# **Necessary Components for Psychological Treatment of Chronic Pain:**

# **A Qualitative Comparative Analysis**

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D.Clin.Psy. thesis (Volume 1), 2020

University College London

## **UCL Doctorate in Clinical Psychology**

## Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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### Overview

The present thesis considers and utilises a relatively new form of meta-analysis, Qualitative Comparative Analysis (QCA), to understand the necessary components of psychological treatment of Chronic Pain (CP). This volume has three parts, a literature review, empirical paper and critical appraisal of the empirical paper.

The literature review considers existing research relating to CP models, theory and treatment as well as the background, principles and methods used in QCA. It then explores the empirical use of QCA in Clinical Health Psychology to date which, to date, has been limited.

The empirical paper is a QCA identifying some of the necessary components of psychological treatment of Chronic Pain. It suggests that, in general, behavioural methods of CP treatment are necessary to improve distress and disability levels and that an additive effect of offering multiple interventions within one treatment programme for CP cannot be assumed.

The critical appraisal reflects on the experience of the author in conducting a relatively new form of meta-analysis in the field of CP, its challenges and benefits.

### **Impact Statement**

The present body of work contributes to both academic clinical health research as well as the field of clinical health psychology.

This is one of very few uses of Qualitative Comparative Analysis (QCA) in Clinical Health Psychology and the first QCA in the field of Chronic Pain (CP). It is also one of the first Clinical Health Psychology QCAs to be carried out in conjunction with a Cochrane Review meta-analysis. The present study provides a detailed model of how a QCA can be conducted alongside a substantial meta-analysis, how decisions can be made to minimise risk of researcher bias and increase transparency, how a large number of heterogenous studies with a mixture of qualitative and quantitative data can be synthesised and effectively analysed to identify necessary components of multi-modal treatment and how challenges that arise during the QCA process can be overcome. The present paper also identifies gaps in QCA guidance and Clinical Psychology Research Methods training curriculum which, if addressed, could facilitate an increase in the use of QCA in Clinical Psychology and expand the scope of Clinical Psychology Research. The paper represents a first step towards the effective use of QCA in the field of Clinical Health Psychology.

This review has provided evidence that it cannot be assumed that combining multiple CP treatments in one programme has an additive effect on outcomes. It has also showed that, generally, behavioural treatments of CP are necessary to effect improvement in pain-related disability and distress. This is contrary to a large body of evidence which suggests that overtly cognitive interventions are essential in producing effective outcomes. This may benefit CP-treating clinicians, who may be able to design more effective and efficient treatment programmes as a result. It may also benefit patients, who might then receive more focused treatment, reducing confusion related to learning multiple treatment approaches in one programme.

For the impact to be brought about, the present paper will be re-formatted for submission for publication in peer-reviewed journals. The study will be shared with international Pain conference organisers to ensure wider dissemination of the findings to

experts in the field of CP treatment and to encourage the introduction of QCA to the analysis of complex pain treatment packages.

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## Acknowledgements

With thanks to:

Dr Amanda C de C Williams who has been my infallible supervisor. Yes (of course) she brought enormous amounts of expertise and wisdom in relation to Chronic Pain, research and meta-analysis but it was her humanity which I would like to thank her for. She was passionate about my project which was immensely motivating, she had huge levels of empathy for the research difficulties I was going through even though they might have been some of the more basic challenges of a student-researcher and somehow she seemed to have confidence in me when I didn't, which meant I weathered the more blustery moments of this journey feeling reassured. I feel lucky to have had Amanda working with me and cannot imagine having got to this point with anyone but her.

Dr Katy Sutcliffe and Dr Dylan Kneale whose QCA expertise, suggestions, patience, support and guidance made the QCA possible.

Professor Christopher Eccleston, Dr Emma Fisher and Les Hearn for generously sharing their Cochrane Review data and taking part in a valuable discussion about how some of my findings could be interpreted.

Dr Ginny Brunton who helped me get started on the QCA path and who put me in touch with Katy and Dylan.

Professor Steven J. Linton, Professor Mark Lumley, Professor Lance McCracken,
Professor Michael Nicholas, Professor Dr Johannes W.S. Vlaeyen and Dr Krystel
Shelmerdine who took time to apply their considerable expertise to help me choose the QCA conditions.

Dr Ciaran O'Driscoll whose R advice got me out of a sticky spot.

# Part 1: Literature Review

A conceptual introduction to the empirical paper "Necessary Components for Psychological Treatment of Chronic Pain: A Qualitative Comparative Analysis"

## Abstract

The present paper forms a conceptual introduction to the empirical paper "Necessary Components for Effective Psychological Intervention for Chronic Pain in Adults". Models of pain, chronic pain (CP) and psychological treatment are introduced. Existing literature on psychological treatment of CP allows limitations and gaps to be identified and highlights the need for qualitative comparative analysis in this field. This paper describes the research technique of Qualitative Comparative Analysis (QCA) and critically explores its application in the field of health and clinical health psychology.

#### Introduction

My thesis aims to develop hypotheses on the necessary and sufficient conditions of psychological treatment of CP. CP is defined as pain which endures for longer than the normal healing time (World Health Organisation [WHO], 1990), which the ICD-10 defines as 3 months (WHO, 2004). Psychological treatment for CP often comprises multiple and varied components (Jensen & Turk, 2014) but the necessary and sufficient components of this multi-modal treatment have yet to be established. 'Necessary' refers to the condition/s to ensure a specified outcome will occur but which does not guarantee its occurrence; 'sufficient' refers to the condition/s which, if present, guarantee/s the outcome's occurrence (Jeffreys & Jeffreys, 1999).

Understanding the necessary and sufficient conditions is straightforward if interventions are developed in a systematic way. Existing theory and evidence can be used to develop a model; each element can then be tested in phases to incorporate appropriate protocols into the treatment. However, in CP practice, interventions have been combined in various ways as complex interventions, relying on the demonstrated efficacy of individual interventions to contribute benefits, but finding few differences in dismantling studies in which one or more elements is removed and the differences in outcome examined. Such studies also assume no synergy or dyssynergy occurs between components, when in fact both occur. Estimating the effectiveness of individual elements in combination with others' is therefore difficult.

Multiple regression analyses and meta-analyses have been tried to resolve this difficulty; but for reasons detailed and explored below, their approaches have been criticised and they fail to arrive at helpful conclusions.

QCA may provide a solution. It is a relatively new meta-analytical approach to understanding the causal contributions of different combinations of factors to an outcome, using set theory (Rihoux & Ragin, 2009). By evaluating and comparing existing studies, QCA aims to identify the necessary and sufficient conditions to produce a specified result. QCA was developed in the field of social and political research. Since then it has been used in

various arenas, but it remains rare in the field of clinical psychology. The advantages of using QCA rather than meta-analysis or regression are detailed further below within Pain Models: Treatment Effectiveness and Efficacy of Psychological Treatment for CP (p. 23).

A 2019 systematic review and meta-analysis of CP management treatments has been completed by a research team as an update of Williams, Eccleston and Morley (2012). The proposed empirical paper is intended to complement the meta-analysis and to address, to a degree, criticisms levelled at the field of CP research by Morley, Williams and Eccleston (2013) and detailed further below.

This conceptual introduction aims to explore the use of QCA in health and pain psychology specifically and to identify its strengths and limitations. It first highlights the prevalence and impact of CP globally and follows by detailing biopsychosocial models which explain current understanding of pain and CP mechanisms. Psychological treatment approaches and models and the evidence supporting their use are then described. The preponderance of multi-modal treatment programmes is subsequently identified, techniques used to analyse such complex interventions are explored and a critique is provided which explains why a novel analytical approach such as QCA may be helpful. The development of QCA is then briefly reported and the QCA method is explained. A literature review of its use within health psychology is given where it has been applied to service level, treatment level and individual level conditions. Finally, the review concludes that there is a gap in health psychology and indeed CP literature which the application of QCA may address; this provides a rationale for the empirical paper.

## Chronic Pain

CP is a worldwide problem. CP (very often low back pain) is the leading cause of years lived with disability in most countries (Blyth, Briggs, Schneider, Hoy, & March, 2019; Hay et al., 2017). Estimates of CP prevalence vary widely due to its complexity, lack of standardisation of definition and measurement and the research question asked; Hay et al. highlight that CP conditions are also under-represented in the International Classification of Diseases (World Health Organization, 2004) which is often used in studies.

A global study estimated that 10% of the population experience CP (Jackson, Stabile & McQueen, 2014); one focussing on European populations suggested levels of disabling CP were higher, at 19% (Breivik et al, 2006) and a UK based meta-analysis found moderate to highly disabling CP prevalence was 10.4% to 14.3% (Fayaz, Croft, Langford, Donaldson, & Jones, 2016). Unsurprisingly, risk factors and CP treatment vary hugely between high and low to middle income countries (Jackson, Stabile & McQueen, 2014), helping to explain prevalence variation. In addition, as suggested, variation in measurement of CP further complicates the picture; some studies measure prevalence of self-report of CP whilst others measure self-report of disabling CP.

Whichever figure is cited, CP is recognised as having a negative impact on both society and the individual, globally. In the US, the impact of pain on the economy is estimated at \$635 billion (Gaskin & Richard, 2012), in Europe, €441 billion (Eurostat, 2017). In the UK the cost of back pain alone to the government is estimated to be £5 billion (British Pain Society, n.d.); £584m is spent annually on analgesic prescriptions, and 25% of individuals with CP lose their job because of pain (Donaldson, 2008).

Its impact is extensive; four of the twelve most disabling conditions in the world are CP conditions (Hoy et al, 2012) and as a result the individual's quality of life is significantly reduced (Bridges, 2011); CP causes so much distress that 16% of sufferers want to die (Donaldson, 2008). Efforts to reduce CP or its impact on individuals and society are therefore warranted and essential.

## Pain models

Many interventions for physical and psychological difficulties associated with CP are developed from an understanding or model of the problem itself.

General, contemporary theories of pain, however, are not only numerous, but some overlap, others address distinct areas of the pain experience, and some conflict. As a result, a single model of pain has not been universally adopted, which presents a challenge both for those developing interventions and for those evaluating them.

This paper will not explore the historical, biomedical models of pain which exclude psychological elements in the pain experience; instead more recent biopsychosocial models are considered; key models include the Gate Control Theory of Pain, (Melzack & Wall, 1965), and the Fear Avoidance Model (Vlaeyen & Linton, 2000).

The **Gate Control Theory** (Melzack & Wall, 1965) was the first to integrate psychological processes into what was previously in Western medicine considered a biological process. It has been established that pain messages from the site of injury are transmitted to the brain but are first modulated at synapses by other peripheral inputs as well as excitatory and inhibitory processes descending from the brain, at the spinal cord level. These processes arise from psychological functions such as attention, memory and, importantly, appraisal of threat. In brief, the brain state can attenuate or amplify the original pain signal. This illustrates how psychological interventions that alter the brain's state have the power to modify the neurophysiology of the pain experience.

Although various details of the theory have not been substantiated in subsequent studies (Moayedi & Davis, 2013), the integration represented a major insight and has been crucial in refocusing research on central pain mechanisms. It is entirely compatible with new neuroscientific models of brain function, such as predictive processing (Friston & Kiebel, 2009).

## Chronic Pain Models

An **operant conditioning model** of pain treats the brain as a black box and focuses only what is observable: behaviour associated with pain. It draws on Skinnerian (Skinner, 1953) principles and suggests that pain behaviours (such as moaning or limping) are initially helpful because they reduce and communicate pain to others. In response, as well as the injured party partially controlling pain, others act with care or allow the injured party to relinquish responsibility for tasks (Fordyce, 1984). These responses reinforce pain behaviours which then persist contingent on those responses, and eventually become maladaptive because they prevent rehabilitation or recovery and may exacerbate pain.

Critics of the model highlight its focus on the overt motor behaviours and lack of consideration for cognitive and emotional aspects of the CP experience (Okifuji & Turk, 2015).

Cognitive behavioural theories draw on studies that have established that beliefs about their pain, its causes, treatment, coping demands and prognosis have a direct impact on patients' experience of pain, their behaviours, quality of life and treatment efficacy (Turk, Dennis & Gatchel, Robert, 2018). Such theories contributed to the **Fear Avoidance Model** (FAM) (Vlaeyen & Linton, 2000) which applies to the maintenance of CP. It attempts to explain why some people recover whilst others can become trapped within a vicious cycle that allows pain to become chronic.

Figure 1 illustrates the FAM, showing how pain behaviour influences an individual's recovery from injury and their future pain experience.

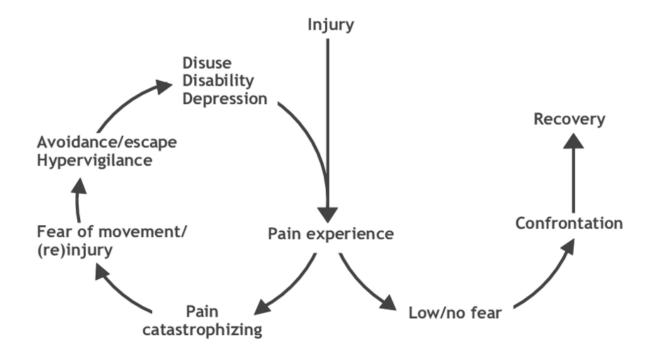


Figure 1. Fear Avoidance Model

Pincus and colleagues (Pincus, Smeets, Simmonds, & Sullivan, 2010) criticised this model for being focused on fear and suggest that other pathways such as social beliefs and vulnerability to negative affect may also be involved. It has also been criticised for not taking

into account motivating factors of behaviour or typical or non-pathological aspects of psychology which contribute to CP (Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012). Further criticisms highlight how the sequencing of the model is incorrect (Legrain, Van Damme, Eccleston, & Davis, 2009), how the path to recovery is over-simplistic and has not been verified and how the model fails to identify clear options for intervention.

A Cognitive Behavioural (CB) approach to CP has been built on the FAM and its conceptualisation of CP is widely used in research and treatment programmes. It incorporates all of the elements of the FAM but focuses on the *appraisal* that a patient makes of his or her CP. It suggests that this then has an effect upon their affect, physiological arousal, attitude and expectations regarding their condition, treatment, prognosis, environment, themselves and behaviour. A CB model assumes that all of these aspects are interlinked, meaning that intervention at one part of the cycle can have an effect on another point and vice-versa, but emphasising that intervention at multiple points may be necessary for improvement. Whilst it incorporates more behavioural models of learning, it also recognises that a patient's behaviours have a reciprocal influence on the environment (in particular on their support network) and as such presents the patient as having more agency in the model (Turk, 2018). The CB approach has resulted in Cognitive Behavioural Therapy interventions which are detailed below.

The Psychological Flexibility Model (McCracken & Morley, 2014) is a metaanalytic approach to CP that explains how pain-related behaviour can arise from
psychological inflexibility; it attempts to address some of the criticisms levelled at the FAM.
Psychological inflexibility occurs when someone sticks to maladaptive rules about
themselves, their illness, pain and the environment, which result in dilemmas preventing
them from acting in ways that would help them reach meaningful goals. It identifies six metaanalytic processes, drawn from Acceptance and Commitment Therapy (ACT) (Hayes,
Strosahl, & Wilson, 2009) that can either help patients overcome problems or undermine
such efforts; connection with the present moment, defusion from thoughts and feelings
(including pain), willingness to accept their experience, recognising that within every

individual there is an aspect of the self which observes their experience, identifying values and taking committed action despite pain. Mindfulness (Kabat-Zinn, 1982) as well as ACT is also considered a treatment which draws on several of these principles of psychological flexibility, despite pre-dating the model.

Whilst the nature of this model gives rise to further avenues for therapeutic intervention, the relative newness of the approach means, nevertheless, that numerous challenges arise; how to quantify psychological flexibility and operationalise its facets, how to monitor the language-based rules, and the enmeshment of the six processes with one another. The last means that conceptual boundaries are unclear, risking the model becoming too all-encompassing and unmanageable, and identifying the sufficient or necessary processes of psychological flexibility is difficult (Vlaeyen, 2014).

### Chronic Pain Treatment Approaches

Whilst CP theories and models are interlinked, they are numerous, so gave rise to a variety of CP treatment paradigms.

Operant and behavioural treatment models focus on reducing pain behaviours and increasing 'well' behaviours. This may start with functional behavioural analysis of the antecedent and consequent conditions (Turk & Melzack, 2011). Interventions include: response prevention and graded exposure to decrease pain behaviours (based on the FAM and taken from phobia treatment models), positive and negative reinforcement, reduction of external controlling stimulus conditions, graded activity scheduling, relaxation based upon respondent learning, time-contingent medication and medication reduction, all of which may involve work with support networks as well as with individuals (Sanders, 2018).

While **Cognitive behavioural treatment (CBT) models** also employ behavioural techniques, they rarely include all of the operant and behavioural methods listed above. They draw on the CB approach detailed previously and aim to reduce unhelpful cognitive schemas that patients have concerning their pain. This is primarily achieved by cognitive restructuring which encourages the patient to use evidence to make more realistic

conclusions about their situation; this process starts with education about illness and pain to dispel erroneous and maladaptive beliefs that pain implies ongoing damage and should be avoided. CBT also involves teaching further coping strategies such as problem solving to overcome situations which trigger stress and pain (although muscle tension is rarely a focus of treatment now), relaxation techniques, distraction and attention training, self-talk, assertiveness and communication training and information seeking (Turk, 2018).

Biofeedback treatments involve measuring patient's physiology, such as muscle tension, heart rate, skin temperature, breathing and brainwaves. The data are then fed back to the patient. The patient is asked to modify thoughts and behaviour (and thereby their emotional state) then notice how the physiology changes; this helps them understand how to control some of their body's maladaptive habits. The changes made to behaviour are either relaxation exercises, or re-education of muscles to increase or decrease tension which is now understood rarely to be the origin of pain. Using a 2 x 2 factorial design where participants were given false electromyographic feedback, Holyroyd and colleagues illustrated that reduced pain symptoms occurred with the belief that muscles were relaxed, not with relaxation (Holroyd et al., 1984) with cognitive self-efficacy underpinning improvement and supporting the CB model of pain treatment (Arena & Tankersley, 2018). Relaxation taught through biofeedback also tends to be dependent on the biofeedback equipment as cue, so is lost once the equipment is withdrawn.

Treatments related to the psychological flexibility model are known as third-wave cognitive behavioural therapies and tend to focus on the *processes* rather than content of the cognitive experience of pain. ACT and Mindfulness are two such treatments which are increasingly used.

**Mindfulness** is the psychological process of purposefully bringing attention to the present moment of the individual's external and internal world in a non-judgemental way (Kabat-Zinn, Lipworth, & Burney, 1985). Treatment is often in the form of Mindfulness Based Stress Reduction (MBSR), developed for CP patients and involving practice of meditation, yoga and body-scanning. MBSR encourages acceptance and curiosity of the pain

experience as well as development of attentional switching skills away from the pain, thereby reducing levels of negative thinking and therefore distress associated with the pain.

ACT involves identifying a patient's values, helping him/her overcome barriers to taking committed action towards these values, then taking action in spite of the CP. It also involves the use of mindfulness to connect with the present moment, using it to allow or accept the experience of pain without judgement, control or secondary suffering and to develop skills in guiding attention towards more adaptive foci. It uses metaphors and exercises to help patients de-fuse from their distressing thoughts, by learning to take a position as the observing self (Mccracken, 2015).

#### Multi-modal CP treatment

As seen above, the more widely adopted pain models incorporate biological, psychological and social variables into their understanding of how pain is experienced. Psychological treatment for CP often involves intervening at each of these three levels (Jensen & Turk, 2014). In practice, though, interventions are often inspired by politics, practicality and inadequate evidence (Craig et al, 2008). This has meant that the predominant approach within CP treatment is towards multi-modal interventions, combining various medical and psychological approaches in a variety of ways, rarely based on a single model.

## Treatment Effectiveness and Efficacy of Psychological Treatment for CP

Various meta-analyses of CP treatments have been undertaken to understand the most effective therapy. Some studies have investigated specific conditions, which result in varied conclusions. Bernardy and colleagues analysed **fibromyalgia** as a condition and only CBT interventions, finding that such therapies were effective for reducing depressed mood but not pain symptoms (Bernardy, Füber, Köllner, & Häuser, 2010). In contrast, Glombiewski and colleagues found that for fibromyalgia, all psychological interventions had a small effect on symptoms in the short-term and small to medium effect on longer term outcomes such as function and sleep, as well as pain (Glombiewski, Sawyer, Gutermann, & Koenig, 2010).

They also noted that CBT produced the largest effects. When considering **arthritis**, Dixon and colleagues also found that psychosocial interventions had a positive impact on pain and psychological, biological and physical functioning compared with controls (Dixon, Keefe, Scipio, & Perri, 2007).

Hoffman and colleagues analysed 22 randomised controlled trials of treatment of chronic **lower back pain** and found that all psychological and multi-component therapies had a significant positive effect on pain intensity (Hoffman, Papas, Chatkoff, & Kerns, 2007). Hoffman et al, similarly to Glombiewski and colleagues, noted that CBT was found to be more effective than other strategies in improving pain intensity, quality of life, depression and pain-related interference.

Williams, Eccleston and Morley (2012) explored the difference in effectiveness between different **combined treatments across a variety of CP** conditions excluding headache<sup>1</sup>. They analysed data from 35 randomised controlled trials of psychological treatment of CP in adults, with an inclusion criterion of more than 20 participants in each treatment arm<sup>2</sup>. The study found that the evidence-base for psychological treatment for CP is for the most part comprised of behavioural and cognitive approaches (ACT interventions were combined with CBT approaches on the basis that the distinction was not clear at this stage). The authors concluded that **CBT** has small to moderate positive effects on a client's mood, disability, pain and tendency to catastrophise compared to treatment as usual immediately after treatment, but improvements were not evident at follow-up except for distress. Effects on disability and catastrophic thinking were small when CBT was compared to other active treatments (such as exercise or education) and there was no effect on mood or pain. Behavioural Therapy did not perform as well; they described "a lack of evidence",

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<sup>&</sup>lt;sup>1</sup> Headache excluded because its episodic nature, meaning that the target of treatment is usually reduction in frequency, length, and intensity of headaches, rather than targeting disability and distress despite pain as do interventions for other CP.

<sup>&</sup>lt;sup>2</sup> Exclusion of studies with lower sample sizes reduced the risk of Type I error.

other than mood improvement, immediately after treatment. Hypnosis, mindfulness and internet-based trials were not included<sup>3</sup>.

While Williams et al. did not include mindfulness approaches in their study, a metaanalysis of **mindfulness** as a treatment for CP incorporated eleven randomised controlled trials and found limited evidence for its effectiveness; it recommended improved quality studies (Bawa et al., 2015).

Vowles et al (in press) conducted a comparative meta-analysis where studies treating chronic pain with ACT alone were compared with those using multi-disciplinary treatment approaches including ACT. Included studies were not all RCTs, but nevertheless found that multi-disciplinary approaches resulted in larger effect sizes than uni-disciplinary ACT treatment and suggested that further treatment-related variables may be related to CP outcome improvement.

It is important to note that the studies included in the meta-analyses vary hugely in sample sizes, conditions included, outcome measures, treatment content and quality, control and effectiveness. Whilst these studies offer considerable external validity, because they reflect how most treatment is offered, such heterogeneity is a problem because it does little to further understanding of the theoretical models of CP and mechanisms of change (Morley, Williams & Eccleston, 2013).

CP treatments are complex interventions, so by understanding the impact of different treatment components we can refine and improve treatment programmes so that they are more efficacious, have very low attrition rates or adverse effects, and avoid research waste represented by many similar small to medium-sized trials of very similar multicomponent packages. Understanding the impact of different treatment components can also help us understand how treatment components interact with patient status at baseline and staff competencies, as well as helping us understand the mechanisms of change within CP

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<sup>&</sup>lt;sup>3</sup> Hypnosis and Mindfulness excluded due to no clearly established psychological mechanism. Internet-based trials were analysed in separate reviews.

treatment, which may help to inform CP models. This may allow us to further understand the barriers to treatment-resistant individuals.

The Medical Research Council (Craig et al, 2008) has published guidelines for researchers examining complex interventions in which they present a model for developing and evaluating such interventions (see Fig 2).

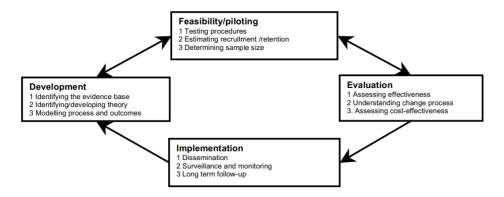


Figure 2. Key elements of the development and evaluation process

The model encourages researchers to maintain a close link to evidence base and theory, understand the change process and monitor use of the intervention at follow-up. However, it has been criticised for failing to make explicit reference to theory-driven evaluation approaches (in particular those described as 'Realistic Evaluation' [Pawson & Tilley, 1997]) and for failure to acknowledge the science of complex systems which has been suggested as a more useful approach (Anderson, 2008).

Multiple regression analyses in randomised control trials have been used to understand mediating conditions for an intervention; studies report the percentage of variance accounted for by a variable, but this does not imply that the factor is the necessary or sufficient variable (Kazdin, 2007). This is because the timeline of mediating condition occurring *before* outcome change is often not established and, as Craig et al. suggest (2008), with complex interventions, other conditions not accounted for nor understood can also influence outcomes or indeed explain the variable which has been identified as mediating outcome change.

Another complicating factor is that in the analysis of complex interventions, the use of multiple outcomes is encouraged (Craig et al, 2008), making it even less likely that the study

can identify one condition producing one outcome (Morley, Williams & Eccleston, 2013); it is unlikely that any psychological intervention has a unique, single effect.

Historically, condition studies, be they additive or dismantling, try to address the challenges above, but are rarely sufficiently powered to detect small differences or draw conclusions; indeed, a meta-analysis of condition studies showed that the putative critical individual conditions of treatment programmes are not responsible for therapeutic benefits (Ahn & Wampold, 2001). Not only is it seldom possible to separate each element of an intervention in practice and conceptually (Papa & Follette, 2015), but different individuals may react differently to the same condition or may respond in the same way to different conditions, thus confounding the linkage of conditions to outcomes (Rehm, 2009).

This leads back to the question: What are the necessary and sufficient conditions of psychological treatment of CP? A QCA approach may help answer this.

## QCA

The QCA approach was borne out of social and political research in the 1980s by Ragin and colleagues. It is a method of analysis developed to help researchers come to conclusions about complex situations with relatively few cases, but a large number of variables to consider, making most statistical analyses problematic. It aims to understand the combined effects of different conditions on an outcome using inferential logic (Ragin, 2014).

In brief, a QCA involves listing numerous possible combinations of conditions which can occur. The researcher then finds all existing cases which illustrate these combinations of conditions and records their outcome. Using Boolean algebra, the researcher derives logical implications from the data concerning the relationships between the combinations of conditions and their outcomes. Examples are given below.

## How QCA works

There are 6 steps to a QCA (Rihoux & Ragin, 2009), as follows:

### 1. Completion of a Data Table

A summary of the content of each of the studies constitutes the data table. Each row consists of a different study, each column a different condition or outcome. If the analysis uses 'crisp' sets, then data are shown in binary form; '0' represents the absence of the condition or outcome, '1' represents the presence of the condition or outcome. See Table 1 for an example (0.5 represents missing data).

**Table 1: Example Data Table** 

Study	Conditions			Outcomes	
	CBT	ACT	Qualified practitioner	Effect Size	Effective?
Jones, 2000	1	0	1	8.4	1
Patel, 2001	0	1	1	5.3	1
Adebayo, 2002	1	1	0	0.4	0

Presence or absence is conceptual. It is often obtained from qualitative data by integrating practical and theoretical criteria. However, presence or absence of a condition is not always denoted in binary form via crisp sets; 'fuzzy' sets can also be used. For this, the extent to which the condition is present in a case (or a case is a member of a set) is described by any decimal between 0 and 1 inclusive. For example, if considering 'tallness' in fuzzy sets, a person who is 6' tall might be given a membership of 0.6 and therefore be more of a member of the 'tallness' set than a person who is 4' and denoted as 0.1; someone who is 7' might be denoted as 1. With more qualitative variables (for example 'hirsuteness'), fuzzy set calibration can be established by using empirical knowledge and theory with qualitative guidelines describing the level of membership in the set as follows (Ragin, 2000):

- 1 = 'full membership'
- 0.9 = 'almost fully in'
- 0.8 = 'mostly in'
- 0.6 = 'more in than out'
- 0.5 = 'the crossover point where the case is neither in nor out'
- 0.4 = 'more out than in'

- 0.2 = 'mostly out'
- 0.1 = 'almost fully out'
- 0 = 'fully out'

### 2. Generation of Truth Tables

A truth table synthesises the data table into each of the different combinations of conditions (called configurations) in relation to their outcomes. Data are represented in binary form with each row representing a different configuration. The columns show how many studies used that configuration and whether that configuration can be defined as a 'member' of an 'effective set' of studies (where effective indicates that the desired outcome was achieved). The table also shows how consistent these findings are. See Table 2 for an example.

**Table 2: Example Truth Table** 

Conditions			No. of	Outcomes	
СВТ	ACT	Qualified practitioner	studies	Membership of Effective Set?	Consistency
1	0	1	10	1	1
0	1	1	5	1	0.66
1	1	0	2	0	0.33

### 3. Resolve contradictory configurations

Sometimes, studies with the same configuration of components result in different outcomes. This contradiction must be resolved before subsequent analytical steps are undertaken. This can involve adding, removing or replacing conditions, re-coding outcomes, using the number of studies as a 'voting' mechanism to assist decisions, undertaking more qualitative exploration of studies to refine coding, and amending included studies based on exploration of their combined heterogeneity.

#### 4. Boolean minimisation

This stage involves Boolean logic to conclude which conditions are 'sufficient' and / or 'necessary' to produce an effective outcome (Ragin, 2014).

First, Boolean operators such as 'AND', 'OR' and 'NOT' are used to describe each of the conditions. For example:

### CBT NOT ACT > Outcome

translates as "the presence of CBT without the presence of ACT is sufficient for the outcome to occur".

#### ACT NOT CBT > Outcome

translates as "the presence of ACT without the presence of CBT is sufficient for the outcome to occur".

However, Boolean minimisation aims to express this in as simple a 'solution' as possible so it combines all of the logical descriptions into one equation. For example:

### CBT OR ACT > Outcome

Translates as "the presence of either CBT or ACT is sufficient for the outcome to occur".

This process is often performed using Boolean algorithms via QCA software but can be completed manually.

## 5. Consideration of logical remainder cases

Occasionally, some configurations occur for which no studies exist: here, the researcher must either use logic to explain this or impute values based on relevant theory and evidence.

#### 6. Interpretation

The Boolean equation is then evaluated against the conceptual framework on which the review was built, the research question and the studies themselves. It may support what, challenge what or suggest how previous theoretical frameworks might be adjusted and may enable comment on the extent to which findings can be generalised. As the analysis is a logical interpretation of multiple studies, it presents not a definitive conclusion but a hypothesis to be tested by further research.

The advantages of using QCA are numerous: it

 bridges the qualitative-quantitative divide, retaining the iterative qualitative approach (whereby the researcher becomes familiar with every case) and the quantitative approach by producing a conclusion, which has been described as analogous to a regression equation, to describe the relationship between intervention conditions and their outcomes

- works without dismantling configurations into disaggregated factors using often flawed assumptions (Kahwati et al, 2016)
- Analyses the interaction between conditions which is often impossible in metaanalyses due to a lack of data (Ragin, 2014). As such it examines and challenges the assumption often made that intervention conditions have an additive effect on outcome.
- forces the researcher to consider every instance of a relationship, including irregularities and contradictions, thus developing a more inclusive and holistic understanding of the situation (Ragin, 2014)

Such advantages can overcome criticisms of more traditional pain management research.

#### Criticisms of QCA

QCA has been widely criticised for adopting deterministic hypotheses; assuming that all measures used are error-free and that cases are independent of each other; for the need to limit the number of conditions included within the analysis; for exposing the analysis too heavily to the author's subjectivity and for the fact that single cases can have considerable influence on the analytical conclusions.

A most prominent criticism is that with crisp-set analysis, the authors must define how a case becomes a member of the set or not; when considering continuous variables this is subjective and arbitrary. Fuzzy-set QCA was developed to address this criticism to some extent, although the cut-offs for each set still remain arbitrary.

In a similar vein, the process relies on two assumptions: (1) a deterministic hypothesis and (2) error free measures, both of which are relatively difficult to establish in the field of clinical health (Hug, 2013). This therefore makes Type I error more likely (Krogslund, Choi, & Poertner, 2015). A further assumption is that each case is independent

of the other/s, an assumption encountered with many analytical methods which is dependent on the topic studied, although Marx and colleagues suggest various ways to overcome such a difficulty should it occur in QCA (Marx, Rihoux, & Ragin, 2014).

Additional criticism is that the inclusion of a single case can alter the findings considerably (Goldthorpe, 1997), although this can also be true in standard meta-analyses. Proponents of the QCA approach have countered that the inclusion of one influential case is exactly why QCA is important; it prompts researchers to consider unusual situations and incorporate them into theoretical understandings (Marx et al., 2014).

Finally, the number of conditions that can be included within a QCA is limited to avoid the number of possible combinations of variables becoming so large that each combination represents a single case and logical reduction is impossible (Scharpf, 1997). This draws more criticism. Ragin has pointed out that this is not the only analysis that encounters this difficulty (Marx et al., 2014).

## QCA in health psychology

Whilst QCA has been applied to various topics in the socio-political arena, a literature search of its use in psychology and health psychology showed that it is less widely used.

The search was conducted using MedLine and searched for peer-reviewed papers including the following terms: QCA or "Qualitative comparative analysis" or "boolean analysis" or "set-theor\*" or "fuzzy set analysis" or "fuzzy-set analysis" or "crisp set analysis" or "crisp-set analysis" and "psychol\*" or "therap\*". Whilst the search resulted in 491 articles, 32 appeared to be relevant from abstract screening. Further reading provided 21 papers of relevance, none of which concerned pain.

A review of QCA papers unrelated to CP, yet still related to clinical health or chronic illness and its treatment, is useful in providing examples of helpful and unhelpful applications of the QCA technique.

Whilst the papers identified were all related to health services, they varied in focus, scrutinising service level, treatment, staff / individual or problem level conditions; areas which all have the potential to impact on CP.

## **Service Level Conditions**

At a macro level, various papers used QCA to analyse the combinations of conditions which are associated with higher quality service provision in the health arena in general (Bickell et al., 2017; Brunton, O'Mara-Eves, & Thomas, 2014; Chuang, Collins-Camargo, & McBeath, 2017; Marcus Thygeson et al., 2012; McAlearney, Walker, Moss, & Bickell, 2016), but only a few authors have used QCA to understand how to improve services for those with chronic illness (Bell & Seidel, 2012; Leykum et al., 2014).

Bell and Seidel's study explored general service level approaches to improving chronic care quality across a variety of illnesses but did not use symptoms or impact of the illnesses as an outcome. The paper therefore gives no indication of the necessary and sufficient conditions or components which result in positive chronic illness outcomes. The paper does, however, illustrate methodological challenges to be avoided in using QCA; outcomes were not standardised or defined by researchers, but by clinician participants who stated that in their service the outcome was ill-defined, and neglected to specify how it was measured. As the authors state, "stakeholder perceptions are not robust measures", a conclusion to bear in mind with the present study.

Leykum's paper used only one part of the QCA process – the truth table – to analyse where the inconsistencies in service improvement results were found. It did not find an explanation. The authors used complexity science theory to conclude that due to the nature of complex systems, outcomes are not predictable. The study therefore also provides no further understanding of the necessary or sufficient components of chronic illness treatment, other than to bear in mind that complexity may be a barrier to prediction.

The paper has various limitations which may have contributed to its failure to answer its own research questions and which are therefore important to note when considering the design of QCA projects. Firstly, the authors only selected papers that they had previously written, risking substantial bias. Secondly, their components were taken from the

characteristics of the studies themselves and not overtly informed by theory. Thirdly, they did not then continue with further QCA steps.

#### **Treatment Level Conditions**

Various papers used QCA on a more micro level more germane to the current study. Several papers have studied which aspects of behaviour change-focused treatment improve outcomes in chronic health populations.

Obesity

The American Medical Association considers obesity to be a chronic disease (Pollack, 2013) and several papers have used QCA to analyse weight management treatments (Burchett, Sutcliffe, Melendez-Torres, Rees, & Thomas, 2018; Kahwati et al., 2011; Melendez-Torres et al., 2018).

Burchett et al. (2018) used qualitative studies of obesity treatment in children to generate treatment components to be analysed. The three conditions necessary for effective weight-loss treatment could all be considered *processes* of delivering an intervention rather than intervention content.

Whilst the quality and breadth of obesity studies might be considered limited and analysis of only the least and most effective studies risks an over-simplified solution, the study provides helpful guidance on how QCA components can be established from existing qualitative studies about multi-component interventions.

The QCA study by Kahwati et al. (2011) examined an adult population to show that for positive weight loss outcomes to occur in veterans' facilities (using an approach called MOVE!), the services needed to use a standard curriculum or avoid using only an individual care-delivery format.

Kahwati and colleagues used surveys and interviews to define their components; then more data sources were used to calibrate these components, a rigorous approach which may also be helpful to adopt in further QCAs.

Nevertheless, one of the study's limitations is that the data were not compared to other treatment approaches; the components were part of one specified therapy used across all services. It can therefore only inform understanding of what works in the given treatment; generalisation is limited.

The paper is further limited by the fact that the study fails to link findings back to theories or models of behavioural change. Commonly accepted health behaviour change theories such as the COM-B model (Michie, van Stralen, & West, 2011) are not directly reflected in Kahwati's findings. The paper therefore highlights how failing to integrate or connect findings to existing models can result in more questions and confusion rather than clarity.

The paper by Melendez-Torres et al (Melendez-Torres et al., 2018) also studied adult weight management programmes and identified components by considering patients' views, identifying factors not previously considered as important in contributing to programme success.

They found that supportive relationships garnered extrinsic motivation were key to the maintenance of behaviour change. The authors take care to compare findings to theory and note that findings contradict self-determination theory (Ryan & Deci, 2000) which asserts that behaviour change benefits from intrinsic motivators.

However, the paper included poor quality studies and filtered out moderately effective interventions in order to reduce noise. This may have unwittingly reduced the solution complexity to an extent that it did not reflect the full spectrum of situations and therefore the paper's approach may not be helpful to apply to the present QCA.

In summary, findings from treatment-level weight loss QCAs may not be generalizable to CP treatment but their use of multiple sources of data to inform the identification of components within QCA, use of theory to triangulate findings, inclusion of only high quality studies as well as a range of levels of effectiveness is to be recommended.

Medication Adherence

Other papers used QCA to consider behaviour change with respect to medication adherence, albeit the outcome was behaviour change rather than an improvement in chronic disease symptoms.

Kahwati and colleagues (Kahwati, Viswanathan, et al., 2016) completed a review considering a wide variety of chronic illnesses. They analysed different behaviour change techniques used in treatment and found that whilst no *one single* technique was sufficient, seven combinations of conditions were sufficient for a positive outcome in medication adherence. The authors identified that a combination of techniques involving increasing the patient's knowledge whilst increasing self-efficacy was most consistently linked with positive outcomes.

Extrapolating this paper's findings to psychological CP treatment, it can be hypothesised that if certain types of behaviour change are expected to improve pain symptoms, then behaviour change interventions targeted at health education, psychoeducation and self-efficacy are likely to be most effective. Poor medication adherence in CP is common, and whilst adherence to self-management strategies is predictive of better outcomes (Nicholas et al, 2012) the link between medication adherence and pain outcomes has not been established (Broekmans, Dobbels, Milisen, Morlion, & Vanderschueren, 2009); medication rarely improves anything more than pain ratings and some medication is associated with poorer mood, poorer sleep and reduced function.

Kahwati's paper also had its limitations. It used crisp-set QCA, which effectively forced researchers to decide whether a condition was present or not, taking no account of grey areas (for example, if one intervention provides 10 minutes of psycho-education whereas another provides 10 hours, how should it be classified?). Kahwati and colleagues explained that they had to make subjective decisions based on (often) limited information provided in papers, which would impact on their results.

This review also warns of the problems associated with merging distinct variables for the purpose of QCA. Doing so may be helpful to the analysis but may mean that subsequent empirical investigation is hard to examine.

Candy and colleagues (Candy et al., 2011) also used crisp-set QCA in studying intervention combinations that resulted in medication adherence. They, too, found that *various* combinations led to the same positive result, combinations which included 'provision of information on how to take medication' (overlapping with the 'knowledge' condition from Kahwati and colleagues' study). One point of difference was that Candy and colleagues' sufficient combinations also specified which conditions needed to be absent in order for medication adherence to occur (for example 'a discussion relating to not stopping taking medication if there are no symptoms' should be absent). This finding is confusing when considered alongside Kahwati's conclusions, as such discussions could be considered as contributing to the provision of 'knowledge' previously defined as necessary. It is therefore necessary to ensure components have distinct definitions so as to avoid contradictory findings.

Candy et al. (2011) *did* identify that one condition of 'focussing on personal risk factors' alone could lead to medication adherence for patients with chronic disease. The authors also spent time analysing which combinations would result in the outcome of *non-adherence* and confirmed that an absence of 'focus on personal risk factors' would result in no medication adherence, (which makes sense when viewed alongside their assertion that inclusion of such a focus was sufficient for adherence). This recommendation is also included in clinical health behaviour change guidelines from the National Institute for Health and Care Excellence (NICE, 2007), so by hypothesising that this recommendation alone may be sufficient for behaviour change, the study offers more parsimonious and thus potentially more efficient guidance.

The findings from Candy et al. and Kahwati and colleagues do not, however, directly represent tests of behaviour change theories such as the COM-B model (Michie et al., 2011), although the components of increasing knowledge and personal risk factors could be

construed as contributing to capability and motivation (or the 'C' and 'M') in COM-B. This observation illustrates how, if QCA components are not chosen to reflect an existing theoretical model, they may add complexity or, worse, confusion to the existing research.

# Individual Level Conditions

No individual level QCA studies could be found related to CP, chronic disease or chronic disease outcomes, however some individual level studies were found which explored attitude and emotional intelligence (in health care staff), and stress, drinking and post-traumatic outcomes (in patients).

Health Care Staff

Gimenez-Espert and colleagues focused on nurses in hospitals and used QCA alongside hierarchical regression to understand the conditions predicting different communication attitudes and emotional intelligence in two papers (Gimenez-Espert & Prado-Gasco, 2018; Gimenez-Espert, Valero-Moreno, & Prado-Gasco, 2019).

Whilst their findings do not inform knowledge of chronic disease and its treatment, the papers do illustrate three points. Firstly, that QCA can be successfully applied to individual participants; secondly, that QCA can explore demographic conditions as well as measures of state and trait conditions and individual differences; thirdly, that QCA can be used in conjunction with regression analyses to explore necessary and sufficient predictors of outcomes.

It is nevertheless important to note that the two papers differ in their conclusions on the combined use of hierarchical regression and QCA; the 2018 paper states that QCA is more helpful as a predictive model than regression, whilst the 2019 paper says that they should be used simultaneously for the best results. Helpfulness of QCA as a predictive model may therefore be related to the conditions chosen and might not be possible to ascertain in advance of analysis.

**Patients** 

Three papers explored factors associated with patients' characteristics. None is necessarily directly related to chronic disease but they illustrate a variety of ways in which QCA has been applied to clinical health studies that may inform further QCA studies.

As in Gimenez-Espert and colleagues' papers, Villanueva and colleagues

(Villanueva, Montoya-Castilla, & Prado-Gasco, 2017) conducted QCA alongside a
hierarchical regression to study individual differences in emotional intelligence associated
with adolescent stress. They found that the QCA analysis 'enriched' regression findings,
confirming which conditions were sufficient but also adding further conditions. Interestingly,
they used two different measures of the stress outcome and thus conducted two different
QCAs which resulted in different combinations of sufficient conditions. Whilst this was
explained by the fact that the two measures did not correlate, it highlights the importance of
careful choice of outcome measure and of clarity of what is being measured.

Eng and Woodside (Eng & Woodside, 2012) explored factors associated with high levels of drinking in the general population. The conditions explored were derived from a book detailing systematic research into the psychology of drinking. The study found seven different combinations associated with drinking. These combinations, ranging from four to six conditions, highlights the complexity of the solutions which can be drawn, which may unfortunately be difficult to apply practically.

Importantly, the case data are drawn from a national survey, suggesting a large number of included cases and therefore illustrates that when QCA is applied to large case numbers it may result in multiple factor combinations.

Haynes and colleagues (Haynes et al., 2017) analysed which aspects of a client's presentation and pre-existing treatment predicted outcomes in a population diagnosed with Post Traumatic Stress Disorder. Unusually in QCA, the cases studied were individuals. While findings are not relevant to CP treatment or theory, the study shows how factors not normally considered to be determinants of outcome success can play a role in recovery. By

focussing on patient factors, the QCA answered the question of "what works and for whom?".

The study also conducted a range of sensitivity tests, using multiple QCA models with different criteria of significance and compared results; this ensured that the impact of different statistical decisions was understood. This was alongside analyses of negative outcomes, illustrating that the associated solutions need not be the opposite of the positive outcome solutions. Both approaches appear to be good QCA practice.

To summarise, QCAs focussing on individual level conditions illustrate how QCA can be used across large sample sizes, as a complement to regression analyses, can explore a wide range of often overlooked component factors, but that outcome measures should be carefully chosen. With regards to solutions, the studies examined above demonstrate how component combinations can sometimes be so complex as to be unwieldly and that negative outcomes are not always brought about by the reverse of the factors which effected the positive outcome. Sensitivity tests are also shown to be useful in QCA to justify statistical decision making.

#### Discussion

The literature review of QCA studies of chronic condition treatment has shown that various components not necessarily previously considered as important<sup>4</sup> may be necessary and / or sufficient in primarily behaviour change interventions. Such components often reflected aspects of the *process* of delivering interventions rather than the content of interventions.

The present paper can, however, provide useful notes of caution in QCA design. It provides a reminder of the limitless scope for different conditions that can be included in QCAs and thus the importance of using theory and evidence to justify their inclusion. It also highlights the limitations of using self-report qualitative information to inform membership of

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<sup>&</sup>lt;sup>4</sup> These components include providing a standard curriculum in group work and refraining from using individual care-delivery formats; showing families how to carry out certain 'healthy' behaviours; providing social support for families; gaining buy-in from the whole family and creating supportive relations which garner extrinsic motivation for behaviour change.

sets. The study also shows how, when qualitative information is sparse, crisp-set QCA may be used at the expense of sophistication where fuzzy-set QCA might be more appropriate if further information regarding cases can be obtained. In a similar vein, using studies with extreme results (high and low level outcomes) may assist researchers in interpretation of findings but may introduce unrepresentative simplicity.

It identifies the need to:

- choose papers systematically to reduce bias
- use high-quality studies or cases
- clearly define outcome measures and cut-offs
- use all of the QCA steps
- apply QCA to both negative and positive outcomes, conducting sensitivity tests by running multiple QCAs using different numerical cut-off levels to identify what is sufficient and necessary.

The study also demonstrates how a large number of cases can be analysed, but that this risks resulting in multiple combinations of necessary and sufficient conditions that may complicate drawing conclusions. In addition, it illustrates how QCA can be used alongside a hierarchical regression to triangulate findings, although the condition choice can influence the helpfulness of either approach. It is also a reminder that a range of heterogeneous contexts should be included within the review if generalisations are to be made.

Finally, it shows how, if hypotheses are to be empirically tested, then any combination of sub-factors into factors should be practically applicable in treatment practice. Most importantly, it highlights a gap in the literature in studies which identify the necessary and sufficient conditions for treatment of CP.

# Conclusion

The social and political field in which QCA was developed is analogous to the field of pain treatment. Here, pain management is often compound and complex; there is a multitude of varying treatments (variables) but few studies (cases) using identical treatment combinations. This makes QCA an ideal tool for this review.

The QCA will not form a conclusive statement about which configurations of pain treatment work best nor the causality of relationships studied; but hypotheses which can be investigated by subsequent researchers.

The empirical paper will use the studies generated by the 2018 meta-analysis search and selection processes and apply a QCA to address the following research question:

What elements of CP programmes are necessary for improvement in outcomes for adults experiencing non-malignant CP (excluding headache)?

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# Part 2: Empirical Paper

# **Necessary Components for Psychological Treatment of Chronic Pain:**

**A Qualitative Comparative Analysis** 

## Abstract

# Background

Chronic pain (CP) is the leading cause of years lived with disability globally.

Treatment within western medicine is often multi-component, incorporating pharmaceutical, physiological and psychological interventions. The psychological element of treatment also varies in process, content and across different patient populations, yet the optimal conditions for effective reduction of pain-related outcomes remain unclear.

# Aim / Design

This review used Qualitative Comparative Analysis (QCA), a relatively new form of meta-analysis in the field of psychology and pain, to ascertain the necessary and sufficient components of psychological treatment of chronic pain in adults.

#### Methods

Data related to patient demographics and presentation, treatment content and process were extracted from 38 studies identified in a concurrent Cochrane Review of psychological treatment of chronic pain in adults. The data were then subjected to a QCA where Boolean algebra is used to identify logical implications about the relationships between the component combinations and clinical outcomes.

### Results

Analysis of the 10 treatments with best outcomes with the 10 treatments with poorest outcomes showed the following:

The combination of Social / Operant treatment without Exposure / Activity treatment OR Exposure / Activity treatment without Social / Operant treatment (only for those with low Baseline Distress levels) consistently results in a reduction of disability levels. All these 'solutions' had a consistency value of 1 and raw coverage of 0.367, metrics which reflect the

level of confidence that can be had in these combinations of treatment effecting positive change.

An alternative treatment combination suggests that Social / Operant without Exposure / Activity OR Exposure / Activity without Social / Operant and without Cognitive Restructuring consistently result in a reduction of disability levels. This solution had a consistency value of 1 and raw coverage of 0.4, reflecting the level of confidence in the solution.

To reduce distress, treatments offering Exposure / Activity interventions combined with either a high number of Treatment Hours to those with high levels of Baseline Disability or Cognitive Restructuring treatment without Social / Operant treatment all have a positive impact on distress levels. This solution had a consistency value of 0.814 and raw coverage of 0.433, reflecting the level of confidence in the solution.

## Conclusions

The QCA found that necessary components of psychological CP treatment are largely behavioural (rather than cognitive) regardless of whether the outcome targeted is distress or disability and that the inclusion of multiple treatment content components does not necessarily have an additive effect as expected. The use of Exposure / Activity or Social / Operant interventions is effective when one is used and not the other. Cognitive Restructuring is only necessary when used alongside Exposure / Activity when distress is an outcome. When distress is targeted and baseline disability levels are high, treatment hours must be high when Exposure / Activity is used. Treatments appear to reduce distress whatever the level of distress at baseline, in the same way that disability improvements are made no matter what the level of baseline disability.

## Introduction

CP

Chronic pain (CP) is non-cancer pain which endures for longer than the normal time taken to heal which the ICD-10 specifies as 3 months (World Health Organization, 2004). It is a global problem, representing the principal cause of years lived with disability in the majority of countries (Blyth et al., 2019; Hay et al., 2017). The prevalence and impact of CP have been described in detail within the conceptual introduction and are of sufficient magnitude to warrant continued efforts to minimise the effect CP has on both society and individuals.

#### Models of Pain

Pain mechanisms have been disappointing as guides to treatment methods. Two models are key: the Gate Control Theory of Pain (Melzack & Wall, 1965) to understand pain plasticity and interaction of top-down and bottom-up neural signals; and the Fear Avoidance Model (Vlaeyen & Linton, 2000) for understanding failure to recover from pain.

The **Gate Control Theory** (Melzack & Wall, 1965) unites psychological processes with biological processes. Pain messages from the physical point of injury or adverse change travel towards the brain but are modulated at spinal cord synapses by further peripheral inputs, as well as by excitatory and inhibitory activities originating in the brain. The brain state can reduce or intensify the initial pain signal, thus psychological treatments which modify the state of the brain can alter the neurophysiological processing of pain and its experience.

The **Fear Avoidance Model** (FAM) (Vlaeyen & Linton, 2000) draws from cognitive and behavioural principles to illustrate how pain remits or is maintained. It proposes that beliefs about pain, its causes, treatment, coping demands and prognosis have a direct

impact on experience of pain, behaviours, quality of life and treatment efficacy (Turk & Gatchel, 2018). Figure 1 shows the FAM.

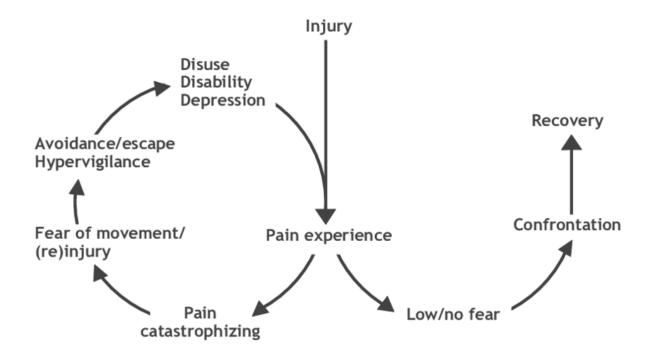


Figure 1. Fear Avoidance Model

However, as detailed within the Conceptual Introduction, shortcomings of the model have been highlighted by various researchers (Crombez et al., 2012, Legrain et al., 2009 and Pincus et al., 2010).();

A new model, of psychological flexibility (McCracken & Morley, 2014), makes efforts to overcome some of the reproval aimed at the FAM; it hypothesises how some unhelpful behaviours related to pain can originate from psychological inflexibility. It identifies six processes, drawn from Acceptance and Commitment Therapy (ACT) (Hayes et al., 2009) that can either help or hinder addressing problems and reaching meaningful goals. A critique of this model is detailed within the Conceptual Introduction (Vlaeyen, 2014).

# Chronic Pain Psychological Treatment Models

Although CP models and theories are interrelated, they have resulted in a range of CP treatment paradigms. **Operant and behavioural treatment models** encourage a

reduction in pain behaviours and increasing 'healthy' behaviours. Treatments include both positive and negative reinforcement, response prevention, graded exposure to reduce pain behaviours, scheduling of activity in a graded pattern, relaxation, reduction of medication and time-contingent medication (Sanders, 2018).

Cognitive behavioural treatment (CBT) packages also incorporate behavioural techniques but also aim to change negative cognitions about pain by cognitive restructuring evaluating evidence and reframing problems more realistically. CBT also involves teaching better problem solving, relaxation techniques, distraction and attention training, assertiveness and communication training (Turk, 2018). While each of these has been found to bring benefits when used singly, when used together the benefit is not necessarily much bigger.

**Biofeedback** treatments involve the learned modification of measurable physiological functions, such as heart rate, using feedback of data to the individual. This increases control of maladaptive responses and can support CBT for pain (Holroyd et al., 1984).

Treatments related to the psychological flexibility model focus on cognitive *processes* rather than contents in pain experience; ACT and Mindfulness are increasingly used in treatment.

**Mindfulness** is a process of bringing an individual's attention to the present moment, on purpose, without judgement (Kabat-Zinn et al., 1985). Treatment follows Mindfulness Based Stress Reduction (MBSR), which involves, among other techniques, meditation.

**ACT** mobilises an individual's values to overcome barriers to desired activity, despite CP. It also aims to de-fuse individuals from their distressing thoughts by mindfulness, metaphors and exercises, and learning to take a self-observing position (McCracken, 2015).

Thus, pain models integrate psychological, biological and social domains into their representation of pain and pain experience. Treatment for CP therefore often requires intervening in each domain (Jensen & Turk, 2014) as **multi-modal CP treatment** whilst also influenced by funding limitations, feasibility, and insufficient evidence (Craig et al., 2008).

# What Chronic Pain Psychological Treatment Intervention is most effective?

Meta-analyses of CP treatments aim to identify the efficacy of psychological therapies. Williams, Eccleston and Morley (2012) explored differences in effectiveness between different **combined treatments across a variety of CP** conditions excluding headache<sup>5</sup>. Data from 35 randomised controlled trials of psychological treatment of CP in adults showed that **CBT** has small to moderate positive effects on mood, disability, pain and catastrophic thinking compared to *treatment as usual* immediately after treatment. Hypnosis, mindfulness and internet-based trials were not included<sup>6</sup>. A meta-analysis of **mindfulness** for CP found limited evidence for its effectiveness and recommended better quality studies (Bawa et al., 2015).

A comparative meta-analysis by Vowles et al. (2019) comparing uni-disciplinary treatment with multi-disciplinary treatment outcomes found that **multi-disciplinary approaches** resulted in larger effect sizes than uni-disciplinary **ACT** treatment, and suggested that outcomes could be determined by other treatment-related variables.

Studies included in the meta-analyses vary hugely in pain conditions included, outcome measures, treatment content, process and effectiveness. Such heterogeneity hardly improves understanding of the theoretical models of CP or mechanisms of change (Morley et al., 2013). A new Cochrane meta-analysis (Williams et al., 2020) of psychological treatment of CP is in process (which serves as an update to Williams, Eccleston and Morley [2012]) but the authors have been unable to identify any changes in CP research which effectively respond to the aforementioned critiques of studies in this field<sup>7</sup>.

Thus, CP treatments are complex interventions whose necessary and sufficient components have yet to be established. 'Necessary' refers to condition/s to ensure that a

<sup>&</sup>lt;sup>5</sup> Headache was excluded because its episodic nature, meaning that the target of treatment is usually reduction in frequency, length, and intensity of headaches, rather than targeting disability and distress despite pain as do interventions for other CP.

<sup>&</sup>lt;sup>6</sup> Hypnosis and Mindfulness excluded due to no clearly established psychological mechanism. Internet-based trials were analysed in separate reviews.

<sup>&</sup>lt;sup>7</sup> Headache is also the subject of Cochrane systematic reviews (Sharpe et al., 2019). A review of treatment for non-migraine headaches is in progress by the same authors.

specified outcome (of positive change) will occur but not to guarantee its occurrence; 'sufficient' refers to condition/s that guarantee/s the positive outcome's occurrence (Jeffreys et al., 1999). Understanding the necessary and sufficient components of effective treatment can help clinicians understand how treatment components interact with patient status at baseline and with staff competencies, as well as suggesting the mechanisms of change; these can inform CP models and improve treatment programmes. Were this to be tackled using regression models, the number of conditions would be so great that impossibly large participant numbers would be required and a risk of over-fitting a model to a single data set would remain.

Qualitative Comparative Analysis (QCA) represents a relatively new way of examining data to understand which combinations of treatment form part of effective treatment. It has not previously been used to investigate CP treatment.

# Qualitative Comparative Analysis

QCA arose from social and political research in the 1980s (C. C. Ragin, 1987) to help researchers draw conclusions about complex situations with relatively few cases but many variables, incompatible with most statistical analyses. It uses inferential logic to understand combined effects of different conditions on outcomes (Marx et al., 2014).

In brief, a QCA involves listing numerous possible combinations of conditions; finding all existing cases with these combinations of conditions and recording their outcome; then, using Boolean algebra, deriving logical implications from data concerning relationships between combinations of conditions and their outcomes.

Criticisms include (1) arbitrariness of decisions presence or absence of a condition; (2) reliance on a deterministic hypothesis and error-free measures, both difficult to achieve in clinical health (Hug, 2013), making Type I error more likely (Krogslund et al., 2015); (3) sensitivity of findings to inclusion/exclusion of a single case (Goldthorpe, 1997); and (4) the limits on number of conditions included in a QCA in order to avoid the possible combinations

of variables becoming so numerous that each combination represents a single case and logical reduction is impossible (Scharpf, 1997).

Nevertheless, the method has several advantages. It combines an iterative qualitative approach with a quantitative method to produce a description of the relationship between intervention conditions and their outcomes. It also avoids dismantling configurations into disaggregated factors, often using flawed assumptions (Kahwati et al., 2016). In addition, it analyses the *interaction* between conditions which is often impossible in meta-analyses due to lack of data (Marx et al., 2014); it challenges assumptions of additivity or synergy of intervention conditions in effects on outcome. It forces the researcher to consider every instance of a relationship, including irregularities and contradictions, thus developing a more inclusive understanding (Marx et al., 2014). Such advantages can overcome criticisms of more traditional pain management research.

# How Qualitative Comparative Analysis works

There are 6 steps to a QCA (Ragin & Rihoux, 2009), as follows:

## 1. Completion of a Data Table

A summary of the content of each study constitutes the data table. Data are generally shown in binary form; '0' represents the absence of the condition or outcome, '1' represents the presence of the condition or outcome which is obtained from qualitative data. Sometimes the extent to which the condition is present in a case is described by any decimal between 0 and 1.

## 2. Generation of Truth Tables

A truth table synthesises the data table into all combination of conditions (called configurations) in relation to their outcomes. Data are represented in binary form with each row representing a different configuration.

## 3. Resolution of contradictory configurations

Studies with the same configuration of components can result in different outcomes. This contradiction must be resolved before subsequent analytical steps are undertaken.

#### 4. Boolean minimisation

This stage involves Boolean logic to conclude which conditions are sufficient and / or necessary to produce an effective outcome (Marx et al., 2014). First, Boolean operators such as 'AND', 'OR' and 'NOT' describe each of the conditions with outcomes. This simple—as-possible 'solution' combines all logical descriptions into one equation.

# 5. Consideration of logical remainder cases

Occasionally, configurations occur for which no studies exist: here, the researcher must either use logic to explain this or impute values based on relevant theory and evidence.

# 6. Interpretation

The Boolean equation is then evaluated against the conceptual framework on which the review was built, the research question and the studies themselves. It presents not a definitive conclusion but a hypothesis or hypotheses to be tested by further research.

# Aims of the study

The present study aimed to use QCA to identify necessary and sufficient components of psychological treatment of chronic pain in adults. More specifically, it aimed to understand how different patient characteristics, treatment context, treatment processes and treatment content would interact to influence the pain experience outcomes of distress and disability. While quantitative studies might develop a hypothesis prior to data collection, the present study adopted a more qualitative ideology and used an iterative approach, whereby hypotheses were developed and refined as data were collected and as the researcher became familiar with the cases.

# Method

## Design

A Cochrane systematic review and meta-analysis undertaken in 2020 addressed the psychological treatment of adults with CP (Williams et al., 2020). The present study drew on

data from the meta-analysis, using QCA. Both studies and their protocols were registered on Prospero, the International Prospective Register of Systematic Reviews (Williams et al, 2018, Batho et al, 2018).

## **Ethics**

Ethics approval for the 2020 meta-analysis and the present study was unnecessary as data were secondary and already published.

#### Search

## Cochrane Review search and inclusion / exclusion criteria

The majority of studies included in this QCA were taken from the aforementioned Cochrane Review (Williams et al., 2020) which analysed studies meeting the following criteria:

- randomised controlled trials published in peer-reviewed science journals
- treatment of adults with CP of longer than three months duration
- comparison of psychological treatment with waiting list control, treatment as usual or active treatment
- 20 or more participants in each arm by the end of treatment

Treatment was considered psychological if it had definable psychotherapeutic content based on an extant psychological model and if it was delivered or supervised by an individual qualified in psychology.

Studies of participants with headache, or pain related to life-threatening disease, were excluded, as were treatments provided remotely via telephone or computer. All are subjects of separate meta-analyses.

Studies were searched in the Cochrane Central Register of Controlled Trials,

MEDLINE, EMBASE and PsychLit databases from their inception to February 2018 and

updated in April 2020, with no language restriction (See Appendix A, search strategy).

Further studies were identified through examination of reference lists of retrieved papers.

Four authors reviewed abstracts; each pair had to reach consensus for a study to be short-

listed. Every paper was then read in full by two authors and screened against inclusion / exclusion criteria before final decision.

# Modification of inclusion / exclusion criteria for QCA

Mindfulness studies were excluded from the Cochrane review but included in the QCA due to specific interest and to ensure sufficient levels of heterogeneity for analysis. For the QCA, the number of studies in the Cochrane review required reduction, so (1) the size criterion was modified: only papers with ≥30 participants in each arm were included to reduce the risk of bias (loannidis, 2018; Nüesch et al., 2009); (2) outcome at end of treatment, not at follow-up, was used; and (3) only comparisons of active treatment against treatment as usual or waiting list controls were considered (as clinically relevant), rather than those that used an active control to distinguish specific from non-specific effects.

### Search Results

38 papers were included in the analysis, each treatment-control contrast constituting a 'case'. Appendix B lists the papers which met inclusion criteria.

# Risk of bias

Within the Cochrane review, the risk of bias in methodologies of the included studies was rated using Cochrane guidance which considers selection, attrition and reporting bias (Higgins et al., 2011) which is modified for psychological trials.

# Measures

#### *Outcome Measures*

The Cochrane review gathered quantitative data on pain experience, disability and distress outcomes for each study. Pain reduction is not a universal aim of treatment trials, although it often occurs; reduced disability and distress were universal aims; most patients experience both disability and distress.

Where more than one scale sampled the same outcome in a single study, the authors selected the more reliable or widely used by other studies<sup>8</sup>. If data were missing, study authors were contacted directly and missing data requested. Standard Mean Difference

<sup>&</sup>lt;sup>8</sup> The outcome measure scale adopted by each paper is shown in Appendices K and L.

(SMD) (effect size) was calculated from post-treatment intervention and control data for pain-related disability and pain-related distress using RevMan software (The Nordic Cochrane Centre, 2014) set to random effects, given the heterogeneity between studies. These two estimates, **SMD distress and SMD disability**, were used as primary outcome measures.

#### Case Data

Data for the QCA were gathered using a grounded approach (Jopke & Gerrits, 2019), to allow maximum heterogeneity in the data set and to avoid early introduction of the author's bias into the analysis.

Variables (known as conditions or components in QCA) were not specified prior to familiarisation with the papers. Rather, as information about participants, research logistics, treatment content and treatment process was uncovered by reading, details were noted in brief qualitative terms. As each paper was read, new conditions arose and were added to the data pool. Once all papers had been read, condition names were allocated to different columns in a spreadsheet and qualitative data for each paper and treatment arm entered. Papers were then re-read so that missed data for every condition was gathered. Further information about how missing data were processed is detailed in the Calibration section below.

Multiple conditions were combined if they were similar in content (such as stretching and physical yoga exercises) or if conceptually similar in theorised mechanism of change (such as attention training and distraction techniques). These decisions are described in Appendix C.

Some conditions were excluded from the analysis if less than a third of cases illustrated their presence, as per QCA guidelines (Rihoux, 2006); examples of this are inpatient treatment and treatment in a pain clinic. Some conditions were excluded because there was no heterogeneity for the component; for example, psycho-education was a component of almost every treatment. Knowledge of pain management programmes suggests that even those studies which did not mention the inclusion of this component were more likely to have omitted its description than to have omitted it from their programme.

Where all studies, effective and ineffective, included a component, it added nothing to analysis. Such decisions are described in Appendix D.

The components could be described in terms of participant-related conditions, research process conditions, treatment content conditions and treatment process conditions.

# The conditions are listed in Table 1:

Patient conditions	Research-related conditions	Treatment Process conditions	Treatment Content conditions
Severe Psychopathology excluded	English speaking country  European study  Recruiter is specialist in pain or specific condition treatment  Attrition	Maximum number	Psychoeducation
		in treatment group	Cognitive
Location of pain:		Only Psychologically trained clinicians facilitating Hours of treatment Use of Group sessions as mode of delivery	Restructuring
Back pain  Location of pain:  Fibromyalgia			Acceptance & Commitment Therapy
Nature of pain: Musculoskeletal			Behavioural Reinforcement
Disability at baseline			Medication Reduction
Distress at baseline		Frequency of sessions	Problem Solving Coping
Age			Mechanisms
Standard deviation of age			Assertive Communication training
Gender: Female			Relaxation
% participants with above mandatory levels of education			Mindful Body Awareness
% participants employed			Use of technology to aid treatment
			Pleasant Activity Scheduling
			Pacing
			Graded Exercise
			Attention / Distraction
			Activity Planning
			Physical Exercise
			Sleep
			Relapse Prevention
			Graded Exposure
			Behavioural Rehearsal
			Family involvement
			less en

**Table 1: Conditions within QCA by category** 

Imagery

#### Condition selection

QCA guidance recommends conducting an analysis with a limited number of conditions. This is because the larger the number of conditions, the more possible combinations. Too many conditions create more combinations of conditions than the number of cases.

To reduce the number of conditions, six specialist pain researchers or clinicians (listed in Appendix E) independently selected the conditions which they thought would have the largest effect (negative or positive) on pain outcomes.

The individual expert responses were tallied together and a short-list of 22 conditions (see Appendix F) were compiled based on those selected by three or more experts. From these, CP theory and extant evidence in the treatment of CP guided a decision to explore: patient age, patient education level, whether the patients were recruited from clinical or general populations, attrition, baseline distress levels, baseline disability levels, use of cognitive restructuring, use of graded exposure, use of family in treatment and communication skills and hours of treatment using exploratory QCA to see which components showed potential for high levels of coverage and consistency (the central measures of confidence in QCA)<sup>9</sup>. The truth tables and minimisation tables output from initial QCA exploration to define the final conditions are reported in Appendix G. This resulted in a list of six components for the final analysis:

# **Baseline Distress**

The quantitative level of distress across participants, pre-treatment, was assessed at baseline by a variety of instruments, although measures of depressive symptoms were most common. Raw distress scores were then indexed to a standardised score from 0 to 100, where 100 is worst distress<sup>10</sup>.

<sup>9</sup> Coverage and consistency are explained in more detail within 'Minimisation'.

<sup>&</sup>lt;sup>10</sup>This process does however mean that the unique quantitative data of each measure (such as its norms, distribution and therefore mean) is lost. A more labour-intensive conversion approach taking into account such quantitative data could have been developed and utilised for Baselines Distress and Disability, however the scope of this study did not allow for this to take place.

## **Baseline Disability**

The quantitative level of disability across participants, pre-treatment, was assessed at baseline by a variety of instruments, although measures of functional ability were most frequently adopted. Raw disability scores from each of these scales were then indexed to a standardised score from 0 to 100, where 100 is worst disability.

# **Cognitive Restructuring**

Cognitive Restructuring is a core element of most CBT programmes. It involves the identification of negative automatic thoughts, a structured evaluation of the accuracy of these thoughts and the development of an alternative, more accurate thought. It aims to address the 'catastrophising' thoughts detailed within the FAM of Chronic Pain.

# **Exposure / Activity**

Avoidance of activity can occur because the individual fears that activity would exacerbate pain or cause injury. Avoidance of activity constitutes disability, since where pain is believed to be avoided or minimised, the individual will continue to avoid the activity. The FAM of Chronic Pain posits that exposure to feared activities (often physical movement) can help patients overcome a vicious cycle of pain behaviours and pain experience. Cases were considered a member of this set if they included practice in graded exposure, graded exercise or an element of behavioural rehearsal of activities of normal life. Although graded exposure proceeds by decrements in anxiety, and graded activity by increments in activity quota, they are often merged in practice.

# Social / Operant

Built largely on the operant behaviour principle that an individual's (social) environment can either positively reinforce or punish her/his behaviours and thus pain experience, interventions involving family or carers in interventions which seek to improve patient communication of support needs (often by assertive communication skills) or interventions that focus on modifying reinforcement contingencies (including self-reinforcement) are considered members of this set. Some theorists in the pain field hold that

the role of social networks is supportive validation of pain, in contrast to the reinforcement model, but none of the studies included were based on this premise.

#### **Hours of Treatment**

The number of hours of intervention to which a patient is exposed. This does not include homework tasks as this was not reliably measured across all studies.

# Analysis

#### Calibration

Interpretation of data in QCA is guided by calibration, where qualitative data are transformed into quantitative data. Data were calibrated into crisp-set and fuzzy-set data (definitions of which are detailed within the Conceptual Introduction).

# **Crisp Set Calibration**

Crisp set data are binary; for example, if a study noted 'graded exposure' as part of treatment, the case was given membership of the 'graded exposure' set (and marked as 1).

A case which did not mention 'graded exposure' was recorded as outside the 'graded exposure' set, having no membership (marked as 0).

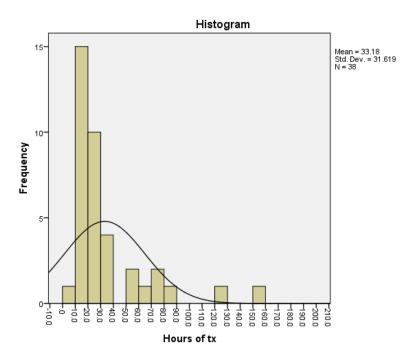
Where there was ambiguity as to membership, the author with her supervisor came to a consensus based on information in the paper and their substantive knowledge of pain treatment. For example, Castro (Castro et al., 2012) described treatment as 'Cognitive Behavioural Therapy' but included little further description of the content. The text referred to thoughts and beliefs, so we considered the case a member of the 'cognitive restructuring' condition.

## **Fuzzy Set Calibration**

Fuzzy sets were created by transforming data into a fraction between 0 and 1. The more representative of a condition a case was, the more membership of the set it was deemed to have and the closer to 1 it was scored. Four points were used to denote the different levels of case membership within each set, according to guidance (Ragin, 2008); they were calibrated in the following way:

- 0 = the case was completely out of the set and is not a member of the condition
- 0.33 = the case was mostly out of the set or more out than in the set
- 0.67 = the case was more in than out of the set or mostly in the set
- 1 = the case was completely in the set and a full member of the condition

The present study chose to use a direct method of calibration (Ragin, 2008) which involved defining, qualitatively, where the cut-offs lie for the given condition using knowledge of the subject and its theory. For example, the condition representing the number of hours of treatment ranged from six to 154, with cases of varying lengths in between. The Pain Society (The British Pain Society, 2013) recommended that the minimum number of hours for a CP management programme should be 36 and thus this was chosen as the point at which a case is deemed "more in than out" (0.67). The frequency distribution of treatment hour data related to treatment hours was also examined (Figure 2), suggesting that there was a jump in case frequency at 10 hours, therefore any case with less than this level of treatment was considered a "non-member of the condition" (0). Cases with between 10 and 36 hours of treatment were considered "more out than in" (0.33). There was also a large gap in the distribution from 90 to 120 hours and as such, any case with more than 120 treatment hours was considered a "full member of the condition" (1).



# Figure 2: Frequency distribution of hours of treatment

Baseline Distress and Baseline Disability scores were also calibrated into the following fuzzy sets (the corresponding frequency distributions of these scores are included in Appendix H):

# **Baseline Disability**

• score of < 20:

• score ≥ 20 and < 50: 0.33

• score ≥ 50 and < 80: 0.67

• score ≥ 80:

### **Baseline Distress**

• score of < 30:

• score ≥ 30 and < 50: 0.33

• score ≥ 50 and < 80: 0.67

• score ≥ 80: 1

# **Fuzzy Set Calibration of Outcome Measures**

In order to calibrate outcome measures, Cohen's description of effect sizes as negligible, small, medium and large was used as guidance (Cohen, 1988). Disability and distress scales often use higher scores to reflect worse symptoms, thus improvements are represented by negative effect sizes and resulted in fuzzy set calibration as follows:

• SMD > -0.2: 0

• SMD  $\leq$  -0.2 and > -0.5: 0.33

• SMD  $\leq$  -0.5 and > -0.8: 0.67

• SMD ≤ -0.8: 1

## Missing Data

Some cases did not provide information in the paper about conditions. Where information about study components was missing, assumptions were made about set membership based on other data available in the text. A list of general assumptions is

presented in Appendix I. A list of these case-specific assumptions and decisions is presented in Appendix J.

#### Rigour

Coding and calibration were completed by the author. When ambiguous data occurred, the author's supervisor independently coded them, the two decisions were compared and a coding agreement was made through discussion to ensure reliability and rigour. Data sets (after exclusion of cases) are presented in Appendix K and L.

The subsequent steps in QCA analysis were completed using R (R Core Team, 2014) and the graphic user interface of the QCA package (Dusa, 2019).

#### Robustness

Schneider (Schneider & Wagemann, 2010) recommends conducting a separate analysis for the negated outcome alongside the standard QCA, allowing the researcher to sense-check any conclusions from the initial analysis. The analysis was therefore split into four parts:

- 1. necessary and sufficient components in relation to Disability
  - a. positive impact
  - b. negative impact
- 2. necessary and sufficient components in relation to Distress
  - a. positive impact
  - b. negative impact

### Truth table

A truth table was created which lists each possible configuration or combination of conditions and how many cases reflected each configuration. The outcome (effective or not effective) was then analysed in relation to the configuration.

#### Remainders

There were some configurations where no cases existed (called remainders) and this is sometimes attributable to limited diversity. This can be dealt with in a number of ways, but

the present study made use of remainders by adopting 'parsimonious solutions' which are explained below.

#### Exclusion of cases

An initial review of Truth Table analysis revealed low consistency scores for all condition combinations which may have been due to a large number of cases with ambiguous set membership scores of the outcome measures. To address this and to understand maximum heterogeneity, other QCAs have excluded cases which are not clear members or non-members of the outcome set (Melendez-Torres et al., 2018). The present analysis created two new data sets, one which included only cases resulting in the top 10 and bottom 10 pain-related *distress* outcome scores (see Appendix K), the other included cases resulting in the top 10 and bottom 10 pain-related *disability* outcome scores (see Appendix L). The truth table analysis was then repeated using these new data sets.

#### **Minimisation**

Boolean minimisation was then carried out using R QCA. This resulted in a solution which reflects the configuration of conditions and absences of conditions which produces an effective outcome.

The present QCA made use of *parsimonious* minimised solutions<sup>11</sup>. Parsimonious solutions utilise *remainders* in the minimisation process. Parsimonious solutions assume that remainders agree with the solution which has been observed.

The software describes the solution in terms of raw **consistency** which represents the proportion of cases which reflect both the conditions and the outcome. All cases exhibiting the condition of interest rarely result in the outcome of interest. For this reason, some inconsistency is allowed, but researchers suggest that solutions should reach a minimum consistency level. Previous QCA have used minimum consistency scores ranging

1

<sup>&</sup>lt;sup>11</sup> QCA can create *conservative*, *intermediate* or *parsimonious* solutions. Conservative solutions use no logical remainders, parsimonious solutions utilise software to determine how remainders are incorporated, intermediate solutions require the software to be guided by the researcher in determining how remainders are incorporated. There is ongoing debate about which solution type should be used, however, parsimonious solutions are used here because they are considered easier to interpret and can imply causality whereas the others cannot (Baumgartner & Thiem, 2020). For transparency, intermediate and conservative solutions were also derived and can be found in Appendix M.

from 0.75 to 0.9 (Schneider & Wagemann, 2010). The present paper chose a 0.8 consistency cut-off.

The software also describes the solution in terms of **coverage** which represents the proportion of cases in the entire analysis which reflect the specific configuration. One paper can illustrate (or be described or 'covered' by) more than one combination of conditions.

### Resolution of contradictory configurations

Contradictory cases occur when one case exhibits the outcome and another exhibits the negation of the outcome, but both have the same combination of conditions. Resolution of these contradictions would normally be necessary, but, by looking at the data set, it was clear that no contradictions occurred in this QCA.

### Results

## Description of Included Studies

The 23 RCTs we included were primarily undertaken in Europe, with four in the US, and two in Australia. Studies were completed between 1990 to 2019.

Seven studies used participants with fibromyalgia, five with back or spine-related pain, two with knee pain, one with rheumatoid arthritis, one with neuropathic pain, one with shoulder pain, the remainder of the studies (n=5) had mixed CP conditions.

The majority of the studies' active treatment arms adopted forms of Cognitive
Behavioural Therapy (CBT) or Behavioural Therapy as the primary basis of their active
treatment, four used Mindfulness Based Stress Reduction (MBSR) and one used
Acceptance and Commitment Therapy.

Some studies had more than one active arm (with, for example, CBT in one arm and Behavioural Therapy in another) in which case, each arm was considered a separate case.

There were therefore 27 different cases in the study.

While most studies included participants of both genders, four papers recruited females only and the majority of participants across all studies were female (mean = 72%). The mean age of participants was 50 years (SD = 7.4 years). Approximately half the

participants were not employed (mean = 51%) and had not attended school for at least the mandatory number of years in their country (mean = 49%).

The risk of bias of the included papers can broadly be described as low where information was supplied, although it is unclear in many studies. A summary of risk of bias can be seen in Figure 3.

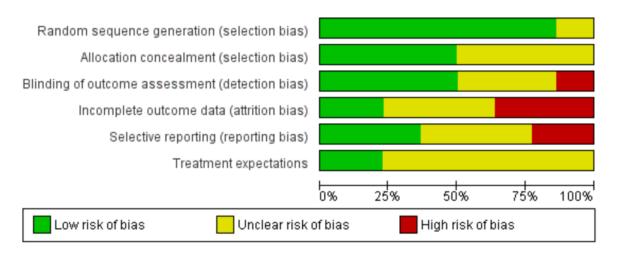


Figure 3: Summary of risk of bias in included studies.

The main problems highlighted in the risk of bias summary were related to detection, attrition and reporting bias. Detection bias occurred in a minority of papers which did not report having made an effort to use non-involved staff to collect patient self-report outcomes.

Attrition bias occurred more frequently and ranged from 2% to 34% in the included studies not using intention-to-treat analysis. These studies only analysed participants who completed the treatment programme which may have resulted in misleading results. Some reporting bias occurred where studies either had not registered their protocol in advance of the study and did not fully report all outcomes detailed in their study design, or where they had registered their protocol in advance but chose to report different outcomes to those planned, resulting in a presentation of results in a more positive light than might have occurred with their original primary outcomes.

### QCA results

A complete data set showing the 10 cases resulting in the highest and lowest Standard Mean Difference Distress and Disability can be found in Appendices K and L respectively with the outcome measure scale adopted by each paper indicated.

For the purposes of readability and formatting, the following shorthand is adopted within minimisation tables:

A: Hours of treatment

B: Baseline Disability

C: Baseline Distress

D: Cognitive Restructuring

E: Social / Operant

F: Exposure / Activity

~: Absence of condition

## 1.a. Positive impact on SMD Disability

The truth table can be found in Table 2. Truth table analysis found 48 remainders.

			Conditions					
Hours	Base Disability	Base Distress	Cognitive Restructuring	Social / Operant	Exposure / Activity	Membership in 'effective intervention' set	Number of cases	Raw Consistency
0	1	0	0	0	1	1	1	1
0	1	0	1	1	0	1	1	1
0	1	1	1	1	0	1	1	1
1	1	1	1	1	0	1	1	1
1	0	0	1	1	1	0	1	0.752
1	1	0	0	1	1	0	1	0.752
1	1	1	0	1	1	0	1	0.752
0	0	0	1	1	1	0	1	0.67
0	1	0	0	0	0	0	3	0.502
0	1	0	0	1	1	0	1	0.496
0	0	1	0	0	0	0	1	0.332
1	0	0	0	0	0	0	1	0.332
0	1	0	1	1	1	0	1	0.33
0	0	0	1	0	0	0	2	0
0	1	0	1	0	0	0	2	0
1	1	1	1	0	1	0	1	0

**Table 2: Truth Table for Positive impact on Disability** 

No contradictions occurred which required resolution. The parsimonious minimisation of the truth table can be found in Table  $3^{12}$ .

<sup>12</sup> Intermediate and conservative solutions can be found in Appendix M

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		Consistency	Raw Coverage	Unique Coverage	(M1)	(M2)	(M3)	cases
Minimisation 1 (M1)	E*~F + (~A*~E*F)	0.917	0.367					
Minimisation 2 (M2)	E*~F + (~C*~E*F)	1	0.367					
Minimisation 3 (M3)	E*~F + (~D*~E*F)	1	0.4					
Individual Solution 1	E*~F	1	0.3	0.3	0.3	0.3	0.3	1; 2; 7
Individual Solution 2	~A*~E*F	0.67	0.067	0	0.067			5
Individual Solution 3	~C*~E*F	1	0.067	0		0.067		5
Individual Solution 4	~D*~E*F	1	0.1	0.033			0.1	5

**Table 3: Minimisation for Positive impact on SMD Disability** 

Minimised solution M1 is not interpreted here as one of the two solutions incorporated within it (Individual Solution 2) had a low individual consistency level.

Minimised solution M2 (E\*~F + (~C\*~E\*F)) met the consistency threshold. M2 suggests that disability was consistently reduced by two combinations: Social / Operant without Exposure / Activity OR Exposure / Activity combined with low Baseline Distress levels and without Social / Operant. This solution had a consistency value of 1 and raw coverage of 0.367.

Minimised solution M3 (E\*~F + (~D\*~E\*F)) and the solutions within it met the consistency threshold. M2 suggests that disability score is consistently reduced by two combinations: Social / Operant without Exposure / Activity OR Exposure / Activity without Social / Operant and without Cognitive Restructuring. This solution had a consistency value of 1 and raw coverage of 0.4.

It is important to note that the individual solution E\*~F (Social / Operant without Exposure / Activity) alone has a consistency value of 1 and unique coverage of 0.3. Case examples of this are Castel et al., 2013; Nicholas et al., 2013 and the cognitive arm of Smeets et al., 2006.

There is only one case example (Garcia-Palacios et al., 2015) of Exposure / Activity without Social / Operant (served by individual solutions ~C\*~E\*F and ~D\*~E\*F).

Consideration of logical remainder cases was unnecessary because a parsimonious solution was adopted.

## 1.b. Negative impact on SMD Disability

The Truth Table can be found in Table 4. Truth table analysis found 48 remainders.

			Conditions			Membership in	Number of	D 6 11	
Hours	Base Disability	Base Distress	Cognitive Restructuring	Social / Operant	Exposure / Activity	'effective intervention' set	cases	Raw Consistency	
0	0	0	1	0	0	1	2	1	
0	1	0	1	0	0	1	2	1	
1	1	1	1	0	1	1	1	1	
0	1	0	1	1	1	0	1	0.67	
0	0	1	0	0	0	0	1	0.668	
1	0	0	0	0	0	0	1	0.668	
0	1	0	0	1	1	0	1	0.504	
0	1	0	0	0	0	0	3	0.498	
0	0	0	1	1	1	0	1	0.33	
1	0	0	1	1	1	0	1	0.248	
1	1	0	0	1	1	0	1	0.248	
1	1	1	0	1	1	0	1	0.248	
0	1	0	0	0	1	0	1	0	
0	1	0	1	1	0	0	1	0	
0	1	1	1	1	0	0	1	0	
1	1	1	1	1	0	0	1	0	

Table 4: Truth Table for Negative impact on SMD Disability

No contradictions occurred which required resolution. The parsimonious minimisation of the truth table can be found in Table  $5^{13}$ .

		Consistency	Raw Coverage	<b>Unique Coverage</b>	cases
Minimisation 1 (M1)	D*~E	1	0.5	-	12,17; 11,19; 15

**Table 5: Minimisation for Negative impact on SMD Disability** 

The analysis of the negated outcome provides a robustness check for the positive outcome solution by checking that the solution for a negative outcome is not the same as the solution for the positive outcome. The result of the negated outcome therefore does not contradict the positive outcome.

## 2.a. Positive impact on SMD Distress

The truth table can be found in Table 6. Truth table analysis found 51 remainders.

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 $<sup>^{13}</sup>$  Intermediate and conservative solutions can be found in Appendix M

			Conditions			Membership in	Number of	
Hours	Base Disability	Base Distress	Cognitive Restructuring	Social / Operant	Exposure / Activity	'effective intervention' set	cases	Raw Consistency
0	1	0	1	0	1	1	1	1
1	1	0	0	1	1	1	1	1
1	1	1	0	1	1	1	1	1
1	1	1	1	0	1	1	1	1
1	0	0	1	1	1	0	2	0.717
1	1	1	1	1	0	0	1	0.67
0	0	0	1	1	1	0	1	0.602
0	1	0	0	0	0	0	5	0.4
0	0	0	1	1	0	0	1	0.33
0	1	0	1	1	1	0	2	0.33
0	1	0	1	0	0	0	2	0
1	0	0	0	0	1	0	1	0
1	1	1	0	1	0	0	1	0

**Table 6: Truth Table for Positive impact on SMD Distress** 

No contradictions occurred which required resolution. The parsimonious minimisation of the truth table can be found in Table 714.

		Consistency	Raw Coverage	<b>Unique Coverage</b>	(M1)	(M2)	cases
Minimisation 1 (M1)	A*B*F + (B*~E*F)	0.788	0.367				
Minimisation 2 (M2)	A*B*F + (D*~E*F)	0.814	0.433				
Individual Solution 1	A*B*F	0.771	0.333	0.233	0.233	0.233	15; 19; 12
Individual Solution 2	B*~E*F	0.802	0.134	0	0.034		11; 12
Individual Solution 3	D*~E*F	1	0.2	0.066		0.1	11; 12

**Table 7: Minimisation for Positive impact on SMD Distress** 

Only one minimised solution M2 (A\*B\*F + (D\*~E\*F)) met the consistency threshold with a consistency value of 0.814 and raw coverage of 0.433. The minimised solution suggests that the presence of Exposure / Activity combined with either:

a) a high number of Hours of Treatment and high levels of Baseline Disability (as exemplified by Bliokas et al., 2007; Thieme et al., 2003; van Koulil et al., 2011 pain avoidance arm)

OR

was adopted.

b) Cognitive Restructuring without Social / Operant (as exemplified by Bliokas et al., 2007 and Cherkin et al., 2016 CBT arm) has a positive impact on distress levels. Consideration of logical remainder cases was unnecessary because a parsimonious solution

<sup>14</sup> Intermediate and conservative solutions can be found in Appendix M

# 2.b. Negative impact on SMD Distress

The truth table can be found in Table 8. Truth table analysis found 51 remainders.

			Conditions			Membership in	Number of	n 6 11
Hours	Base Disability	Base Distress	Cognitive Restructuring	Social / Operant	Exposure / Activity	'effective intervention' set	cases	Raw Consistency
0	1	0	1	0	0	1	2	1
1	0	0	0	0	1	1	1	1
1	1	1	0	1	0	1	1	1
0	0	0	1	1	0	0	1	0.67
0	1	0	1	1	1	0	2	0.67
0	1	0	0	0	0	0	5	0.6
0	0	0	1	1	1	0	1	0.398
1	1	1	1	1	0	0	1	0.33
1	0	0	1	1	1	0	2	0.283
0	1	0	1	0	1	0	1	0
1	1	0	0	1	1	0	1	0
1	1	1	0	1	1	0	1	0
1	1	1	1	0	1	0	1	0

**Table 8: Truth Table for Negative impact on SMD Distress** 

No contradictions occurred which required resolution. The parsimonious minimisation of the truth table can be found in Table 9<sup>15</sup>.

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 $<sup>^{\</sup>rm 15}$  Intermediate and conservative solutions can be found in Appendix M

		Consistency	Raw Coverage	Unique Coverage
Minimisation 1 (M1)	~B*~D + A*~D*~F + D*~E*~F	0.779	0.779	0.466
Minimisation 2 (M2)	~B*~D + A*~D*~F + ~A*B*D*~F	0.724	0.724	0.433
Minimisation 3 (M3)	~B*~D + A*~D*~F + B*~C*D*~F	0.724	0.724	0.433
Minimisation 4 (M4)	~B*~D + C*~D*~F + D*~E*~F	0.766	0.766	0.433
Minimisation 5 (M5)	~B*~D + C*~D*~F + ~A*B*D*~F	0.708	0.708	0.4
Minimisation 6 (M6)	~B*~D + C*~D*~F + B*~C*D*~F	0.708	0.708	0.4
Minimisation 7 (M7)	~B*~D + ~D*E*~F + D*~E*~F	0.779	0.779	0.466
Minimisation 8 (M8)	~B*~D + ~D*E*~F + ~A*B*D*~F	0.724	0.724	0.433
Minimisation 9 (M9)	~B*~D + ~D*E*~F + B*~C*D*~F	0.724	0.724	0.433
Minimisation 10 (M10)	~B*~E + A*~D*~F + D*~E*~F	0.779	0.779	0.466
Minimisation 11 (M11)	~B*~E + A*~D*~F + ~A*B*D*~F	0.724	0.724	0.433
Minimisation 12 (M12)	~B*~E + A*~D*~F + B*~C*D*~F	0.724	0.724	0.433
Minimisation 13 (M13)	~B*~E + C*~D*~F + D*~E*~F	0.766	0.766	0.433
Minimisation 14 (M14)	~B*~E + C*~D*~F + ~A*B*D*~F	0.708	0.708	0.4
Minimisation 15 (M15)	~B*~E + C*~D*~F + B*~C*D*~F	0.708	0.708	0.4
Minimisation 16 (M16)	~B*~E + ~D*E*~F + D*~E*~F	0.779	0.779	0.466
Minimisation 17 (M17)	~B*~E + ~D*E*~F + ~A*B*D*~F	0.724	0.724	0.433
Minimisation 18 (M18)	~B*~E + ~D*E*~F + B*~C*D*~F	0.724	0.724	0.433
Minimisation 19 (M19)	A*~C*~E + A*~D*~F + D*~E*~F	0.825	0.825	0.466
Minimisation 20 (M20)	A*~C*~E + A*~D*~F + ~A*B*D*~F	0.766	0.766	0.433
Minimisation 21 (M21)	A*~C*~E + A*~D*~F + B*~C*D*~F	0.766	0.766	0.433
Minimisation 22 (M22)	A*~C*~E + C*~D*~F + D*~E*~F	0.814	0.814	0.433
Minimisation 23 (M23)	A*~C*~E + C*~D*~F + ~A*B*D*~F	0.752	0.752	0.4
Minimisation 24 (M24)	A*~C*~E + C*~D*~F + B*~C*D*~F	0.752	0.752	0.4
Minimisation 25 (M25)	A*~C*~E + ~D*E*~F + D*~E*~F	0.825	0.825	0.466
Minimisation 26 (M26)	A*~C*~E + ~D*E*~F + ~A*B*D*~F	0.766	0.766	0.433
Minimisation 27 (M27)	A*~C*~E + ~D*E*~F + B*~C*D*~F	0.766	0.766	0.433
Minimisation 28 (M28)	A*~D*~E + A*~D*~F + D*~E*~F	0.876	0.876	0.466
Minimisation 29 (M29)	A*~D*~E + A*~D*~F + ~A*B*D*~F	0.814	0.814	0.433
Minimisation 30 (M30)	A*~D*~E + A*~D*~F + B*~C*D*~F	0.814	0.814	0.433
Minimisation 31 (M31)	A*~D*~E + C*~D*~F + D*~E*~F	0.868	0.868	0.433
Minimisation 32 (M32)	A*~D*~E + C*~D*~F + ~A*B*D*~F	0.802	0.802	0.4
Minimisation 33 (M33)	A*~D*~E + C*~D*~F + B*~C*D*~F	0.802	0.802	0.4
Minimisation 34 (M34)	A*~D*~E + ~D*E*~F + D*~E*~F	0.876	0.876	0.466
Minimisation 35 (M35)	A*~D*~E + ~D*E*~F + ~A*B*D*~F	0.814	0.814	0.433
Minimisation 36 (M36)	A*~D*~E + ~D*E*~F + B*~C*D*~F	0.814	0.814	0.433
Minimisation 37 (M37)	A*~D*~F + ~D*~E*F + D*~E*~F	0.883	0.883	0.499
Minimisation 38 (M38)	A*~D*~F + ~D*~E*F + ~A*B*D*~F	0.825	0.825	0.466
Minimisation 39 (M39)	A*~D*~F + ~D*~E*F + B*~C*D*~F	0.825	0.825	0.466
Minimisation 40 (M40)	C*~D*~F + ~D*~E*F + D*~E*~F	0.876	0.876	0.466
Minimisation 41 (M41)	C*~D*~F + ~D*~E*F + ~A*B*D*~F	0.814	0.814	0.433
Minimisation 42 (M42)	C*~D*~F + ~D*~E*F + B*~C*D*~F	0.814	0.814	0.433
Minimisation 43 (M43)	~D*~E*F + ~D*E*~F + D*~E*~F	1	1	0.4
Minimisation 44 (M44)	~D*~E*F + ~D*E*~F + ~A*B*D*~F	0.917	0.917	0.367
Minimisation 45 (M45)	~D*~E*F + ~D*E*~F + B*~C*D*~F	0.917	0.917	0.367
Individual Solution 1	~B*~D	0.621	0.216	0.367
Individual Solution 2	~B*~E	0.637	0.232	0
Individual Solution 3	A*~C*~E	0.701	0.232	0
Individual Solution 4	A*~D*~E	0.716	0.166	0
Individual Solution 5	A*~D*~F	0.751	0.199	0
Individual Solution 6	C*~D*~F	0.716	0.166	0
Individual Solution 6	~D*~E*F			
Individual Solution 7	~D*E*~F	1 1	0.1	0.033
Individual Solution 8	D*~E*~F	1		
Individual Solution 9 Individual Solution 10	~A*B*D*~F		0.2	0.066
THORNOUGH SOIUTION TO	I A D'U' F	0.835	0.167	0

**Table 9: Minimisation for Negative impact on SMD Distress** 

The analysis of the negated outcome provides a robustness check for the positive outcome solution. The result of the negated outcome does not contradict the positive outcome.

# Discussion

Sufficient components of psychological treatment of CP were not found. Findings were surprising in identifying particular combinations of treatment – or treatments that are best *not* combined – rather than the 'more is better' smorgasbord approach to designing treatment programmes that is the norm. They also, less surprisingly, indicated that while the necessary components of psychological treatment of CP differ somewhat depending on whether disability or distress is targeted, the similarities are more noticeable. The findings contrast somewhat with those from meta-analysis, which show greatest benefit from CBT programmes, and little from behavioural treatment alone (Williams et al. 2012, 2020).

# Disability

The QCA found that Social or Operant and Exposure or Activity treatments reduce disability levels when one approach is applied but not both. An explanation for this might again be that "more is not better". The 'smorgasbord' model of multi-component treatment models may be unhelpful in reducing disability; it may be better to do one intervention to a sufficient level, rather than many at superficial levels, although there is little research to suggest this is the case. It is possible that the assumption of synergy between different CBT components is wrong and a combination can create confusion for a patient, impeding therapy.

Interestingly, for Exposure or Activity to be effective in eliciting improvement in disability levels, either patients must have low baseline *distress* levels or it must be delivered without Cognitive Restructuring (again both without operant treatment). Baseline disability does not appear to be an important factor in predicting whether disability improvement will occur i.e. these methods can be effective for high or low levels of disability.

It may be that disability improvements occur with Exposure or Activity when distress levels are at a sufficiently low level or that high levels of distress make it hard for patients to engage in Exposure or Activity. This broadly fits within the FAM of pain; as the patient exposes themselves to the feared situation, they habituate to the situation, distress levels reduce and they feel more confident to tackle activities of daily living.

With regard to Cognitive Restructuring, these findings also support the idea that more than one intervention may introduce unnecessary burden but they also lend weight to the ACT argument that introspection may undermine behavioural work because it can be considered experiential avoidance, and behavioural experience in relation to reducing disability is particularly important.

A surprising finding is that the presence of Cognitive Restructuring was not found to be necessary in any solution eliciting positive change in disability levels. It is a basic principle of CBT for pain that reducing catastrophizing is necessary for reducing disability, and that catastrophizing is best addressed by cognitive methods that enable patients to identify and challenge their overly pessimistic predictions about becoming more active. This suggests that behavioural work (either in terms of the operant conditioning involved in reinforcement or anxiety reduction or increased self-efficacy from Exposure or Activity) has a stronger effect than Cognitive Restructuring in relation to disability.

The findings above, taken together, support the argument that researchers cannot assume that combining individually effective interventions has an additive effect (Morley, Williams & Eccleston, 2013). This may be related to the assertion in psychotherapy literature that specific technique is not as important as the therapeutic rapport (not measured here) developed between clinician and patient to bring about change (Horvath & Symonds, 1991; Luborsky et al., 2006).

## Distress

The QCA highlighted that Exposure or Activity can improve distress levels when combined with Cognitive Restructuring as long as Social or Operant is not included in treatment. It may be the case that family involvement / reinforcement is unhelpful because it is so difficult to switch from a pattern of punishment to positive reinforcement and that trying to do so, as well as trying to increase activity levels and think about things in a different way is distressing. Interestingly, the necessity of Cognitive Restructuring here suggests that

perhaps distress-reducing insight is not simply gained through experiential Exposure or Activity work alone, that it must be made explicit through evaluating beliefs.

The analysis also showed that Exposure or Activity alone has a positive effect on distress levels when patients have high levels of baseline disability and a high number of treatment hours are provided. An explanation for this may lie in the fact that Graded Exposure is perhaps a more technical or specific intervention that needs focus and works best in higher intensity situations and specific contexts (Vlaeyen et al., 2018). Patients with high levels of disability may find this kind of behavioural work particularly difficult and so a gradual, lengthier process may be beneficial and may be more suitable to reducing distress. More hours of treatment offer more staff-supervised or supported increase in activity. More detailed research into the trajectory of change would be helpful in answering these hypotheses.

Neither high nor low levels of baseline distress appear to be important when predicting effectiveness. In general, treatments worked for any level of baseline distress, perhaps because all were delivered by psychologists trained in managing distress.

### Strengths

Schneider lists 26 guidelines to ensure good quality QCA (Schneider & Wagemann, 2010). The present study has met many of these standards: it was used for its original aims; read alongside the 2020 Cochrane Review it was not the only analysis technique used; it was developed from a close connection and familiarity with the original cases and theory; the raw data table, truth table, solution formulae, consistency and coverage measures were reported; traditional QCA terminology was used; exclusion of cases was justified; outcome measures and conditions were chosen based on theory; the number of conditions was reasonable; calibration of crisp and fuzzy sets was detailed fully; case and variable-oriented aspects of QCA were depicted in a number of different forms; computer software was used to minimise the truth table; use of logical remainders was explained in full; outcome and negation of the outcome were analysed in separate steps; solution formulae have been

connected back to the cases; consistency and coverage measures have been recognised as important aspects of the analysis; prioritisation of one solution over another has been justified; analysis does not rely on one solution formulae to evidence a causal relationship between conditions, the way in which inconsistent truth table rows were treated was transparent and single conditions of a combinatorial solution have not been over-interpreted. The present study has also used a large number of high-quality, peer-reviewed papers which adds to the credibility of its findings.

#### Limitations

Nevertheless, the following standards have not been met: necessary and sufficient conditions were not analysed in separate analytical steps because sufficient conditions were not indicated. This may mean that sufficiency has been inadequately explored. Beyond Schneider's standards, the present QCA has further limitations.

### Loss of complexity

Time restrictions meant that only six conditions could be incorporated. By narrowing the analysis, 'key' components may have been missed and important interactions overlooked. Parsimonious minimisation also adds risk of error to the analysis; comparison of conservative, intermediate and parsimonious solutions would have allowed assessment of the reliability of findings. QCA also involves calibration, a simplification process in itself. Measures in papers are already calibrations of the patient's experience and thus to calibrate again reduces the data once more and allows more error.

#### Choice of papers

An analysis is only as good as the data within it and whilst the papers were of relatively high quality, they were limited in their diversity and their risk of bias.

The majority of papers came from white, educated, industrialised, rich and democratic countries. This means that the variation in psychological approach to treatment of pain was limited; the content was based on psychological theory developed in the west.

The participants themselves were largely white, of European descent and their mother

tongue was that spoken by the majority in their country. This, again, limits the generalisations that can be made from the QCA. A lack of consistent reporting of such variables meant it was not possible to incorporate these components into this QCA.

The papers also illustrated a risk of detection, attrition and reporting bias. Detection bias only occurred in a minority of papers and most participants reported outcomes using self-report questionnaires which reduced the risk of the investigator being able to influence measures. In addition, reporting bias has been, in some way, negated by the fact that the present study focused on outcomes regardless of whether they were planned and named as primary outcomes or not. The level of attrition bias, however, does present a difficulty; if participants who dropped out had done so because the treatment hadn't worked for them, their outcome scores would have reflected no or little change and had their scores been included in the paper, the overall effects of treatment might have been shown to be negligible. Of the papers highlighted as having a risk of attrition bias, one of these (Bliokas et al., 2007) was a case which covered the solution relating to effective reduction of distress levels<sup>16</sup>. Whilst it was not the only case covering this particular solution, the risk of bias means that any conclusions arising from this solution (which suggested that Exposure / Activity treatment combined with either high Treatment Hours and high levels of Baseline Disability or Cognitive Restructuring without Social / Operant treatment result in Distress reduction) must be drawn tentatively.

A further limitation is the use of just the papers with the highest ten and lowest ten outcome measures rather than the whole set of 38 papers. It means that conclusions are limited in their generalisability; we can say that "for high levels of effectiveness the following combination of components are necessary" but we have not answered what contributes to moderate levels of outcome change.

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<sup>&</sup>lt;sup>16</sup> Exposure / Activity treatment combined with EITHER a high number of Treatment Hours and high levels of Baseline Disability OR Cognitive Restructuring without Social / Operant treatment.

#### Reporting

Reporting of the research process in the studies analysed was variable with some key information omitted and descriptions which were open to multiple interpretations. This meant that subjective interpretation was utilised and thus the chance of error increased, however transparently decisions have been documented.

A challenge in any meta-analysis is how to compare studies using different measures and while decisions adopting reliable, valid and simple measures were made transparent, very few scales used in pain research can be validated as they sample subjective experience which is not possible to validate. Scale choice was a subjective decision, adding further error.

QCA focused on pain-related disability and pain-related distress, both of which are important aspects of the pain experience, but there are other aspects which more closely reflect the patient's priorities such as enjoyment of life, fatigue, weakness, sleep and concentration (Beale et al., 2011). Patients are rarely involved in designing patient-reported outcome measures (Pogatzki-Zahn, Schnabel & Kaiser, 2019), certainly there is an argument that scales assessing the patient's impression of change or goal achievement might more effectively mirror patient priorities than those examined here.

Additionally, while psychological treatment of CP does not carry the same level of risk as surgical intervention, adverse events or iatrogenic effects (such as pain increase or incidence of other mental or physical difficulties (Duggan et al., 2014)) can occur during treatment but few studies reported these and they could not be analysed. This may be particularly important when considering distress, particularly in relation to some of the hypotheses generates here, that multiple component treatment can represent excess psychological burden.

## Implications for clinical practice

Specific recommendations for clinicians are hard to make here because many aspects of treatment have not been included within the QCA. Although these results seem to

suggest that 'less is more', analysis of different treatment components might uncover alternative conclusions, therefore further QCA in this field is indicated.

Although there are limitations to this review, the strengths of the present analysis do offset many of these and therefore the following recommendations can be made for clinical practice:

When targeting disability as an outcome:

- Social or Operant interventions are effective as long as Exposure or Activity
   interventions are not offered within the same programme
- Exposure or Activity interventions should be offered without Cognitive
   Restructuring in the same programme
- Exposure or Activity interventions should only be offered to patients with low,
   rather than high levels of Baseline Distress

When targeting distress as an outcome:

- Exposure or Activity interventions should be offered alongside Cognitive
   Restructuring but without Social or Operant interventions
- Exposure or Activity interventions can also be effective in reducing distress for patients with high Baseline Disability as long as a high number of treatment hours is offered

This review suggests that when planning CP interventions, treatment components (Exposure or Activity, Social or Operant and Cognitive Restructuring) should not be assumed to be synergistic and provided in a single package. Clinicians should equally not assume that all aspects of the pain experience can be improved at once; therefore, whilst both distress and disability are improved, generally, by behavioural interventions, clinicians may benefit from an awareness that some specific combinations of components are more likely to be effective dependent on whether influenced by whether pain-related distress or disability is being targeted. Equally, because interventions were largely not dependent on baseline levels to effect positive change, it may be unnecessary to segregate patient by baseline distress and disability levels; indeed, many patients need both targeted.

Consideration may need to be given to the severity of baseline disability and number of hours of treatment when targeting distress, but further research would be necessary to establish this requirement.

# Implications for future research

There remains an abundance of data to explore from the present study's data gathering process which may be necessary or even sufficient for a positive change in disability or distress. QCA may be helpful in exploring whether using a single modality of treatment content is better than a package but further analyses would need to be undertaken before this could be concluded.

The hypotheses generated relating to the interaction between distress and disability may need exploration with single case studies, serial treatment or trajectory studies.

It may be helpful to systematically, one by one, introduce and alternate further patient characteristics, treatment content and treatment process components into the QCA, alongside the components already found to be necessary in the present study. This would allow researchers to see whether some conditions are more consistently necessary than those identified here, and, with confidence, which solution most consistently reduces distress and / or disability.

In order to inform theory, it may be helpful to un-merge the previously merged necessary conditions (such as Exposure or Activity and Social or Operant) into conditions aligned with one model of pain or CP and incorporate these more granular conditions into QCA to ascertain which theoretical approach is necessary for positive change.

Qualitative exploration of these topic could also aid understanding of how these factors interact.

#### Conclusion

The present study has shown that the necessary components of psychological CP treatment are largely behavioural rather than cognitive regardless of whether the outcome targeted is distress or disability, and for both outcomes, the QCA has shown that the

inclusion of multiple treatment content components does not necessarily have an additive effect.

The QCA suggests that with regards Exposure or Activity, Cognitive Restructuring and Social or Operant treatment, the use of all three components together is not associated with improved outcomes.

Exposure or Activity and Social or Operant treatment only ever seem to be effective when one of them is used at a time. When Exposure / Activity and Cognitive Restructuring treatment are combined they are only necessary for the improvement of distress and not disability levels.

Baseline disability is a necessary factor to consider when planning interventions targeted at reducing distress.

This review has also highlighted the importance of exploring further treatment component interactions using the QCA approach in the future.

# Glossary of QCA Terminology

**Calibration** Process whereby fuzzy or crisp set membership scores are given to

cases

**Case** In the context of this review, a case refers to one active treatment arm

of a peer-reviewed Randomised Controlled Trial

**Condition** (also **Component**) An aspect of the case which could be used to

explain the outcome, In the context of this review this could be the

treatment content, a descriptive aspect of the participants or the

research / treatment process

**Conservative** A complex solution type which uses no logical remainders in its

determination

**Consistency** The proportion of cases which reflect both the conditions and the

outcome

**Counterfactual** A combination of conditions which has not been observed

**Coverage** The proportion of cases in the analysis which reflect the solution

Crisp Set A binary set which allows only full-membership or non-membership of

1 or 0

Fuzzy Set A set which allows levels of membership described on a continuum of

fractions from 0 to 1

**Intermediate** A type of solution which requires QCA software to be guided by the

researcher in determining how remainders are incorporated

**Minimisation** Summary of the data set after application of Boolean Logic to a Truth

Table

**Necessary**Used to describe a condition which ensures a specified outcome will

occur but which does not, alone, guarantee its occurrence

**Parsimonious** A type of solution which utilise software to determine how remainders

are incorporated

**Remainders** In a truth table, a combination of conditions for which no case exists

and therefore no outcome has been derived

**Solution** The end result of QCA minimisation; a combination of conditions

resulting in the specified outcome

**Sufficient** Used to describe a condition which, if present, guarantees an

outcome's occurrence

**Truth Table** Case data sorted into each of the different combinations of conditions

which they exhibit and to which a column of outcome values is applied

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# Part 3: Critical Appraisal

The production of a QCA, or indeed any research project, takes the author on a journey of changing emotions as the author learns about the topic, the process and the field in which they are working. The reflections below explore some of the more pertinent aspects of this journey, resulting in suggestions which might allow future researchers new to QCA a less challenging ride.

# An emotional expedition

### Excitement

If qualitative research has, in the past, been treated as a second-class citizen compared to quantitative work, QCA may now be a helpful advocate for its right to a better seat at the research table. QCA bridges the gap between the two, incorporating some of the best aspects of both into a plane where each fuels the other. Indeed, its use is encouraged by Cochrane who are often wrongly assumed to be inimical to the field of qualitative research. This is heartening for a researcher; it feels as though respect is being paid to the spirit of each of the studies being analysed as well as to the fundamental aspects of the story told by the numbers.

Of course, QCA does not have to merge these two elements, it can be done using purely qualitative or purely quantitative data, and these approaches may be equally valid, so it's exciting to see so many more analytical options open up and with them, further insights to be gained. It's also exciting that the present paper looked beyond the usual canon of psychology methodologies at a social science development, which is, itself, often considered as second-class in research stakes.

Embarking upon and completing analysis for this project has been stimulating in every sense of the word, although not always in a positive way.

The initial qualitative familiarisation with the studies elicited a multitude of variables, all of which could be included in the analysis. It was never going to be feasible to incorporate all of these as components, a fact which led to considerable frustration. This meant that there was often a thought, particularly after minimisation when a consistent solution was

found, that adding just one more component into the analysis would result in a different picture and important insights about moderating and mediating factors in the treatment of CP. This is, nevertheless, what makes QCA an exciting process; every step you take opens up further questions and draws further enquiry.

# Impostor Syndrome

As mentioned, the QCA approach provides an appealing, structured and fertile middle-ground between quantitative and qualitative methodology, but it is this very quality which, to the researcher rehearsed in more typical qualitative and quantitative analysis, can feel uncomfortable. The standards of rigour, reliability and validity which a quantitative study aims to meet do not feel possible to maintain within QCA, yet the spirit of a more grounded qualitative approach is not present in the same way that it would be with, say, a thematic analysis of the material. The researcher can feel an element of 'impostor syndrome' when using the approach for the first time, particularly when working in a field where there are few QCA allies, examples or experts.

Working alongside another meta-analysis also added to this. An advantage was that some of the data gathering was completed as a team, reducing the workload of individual researchers, but it meant that the author does not feel as completely immersed or familiar with the data as if they had done all of work alone. Additionally, the differences between the scope of the Cochrane meta-analysis and the present study meant that data did not automatically translate from one to another, making summarising the information much more complicated than it would ordinarily be and adding to doubts that mistakes would be made and therefore that the author was somehow falling short of what constitutes a credible researcher.

The doubt did not stop there, however.

Doubt, dilemmas and guilt

#### Abundance of data

A key challenge was choosing where to start. Qualitative familiarisation resulted in a multitude of prospective components which could be included in the study. Each of the variables uncovered (and in all likelihood, many which were not identified) could feasibly be necessary components of psychological treatment of CP. This, combined with the fact that once the data has been imported, the software R makes analysis so quick and easy, meant that it was tempting to look at all possible components in order to uncover those which were necessary parts of the solution. While the QCA community does not seem to weigh against this approach as heavily as quantitative researchers might against data snooping, time restrictions meant that a structured approach to a focused group of variables would not only be more feasible but would also assist in the formation of interpretations and conclusions. This left, however, a nagging, yet entirely possible doubt that by narrowing the analysis, 'key' or even sufficient components had somehow been missed. By narrowing the focus, much of the gathered data has been left unused which elicits both sadness and frustration. The data can, of course, be taken and analysed by future researchers but whether or not this will happen is uncertain and it is therefore likely that some data will never be used. This likelihood comes with a huge sense of loss.

#### Choice of measures

Most examples of meta-analysis have had to grapple with how to compare studies using different measures. While this review overcame this challenge by choosing the most reliable or valid measures and by being transparent about these decisions, very few of the scales used in pain research can be validated. Again, this idea that the 'wrong' measures were chosen casts yet more doubt as to the quality of the research produced here. Even though the measures in the original papers present a large part of the problem themselves, the choice ultimately lies with the QCA researcher who then must sit with the doubt that a different decision could have resulted in more reliable or valid analysis and conclusions.

#### Component choice

A difficult aspect of the process was using theory to inform decisions. This was particularly difficult because there are multiple models of chronic pain (CP) and CP treatment which, to date, do not fully explain the mechanisms of pain, change in pain or the associated behaviour, thoughts and emotions. Some theories detail concepts are so over-arching that they could include innumerable components. Using theory to inform decisions therefore felt deeply unsatisfying because theory could be used in so many different ways to influence the choices which were made. At times it felt that if I only knew more, or understood better, then the decisions would become clear. The fact that there was some heterogeneity among the components that the experts felt would result in the most conclusive change suggests that understanding (or lack of understanding) of the theory was not the issue here. Decision making, particularly relating to component analysis choice, was sometimes, therefore, made based on curiosity, provided the relevant theory did not preclude that choice. Research methods training courses do not encourage decisions based solely on curiosity and thus the shadow of doubt fell again over the choices made in this QCA journey. Components were also sometimes excluded from the study and sometimes merged together. On some occasions, these decisions prevented further guesswork and estimations having to be made, thereby reducing error, but other decisions were less easily made and again contributed to the doubt that the conclusions were based upon shaky foundations.

However, it was also important to remain open to the possibility of the data. At some stages in the process, when considering which components to include or exclude, it was easy to think "this is too inconsequential to be useful", but the beauty of QCA is that 'small' factors in combination with others can still have an influence on the outcome, and as such, even erroneous decisions could bring forth important findings. Indeed, the hope in doing this review was that the findings would, in turn, help inform theory and further QCA analyses, closing the feedback loop and addressing some of the theoretical shortcomings.

#### Codina

A further difficult yet key decision was the choice to use crisp or fuzzy set data. Whilst some components clearly lend themselves to crisp set, other components are less obvious. Either choice can leave the researcher with a nagging doubt that either valuable information has been excluded or that adding complexity limits the power of the conclusions that can be drawn.

At points in the analysis, the 'coding' of data, particularly when qualitative and drawn into crisp sets, can feel arbitrary, even when decision making is recorded, transparent and agreed on with fellow researchers. When there is ambiguous data, the responsibility for coding into a crisp set falls to the researcher and this can feel both difficult and unsatisfying. The problem, of course, started when the author of the original paper chose to convey their study in words which leave room for multiple interpretations, but this does little to disperse feelings of discomfort in the researcher. The challenge can be overcome by asking for and receiving additional information from the author of the paper but this is only possible with the luxury of time.

Missing data too presented further challenge; data was estimated based on assumptions made from the data which did exist. Again, such guesswork, however transparent and informed by theory, sows seeds of doubt in the researcher and possibly the reader's mind which can reduce confidence in both the process and its findings.

#### Choice of paper

Striving for perfection is commonplace amongst psychologists, no matter how unrealistic that goal might be. The decision to use only the papers with the highest ten and lowest ten outcome measures rather than the whole set of papers was a difficult one, even though the advantages of using this method are clear (these are detailed in the empirical paper). The disadvantages of the decision remain, of course and reduce the quality of the paper, prompting feelings of disappointment and guilt. The knowledge that this was done in a considered and transparent way does little to assuage any discomfort.

It is worth remarking, however, that the dilemmas that arose in this QCA are true across many areas of psychology research, including meta-analysis and Cochrane review processes. The difference between QCA and more well-established research methods in psychology is that there are conventions for handling dilemmas in the latter, which allow researchers to feel more comfortable with their decisions and to perhaps ignore their importance. QCA within psychology is a new area and thus these dilemmas had to be tackled alone, without reassuring examples of experts in the field who had gone before which generated considerable levels of doubt and uncertainty.

## Development as a researcher

The excitement, frustration, doubt, uncertainty and guilt that were elicited during the QCA process were nevertheless good teachers. The ability to 'sit with' such difficult emotions is a skill which many psychologists try to engender in their patients during therapeutic work and the irony that I developed this skill while working on a study about chronic pain is not lost. A key factor which helped me to come to this position was support from an experienced, thoughtful and empathetic supervisor who could recognise these difficulties and normalise them in a way which was reassuring. These emotions coupled with my supervisor's insight allowed me to come to a place of realisation that all studies are all imperfect in some way, that they all have weaknesses and ways in which they could have been improved. In coming to this conclusion I became more sensitive to the limitations of research, that even results from well-resourced studies with highly-respected authors would not easily translate into tangible, replicable, reliable change in real world target populations. In realising this, I came to understand that one of the most important qualities, if not the most important quality (and one which is, luckily, both a realistic and attainable goal) in research projects is that of transparency of decision making. It brings comfort to know that even if an error of judgement has been made, it has been justified and explained openly, and can therefore provide a learning opportunity and springboard for future researchers and research projects.

## Clinical Psychology Research Methods Training

The present study was completed as part of a doctoral programme in Clinical Psychology. In terms of statistical computer software, Clinical Psychology training courses tend to teach the fundamentals of SPSS (IBM Corp, 2017) which is a software which does not support QCA analysis. The QCA field has a choice of software available; fsQCA (Ragin & Davey, 2016), QCA for R (Dusa, 2019), Tosmana (Cronqvist, 2019) to name but three. Each is slightly different from the other with advantages and disadvantages. The present study used QCA for R on recommendation from another author who had used it successfully; however, R requires the researcher to learn its language in order to code the functions that that need to be performed. R as an analytical tool is being used more and more frequently in academic research as the use of SPSS declines (Muenchen, 2016), yet it remains relatively under-taught. This is peculiar, given that R is free, encourages people to share their development of coding packages and thus facilitates research whereas IBM (who own SPSS) has a business model focused on profit. This learning process, without a training course or tutor and just textbooks to learn from proved difficult and stressful. It was fortunate that the QCA package for R came with a 'shiny' interface which was more user-friendly. Conducting the present QCA would have been an easier experience if the fundamentals of R coding had been grasped prior to starting and perhaps a higher quality of analysis could have been reached. It would therefore be helpful, and perhaps wise, if doctoral programmes in clinical psychology or indeed, any course of study which uses statistical analysis taught basic R programming skills in addition to SPSS.

## More guidance needed

Much of the learning taken from this process related to how the research and academic community could assist students and researchers embarking upon QCA.

## Reporting

As alluded to in previous points, the quality of reporting in the studies analysed was variable which put more responsibility onto the author's subjective reading of the material and therefore increased the chance of error. Later papers, more frequently, had registered

their study in advance with a detailed protocol, in which case, the data was rich and contributed to more accurate coding. Indeed, there is an increasing number of guidelines on what needs to be included in studies to make them more accessible to any review, such as CONSORT for randomised controlled trials (Schulz et al., 2011). It would be of great benefit if authors of randomised controlled trials adhered to such quality guidelines. In addition, the quality of reporting could, in future QCAs be included as a component to examine the difference that this lack of information can make on an analysis.

## QCA benchmarks

One of the biggest challenges in conducting a QCA in the field of psychological treatment for CP was that no QCA has been done in this area before. There are only a few QCAs relating to clinical health psychology; few exemplars exist which would have been useful in informing the process for the present study. As a result of this, a further challenge was integrating expertise from different fields of research; my supervisor brought knowledge and experience in pain research while Dylan Kneale and Katy Sutcliffe brought an understanding of the use of QCA in other areas of physical health but there was not one individual who could be seen as an expert in both. This meant that I was responsible for assimilating both pools of knowledge to forge a way forward. More use of QCA in the health psychology field and CP itself would be particularly helpful therefore in terms of exemplars and expertise for guidance. It would be remiss not to mention that these challenges were, however, some of the most exciting aspects of the work; the knowledge that the steps forward, the mistakes and learnings that I made would hopefully open up a new space in CP treatment research.

#### QCA standards

Guidelines regarding the components of a good quality QCA have been established (Schneider & Wagemann, 2010), but they represent broad recommendations and are not specific. Ragin has provided some rules on minimum levels of consistency (Ragin & Rihoux, 2009) but there remain other aspects of QCA which are left open to the researcher's

decision making. One particular gap in guidance is relating to the use of conservative versus parsimonious solutions; the debate about which to adopt and how they relate to causality is in progress; the jury is out but a verdict would be helpful for future studies.

Guidelines relating to fuzzy versus crisp sets would also be welcome. Some components were continuous measures which the present study calibrated into fuzzy set measures but this approach may mean that valuable diversity of data is lost to the process. How the calibration is carried out dictates how much of the variation can be retained; dividing the data into six fuzzy sets will represent more heterogeneity than four. Crisp sets would reduce this information even further. Information detailing when it is best to use fuzzy sets and if so, what number of sets should be drawn from different types of continuous data would be beneficial for forthcoming research.

Institutions such as The Cochrane Collaboration have developed frameworks for systematically judging the quality of reviews used in meta-analyses, a similar framework is being developed for QCAs and would be a welcome benchmark against which QCAs could be designed and planned.

# QCA decision reporting

Schneider (Schneider & Wagemann, 2010) argues that a good quality QCA should be transparent about the decisions made and report them clearly, but it is unclear which of these decisions should be communicated. The larger the number of papers, the larger the volume of coding decisions and decisions relating to missing values or information.

Reporting all of this would aid critical reading of the work and enable replication of the study (should that be desired), but it is not practical to detail so much information, and the question of how best to convey these decisions in a user-friendly manner also arises. Again, further clarification and examples of how this can be done in a helpful way would be welcomed.

## Summary

Forging my way through a new form of analysis in a field of psychology which was relatively new to me has been a challenge which has prompted significant levels of doubt but

which has ultimately resulted in personal growth and learning. While QCA (and R) training, guidelines and exemplars in clinical health psychology would be beneficial, I'm proud that I've played a part in progress in this field.

Appendices: Part 2 (Empirical Paper)

# Appendix A

## Search terms

- 1. PAIN explode all trees (MeSH)
- 2. (chronic\* near pain\*)
- 3. (#1 and (chronic\* near pain\*))
- 4. (chronic\* near discomfort)
- 5. (chronic\* near ache\*)
- 6. (chronic\* near fibromyalgia:ab)
- 7. (chronic\* near fibromyalgia:ti)
- 8. (chronic\* near neuralgi\*:ab)
- 9. (chronic\* near neuralgi\*:ti)
- 10. (chronic\* near dysmenorrhea:ti)
- 11. (chronic\* near dysmenorrhea:ab)
- 12. (chronic\* near dysmenorrhoea:ti)
- 13. (chronic\* near dysmenorrhoea:ab)
- 14. (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)
- 15. PSYCHOTHERAPY explode tree 1 (MeSH)
- 16. COGNITIVE THERAPY single term (MeSH)
- 17. BEHAVIOR THERAPY explode tree 1 (MeSH)
- 18. BIOFEEDBACK (PSYCHOLOGY) single term (MeSH)
- 19. ((behaviour\* next therapy) or (behaviour\* next therapies))
- 20. ((cognitive next therapy) or (cognitive next therapies))
- 21. (relax\* near technique\*)
- 22. ((relax\* near therapy) or (relax\* near therapies))
- 23. meditat\*
- 24. psychotherap\*
- 25. (psychological next treatment)
- 26. ((psychological next therapy) or (psychological next therapies))
- 27. (group next therapy)
- 28. (self-regulation next training)

- 29. (coping next skill\*)
- 30. (pain-related next thought\*)
- 31. (behaviour\* near rehabilitat\*)
- 32. (psychoeducation\* next group)
- 33. (psychoeducation\* next groups)
- 34. (psycho-education\* next groups)
- 35. (psycho-education\* next group)
- 36. (mind and (body next relaxation next technique\*))
- 37. MIND-BODY AND RELAXATION TECHNIQUES explode tree 1 (MeSH)
- 38. (#15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37)
- 39. (#14 and #38)

## Appendix B

List of papers (and their associated protocols) meeting search inclusion criteria

## Alda 2011

Alda M, Luciano JV, Andrés E, Serrano-Blanco A, Rodero B, López del Hoyo Y, et al. Effectiveness of cognitive behaviour therapy for the treatment of catastrophisation in patients with fibromyalgia: a randomised controlled trial. Arthritis Research & Therapy 2011;13:R173.

Luciano JV, D'Amico F, Cerda-Lafont M, Peñarrubia-Maria MT, Knapp M, Cuesta-Vargas AI, et al. Cost-utility of cognitive behavioral therapy versus U.S. Food and Drug Administration recommended drugs and usual care in the treatment of patients with fibromyalgia: an economic evaluation alongside a 6-month randomized controlled trial. Arthritis Research and Therapy 2014;16:451.

## Basler 1997

Basler HD, Jakle C, Kroner-Herwig B. Incorporation of cognitive-behavioral treatment into the medical care of chronic low back patients: a controlled randomized study in German pain treatment centers. Patient Education & Counseling 1997;31:113-24.

## Bliokas 2007

Bliokas VV, Cartmill TK, Nagy BJ. Does systematic graded exposure in vivo enhance outcomes in multidisciplinary chronic pain management groups? Clinical Journal of Pain 2007;23:361-74.

## Carson 2006

Carson JW, Keefe FJ, Affleck G, Rumble ME, Caldwell DS, Beaupre PM, et al. A comparison of conventional pain coping skills training and pain coping skills training with a

maintenance training component: a daily diary analysis of short- and long-term treatment effects. Journal of Pain 2006;7(9):615-25.

#### Castel 2013

Castel, A., Fontova, R., Montull, S., Perinan, R., Poveda, M. J., Miralles, I., Cascon-Pereira, R., Hernandez, P., Aragones, N., Salvat, I., Castro, S., Monterde, S., Padrol, A., Sala, J., Anez, C., & Rull, M. (2013). Efficacy of a multidisciplinary fibromyalgia treatment adapted for women with low educational levels: a randomized controlled trial. Arthritis Care & Research, 65(3), 421–431. https://doi.org/https://dx.doi.org/10.1002/acr.21818

## Castro 2012

Castro MM, Daltro C, Kraychete DC, Lopes J. The cognitive behavioral therapy causes an improvement in quality of life in patients with chronic musculoskeletal pain [A terapia cognitiva-comportamental causa melhora na qualidade de vida em pacientes com dor crônica musculoesquelética]. Arquivos Neuro-psiquiatria 2012;70(11):864-8.

## Cash 2015

Cash E, Salmon P, Weissbecker I, Rebholz W N, Bayley-Veloso R, Zimmaro L A, et al. Mindfulness meditation alleviates fibromyalgia symptoms in women: results of a randomized clinical trial. Annals of Behavioral Medicine 2015;49(3):319-30.

## Castel 2013

Castel, A., Fontova, R., Montull, S., Perinan, R., Poveda, M. J., Miralles, I., Cascon-Pereira, R., Hernandez, P., Aragones, N., Salvat, I., Castro, S., Monterde, S., Padrol, A., Sala, J., Anez, C., & Rull, M. (2013). Efficacy of a multidisciplinary fibromyalgia treatment adapted for women with low educational levels: a randomized controlled trial. Arthritis Care & Research, 65(3), 421–431. https://doi.org/https://dx.doi.org/10.1002/acr.21818

#### Cherkin 2016

Cherkin Daniel C, Sherman Karen J, Balderson Benjamin H, Cook Andrea J, Anderson Melissa L, Hawkes Rene J, et al. Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: A randomized clinical trial. JAMA - Journal of the American Medical Association 2016;315(12):1240-9.

#### De Souza 2008

De Souza JB, Bourgault P, Charest J, Marchand S. Interactional School of Fibromyalgia: learning to cope with pain - a randomized controlled study [Escola Inter-relacional de Fibromialgia: aprendendo a lidar com a dor - estudo clinico randomizado]. Revista Brasileira de Reumatologia 2008;48:218-25.

## **Evers 2002**

Evers AW, Kraaimaat FW, van Riel PL, de Jong AJ. Tailored cognitive-behavioral therapy in early rheumatoid arthritis for patients at risk: a randomized controlled trial. Pain 2002;100:141-53.

## Falcao 2008

Falcão DM, Sales L, Leite JR, Feldman D, Valim V, Natour J. Cognitive behavioral therapy for the treatment of fibromyalgia syndrome: a randomized controlled trial. Journal of Musculoskeletal Pain 2008;16:133-40.

#### Ferrando 2012

Ferrando M, Galdon MJ, Dura E, Andreu Y, Jimenez Y, Poveda R. Enhancing the efficacy of treatment for temporomandibular patients with muscular diagnosis through cognitive-

behavioral intervention, including hypnosis: a randomized study. Oral Medicine 2012;113(1):81-9.

## Garcia-Palacios 2015

Garcia-Palacios A, Herrero R, Vizcaino YBelmonte MA, Castilla D, Molinari G. Integrating virtual reality with activity management for the treatment of fibromyalgia acceptability and preliminary efficacy. Clinical Journal of Pain 2015;31(6):564-72.

## Geraets 2005

Geraets J, Goossens M, De Bruijn CPC, De Groot IJM, Koke AJS, Pelt R, et al. Costeffectiveness of a graded exercise therapy program for patients with chronic shoulder complaints. International Journal of Technology Assessment in Health Care 2006;22:76-83.

Geraets J, Goossens M, de Groot IJM, de Bruijn CPC, de Bie RA, Dinant GJ, et al. Effectiveness of a graded exercise therapy program for patients with chronic shoulder complaints. Australian Journal of Physiotherapy 2005;51:87-94.

Geraets JJ, Goossens ME de Bruijn CP, Koke AJ, de Bie RA, Pelt RAGB, et al. A behavioural treatment for chronic shoulder complaints: concepts, development, and study design. Australian Journal of Physiotherapy 2004;50:33-8.

## Glombiewski 2010b

Glombiewski JA, Hartwich-Tersek J, Rief W. Two psychological interventions are effective in severely disabled, chronic back pain patients: a randomised controlled trial. International Journal of Behavioral Medicine 2009;17:97-107.

## Haldorsen 1998

Haldorsen EM, Kronholm K, Skouen JS, Ursin H. Multimodal cognitive behavioral treatment of patients sicklisted for musculoskeletal pain: a randomized controlled study. Scandinavian Journal of Rheumatology 1998;27:16-25.

## Helminen 2015

Helminen E-E, Sinikallio SH, Valjakka AL, Väisänen-Rouvali RH, Arokoski JPA.

Effectiveness of a cognitive–behavioural group intervention for knee osteoarthritis pain: a randomized controlled trial. Clinical Rehabilitation 2015;29(9):868-81.

## Heutink 2012

Heutink M, Post MW, Bongers-Janssen HM, Dijkstra CA, Snoek GJ, Spijkerman DC, et al. The CONECSI trial: Results of a randomized controlled trial of a multidisciplinary cognitive behavioral program for coping with chronic neuropathic pain after spinal cord injury. Pain 2012;153:120-8.

## Hussain 2019

Hussain N, Said A S A. Mindfulness-Based Meditation Versus Progressive Relaxation Meditation: Impact on Chronic Pain in Older Female Patients With Diabetic Neuropathy. Journal of Evidence-based Integrative Medicine 2019;24:2515690X19876599.

# Jensen 2001

Bergstrom C, Jensen I, Hagberg J, Busch H, Bergstrom G. Effectiveness of different interventions using a psychosocial subgroup assignment in chronic neck and back pain patients: a 10-year follow-up. Disability and Rehabilitation 2012;34(2):110-8.

Busch H, Bodin L, Bergstrom G, Jensen IB. Patterns of sickness absence a decade after pain-related multidisciplinary rehabilitation. Pain 2011;152:1727-33.

Jensen IB, Bergstroem G, Ljungquist T, Bodin L, Nygren AL. A randomized controlled component analysis of a behavioral medicine rehabilitation program for chronic spinal pain: are the effects dependent on gender? Pain 2001;91:65-78.

Jensen IB, Bergstrom G, Ljungquist T, Bodin L. A 3-year follow-up of a multidisciplinary rehabilitation programme for back and neck pain. Pain 2005;115:273-83. [CRSREF: 3105378]

## Keefe 1990

Keefe FJ, Caldwell DS, Williams DA, Gil KM, Mitchell D, Robertson C, et al. Pain coping skills training in the management of osteoarthritic knee pain: II. Follow-up results. Behavior Therapy 1990;21:435-47.

Keefe FJ, Caldwell DS, Williams DA, Gil KM, Mitchell D, Robertson C, et al. Pain coping skills training in the management of osteoarthritic knee pain: a comparative study. Behavior Therapy 1990;21:49-62.

## La Cour 2015

La Cour Peter, Petersen Marian. Effects of Mindfulness Meditation on Chronic Pain: A Randomized Controlled Trial. Pain Medicine (United States) 2015;16(4):641-52.

# Luciano 2014

Luciano, JV, Guallar JA, Aguado J, Lopez-del-Hoto, Y Magallon R, Alda M, et al. Effectiveness of group acceptance and commitment therapy forfibromyalgia: A 6-month randomized controlled trial (EFFIGACT. Pain 2013;155:693-702.

## Martin 2012

Martin J, Torre F, Padierna A, Aguirre U, Gonzalez N, Garcia S, et al. Six-and 12-month follow-up of an interdisciplinary fibromyalgia treatment programme: results of a randomised trial. Clinical and Experimental Rheumatology 2012;30 (Suppl. 74):S103-11.

## McCracken 2013

McCracken LM, Sato A, Taylor GJ. A trial of a brief group-based form of acceptance and commitment therapy (ACT) for chronic pain in general practice: pilot outcome and process results. Journal of Pain 2013;14(11):1398-1406.

## McCrae 2019

McCrae, C. S., Williams, J., Roditi, D., Anderson, R., Mundt, J. M., Miller, M. B., Curtis, A. F., Waxenberg, L. B., Staud, R., Berry, R. B., & Robinson, M. E. (2019). Cognitive behavioral treatments for insomnia and pain in adults with comorbid chronic insomnia and fibromyalgia: clinical outcomes from the SPIN randomized controlled trial. *Sleep*, *42*(3), 1. https://doi.org/https://dx.doi.org/10.1093/sleep/zsy234

## Morone 2016

Morone Natalia E, Greco Carol M, Moore Charity G, Rollman Bruce L, Lane Bridget, Morrow Lisa A, et al. A mind-body program for older adults with chronic low back pain a randomized clinical trial. JAMA Internal Medicine 2016;176(3):329-37.

## Nicholas 2013

Nicholas MK, Asghari A, Blyth FM, Wood BM, Murray R, McCabe R, et al. Self-management intervention for chronic pain in older adults: A randomised controlled trial. Pain 2013;154:824-35.

## Perez-Aranda 2019

Perez-Aranda A, Feliu-Soler A, Montero-Marin J, Garcia-Campayo J, Andres-Rodriguez L, Borras X, et al. A randomized controlled efficacy trial of Mindfulness-Based Stress Reduction compared to an active control group and usual care for fibromyalgia: the EUDAIMON study. Pain 2019.

#### **Puder 1988**

Puder RS. Age analysis of cognitive-behavioral group therapy for chronic pain outpatients. Psychology and Aging 1988;3:204-7.

## Schmidt 2011a

Schmidt Stefan, Grossman Paul, Schwarzer Barbara, Jena Susanne, Naumann Johannes, Walach Harald. Treating fibromyalgia with mindfulness-based stress reduction: Results from a 3-armed randomized controlled trialâ<sup>\*</sup>†. Pain 2011;152(2):361-9.

## Smeets 2006

Smeets R, Vlaeyen JWS, Hidding A, Kester ADM, Van Der Heijden G, Van Geel ACM, et al. Active rehabilitation for chronic low back pain: cognitive-behavioral, physical, or both? First direct post-treatment results from a randomized controlled trial. BMC Musculoskeletal Disorders 2006;7:1-16.

Smeets R, Vlaeyen JWS, Kester ADM, Knottnerus JA. Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. Journal of Pain 2006;7:261-71.

Smeets RJEM, Vlaeyen JWS, Hidding A, Kester ADM, van der Heijden GJMG, Knottnerus JA. Chronic low back pain: physical training, graded activity with problem solving training, or both? The one-year post-treatment results of a randomized controlled trial. Pain 2008;134:263-76. [CRSREF: 3105413]

## Somers 2012

Somers TJ, Blumenthal JA, Guilak F, Kraus VB, Schmitt DO, Babyak MA, et al. Pain coping skills training and lifestyle behavioral weight management in patients with knee osteoarthritis: a randomized controlled study. Pain 2012;153:1109-1209.

## Thieme 2003

Thieme K, Gromnica-Ihle E, Flor H. Operant behavioral treatment of fibromyalgia: a controlled study. Arthritis and Rheumatism 2003;49:314-20.

## Van Koulil 2010

Van Koulil S, Van Lankveld W, Kraaimaat FW, Van Helmond T, Vedder A, Van Hoorn H, et al. Tailored cognitive-behavioral therapy and exercise training for high-risk patients with fibromyalgia. Arthritis Care and Research 2010;62:1377-85.

## Wang 2018

Wang, J., Liang, K., Sun, H., Li, L., Wang, H., & Cao, J. (2018). Psychotherapy combined with drug therapy in patients with category III chronic prostatitis/chronic pelvic pain syndrome: A randomized controlled trial. *International Journal of Urology*, *25*(8), 710–715. https://doi.org/https://dx.doi.org/10.1111/iju.13706

## Williams 1996

Williams A, Richardson P, Nicholas M, Pither C, Harding VR, Ridout KL, et al. Inpatient vs. outpatient pain management: results of a randomised controlled trial. Pain 1996;66:13-22.

# Appendix C

## Merged conditions

Several conditions were merged with each other as either there were too few instances of them occurring on their own or, conceptually, they were considered to overlap with another condition:

- Different elements of cognitive restructuring (identification of triggers, identification of thoughts, challenging and re-appraisal) were merged into Cognitive Restructuring
- Different elements of ACT (contacting the present moment, defusion, acceptance, selfas-context, values, and committed action) were merged into ACT
- Coping mechanisms were merged with problem solving, mental coping strategies,
   emotional processing and stress management
- Self-reinforcement was merged with reinforcement
- Cognitive exposure and virtual reality was merged with graded exposure
- Hypnosis was merged with relaxation, bio-feedback and self-relaxation
- Body awareness was merged with mindfulness
- Attention diversion was merged with distraction
- Changing maladaptive behaviours was merged with both (individually) pacing and with graded exposure
- Posture training was merged with graded exposure
- Activity planning was merged with graded activity
- Yoga was merged with physical exercise

# Appendix D

## Conditions excluded from analysis

Homework and use of diaries were initially considered as conditions but because, frequently, no measure of level of completion of homework or diaries was provided, it was excluded from the analysis.

The taking of medication / analgesia was initially considered as a condition but because most studies reported this as positive, and those who did not, had not specified whether participants took medication at all, it was assumed that there was no heterogeneity within this condition and thus it was excluded from the analysis.

Protocolised or manualised treatment was initially considered as a condition, but the extent to which studies adhered to the protocol, the quality of the protocol and the definition of protocol or manual was ambiguous and variable from one study to another, therefore it was excluded from the analysis.

Ethnic background of participants and comorbidities were both reported in a range of ways, which meant that definition of different ethnicities and comorbidities were not consistent and standardisation across studies would not be meaningful. They were both, therefore, sadly excluded from the analysis.

Time since diagnosis was initially considered as a condition, but the length of time that it takes for an individual to get to diagnosis since first symptoms is hugely variable. This perhaps explains why time since diagnosis has not been shown to be a relevant variable and justifies its exclusion in the present paper.

Psycho-education was assumed to occur in all studies; therefore no heterogeneity existed and thus this condition was excluded from analysis.

Various further conditions were initially considered as conditions but due to inadequate levels of reporting in studies, they were subsequently excluded; they are listed below:

- Socio-economic status
- Levels of interaction within treatment groups
- Tailoring of materials to participants' needs
- Satisfaction with treatment
- Expectations of treatment
- Treatment preferences
- Litigation

## Appendix E

## Biographies of Experts Selecting Key Conditions

Professor Steven J. Linton, PhD is professor of Clinical Psychology and the director of the Center for Health and Medical Psychology (CHAMP) in Orebro, Sweden. He is also active in teaching in the clinical and doctoral programs. Current research interests are, early identification and treatment of back pain, mechanisms driving pain chronicity, the role of context in chronic pain and treating comorbid chronic pain and depression. His h-index is 85.

Professor Mark Lumley, PhD is a Distinguished Professor and Director of Clinical Psychology Doctoral Training at Department of Psychology at Wayne State University, Michigan, USA. His work focusses on advancing knowledge at the interface of stress, emotional processes, and health (particularly chronic pain). He is on the editorial boards of numerous journals in health psychology and psychosomatic medicine, and has been on the Executive Committees of the American Psychosomatic Society, the Society for Health Psychology, and the Council of University Directors of Clinical Psychology. Dr. Lumley is a Fellow of the American Psychological Association. His h-index is 63.

Professor Lance McCracken, PhD has primary research interests in chronic pain management. Most of this research is applied clinic-based research focused on the development of psychological and interdisciplinary treatment methods. Lance is Honorary Consultant Clinical Psychologist at INPUT Pain Management Centre, Guy's and St Thomas' NHS Trust, Professor of Clinical Psychology at Uppsala University, Sweden; Visiting Professor within the Health Psychology Section at the Institute of Psychiatry, Psychology & Neuroscience at King's College London and Expert Panel Member at Fonds Wetenschappelijk Onderzoek (FWO) Research Foundation. In 2014 he was made Fellow of the Association for Contextual Behavioral Science and in 2015 was made Distinguished International Affiliate, APA Division of Health Psychology (for "Outstanding Contribution to Health Psychology"). His h-index is 76.

Professor Michael Nicholas, PhD is full professor at the Pain Management Research Institute, University of Sydney at Royal North Shore Hospital and Secretary of the IASP. His main interest has been combining research and clinical pain practice, especially multidisciplinary applications of psychology. This has meant working as a member of Scientific Committee for the 2008 IASP conference; as a reviewer and now an associate editor for PAIN; from 1988-1990 as the inaugural program director, INPUT program at St Thomas' Hospital, London. His h-index is 62.

Professor Dr Johannes W.S. Vlaeyen, PhD is full professor at the Universities of Leuven (Belgium) and Maastricht (Netherlands). His main research interests/expertise are the behavioral, cognitive and motivational mechanisms leading to disability, and the development and evaluation of customized cognitive-behavioral management strategies for individuals suffering chronic bodily symptoms (pain, fatigue, tinnitus). His h-index is 99.

Dr Krystel Shelmerdine is a Clinical Psychologist at University College London

Hospital and Barts Health NHS Foundation Trust within the Chronic Pain departments and sits on the chronic pain guidelines panel within the National Institute for Health and Care Excellence.

# Appendix F

# Short-list of Expert Selected Conditions

Activity Management Treatment (i.e. physical actions / task-based work)
Attrition
Baseline disability
Baseline distress
Behavioural Rehearsal
СВТ
Education level
Employed
Family / Social network involvement in treatment
Graded Exercise
Graded Exposure
Group (as opposed to individual treatment)
Hours of treatment
Medication reduction
Pacing
Participants did not have severe psychological comorbidities
Pleasant Activity Scheduling
Problem Solving / Coping Strategies
Recruiter / Recruitment centre is a specialist in pain treatment
Reinforcement
Sleep
Sleep

## Appendix G

## Initial explorations of data using QCA: Truth Tables and Minimisation

Initial explorations looked at the following combinations of conditions and their outcomes:

- 1. Exposure / Activity and Baseline Disability: their effect on Disability
- 2. Exposure / Activity, Baseline Disability and Age: their effect on Disability
- 3. Exposure / Activity and Baseline Distress: their effect on Disability
- 4. Baseline Distress, Age, Patient population and Hours of treatment: their effect on attrition
- 5. Patient Education level, CBT, Cognitive Restructuring: their effect on Distress
- Social / Operant, Exposure / Activity and Patient Education level: their effect on Disability
- Cognitive Restructuring, Patient population and Hours of treatment: their effect on Disability
- Exposure / Activity, Patient population and Hours of treatment: their effect on Disability

## Truth Table 1:

```
A: DISABILITYFZ
```

B: GEXPBHVRHRSL (Exposure / Activity)

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

```
OUT
   А В
                    incl PRI
                n
                             cases
                2
                   0.858 0.858 3,6
2
   0 1 1
                   0.749 0.749 4,5,16
4
   1 1
          0
                3
                12 0.429 0.429 1,2,7,8,9,10,11,12,13,14,18,20
3
   1 0
           0
                   0.351 0.351 15,17,19
```

#### Minimisation 1:

A: DISABILITYFZ

B: GEXPBHVRHRSL (Exposure / Activity)

```
n OUT = 1/0/C: 2/18/0
Total : 20
```

Number of multiple-covered cases: 0

```
M1: ~A*B => SMDDISABILITYCRISP
```

## Truth Table 2:

A: DISABILITYFZ

B: FZAGE

C: GEXPBHVRHRSL (Exposure / Activity)

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

	Α	В	C	OUT	n	incl	PRI	cases
2	0	0	1	1	2	0.858	0.858	3,6
6	1	0	1	0	3	0.749	0.749	4,5,16
5	1	0	0	0	10	0.418	0.418	1,2,8,9,10,11,12,14,18,20
7	1	1	0	0	2	0.358	0.358	7,13
3	0	1	0	0	1	0.332	0.332	19
1	0	0	0	0	2	0.332	0.332	15,17
4	0	1	1	?	0	-	-	
8	1	1	1	j	0	-	-	

#### Minimisation 2:

A: DISABILITYFZ

B: FZAGE

C: GEXPBHVRHRSL (Exposure / Activity)

n OUT = 1/0/C: 2/18/0 Total : 20

Number of multiple-covered cases: 0

M1: ~A\*C => SMDDISABILITYCRISP

		inclS	PRI	covS	covU	cases
1	~A*C	0.858	0.858	0.200	-	3,6
	M1	0.858	0.858	0.200		

## Truth Table 3:

A: DISTRESSFZ

B: GEXPBHVRHRSL (Exposure / Activity)

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

A B OUT n incl PRI cases

```
1
2 0 1
                4
                    1.000 1.000 3,4,5,6
4
  1 1
           0
                1
                    0.569 0.569 16
3
   1 0
           0
                2
                    0.464 0.464 2,7
1
   0 0
                13 0.374 0.374 1,8,9,10,11,12,13,14,15,17,18,19,20
```

#### Minimisation 3:

A: DISTRESSFZ

B: GEXPBHVRHRSL (Exposure / Activity)

n OUT = 1/0/C: 4/16/0 Total : 20

Number of multiple-covered cases: 0

M1: ~A\*B => SMDDISABILITYCRISP

		inclS	PRI	covS	covU	cases
1	~A*B	1.000	1.000	0.268	-	3,4,5,6
	M1	1.000	1.000	0.268		

#### Truth Table 4:

A: POPNCLINICAL

B: HOURSFZ

C: DISTRESSFZ

D: FZAGE

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

PRI: proportional reduction in inconsistency

```
OUT
                       n incl PRI
    A B C D
                                   cases
1
    0 0
         0 0
                 0
                       1 0.711 0.557 13
    0 0 1 0
3
                       1 0.616 0.000 7
    1 0 1 0
                       2 0.583 0.335 1,18
11
                 0
15
    1 1 1 0
                 0
                       2 0.538 0.274 8,20
9
    1 0 0 0
                 0
                      9 0.534 0.362 3,5,10,11,12,15,16,17,19
13
    1 1 0 0
                 0
                       3 0.458 0.215 4,9,14
10
    1 0 0 1
                 0
                       2
                         0.421 0.166 2,6
2
    0 0 0 1
                 ?
                       0
4
    0 0 1
           1
                 ?
                      0
5
    0 1 0 0
                 ?
                       0
                 ?
6
    0 1 0 1
                      0
7
    0 1 1 0
                 ?
                       0
                 ?
8
    0 1 1 1
                       0
12
    1 0 1 1
                 ?
                       0
14
    1 1 0 1
                 ?
                       0
    1 1 1 1
                 ?
16
                       0
```

Minimisation was not undertaken because consistency was not high enough to warrant minimisation.

#### *Truth Table 5:*

- A: CRISPMANDED
- **B:** COGNITIVETREATMENTCRISP
- C: CR
- OUT: output value
  - n: number of cases in configuration
- incl: sufficiency inclusion score
- PRI: proportional reduction in inconsistency

	Α	В	C	OUT	n	incl	PRI	cases
7	1	1	0	0	3	0.667	0.667	1,5,11
4	0	1	1	0	7	0.539	0.539	4,6,8,10,15,16,17
8	1	1	1	0	6	0.538	0.538	3,7,9,12,13,18
5	1	0	0	0	3	0.333	0.333	2,14,19
1	0	0	0	0	1	0.000	0.000	20
2	0	0	1	?	0	-	-	
3	0	1	0	?	0	-	-	
6	1	0	1	?	0	-	-	

## Minimisation 5:

## Truth Table 6:

- A: CRISPMANDED
- B: FAMREINFORCE (Social / Operant)
- C: GEXPBHVRHRSL (Exposure / Activity)
- OUT: output value
  - n: number of cases in configuration
- incl: sufficiency inclusion score
- PRI: proportional reduction in inconsistency

	Α	В	C	OUT	n	incl	PRI	cases
4	0	1	1	1	1	1.000	1.000	6
8	1	1	1	1	2	1.000	1.000	3,4
3	0	1	0	1	2	0.800	0.800	8,10
7	1	1	0	0	4	0.571	0.571	2,7,13,18
2	0	0	1	0	2	0.500	0.500	5,16
5	1	0	0	0	4	0.250	0.250	1,11,12,15
1	0	0	0	0	5	0.200	0.200	9,14,17,19,20
6	1	0	1	?	0	_	_	

#### Minimisation 6:

- A: CRISPMANDED
- B: FAMREINFORCE (Social / Operant)
- C: GEXPBHVRHRSL (Exposure / Activity)

n OUT = 1/0/C: 5/15/0 Total : 20

Number of multiple-covered cases: 1

M1: ~A\*B + B\*C => SMDDISABILITYCRISP

inclS PRI covS covU cases

```
1 ~A*B 0.857 0.857 0.300 0.200 8,10; 6
2 B*C 1.000 1.000 0.300 0.200 6; 3,4
-----
       0.909 0.909 0.500
  M1
Truth Table 7:
   A: POPNCLINICAL
   B: HOURSFZ
   C: CR
 OUT: output value
   n: number of cases in configuration
incl: sufficiency inclusion score
 PRI: proportional reduction in inconsistency
   АВС
            OUT
                 n incl PRI cases
   1 1 1 0
8
                 2 0.571 0.571 3,16
7
  1 1 0
                 3 0.546 0.546 2,4,17
  1 0 0 0 5 0.500 0.500 1,5,11,12,18
1 0 1 0 10 0.455 0.455 6,7,8,9,10,13,14,15,19,20
5
6
            ?
1
  0 0 0
                 0
   0 0 1
2
            ?
                  0
```

Minimisation was not undertaken because consistency was not high enough to warrant minimisation.

#### Truth Table 8:

3 0 1 0

0 1 1

A: POPNCLINICAL

B: HOURSFZ

C: GEXPBHVRHRSL (Exposure / Activity)

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score

?

?

PRI: proportional reduction in inconsistency

0

```
A B C
          OUT
               n incl PRI cases
  1 0 1
6
          1
                2 0.835 0.835 5,6
 1 1 1
              3 0.777 0.777 3,4,16
          0
8
7
 1 1 0
          0
               2 0.438 0.438 2,17
              13 0.393 0.393 1,7,8,9,10,11,12,13,14,15,18,19,20
5
  1 0 0
          0
1
 0 0 0
          ?
               0
2
  0 0 1
          ?
               0
          ?
3
  0 1 0
              0
  0 1 1
               0
```

#### Minimisation 8:

A: POPNCLINICAL

B: HOURSFZ

C: GEXPBHVRHRSL (Exposure / Activity)

n OUT = 1/0/C: 2/18/0

Total : 20

Number of multiple-covered cases: 0

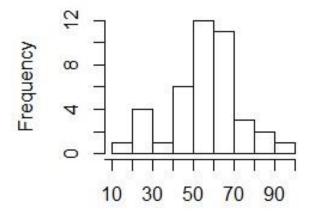
M1: ~B\*C => SMDDISABILITYCRISP

		inclS	PRI	covS	covU	cases
1	~B*C	0.835	0.835	0.167	-	5,6
	M1	0.835	0.835	0.167		

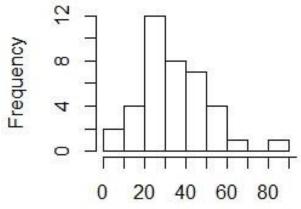
# Appendix H

# Frequency Distributions

Baseline Disability score frequency distribution:



Baseline Distress score frequency distribution:



## Appendix I

General coding and calibration assumptions and decisions regarding *outcome measures and conditions* 

## General coding and calibration assumptions and decisions regarding outcome measures

Baseline distress and baseline disability were converted into a standardised scale by dividing the original mean score by the maximum score possible and multiplying by 100. In cases where the measure was reverse scored, the score was calculated by dividing the original mean score by the maximum score possible, subtracting from 1 and multiplying by 100.

## General coding and calibration assumptions and decisions regarding conditions

'Bi-weekly' treatment was understood to mean twice a week rather than fortnightly.

Where data for frequency of treatment sessions only states total hours of treatment, five hours of treatment was assumed to be one day of treatment. 'Daily' was assumed to be five days per week and not seven.

'Musculoskeletal' pain, unless otherwise specified, was assumed to involve back pain for the majority of participants.

Employment was assumed to include those employed, on sick pay and those who volunteered, but not those with permanent disability status, unemployed, a home-maker or retired.

MBSR was assumed to include: body scan, guiding attention, breathing focus, walking, meditation, stretching / yoga, use of diary and CD / audio, psychoeducation. Where mindfulness occurred, attention / distraction was also assumed, as was relaxation.

CBT was assumed to include: goal-setting, psycho-education, cognitive restructuring, activity planning, relapse prevention, relaxation, problem solving and graded activity.

If more than 50% of participants had a condition (back-pain or fibromyalgia) it was considered to have full membership of the condition set.

Case specific coding assumptions and decisions regarding conditions where data was ambiguous or missing

(Basler et al., 1997): This paper was written in 1997, the average age of participants was 49, meaning that they were born in 1948 and were 18 years old by 1966. In the 1960s, mandatory education was 10 years in Germany so less than the study's average of 12 years, therefore the education was coded as 0.499. Baseline disability levels were low so distress levels were likely to be low too therefore it was coded at 0.499. The paper was written by two psychologists so it was assumed that clinicians were predominantly psychologists and as such the respective condition was coded as 0.501.

(Bliokas et al., 2007): The average age of participants was over 60, with baseline distress and disability levels high so employment was likely to be lower and was coded as 0.499. The two arms of treatment which were merged for analytical purposes in the present study. Only one arm used graded exposure, but for ease of analysis, it was assumed that every participant in both arms did receive graded exposure.

(Carson et al., 2006): Two recruitment methods were detailed, but normally there are more participants from connected referrers rather than the media, therefore recruitment was coded at 0.501. There were low levels of baseline distress, low average age and high levels of education, therefore disability was coded as low (0.499) and employment as higher (0.501).

(Cash et al., 2015): Perceived Stress Scale (PSS) was used to reflect distress levels as it was more akin and comparable to the other paper's distress scales. Half a day of treatment was assumed to be 3.5 hours; although previously we had specified a day as five hours but a "half day retreat" of 2.5 hours would be no different from the paper's normal 2.5 hours session, so it must have been longer, therefore assume 9am to 5pm was a full day with an hour for lunch and two half-hour breaks thus 'half-day' = 3.5 hours. Age was described as "peri-menopausal". According to the North American Menopause Society, peri-

menopause can last for 4 to 8 years, which makes the average age for perimenopause around mid to late 40s, thus average age was assumed to be 47 years. Educational level was described as "typical college educated", so it was coded as 1.

(Castro et al., 2012): Most papers do not have only psychologist clinicians so this paper was assumed to be aligned with the others and was coded as 0.499. The closest paper with a similar average age of 45 and high disability levels was (Thieme et al., 2003) which had high baseline distress levels so distress was coded as 0.501. Mandatory education at the time was from six to 17 equating to 11 years which is slightly lower than the average of other papers, therefore education was coded as 0.499.

(Cherkin, Sherman, Balderson, et al., 2016): It was assumed that the maximum number in groups was the mean of all other studies (9.35) therefore this was coded as 0.67. Disability at baseline was 50 but as there was no significant difference reported between the treatment and control group in this variable, with the control group being slightly higher than 50, baseline disability was coded at 0.67.

(Ferrando et al., 2012): Participants were diagnosed with temporomandibular disorder therefore levels of unemployment were likely to be lower than other more disabling pain diagnoses; participants were also young and not retired therefore employment was marked as 0.501. It was assumed that most people had above mandatory levels of education, therefore education was coded as 0.501. The average maximum number of people in groups was 9.35 and therefore the number of participants in group was coded as 0.67.

(Geraets et al., 2005): Participants had lower average age than other studies, low baseline distress levels and a shoulder pain diagnosis with mention of job in the protocol, therefore it was assumed that employment was higher than average and was coded as 0.501. In the 1960s, education was at least 12 years so mandatory education was coded as 0.501. The percentage of participants with medium to high levels of baseline distress was reported, thus scores were calculated based on a mean average using the mid-point of the

medium to high scale of baseline distress, and the mid-point of the low scale of distress, multiplying this by the proportion of participants within the respective ranges and dividing by the total number of participants.

(Glombiewski et al., 2010): 54.3% of participants came from anaesthesiology centres therefore 'recruiter specialist' was coded as 1. Treatment was individual therefore maximum number in groups was coded as 0.

(Haldorsen et al., 1998): Treatment was given partly via group, partly via individual sessions therefore the maximum group size was less than average and coded at 0.499. 'Group' component was coded as 1 as there was group work. As there were high employment levels and a young mean age, disability was coded as 0.499. The study mentions psycho-education and different clinicians so it was assumed that this was related to group treatment and thus 'groups' was coded as 0.501.

(Heutink et al., 2012): With low mean age, low depression levels and low disability levels reported it was decided that employment would likely be above average and coded at 0.501.

(Keefe et al., 1990): The study was conducted in 1990, the average age of participants was 64 and they would have reached the age of 18 in 1944 therefore were educated across World War II where it can be assumed that education was somewhat disrupted, so it was assumed that most participants had less than mandatory education and coded at 0.499. Similarly, most participants were above retirement age in 1990 therefore employment was coded as 0.499.

(McCracken et al., 2013): The most frequent diagnosis was fibromyalgia at 32% but most did not have it therefore fibromyalgia was coded as 0.

(Morone et al., 2016): It was assumed that older adults over 65 are likely to be retired therefore employment was coded at 0. Recruitment was listed but more of the recruitment types were via general rather than pain specific lists, therefore recruitment was coded at 0.499.

(Nicholas et al., 2013): 45% of participants had generalised pain sites therefore fibromyalgia was coded as 0.

(Puder, 1988): Six types of recruitment were listed of which only two were pain specialists so recruitment was coded as 0.499. Disability baseline levels were high therefore distress baseline was coded as 0.501.

(Schmidt et al., 2011): Recruitment was via six sources of which only two were specialist pain, therefore specialist recruitment was coded as 0.

(Smeets, Vlaeyen, Hidding, et al., 2006) (Cognitive arm): Female gender of participants was 59%, therefore female gender was coded as 0.67.

(Somers et al., 2012): As participants were recruited from the community with low disability and of working age on average, it was assumed that more were working than not and employment was coded as 0.501.

(Thieme et al., 2003): Employment was 50% but this included 'workers compensation' so the authors coded it as 0.499.

(Saskia Van Koulil et al., 2010): Employment was not specified but 'high risk' and high levels of disability were noted, therefore employment was coded at 0.501.

(A. C.de C. Williams et al., 1996): Participants were recruited predominantly from other pain clinics therefore specialist recruiter was coded as 1. 'Pain in back / legs' was assumed as back pain therefore back pain was coded as 1. 'Pain source unknown' was assumed to be fibromyalgia; with levels at 71% in the outpatient arm and 51% in the inpatient arm, they were coded as 1.

Appendix K
Updated data set based on top 10 and bottom 10 pain-related distress outcome measure scores

Author	Year	SMD Distress	SMD Distress (Crisp set)	SMD Distress (Fuzzy set)	Hours of treatment	Hours of treatment (Fuzzy set)	Baseline Disability (Fuzzy set)	Baseline Distress (Fuzzy set)	Age	Age (Fuzzy set)	Education level	Education (Crisp set)	Cognitive Restructuring (Crisp set)	Social / Operant (Crisp set)	Exposure / Activity (Crisp set)
Jensen (behavioural) <sup>a</sup>	2001	0.18	0	0	80	0.67	0.33	0.33	42.5	0	0.43	0	0	0	1
La Cour <sup>b</sup>	2015	-0.01	0	0	28.5	0.33	0.67	0.33	46.5	0.33	0.85	1	0	0	0
Heutink <sup>c</sup>	2012	-0.03	0	0	33	0.33	0.33	0.33	58.8	0.33	0.61	1	1	1	0
Glombiewski (CBT + biofeedback) <sup>d</sup>	2010	-0.07	0	0	23	0.33	0.67	0	48.9	0.33	0.23	0	1	0	0
Glombiewski (CBT) <sup>d</sup>	2010	-0.07	0	0	23	0.33	0.67	0	48.6	0.33	0.07	0	1	0	0
Smeetsc (physical and cognitive) <sup>d</sup>	2006	-0.08	0	0	11	0.33	0.67	0	40.7	0	0.43	0	1	1	1
Schmidt (mindfulness) <sup>d</sup>	2011	-0.1	0	0	27	0.33	0.67	0.33	53.4	0.33	0.59	1	0	0	0
Helminen <sup>d</sup>	2015	-0.11	0	0	12	0.33	0.67	0	64.5	0.67	0.78	1	1	1	1
Haldorsen <sup>e</sup>	1998	-0.15	0	0	120	1	0.501	0.67	43	0	0.61	1	0	1	0
Perez (FibroQOL)b	2019	-0.16	0	0	16	0.33	0.67	0.33	54.21	0.33	0.413	0	0	0	0
Cherkin (CBT) <sup>f</sup>	2016	-0.57	1	0.67	16	0.33	0.67	0	49.1	0.33	0.94	1	1	0	1
Bliokas <sup>g</sup>	2007	-0.6	1	0.67	66.5	0.67	0.67	1	45.5	0.33	0.25	0	1	0	1
Van Koulil (pain persistence) <sup>h</sup>	2010	-0.63	1	0.67	76	0.67	0.33	0	41.1	0	0.91	1	1	1	1
Perez (mindfulness) <sup>b</sup>	2019	-0.63	1	0.67	22	0.33	0.67	0.33	52.96	0.33	0.466	0	0	0	0
Van Koulil (pain avoidance) <sup>h</sup>	2010	-0.75	1	0.67	76	0.67	0.67	0.33	42.3	0	0.96	1	0	1	1
Williams (outpatient) <sup>d</sup>	1996	-0.76	1	0.67	31.5	0.33	0.33	0	50.4	0.33	0.4	0	1	1	1
Castel <sup>i</sup>	2013	-0.84	1	1	48	0.67	0.67	0.67	49	0.33	0	0	1	1	0
Williams (inpatient) <sup>d</sup>	1996	-1.03	1	1	90	1	0.33	0	48.7	0.33	0.67	1	1	1	1
Thieme <sup>j</sup>	2003	-1.58	1	1	75	0.67	0.67	0.67	46.6	0.33	0.55	1	0	1	1
Luciano <sup>b</sup>	2014	-1.84	1	1	20	0.33	0.67	0.33	48.9	0.33	0.55	1	0	0	0

a SF36 mental health; b HADS Depression; c HADS Anxiety; d Beck Depression Inventory; e HSCL Distress; f PHQ-8; g Depression Anxiety Stress Scale (Depression); h IRGL Negative Mood; i HADS; j MPI Affective Distress

Updated data set based on top 10 and bottom 10 pain-related disability outcome measure scores

Appendix L

Author	Year	SMD Disability (Crisp Set)	SMD Disability	SMD Disability (Fuzzy set)	Hours of Treatment	Hours of Treatment (Fuzzy set)	Baseline Disability (Fuzzy set)	Baseline Distress (Fuzzy set)	Age	Age (Fuzzy set)	Education (Crisp set)	Cognitive Restructuring (Crisp set)	Social / Operant (Crisp set)	Exposure / Activity (Crisp set)
Smeetsb (cognitive) <sup>a</sup>	2006	1	-0.51	0.67	26.5	0.33	0.67	0	42.5	0	0	1	1	0
Nicholas <sup>b</sup>	2013	1	-0.59	0.67	16	0.33	0.67	0.67	74.6	1	1	1	1	0
Perez (mindfulness) <sup>c</sup>	2019	1	-0.62	0.67	22	0.33	0.67	0.33	52.96	0.33	0	0	0	0
Williams (outpatient) <sup>d</sup>	1996	1	-0.81	1	31.5	0.33	0.33	0	50.4	0.33	0	1	1	1
Garcia-Palacios <sup>e</sup>	2015	1	-0.87	1	12	0.33	0.67	0.33	50.5	0.33	0	0	0	1
Van Koulil (pain avoidance) <sup>f</sup>	2010	1	-0.96	1	76	0.67	0.67	0.33	42.3	0	1	0	1	1
Castel <sup>e</sup>	2013	1	-0.98	1	48	0.67	0.67	0.67	49	0.33	0	1	1	0
Williams (inpatient) <sup>d</sup>	1996	1	-1.24	1	90	1	0.33	0	48.7	0.33	1	1	1	1
Thieme <sup>g</sup>	2003	1	-2.03	1	75	0.67	0.67	0.67	46.6	0.33	1	0	1	1
Luciano <sup>e</sup>	2014	1	-2.31	1	20	0.33	0.67	0.33	48.9	0.33	1	0	0	0
Evers <sup>h</sup>	2002	0	0.14	0	10	0.33	1	0	53.9	0.33	0	1	0	0
Keefe <sup>i</sup>	1990	0	0.08	0	15	0.33	0.33	0	62.4	0.67	0.499	1	0	0
Geraets <sup>j</sup>	2005	0	0.07	0	18	0.33	0.67	0.33	51.2	0.33	0.501	0	1	1
Jensen (CBT) <sup>k</sup>	2001	0	0.04	0	54	0.67	0.33	0.33	43.8	0	0	0	0	0
Bliokas <sup>I</sup>	2007	0	0.03	0	66.5	0.67	0.67	1	45.5	0.33	0	1	0	1
Cashe	2015	0	0	0	23.5	0.33	0.33	0.67	47	0.33	1	0	0	0
Ferrando <sup>m</sup>	2012	0	-0.01	0	6	0	0.33	0	39.6	0	0.501	1	0	0
Perez (FibroQOL) <sup>c</sup>	2019	0	-0.05	0	16	0.33	0.67	0.33	54.21	0.33	0	0	0	0
Glombiewski (CBT) <sup>I</sup>	2010	0	-0.09	0	23	0.33	0.67	0	48.6	0.33	0	1	0	0
Helminen <sup>n</sup>	2015	0	-0.11	0	12	0.33	0.67	0	64.5	0.67	1	1	1	1

a Roland & Morris Disability Scale; b Roland & Morris Disability Scale (modified); c Fibromyalgia Impact Questionnaire (revised); d SIP Patient Rated; e Fibromyalgia Impact Questionnaire; f IRGL Mobility; g MPI Interference; h IRGL Functional Disability; i AIMS physical disability; j Shoulder Disability Questionnaire; k SF-36 Physical Function; l Pain Disability Index; m Pain Interference; n WOMAC Physical Function Self Report

## Appendix M

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R coding, Truth Tables and Intermediate and Conservative Minimisation results

```
> #Disability as an outcome: truth tables
> TT1 <- truthTable(Disability, outcome = "SMD.Disability.Crisp", conditions</pre>
  = "HoursFZ, DisabilityFZ, DistressFZ, CR, Family.Reinforcement,
  Graded.Exposure.Graded.Exercise.Behavioural.Rehearsal", incl.cut = 0.8,
  complete = TRUE, use.letters = TRUE, show.cases = TRUE, dcc = TRUE,
  sort.by = "incl")
> TT1
    A: HOURSFZ
    B: DISABILITYFZ
    C: DISTRESSFZ
    D: CR
    E: FAMILY.REINFORCEMENT (Social / Operant)
    F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
  OUT: output value
    n: number of cases in configuration
 incl: sufficiency inclusion score
  PRI: proportional reduction in inconsistency
  DCC: deviant cases consistency
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### > # Repeated with negative outcome

```
> TT1negated <- truthTable(Disability, outcome = "~SMD.Disability.Crisp",
  conditions = "HoursFZ, DisabilityFZ, DistressFZ, CR,
  Family.Reinforcement,
  Graded.Exposure.Graded.Exercise.Behavioural.Rehearsal", incl.cut = 0.8,
  complete = TRUE, use.letters = TRUE, show.cases = TRUE, dcc = TRUE,
  sort.by = "incl")</pre>
```

#### > TT1negated

```
A: HOURSFZ
B: DISABILITYFZ
C: DISTRESSFZ
D: CR
```

E: FAMILY.REINFORCEMENT (Social / Operant)

F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)

OUT: output value

n: number of cases in configuration

incl: sufficiency inclusion score
PRI: proportional reduction in inconsistency

DCC: deviant cases consistency

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24	0	1	0	1	1	1		1	0.670		
9	0	0	1	0	0	0		1	0.668		
33	1	0	0	0	0	0		1	0.668		
20	0	1	0	0	1	1		1	0.504		2 40
17	0	1	0	0	0	0		3		0.498	3,10
8	0	0	0	1	1	1		1	0.330		4
40	1	0	0	1	1	1		1	0.248		8
52	1	1	0	0	1	1		1	0.248		6
60	1	1	1	0	1	1		1	0.248		9
18	0	1	0	0	0	1		1	0.000		5
23	0	1	0	1	1	0	0 1	1	0.000	0.000	1
31	0	1	1	1	1	0	0 1	1	0.000	0.000	2
63	1	1	1	1	1	0	0 1	1	0.000	0.000	7
1	0	0	0	0	0	0	? 6	9	-	-	
2	0	0	0	0	0	1	? 6	9	-	-	
3	0	0	0	0	1	0		9	-	-	
4	0	0	0	0	1	1		9	_	_	
6	0	0	0	1	0	1		9	_	_	
7	0	0	0	1	1	0		9	_	_	
10	0	0	1	0	0	1		9	_	_	
11	0	0	1	0	1	0	? 6		_	_	
12	0	0	1	0	1	1		9	_	_	
13	0	0	1	1	0	0		9	_	_	
14	0	0	1	1	0	1		9	_	_	
15	0	0	1	1	1	0		9	_	_	
16	0	0	1	1	1	1	? 6		_	_	
19	0	1	0	0	1	0		9	_	_	
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25	0	1	1	0	0	0	r e	9	-	-	
26	0	1	1	0	0	1		9	-	-	
27	0	1	1	0	1	0	? 6		-	-	
28	0	1	1	0	1	1		9	-	-	
29	0	1	1	1	0	0		9	-	-	
30	0	1	1	1	0	1		9	-	-	
32	0	1	1	1	1	1		9	-	-	
34	1	0	0	0	0	1	? 6		-	-	
35	1	0	0	0	1	0		9	-	-	
36	1	0	0	0	1	1		9	-	-	
37	1	0	0	1	0	0		9	-	-	
38	1	0	0	1	0	1		9	-	-	
39	1	0	0	1	1	0	? 6	9	-	-	
41	1	0	1	0	0	0	? 6	9	-	-	
42	1	0	1	0	0	1	? 6	9	-	-	
43	1	0	1	0	1	0	? 6	9	-	-	
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> # Distress as an outcome: truth tables
> TT2 <- truthTable(Distress, outcome = "SMD.Distress.Crisp", conditions =</pre>
  "HoursFZ, DisabilityFZ, DistressFZ, CR, Family.Reinforcement,
  Graded.Exposure.Graded.Exercise.Behavioural.Rehearsal", incl.cut = 0.8,
  complete = TRUE, use.letters = TRUE, show.cases = TRUE, dcc = TRUE,
  sort.by = "incl")
> TT2
    A: HOURSFZ
    B: DISABILITYFZ
    C: DISTRESSFZ
    D: CR
    E: FAMILY.REINFORCEMENT (Social / Operant)
    F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
  OUT: output value
    n: number of cases in configuration
 incl: sufficiency inclusion score
  PRI: proportional reduction in inconsistency
  DCC: deviant cases consistency
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                               ?
48
                       1
                                      0
49
     1
         1
             0
                               ?
                                      0
                0
                    0
                       0
                               ?
50
         1
             0
                0
                    0
                       1
                                      0
      1
51
     1
         1
             0
                0
                    1
                       0
                               ?
                                      0
53
         1
                               ?
                                      0
     1
             0
                1
                    0
                       0
54
      1
         1
             0
                1
                    0
                       1
                               ?
                                      0
55
     1
         1
             0
                1
                    1
                       0
                               ?
                                      0
     1
         1
             0
                1
                    1
                       1
                               ?
                                      0
56
                               ?
57
     1
         1
             1
                0
                    0
                       0
                                      0
58
         1
                0
                    0
                       1
                               ?
                                      0
      1
             1
61
      1
         1
             1
                1
                    0
                       0
                               ?
                                      0
64
         1
             1
                1
                    1
                               ?
                                      0
```

<sup>&</sup>gt; # Repeated with a negated outcome

<sup>&</sup>gt; TT2negated <- truthTable(Distress, outcome = "~SMD.Distress.Crisp",
 conditions = "HoursFZ, DisabilityFZ, DistressFZ, CR,
 Family.Reinforcement,</pre>

```
Graded.Exposure.Graded.Exercise.Behavioural.Rehearsal", incl.cut = 0.8,
complete = TRUE, use.letters = TRUE, show.cases = TRUE, dcc = TRUE,
sort.by = "incl")
```

## > TT2negated

1 1 1 0 0

?

```
A: HOURSFZ
    B: DISABILITYFZ
    C: DISTRESSFZ
    D: CR
    E: FAMILY.REINFORCEMENT (Social / Operant)
    F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
  OUT: output value
    n: number of cases in configuration
 incl: sufficiency inclusion score
  PRI: proportional reduction in inconsistency
  DCC: deviant cases consistency
            C
                   Ε
                      F
     Α
        В
               D
                            OUT
                                       incl PRI
                                    n
                                                     DCC
21
                                       1.000 1.000
     0
         1
            0
                1
                   0
                      0
                             1
                                    2
34
     1
         0
            0
               0
                   0
                      1
                             1
                                    1
                                       1.000 1.000
                                       1.000 1.000
59
                   1
     1
         1
            1
               0
                      0
                             1
                                    1
     0
         0
            0
               1
                   1
                      0
                             0
                                    1
                                       0.670 0.670
 7
24
     0
         1
            0
                1
                   1
                      1
                             0
                                    2
                                       0.670 0.670
17
     0
         1
            0
                0
                   0
                      0
                             0
                                    5
                                       0.600 0.600 14,20
         0
            0
               1
                   1
                             0
                                    1
                                       0.398 0.398 16
 8
     0
                      1
                1
     1
         1
            1
                   1
                      0
                             0
                                    1
                                       0.330 0.330 17
63
40
     1
         0
            0
               1
                   1
                             0
                                    2
                                       0.283 0.283 13.18
22
     0
         1
            0
               1
                   0
                      1
                             0
                                    1
                                       0.000 0.000 11
                                       0.000 0.000 15
52
     1
         1
            0
               0
                   1
                      1
                             0
                                    1
60
     1
         1
            1
               0
                   1
                      1
                             0
                                    1
                                       0.000 0.000 19
                   0
                      1
                             0
                                    1
                                       0.000 0.000 12
62
     1
        1
            1
               1
 1
     0
         0
            0
               0
                   0
                      0
                             ?
                                    0
                      1
                             ?
                                    0
 2
     0
         0
            0
               0
                   0
                             ?
 3
     0
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            0
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                   1
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                                    0
                             ?
 4
     0
         0
            0
                0
                   1
                      1
                                    0
 5
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         0
            0
               1
                   0
                      a
                             ?
                                    a
                             ?
 6
     0
         0
            0
               1
                   0
                      1
                                    0
 9
                             ?
                                    0
     0
         0
            1
               0
                   0
                      0
                      1
                             ?
                                    0
10
        0
            1
               0
                   0
     0
11
     0
        0
            1
               0
                   1
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                             ?
                                    0
                             ?
12
     0
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            1
               0
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                                    0
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                             ?
                                    0
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            1
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13
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               1
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                      1
                             ?
                                    0
14
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15
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                             ?
                                    0
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            1
                1
                   1
                      1
                             ?
16
     0
         0
                                    0
                0
                             ?
                                    0
18
     0
         1
            0
                   0
                      1
                             ?
         1
            0
               0
                   1
                      0
                                    0
19
     0
20
     0
        1
            0
                0
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                             ?
                                    0
23
     0
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                             ?
                                    0
                             ?
25
     0
        1
            1
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                                    0
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        1
            1
               0
                   0
                      1
                             ?
                                    0
26
27
     0
        1
            1
               0
                   1
                      0
                             ?
                                    0
                                          _
                   1
                      1
                             ?
28
     0
        1
            1
                0
                                    0
```

```
30
    0 1 1 1 0 1
                            0
           1 1 0
31
    0 1
         1
                      ?
                            0
32
    0 1
         1
           1 1 1
                      ?
                            0
33
    1 0 0 0 0 0
                            0
35
    1
       0 0 0 1 0
                      ?
                            0
              1 1
                      ?
36
    1
       0
         0
            0
                            0
37
                      ?
    1
       0
         0
            1 0 0
                            0
         0 1 0 1
                      ?
38
    1 0
                           0
39
    1 0 0 1 1 0
                            0
41
    1 0 1 0 0 0
                      ?
                            0
42
    1 0 1
           0 0 1
                      ?
                            0
43
    1
       0
         1
           0
              1 0
                      ?
                            0
    1 0 1 0 1 1
                      ?
                            0
44
    1 0 1 1 0 0
                      ?
45
                            0
46
    1
       0 1 1 0 1
                      ?
                            0
47
           1 1 0
                      ?
    1
       0
         1
                            0
48
    1
       0
         1
            1 1 1
                      ?
                            0
49
    1 1 0 0 0 0
                      ?
                            0
50
    1 1 0 0 0 1
                     ?
                            0
    1 1 0 0 1 0
                     ?
                            0
51
                      ?
53
    1 1 0 1 0 0
                            0
54
    1
      1
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            1
              0 1
                       ?
                            0
55
    1 1 0 1 1 0
                      ?
                            0
                      ?
    1 1 0 1 1 1
                            0
56
57
    1 1 1 0 0 0
                      ?
                            0
58
    1 1 1 0 0 1
                      ?
                            0
61
    1 1
         1
            1
              0 0
                       ?
                            0
    1 1 1 1 1 1
                      ?
64
                            0
> # Minimisation: Disability / positive outcome / Conservative
> M1Conservative <- minimize(TT1, details = TRUE, use.tilde = TRUE, row.dom
 = TRUE)
> M1Conservative
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 4/16/0
 Total
         : 20
Number of multiple-covered cases: 1
M1: ~A*B*D*E*~F + B*C*D*E*~F + ~A*B*~C*~D*~E*F => SMD.DISABILITY.CRISP
                 inclS PRI covS covU cases
1 ~A*B*D*E*~F
                1.000 1.000 0.167 0.067 1; 2
2 B*C*D*E*~F 1.000 1.000 0.134 0.034 2; 7
```

```
3 ~A*B*~C*~D*~E*F 1.000 1.000 0.067 0.067 5
                   1.000 1.000 0.268
> # Minimisation: Disability / positive outcome / Intermediate
> # predicted all components as having a positive impact on outcome
> M1Intermediate <- minimize(TT1, include = "?", dir.exp = "1,1,1,1,1,1",
  details = TRUE, use.tilde = TRUE, row.dom = TRUE)
> M1Intermediate
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 4/16/0
 Total : 20
From C1P1:
Number of multiple-covered cases: 0
     ~A*B*~E*F + B*D*E*~F => SMD.DISABILITY.CRISP
M1:
             inclS PRI covS covU cases
1 ~A*B*~E*F 0.670 0.670 0.067 0.067 5
2 B*D*E*~F 1.000 1.000 0.201 0.201 1; 2; 7
           0.890 0.890 0.268
From C1P2:
Number of multiple-covered cases: 0
M1:
      B*~C*~E*F + B*D*E*~F => SMD.DISABILITY.CRISP
             inclS PRI covS covU cases
1 B*~C*~E*F 1.000 1.000 0.067 0.067 5
2 B*D*E*~F 1.000 1.000 0.201 0.201 1; 2; 7
            1.000 1.000 0.268
```

From C1P3:

Number of multiple-covered cases: 0

```
B*D*E*~F + B*~D*~E*F => SMD.DISABILITY.CRISP
M1:
            inclS PRI covS covU cases
1 B*D*E*~F 1.000 1.000 0.201 0.201 1; 2; 7
2 B*~D*~E*F 1.000 1.000 0.067 0.067 5
-----
           1.000 1.000 0.268
> # Minimisation: Disability / negative outcome / Conservative
> M1negatedConservative <- minimize(TT1negated, details = TRUE, use.tilde =</pre>
 TRUE, row.dom = TRUE)
> M1negatedConservative
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 5/15/0
 Total : 20
Number of multiple-covered cases: 0
M1: ~A*~C*D*~E*~F + A*B*C*D*~E*F => ~SMD.DISABILITY.CRISP
               inclS PRI covS covU cases
1 ~A*~C*D*~E*~F 1.000 1.000 0.301 0.301 12,17; 11,19
2 A*B*C*D*~E*F 1.000 1.000 0.067 0.067 15
______
                1.000 1.000 0.368
> # Minimisation: Disability / negative outcome / Intermediate
> # predicted all components predicted positive outcome
> M1negatedIntermediate <- minimize(TT1negated, include = "?", dir.exp =
  "1,1,1,1,1", details = TRUE, use.tilde = TRUE, row.dom = TRUE)
> M1negatedIntermediate
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
```

```
F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 5/15/0
 Total
       : 20
From C1P1:
Number of multiple-covered cases: 0
     D*~E => ~SMD.DISABILITY.CRISP
M1:
        inclS PRI covS covU cases
1 D*~E 1.000 1.000 0.500 - 12,17; 11,19; 15
  M1 1.000 1.000 0.500
> # Minimisation: Disability / negative outcome / Conservative
> # Minimisation: Distress / positive outcome / Conservative
> M2Conservative <- minimize(TT2, details = TRUE, use.tilde = TRUE, row.dom
 = TRUE)
> M2Conservative
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 4/16/0
 Total : 20
Number of multiple-covered cases: 0
M1: A*B*~D*E*F + A*B*C*D*~E*F + ~A*B*~C*D*~E*F => SMD.DISTRESS.CRISP
                 inclS PRI covS covU cases
1 A*B*~D*E*F 1.000 1.000 0.134 0.134 15; 19
2 A*B*C*D*~E*F 1.000 1.000 0.067 0.067 12
3 ~A*B*~C*D*~E*F 1.000 1.000 0.067 0.067 11
_____
  Μ1
                 1.000 1.000 0.268
> # Minimisation: Distress / positive outcome / Intermediate
> M2Intermediate <- minimize(TT2, include = "?", dir.exp = "1,1,1,1,1,1",</pre>
 details = TRUE, use.tilde = TRUE, row.dom = TRUE)
```

#### > M2Intermediate

```
A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 4/16/0
 Total : 20
From C1P1, C1P2:
Number of multiple-covered cases: 0
M1:
      A*B*E*F + B*D*~E*F => SMD.DISTRESS.CRISP
           inclS PRI covS covU cases
1 A*B*E*F 0.779 0.779 0.233 0.233 15; 19
2 B*D*~E*F 1.000 1.000 0.134 0.134 11; 12
  M1 0.848 0.848 0.367
> # Minimisation: Distress / negative outcome / Conservative
> M2negatedConservative <- minimize(TT2negated, details = TRUE, use.tilde =
 TRUE, row.dom = TRUE)
> M2negatedConservative
   A: HOURSFZ
   B: DISABILITYFZ
   C: DISTRESSFZ
   D: CR
   E: FAMILY.REINFORCEMENT (Social / Operant)
   F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)
n OUT = 1/0/C: 4/16/0
 Total : 20
Number of multiple-covered cases: 0
M1: A*B*C*~D*E*~F + A*~B*~C*~D*~E*F + ~A*B*~C*D*~E*~F
   => ~SMD.DISTRESS.CRISP
                  inclS PRI covS covU cases
-----
1 A*B*C*~D*E*~F
                 1.000 1.000 0.050 0.050 9
2 A*~B*~C*~D*~E*F 1.000 1.000 0.067 0.067 1
3 ~A*B*~C*D*~E*~F 1.000 1.000 0.134 0.134 4,5
```

\_\_\_\_\_\_

- > # Minimisation: Distress / negative outcome / Intermediate
- > M2negatedIntermediate <- minimize(TT2negated, include = "?", dir.exp =
   "1,1,1,1,1", details = TRUE, use.tilde = TRUE, row.dom = TRUE)</pre>
- > M2negatedIntermediate

A: HOURSFZ

B: DISABILITYFZ

C: DISTRESSFZ

D: CR

E: FAMILY.REINFORCEMENT (Social / Operant)

F: GRADED.EXPOSURE.GRADED.EXERCISE.BEHAVIOURAL.REHEARSAL (Exposure / Activity)

n OUT = 1/0/C: 4/16/0 Total : 20

From C1P1, C1P4, C1P7:

Number of multiple-covered cases: 0

M1:  $A^* - B^* - D^* F + B^* D^* - E^* - F + A^* B^* C^* - D^* E^* - F = > -SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~B*~D*F B*D*~E*~F A*B*C*~D*E*~F	1.000	0.504 1.000 1.000	0.134	0.134	4,5
	M1	0.792	0.792	0.251		

From C1P2, C1P5, C1P8:

Number of multiple-covered cases: 0

M1:  $A^* \sim B^* \sim D^* F + \sim A^* B^* D^* \sim F + A^* B^* C^* \sim D^* E^* \sim F \Rightarrow \sim SMD.DISTRESS.CRISP$ 

From C1P3, C1P6, C1P9:

Number of multiple-covered cases: 0

M1:  $A^* \sim B^* \sim D^* F + B^* \sim C^* D^* \sim F + A^* B^* C^* \sim D^* E^* \sim F = > \sim SMD.DISTRESS.CRISP$ 

```
inclS PRI covS covU cases

1 A*~B*~D*F 0.504 0.504 0.067 0.067 1

2 B*~C*D*~F 0.835 0.835 0.167 0.167 4,5

3 A*B*C*~D*E*~F 1.000 1.000 0.050 0.050 9

M1 0.742 0.742 0.284
```

From C1P10, C1P13, C1P16:

Number of multiple-covered cases: 0

M1:  $A^* \sim B^* \sim E^* + B^* D^* \sim E^* \sim F + A^* B^* C^* \sim D^* E^* \sim F = > \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~B*~E*F B*D*~E*~F A*B*C*~D*E*~F	1.000	1.000	0.134	0.067 0.134 0.050	4,5
	M1	0.792	0.792	0.251		

From C1P11, C1P14, C1P17:

Number of multiple-covered cases: 0

M1:  $A^* \sim B^* \sim E^* F + \sim A^* B^* D^* \sim F + A^* B^* C^* \sim D^* E^* \sim F = > \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~B*~E*F ~A*B*D*~F A*B*C*~D*E*~F	0.835		0.167	0.167	4,5
	M1	0.742	0.742	0.284		

From C1P12, C1P15, C1P18:

Number of multiple-covered cases: 0

M1:  $A^*\sim B^*\sim E^*F + B^*\sim C^*D^*\sim F + A^*B^*C^*\sim D^*E^*\sim F => \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~B*~E*F B*~C*D*~F A*B*C*~D*E*~F	0.835	0.504 0.835 1.000	0.167	0.167	4,5
	M1	0.742	0.742	0.284		

From C1P19, C1P22, C1P25:

Number of multiple-covered cases: 0

M1:  $A^*\sim C^*\sim E^*F + B^*D^*\sim E^*\sim F + A^*B^*C^*\sim D^*E^*\sim F => \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~C*~E*F B*D*~E*~F A*B*C*~D*E*~F	1.000	0.670 1.000 1.000	0.134	0.134	4,5
	M1	0.884	0.884	0.251		

From C1P20, C1P23, C1P26:

Number of multiple-covered cases: 0

M1:  $A^* \sim C^* \sim E^* F + \sim A^* B^* D^* \sim F + A^* B^* C^* \sim D^* E^* \sim F = > \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~C*~E*F ~A*B*D*~F A*B*C*~D*E*~F	0.835	0.835		0.167	4,5
	M1	0.811	0.811	0.284		

From C1P21, C1P24, C1P27:

Number of multiple-covered cases: 0

M1:  $A^*\sim C^*\sim E^*F + B^*\sim C^*D^*\sim F + A^*B^*C^*\sim D^*E^*\sim F \Rightarrow \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~C*~E*F B*~C*D*~F A*B*C*~D*E*~F	0.835	0.835	0.167		4,5
	M1	0.811	0.811	0.284		

From C1P28, C1P31, C1P34, C1P37, C1P40, C1P43:

Number of multiple-covered cases: 0

M1:  $A^*\sim D^*\sim E^*F + B^*D^*\sim E^*\sim F + A^*B^*C^*\sim D^*E^*\sim F \Rightarrow \sim SMD.DISTRESS.CRISP$ 

	inclS	PRI	covS	covU	cases
1 A*~D*~E*F 2 B*D*~E*~F 3 A*B*C*~D*E*~F	1.000	1.000 1.000 1.000	0.134	0.134	4,5

# M1 1.000 1.000 0.251

From C1P29, C1P32, C1P35, C1P38, C1P41, C1P44:

Number of multiple-covered cases: 0

M1:  $A^*\sim D^*\sim E^*F + \sim A^*B^*D^*\sim F + A^*B^*C^*\sim D^*E^*\sim F \Rightarrow \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases
2	A*~D*~E*F ~A*B*D*~F A*B*C*~D*E*~F	0.835	0.835	0.067 0.167 0.050	0.167	4,5
	M1	0.896	0.896	0.284		

From C1P30, C1P33, C1P36, C1P39, C1P42, C1P45:

Number of multiple-covered cases: 0

M1:  $A^*\sim D^*\sim E^*F + B^*\sim C^*D^*\sim F + A^*B^*C^*\sim D^*E^*\sim F \Rightarrow \sim SMD.DISTRESS.CRISP$ 

		inclS	PRI	covS	covU	cases	
2	A*~D*~E*F B*~C*D*~F A*B*C*~D*E*~F	0.835	0.835		0.167	4,5	
	M1	0.896	0.896	0.284			