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Sufficient conditions for effective psychological treatment of chronic pain: a qualitative comparative analysis

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Abstract

Chronic pain (CP) is the leading cause of years lived with disability globally. Treatment within western medicine is often multi-component; the psychological element of treatment varies, yet the optimal conditions for effective reduction of pain-related outcomes remain unclear. This study used Qualitative Comparative Analysis (QCA), a relatively new form of evidence synthesis in the field based on set-theory to ascertain configurations of intervention

components and processes of psychological treatment of CP in adults that lead to more effective interventions. Data were extracted from 38 studies identified in a concurrent Cochrane Review and were then subjected to QCA. Two analyses were conducted, one to examine what is most effective for reducing disability and one to examine what is most effective for reducing distress. Analysis and comparison of the 10 treatments with best outcomes with the 10 treatments with poorest outcomes showed that interventions using graded exposure, graded exercise or behavioural rehearsal (Exposure / Activity) and interventions aiming to modify reinforcement contingencies (Social / Operant) reduced disability levels when either approach was applied but not both. Exposure / Activity can improve distress levels when combined with Cognitive Restructuring, as long as Social / Operant methods are not included in treatment. Clinical implications of this study suggest that treatment components should not be assumed to be synergistic and provided in a single package.

Keywords: Pain; chronic; psychology; QCA

Introduction

Chronic non-cancer pain (CP) is defined as pain that outlasts normal healing times or that lasts for 3 months or more [62]. A global study suggested 10% of the population experience CP [23] and its economic impact is estimated at €441 billion in Europe [11]. Effective treatment to reduce CP and its impact is therefore important.

Rehabilitative treatment, offered after attempts at pain relief fail, draw on multiple psychological models [51]. Operant and behavioural treatment models [12,13] focus on reducing pain behaviours and increasing 'well' behaviours using interventions such as response prevention, positive and negative reinforcement [42], and graded exposure to

decrease activity-inhibiting fear [57]. Cognitive interventions aim to change unhelpful beliefs and biases concerning pain by cognitive restructuring [50]. Mindfulness Based Stress Reduction focuses on cognitive *processes*, purposefully bringing attention to the present moment in a non-judgemental way [26]. Acceptance and Commitment Therapy (ACT) [17] mobilises an individual's values to engage in meaningful activity and de-fuses individuals from their distressing thoughts. Various configurations of these interventions are often combined with exercise, activity increase, relaxation and other rehabilitative techniques [24].

Meta-analyses of CP treatments to identify the efficacy of different forms of psychological therapies have found that CBT has small yet robust positive effects on pain, disability and distress when compared to treatment-as-usual [60]. There is limited evidence of small effects of mindfulness for pain, depression, sleep, quality of life, pain acceptance and analgesic use outcomes due to a lack of high-quality, large scale trials [4,19] and ACT meta-analyses range from identifying almost no beneficial effect on pain intensity, depression, anxiety, pain interference, disability and quality of life to small to moderate effects on disability and distress; again further quality trials are needed [53,54].

Trials proliferate without evidence of progress towards what treatments work best for whom [35]. Dismantling studies (which evaluate discrete components of a multi-component therapy) assume an additive model that is poorly supported, and regression models tend to overfit unique models to the particular data set. Rather than seeking the perfect configuration, the question of which are the sufficient components for each outcome to improve might be more productive. Delphi studies (most recently [45]) used to define necessary components can provide only low certainty of evidence [30]. There can be more than one pathway to effectiveness; components may not independently generate a successful outcome but may require the presence of others. Qualitative Comparative Analysis (QCA) represents a new way to investigate which components result in change.

QCA is an abductive approach that takes advantage of heterogeneity between cases, first generating sets of effective and ineffective outcomes. It then uses these sets to theorise the possible configurations of conditions (aspects of an intervention and its context) that provide the most logical explanation for the outcomes using Boolean algebra [39].

The present study aimed to use QCA to identify sufficient components of psychological treatment of CP by understanding how patient characteristics, treatment context, processes and content interact to influence outcomes of distress and disability.

Method[1]

Design

A Cochrane systematic review and meta-analysis undertaken in 2020 addressed the psychological treatment of adults with CP [59]. 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 [2,61].

Ethics

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

Search

[1] The authors acknowledge that since a QCA methodology is likely to be new to most readers, the process and results will be, to some extent, taken on trust. Every effort has therefore been made to ensure that this analysis is described in sufficient detail that the steps can be replicated.

Cochrane Review search and inclusion / exclusion criteria

The majority of studies included in this QCA were taken from the aforementioned Cochrane Review [60] that 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 computer. All are subjects of separate meta-analyses, published or in progress [16,28,58].

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 Supplementary Online File A, search strategy, available at http://links.lww.com/PAIN/B311). 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 needed 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 [22,37]; (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 being most 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'. Supplementary online file B lists the papers that met inclusion criteria (available at http://links.lww.com/PAIN/B311).

Risk of bias

Within the Cochrane review, the risk of bias in methodologies of the included studies was rated using Cochrane guidance that considers selection, attrition and reporting bias [18], modified for psychological trials [60].

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 and so were the target of investigation.

Where more than one scale sampled the same outcome in a single study, authors selected the more reliable or widely used by other studies[2]. If data were missing, study authors were contacted directly, and missing data requested. Standard Mean Difference (SMD) (effect size) was calculated from post-treatment intervention and control data for pain-related disability and pain-related distress using RevMan 5.3 software [48], selecting random effects given the heterogeneity between studies. These two estimates, **SMD distress and SMD disability**, were used as the two primary outcome measures and were subjected to two separate QCAs.

To understand *maximum* heterogeneity, other QCAs have excluded cases that are not clear members or non-members of the outcome set [31]. The present analysis created two data sets, one that included only cases resulting in the top 10 and bottom 10 pain-related *distress* outcome scores, the other included cases resulting in the top 10 and bottom 10 pain-related *disability* outcome scores. If a case fell into the top 10 outcome scores, the outcome was calibrated into the 'effective' membership set, if it fell into the bottom 10 outcome scores, the outcome was calibrated into the 'ineffective' membership set. Cases featuring neither top nor bottom outcome scores were therefore excluded from the original set of 38 studies, resulting in 23 cases.

[2] The outcome measure scale adopted by each paper is shown in Appendices G and H.

QCA process

The QCA process involves six steps [39]:

1. **Completion of a Data Table**

   A summary of the content of each study is made; data are represented by a decimal from 0 to 1 where 0 represents absence of the condition or outcome and 1 represents presence.

2. **Generation of Truth Tables**

   All configurations of conditions in relation to outcomes are synthesised with data from the data table.

3. **Resolution of contradictory configurations**

   Studies with the same configuration of components resulting in different outcomes are resolved.

4. **Boolean minimisation**

   Boolean logic is used to conclude which conditions are sufficient / necessary to produce an effective outcome.

5. **Consideration of logical remainder cases**

   Configurations for which no studies exist are explained using logic and theory.

6. **Interpretation**

   Theory and case knowledge are used to ground empirical findings and check that the solution makes meaningful sense.

Case Data

Data for the QCA were gathered using a grounded approach [25], alongside substantive theory to allow maximum heterogeneity in the data set and to avoid early introduction of the authors' 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 but only if theoretical knowledge also suggested that the conditions were likely to have an influence on outcomes. 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 sufficiently 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 Supplementary online file C (available at http://links.lww.com/PAIN/B311).

Some conditions were excluded from the analysis if less than a third of cases illustrated their presence, as per QCA guidelines [41]; examples of this are inpatient treatment and treatment in a pain clinic. Some conditions were excluded because there was no heterogeneity and therefore that component could add nothing to the analysis. For example, psychoeducation was a component of almost every treatment. Knowledge of pain management programmes suggests that even those studies that did not mention the inclusion of this component were more likely to have omitted its description than to have omitted it from their programme content. Such decisions are also described in Supplementary online file C (available at http://links.lww.com/PAIN/B311).

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

Condition selection

QCA guidance recommends conducting an analysis with a limited number of conditions, since the larger the number of conditions, the more possible configurations. Too many conditions create more configurations of conditions than the number of cases.

To reduce the number of conditions, six specialist pain researchers or clinicians selected the conditions that they thought would be influential in generating negative or positive outcomes. The responses were pooled and a shortlist of 22 conditions were compiled based on those selected by three or more experts. The use of such a specialist 'steering' group is innovative within QCA. From these, CP theory and extant evidence in the treatment of CP guided a decision to include the following variables, at the level of the trial: patient age, patient education level, patients recruitment source (clinical or general populations), percentage attrition, baseline distress levels, baseline disability levels, use of cognitive restructuring, use of graded exposure, use of family in treatment, 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)[3]. The truth tables and minimisation tables output from initial QCA exploration to define the final conditions are reported in Supplementary online file D (available at http://links.lww.com/PAIN/B311). This routine approach in QCA enabled improvement of model fit before settling on the combination of six components for the final analysis; two were baseline variables, three were intervention components and the final variable related to the way in which intervention was implemented. A flow diagram of the selection of components can be found in Figure 1.

[3] Coverage and consistency are explained in more detail within 'Minimisation'.

Baseline Distress was quantified at baseline by a variety of instruments, although checklists of depressive symptoms were most common. Raw distress scores were then indexed to a standardised score from 0 to 100, where 100 is worst.

The level of **Baseline Disability** was assessed by a variety of instruments, mainly self-report checklists of function and activity. Raw disability scores were then indexed to a standardised score from 0 to 100, where 100 is worst disability.

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 alternative, more accurate thoughts. It aims to address 'catastrophising' in particular.

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 Fear-Avoidance Model 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 aiming to improve patient communication of support needs (often by assertive communication skills) or interventions that focused on modifying reinforcement contingencies (including self-

reinforcement) were 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.

The number of **Hours of Treatment** to which a patient is exposed was used, not including homework tasks since they were not reliably assessed 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 below).

Crisp Set Calibration creates binary data; either a case is considered to have full membership of a condition (recorded as 1) or no membership (recorded as 0). 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 that 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 authors came to a consensus based on information in the paper and their knowledge of pain treatment. For example, Castro [8] 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' set.

Fuzzy Set Calibration transforms data into a fraction between 0 and 1. This allows cases to be recognised as partial members of condition sets. Four points were used to denote the different levels of case membership within each set, according to guidance [34]; they were calibrated in the following way:

- 0 = the case was completely out of the set and is not a member
- 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 a full member of the condition set

The present study chose to use a direct method of calibration [38] that involved defining, qualitatively, where the cut-offs lie for the given condition using knowledge of the subject and its theory. For example, the number of hours of treatment ranged from six to 154. The Pain Society [47] recommended 36 as the minimum number of hours for a CP management programme so 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, suggesting that there was a disjunction 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).

Baseline Distress and Baseline Disability were also calibrated into the fuzzy sets detailed in Table 1. Disability and distress scales often use higher scores to reflect worse symptoms, thus improvements are represented by negative effect sizes.

Table 1: Fuzzy Set Membership scores for conditions

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.

Rigour

Coding and calibration were completed by the first author. When ambiguous data occurred, the last author independently coded them, the two decisions were compared and a coding agreement was made through discussion to ensure reliability and rigour.

The subsequent steps in QCA analysis were completed using R [40] and the graphic user interface of the QCA package [10].

Robustness

Schneider [44] 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. sufficient components in relation to Disability
    a. positive impact
    b. negative impact
2. sufficient components in relation to Distress
    a. positive impact
    b. negative impact

Truth table

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

Logical remainders

There were some possible configurations where no cases existed (called logical remainders), a situation 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' that are explained below[4].

Exclusion of cases

As explained within 'Outcome Measures', cases that did not fall into the top 10 most effective cases or bottom 10 least effective cases were excluded to maximise heterogeneity for both distress and disability outcomes.

Minimisation

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

The present QCA made use of *parsimonious* minimised solutions. Parsimonious solutions utilise *logical remainders* in the minimisation process. Parsimonious solutions assume that remainders agree with the solution that has been observed.

The software describes the solution in terms of **consistency,** representing the strength of the relationship between the condition set and outcome set. All cases exhibiting the condition of interest rarely fully trigger the outcome of interest when using fuzzy-set QCA. For this reason, a minimum consistency threshold is used to denote subset relationships. Previous QCA have used minimum consistency scores ranging from 0.75 to 0.9 [39]. The present paper chose a 0.8 consistency cut-off.

The software also describes the solution in terms of **coverage,** indicating the degree to which the configuration or solution explains all cases of the outcome. One case can feature in

[4] QCA can create *complex*, *intermediate* or *parsimonious* solutions. Complex 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 [3]. For transparency, intermediate and complex solutions were also derived and can be found in Supplementary Online File E (available at http://links.lww.com/PAIN/B311).

more than one configuration of conditions; unique coverage represents the degree to which that configuration *alone* explains all cases of the outcome.

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 configuration of conditions. Resolution of these contradictions would normally be necessary, but the data set showed none.

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.

The studies within the two distress and disability data sets overlapped; 48% of the studies were used within both data sets, a degree of overlap seen within many conventional meta-analyses.

Some studies also 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 2. 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 that did not report having made an effort to use staff to collect patient self-report outcomes who were blinded to patient allocation. 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, possibly producing 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

Complete data sets showing the 10 cases resulting in the highest and lowest Standard Mean Difference for Distress and Disability can be found in Table 2 and 3 respectively with the outcome measure scale adopted by each paper indicated.

Table 2: Data set based on top 10 and bottom 10 pain-related distress outcome measure scores

Table 3: Data set based on top 10 and bottom 10 pain-related disability outcome measure scores

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 4. Truth table indicated 48 condition combinations for which no case example exists (logical remainders).

Table 4: Truth Table for Positive impact on Disability

No cases existed featuring the same combination of conditions but a different outcome (called contradictions), thereby avoiding the need for resolution. The parsimonious minimisation of the truth table can be found in Table 5[5]. Despite only one case supporting each individual combination of conditions, it was evident from the Truth Table that minimisation was likely to progress beyond a description of individual cases towards a more meaningful conclusion.

Table 5: Minimisation for Positive impact on SMD Disability

Three candidate solutions were identified after minimization (Table 4), with a common 'essential' configuration across all three models identified as triggering success

[5] Intermediate and complex solutions can be found in Supplementary Online File E (available at http://links.lww.com/PAIN/B311)

('Social / Operant without Exposure / Activity')[6]. The studies supporting this 'essential' configuration were Castel et al., 2013; Nicholas et al., 2013 and the cognitive arm of Smeets et al., 2006 [7,36, 46]. The three candidate solutions differed according to an interchangeable configuration (each involving the study by Garcia-Palacios et al., 2015, [14]). Model 1 (M1) is not interpreted here, as the interchangeable pathway incorporated within it[7] had low consistency (a measure of the degree of sufficiency between the condition set and the outcome set). Minimised solution M2 and Minimised solution M3 suggested that in addition to 'Social / Operant without Exposure / Activity', that either ('Exposure / Activity with 'low Baseline Distress levels' but without Social / Operant') or ('Exposure / Activity without Cognitive Restructuring and without Social / Operant) were sufficient to trigger a successful outcome. Both had similar levels of 'coverage' in that they explained similar proportion of successful outcomes (0.37 and 0.4 respectively). The papers included in the solution covered a range of CP diagnoses and patient characteristics. It is worth noting, however, that Garcia-Palacios et al [14] used virtual reality within treatment, a variable that was not considered as a condition within the QCA. Use of a parsimonious solution meant that combinations of conditions for which no case existed (logical remainders) were accounted for.

1.b. Negative impact on SMD Disability

The analysis of an outcome of *decrease or minimal improvement* in disability provides a robustness check for the solution found for an outcome of *improvement* in disability. The solution for *decrease or minimal improvement* disability outcome is consistent with the findings for the solution for *improvement* in disability. The truth table and the

[6] Prime Implicant 1
[7] Prime Implicant 2

parsimonious minimisation of the truth table can both be found in Supplementary Online File F (available at http://links.lww.com/PAIN/B311)[8].

2.a. Positive impact on SMD Distress

The truth table can be found in Table 6. The truth table indicated 51 possible combinations of conditions were unobserved in the data (logical remainders).

Table 6: Truth Table for Positive impact on SMD Distress

No cases existed that featured the same combination of conditions but a different outcome (contradictions), thereby avoiding the need for resolution. The parsimonious minimisation of the truth table can be found in Table 7[9].

Table 7: Minimisation for Positive impact on SMD Distress

Only one minimised solution M2 (High Hours of Treatment combined with High Baseline Disability and Exposure / Activity OR Cognitive Restructuring combined with Exposure / Activity without Social / Operant) had a high enough proportion of cases that reflected both the condition combination and the positive outcome, thereby meeting the consistency threshold with a consistency value of 0.814. The proportion of cases that reflect the solution (raw coverage) was 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 [6,49,52]

OR

[8] Intermediate and complex solutions can be found in Supplementary Online File E (available at http://links.lww.com/PAIN/B311)

[9] Intermediate and complex solutions can be found in Supplementary Online File E (available at http://links.lww.com/PAIN/B311)

b) Cognitive Restructuring without Social / Operant as exemplified by Bliokas et al., 2007 and Cherkin et al., 2016 CBT arm [6,9] has a positive impact on distress levels.

The papers covered a range of CP diagnoses and patient characteristics. It is worth noting, however, that Thieme et al [49] and van Koulil et al [52] both described unusual approaches in their studies; the former used *inpatient* participants and the latter used participants deemed to be at high risk of exacerbation of symptoms as well as adopting an intervention tailored to the particular unhelpful pain behaviours (pain avoidance or pain persistence) displayed by each patient. These variables were not considered as conditions within the QCA.

Consideration of combinations of conditions for which no case existed was unnecessary because a parsimonious solution was adopted.

2.b. Negative impact on SMD Distress

The analysis of an outcome of *decrease or minimal improvement* in distress provides a robustness check for the solution found for an outcome of *improvement* in distress. The solution for *decrease or minimal improvement* distress outcome is consistent with the findings for the solution for *improvement* in distress.

The truth table and the parsimonious minimisation of the truth table can both be found in Supplementary Online File F (available at http://links.lww.com/PAIN/B311)[10].

[10] Intermediate and complex solutions can be found in Supplementary Online File E (available at http://links.lww.com/PAIN/B311)

Discussion

Individual stand-alone components of psychological treatment of CP were not identified as necessary for effective interventions, neither did we identify an additive effect of the 'more is better' approach to designing treatment programmes. Instead, findings indicated that particular configurations of treatment components needed incorporation into interventions for effective change. Whereas meta-analysis complicated by heterogeneity between studies concludes that behavioural treatments alone cannot demonstrate efficacy [60], QCA takes advantage of heterogeneity, finding support for *operant* behavioural treatment.

Disability

The QCA found that Social / Operant and Exposure / Activity treatments reduced disability levels separately but not combined. Assuming synergy between different CBT components needs challenging, as multiple components could confuse patients, impeding therapy.

Interestingly, for Exposure / Activity to elicit improvement in disability levels, patients should either have low baseline *distress* levels or it should be delivered without Cognitive Restructuring (both without operant treatment). Might high levels of distress undermine persistence in Exposure / Activity, consistent with the FAM of pain; and might Cognitive Restructuring, as argued by proponents of ACT [1], undermine behavioural work by using introspection as experiential avoidance?

Surprisingly, Cognitive Restructuring was not found 'necessary' (in the QCA sense of the word) in any solution with improvement in disability, suggesting that behavioural work

outperforms Cognitive Restructuring in reducing disability, fostering renewed interest in behavioural exposure as intervention.

Taken together, findings support the argument that researchers cannot assume additivity of gains from individually effective interventions when combined [35].

Distress

According to our results, Exposure / Activity can improve distress levels when combined with Cognitive Restructuring, as long as Social / Operant methods are excluded. It may be that it is too challenging for others, such as family, to adopt a consistent pattern of positive reinforcement required for Social / Operant methods, or for patients to adhere to this method while increasing activity levels and reformulating pain-related problems. Interestingly, the 'necessity' of Cognitive Restructuring suggests that insight that helps reduce distress is not only gained through experiential Exposure / Activity work (perhaps because fears of activity are not extinguished by exceptions [55,56]), but must be made explicit through re-evaluating beliefs and enabling self-talk that encourages activity.

Analysis also showed that Exposure / Activity alone has reduces distress when patients with substantial baseline disability are treated over a high number of treatment hours. Graded Exposure techniques may need focus, as in higher intensity situations and specific contexts [57] often with expert physiotherapist guidance, such that attempts without expert guidance may be unsuccessful. Patients with high levels of disability may find such behavioural work particularly anxiety-inducing and rely, perhaps initially, on expert guidance and a gradual process.

Strengths and limitations

The present study has adhered to a traditional QCA methodology as well as meeting the vast majority of 26 guidelines listed by Schneider to ensure good quality QCA [44]; to ensure transparency and replicability the methodology has been justified and analytical outputs have been reported according to QCA standards; analysis has been developed from cases and subject theory and conclusions linked back to said cases and theory; effort has been made to reduce bias and an adequate number of high-quality cases used.

Nevertheless, the following standard was not met: necessary and sufficient conditions are ideally analysed in separate analytical steps where sufficient conditions are not indicated. Further, resource restrictions meant that only six conditions could be incorporated, possibly missing 'key' treatment components and their interactions. Thus some effective cases exemplifying a minimised solution included conditions not analysed within the QCA (for example virtual reality techniques in Garcia-Palacios et al [14]). The choice of whether to draw on parsimonious vs intermediate solutions is an unresolved debate in QCA methodology. Although we present the parsimonious solution here, following some of the arguments made by Baumgartner and Thiem [3] for example, we acknowledge that an intermediate solution could bring several other advantages and is favoured in a number of other QCA syntheses. In addition, QCA itself has been criticised for limiting the number of components that can be analysed [43], allowing single cases disproportionate influence [15], using deterministic hypotheses and assuming error-free measures [20] that increase Type I error [27] although QCA is not the only approach to suffer these limitations [29].

Although study quality was high, papers were limited in population diversity and methodology; the majority of papers came from white, educated, industrialised, rich and democratic countries; variation in psychological approach to treatment of pain was limited;

and participants were largely white and spoke the majority mother tongue. This limits generalisations that can be made from the QCA to more diverse populations with chronic pain. Inconsistent reporting of these variables precluded their incorporation as conditions in this QCA.

The papers also demonstrated risks of detection, attrition and reporting biases. Detection bias only affected a minority of papers, since most used self-report of outcomes, and reporting bias was rendered less important since the present study focussed on outcomes regardless of whether they were planned as primary outcomes or not. However, the level of attrition bias is of concern; estimated effect sizes may have been inflated if those dropping out of treatment did so because they made no progress or worsened on our chosen outcomes. Of the papers with a risk of attrition bias, one [6] constituted a case that illustrated the exact configuration of components found by the QCA to be necessary for an effective reduction of distress. This means that this case represented key information within the QCA process and therefore, while it was not the only case representing the particular configuration of components, any conclusions arising from this solution must be tentative.

A further limitation is the use of the highest ten and lowest ten outcome measures rather than the whole set of 38 papers, 23 of which were used across all analyses. Despite the fact that the number of cases is adequate[11], generalisability is limited: we can say that "for *high* levels of effectiveness this configuration of components are necessary" and this is of greater interest, but we have not answered what contributes to *moderate* levels of outcome change.

Although decisions on content of studies are documented as transparently as possible, there was inevitably some subjective interpretation necessary; similarly, while outcome

[11] The median number of cases across QCAs has been found to be 22 [29].

scales themselves may be reliable, validation and measurement of subjective experience is fraught [33].

Importantly, this QCA focussed on disability and distress, but other outcomes may more closely reflect patient priorities [5], in particular pain intensity, that was excluded. This was in part necessitated by feasibility, but also by difficulty interpreting pain ratings and change [59].

Implications for clinical practice

Specific recommendations for clinicians are hard to make because many aspects of treatment were not included in the QCA, and further exploration in this field, using QCA, is warranted.

This study suggests that when planning CP interventions, treatment components (Exposure / Activity, Social / Operant and Cognitive Restructuring) should not be assumed to be synergistic until proven so. Clinicians should equally not assume that all pain-related outcomes can be improved at once; different configurations of components are recommended according to whether the target is distress or disability. Consideration may need to be given to the severity of baseline disability and hours of treatment when targeting distress, but further research would be necessary to establish such requirements. In combination with a recent meta-analysis [60], our findings suggest that while overall, CBT is beneficial compared to no or minimal treatment, larger gains may lie in developing clearer relationships between specific components and outcomes, in the context of baseline scores and delivery variables, a task for which QCA is well suited.

Implications for future research

There remains data to explore from the present study's data gathering process to continue to pursue the question of necessary or sufficient conditions for improvement in disability or distress or both.

It may be helpful to systematically introduce and alternate further conditions beyond those prioritised by the expert panel in the present study, possibly using single case methods [30]. This would allow researchers to detect further conditions that may be consistently necessary for improvement in particular outcomes.

In order to inform theory, it may be helpful to un-merge previously merged necessary conditions into conditions aligned with one model of pain and to incorporate granular conditions into QCA using a larger data set, to ascertain which theoretical approach is necessary for change.

The hypotheses generated relating to the interaction between distress and disability may need exploration with single-case studies, or serial treatment or trajectory studies. Qualitative exploration of these topics could also aid understanding of how these factors interact.

Conclusion

The present study implies that sufficient components of psychological CP treatment to reduce distress and disability are predominantly behavioural rather than cognitive, and that certain components may act to nullify or undermine others rather than synergistically, as generally assumed; their benefits may also depend on baseline severity. This study has also highlighted the potential of QCA for exploring further treatment component interactions.

Glossary of QCA Terminology

Calibration	Process whereby fuzzy or crisp set membership scores are given to cases
Case	In the context of this study, a case refers to one active treatment arm of a peer-reviewed Randomised Controlled Trial
Condition	(also **Component**) An aspect of the case that could be used to explain the outcome, In the context of this study this could be the treatment content, a descriptive aspect of the participants or the research / treatment process
Complex	A complex solution type that uses no logical remainders in its determination, also known as 'conservative'.
Consistency	The proportion of cases that reflect both the conditions and the outcome
Coverage	The proportion of cases in the analysis that reflect the solution
Crisp Set	A binary set that allows only full-membership or non-membership of 1 or 0
Fuzzy Set	A set that allows levels of membership described on a continuum of fractions from 0 to 1
Intermediate	A type of solution that requires QCA software to be guided by the researcher in determining how remainders are incorporated

Logical remainders	In a truth table, a configuration of conditions for that no case exists and therefore no outcome has been derived
Minimisation	Summary of the data set after application of Boolean Logic to a Truth Table
Necessary	Used to describe a condition that ensures a specified outcome will occur but which does not, alone, guarantee its occurrence
Parsimonious	A type of solution that utilises software to determine how remainders are incorporated
Prime Implicant	The end product of a logical minimisation process
Solution	The end result of QCA minimisation; a configuration of conditions resulting in the specified outcome
Sufficient	Used to describe a condition that, if present, guarantees an outcome's occurrence
Truth Table	Case data sorted into each of the different configurations of conditions that they exhibit and to which a column of outcome values is applied

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Figure Legend

Figure 1: Flow diagram of component selection steps

Figure 2: Summary of risk of bias in studies included within the QCA.

Tables

Table 1: Fuzzy Set Membership scores for conditions

Fuzzy Set Membership	Hours of Treatment (A)	Baseline Disability (B)	Baseline Distress (C)
0	< 10	score of < 20	score of < 30
0.33	≥ 10 and < 36	score ≥ 20 and < 50	score ≥ 30 and < 50
0.67	≥ 36 and ≤ 120	score ≥ 50 and < 80	score ≥ 50 and < 80
1	> 120	score ≥ 80	score ≥ 80

Table 2: 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)	Ag
Jensen (behavioural)[a]	2001	0.18	0	0	80	0.67	0.33	0.33	42
La Cour[b]	2015	-0.01	0	0	28.5	0.33	0.67	0.33	46
Heutink[c]	2012	-0.03	0	0	33	0.33	0.33	0.33	58
Glombiewski (CBT + biofeedback)[d]	2010	-0.07	0	0	23	0.33	0.67	0	48
Glombiewski (CBT)[d]	2010	-0.07	0	0	23	0.33	0.67	0	48
Smeetsc (physical and cognitive)[d]	2006	-0.08	0	0	11	0.33	0.67	0	40
Schmidt (mindfulness)[d]	2011	-0.1	0	0	27	0.33	0.67	0.33	53
Helminen[d]	2015	-0.11	0	0	12	0.33	0.67	0	64
Haldorsen[e]	1998	-0.15	0	0	120	1	0.501	0.67	
Perez (FibroQOL)[b]	2019	-0.16	0	0	16	0.33	0.67	0.33	54.

Cherkin (CBT)[f]	2016	-0.57	1	0.67	16	0.33	0.67	0	49
Bliokas[g]	2007	-0.6	1	0.67	66.5	0.67	0.67	1	45
Van Koulil (pain persistence)[h]	2010	-0.63	1	0.67	76	0.67	0.33	0	41
Perez (mindfulness)[b]	2019	-0.63	1	0.67	22	0.33	0.67	0.33	52.
Van Koulil (pain avoidance)[h]	2010	-0.75	1	0.67	76	0.67	0.67	0.33	42
Williams (outpatient)[d]	1996	-0.76	1	0.67	31.5	0.33	0.33	0	50
Castel[i]	2013	-0.84	1	1	48	0.67	0.67	0.67	
Williams (inpatient)[d]	1996	-1.03	1	1	90	1	0.33	0	48
Thieme[j]	2003	-1.58	1	1	75	0.67	0.67	0.67	46
Luciano[b]	2014	-1.84	1	1	20	0.33	0.67	0.33	48

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

Table 3: Data set based on top 10 and bottom 10 pain-related disability outcome measure scores

Author	Year	SMD Disability	SMD Disability (Crisp Set)	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)
Evers[h]	2002	0.14	0	0	10	0.33	1	0	53.9	0.33	
Keefe[i]	1990	0.08	0	0	15	0.33	0.33	0	62.4	0.67	0.4
Geraets[j]	2005	0.07	0	0	18	0.33	0.67	0.33	51.2	0.33	0.5
Jensen (CBT)[k]	2001	0.04	0	0	54	0.67	0.33	0.33	43.8	0	
Bliokas[l]	2007	0.03	0	0	66.5	0.67	0.67	1	45.5	0.33	
Cash[e]	2015	0	0	0	23.5	0.33	0.33	0.67	47	0.33	
Ferrando[m]	2012	-0.01	0	0	6	0	0.33	0	39.6	0	0.5
Perez (FibroQOL)[c]	2019	-0.05	0	0	16	0.33	0.67	0.33	54.21	0.33	

Glombiewski (CBT)[l]	2010	-0.09	0	0	23	0.33	0.67	0	48.6	0.33	
Helminen[n]	2015	-0.11	0	0	12	0.33	0.67	0	64.5	0.67	
Smeetsb (cognitive)[a]	2006	-0.51	1	0.67	26.5	0.33	0.67	0	42.5	0	
Nicholas[b]	2013	-0.59	1	0.67	16	0.33	0.67	0.67	74.6	1	
Perez (mindfulness)[c]	2019	-0.62	1	0.67	22	0.33	0.67	0.33	52.96	0.33	
Williams (outpatient)[d]	1996	-0.81	1	1	31.5	0.33	0.33	0	50.4	0.33	
Garcia-Palacios[e]	2015	-0.87	1	1	12	0.33	0.67	0.33	50.5	0.33	
Van Koulil (pain avoidance)[f]	2010	-0.96	1	1	76	0.67	0.67	0.33	42.3	0	
Castel[e]	2013	-0.98	1	1	48	0.67	0.67	0.67	49	0.33	
Williams (inpatient)[d]	1996	-1.24	1	1	90	1	0.33	0	48.7	0.33	
Thieme[g]	2003	-2.03	1	1	75	0.67	0.67	0.67	46.6	0.33	
Luciano[e]	2014	-2.31	1	1	20	0.33	0.67	0.33	48.9	0.33	

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

Table 4: Truth Table for Positive impact on Disability

Conditions						Membership in 'effective intervention' set	Number of cases	Raw Consistency
Hours (A)	Base Disability (B)	Base Distress (C)	Cognitive Restructuring (D)	Social / Operant (E)	Exposure / Activity (F)			
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

Shaded areas indicate membership in 'ineffective intervention' set

Table 5: Minimisation for Positive impact on SMD Disability

		Consistency	**Raw Coverage**	**Unique Coverage**	**(M1)**	**(M2)**	**(M3)**	**cases**
Minimisation 1 (M1)	E*~F + (~A*~E*F)	0.92	0.37					
Minimisation 2 (M2)	E*~F + (~C*~E*F)	1	0.37					
Minimisation 3 (M3)	E*~F + (~D*~E*F)	1	0.4					
Prime Implicant 1	E*~F	1	0.3	0.3	0.3	0.3	0.3	Smeets, 2006 (cognitive arm); Nicholas, 2013; Castel,

								2013
Prime Implicant 2	~A*~E*F	0.67	0.07	0	0.07			Garcia-Palacios, 2015
Prime Implicant 3	~C*~E*F	1	0.07	0		0.07		Garcia-Palacios, 2015
Prime Implicant 4	~D*~E*F	1	0.1	0.03			0.1	Garcia-Palacios, 2015

Table 6: Truth Table for Positive impact on SMD Distress

Conditions						Membership in 'effective intervention' set	Number of cases	Raw Consistency
Hours (A)	**Base Disability (B)**	**Base Distress (C)**	**Cognitive Restructuring (D)**	**Social / Operant (E)**	**Exposure / Activity (F)**			
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

Shaded areas indicate membership in 'ineffective intervention' set

Table 7: Minimisation for Positive impact on SMD Distress

		Consistency	**Raw Coverage**	**Unique Coverage**	**(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				
Prime Implicant 1	A*B*F	0.771	0.333	0.233	0.233	0.233	Van Koulil, 2010; Thieme, 2003; Bliokas, 2007

Prime Implicant 2	B*~E*F	0.802	0.134	0	0.034		Cherkin, 2016 (CBT arm); Bliokas, 2007
Prime Implicant 3	D*~E*F	1	0.2	0.066		0.1	Cherkin, 2016 (CBT arm); Bliokas, 2007