attending the programme was facilitated through the researcher's own-knowledge and clinical experience during interpretation, analysis and reflection, during the research interviews and afterwards in the generation of themes (*i.e.* theoretically driven analysis). The interpretative aspect allowed for reflection about how participants achieved meaning, and made sense of their experiences. These accounts can help to refine protocols for ACT, Mindfulness and CCBT interventions within the chronic pain population. Taking individual experience into account is an important step towards informed practice in health care.

Despite the focus of IPA being on the interpretations of the analyst or 'the making sense of the individual participant accounts', the credibility of the findings were checked and approved by two-research supervisors and the original informants. Both credibility methods provided evidence that the researcher had not made connections where there were none as a result of previous reading and theoretical exploration in the area. The study did not however, involve the triangulation of finding e.g. cross-checking the results with external factors such as quantitative data. This would be easily accessible for the acceptance-based PMP as facilitators routinely administer a battery of measures pre and post group, then again at 3, 6 and 12 month follow-up periods. Measures currently

administered by the PMP are as follows: Brief Pain Inventory, Hospital Anxiety and Depression Scale (HADS), Pain self-efficacy, Beck Depression Inventory-Second Edition (BDI-II) and objective physical measures such as a 5-minute walk distance and 1 minute sit-to-stand frequency.

Constructs such as acceptance, control/coping, self-esteem and Quality of Life (QoL) could also be explored alongside qualitative methodology. Acceptance could be measured using the Chronic Pain Acceptance Questionnaire (McCracken, Vowles & Eccleston, 2004), control/coping using the Coping Strategies Questionnaire (Rosenstiel & Keefe, 1983), self-esteem and confidence using the Self-Esteem Scale (Rosenberg, 1965) and QoL using the WHOQoL-Pain (Mason, Skevington, & Osborne, 2008). All measures have good reliability and validity. It would be beneficial if such measures were taken at start, finish and follow-up. This longitudinal mixed (quantitative and qualitative) design would allow deeper consideration into the mechanism of change and how this develops over time. The use of process measures is particularly important in light of the favorable evidence regarding positive outcome in several areas of functioning following acceptance-based interventions (*e.g.* Kabat-Zinn et al., 1985; McCracken, Vowles & Eccleston, 2005; Vowles & McCracken, 2008). However, sample sizes should be large enough to ensure adequate power for conclusions to be drawn. The addition of a control group (such as a waiting list control) would also enable more solid conclusions to be made.

Concluding remarks

The main value of this study, is that it has 'given voice' to the participants of acceptance-based interventions. It has explored issues through their own words, phenomenological worlds, and frames of reference (rather than preconceived hypotheses). In so doing, the study has made a valuable contribution to existing theory, which is further strengthened by its links with the ACP model created entirely from an up-to-date review of models of acceptance and adaptation to chronic pain. However, the additional areas participants voiced as of great importance for adaptation during an acceptance-based intervention (such as, pain-relevant social support, psychoeducation and a freedom from pain taking over via positive acceptance of pain and proactive coping strategies) provide further support for the necessity of qualitative research for intervention studies.

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Section 6: Thesis Word Count

Main Abstract	296
Section 1: Ethics	
Word Count (excluding references, figures, tables and appendices):	2,859
Word Count (including references, figures, tables and appendices):	6,832
Section 2: Reflective Commentary	
Word Count (excluding references, figures, tables and appendices):	695
Word Count (including references, figures, tables and appendices):	695
Section 3: Literature Review	
Word Count (excluding references, figures, tables and appendices):	5,740
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Section 4: Research Paper	
Word Count (excluding references, figures, tables and appendices):	6,559
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Section 5: Extended Discussion	
Word Count (excluding references, figures, tables and appendices):	2,847
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