Evidence Compass

Technical Report

What are effective psychological or multi-modal interventions for adults experiencing chronic pain?

A Rapid Evidence Assessment

October 2014

Australian Government
Department of Veterans' Affairs

Disclaimer

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Please forward any comments or queries about this report to at-ease@dva.gov.au

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List of Abbreviations

ACPMH	Australian Centre for Posttraumatic Mental Health
ACT	Acceptance and commitment therapy
ART	Accelerated resolution therapy
CB-CFT	Classification-based cognitive functional therapy
CBT	Cognitive behavioural therapy
CFT	Cognitive functional therapy
DVA	Department of Veterans' Affairs
EAC	Exercise attention control
EMG	Electromyographic
iCBT	Internet delivered CBT
IMMPACT	Initiative on Methods, Measurement and Pain Assessment in Clinical Trials
MBI	Mindfulness based interventions
MBSR	Mindfulness based stress reduction
MI	Motivational interviewing
MORE	Mindfulness oriented recovery enhancement
MPMP	Multidisciplinary pain management programs
OBT	Operant behavioural therapy
PE	Physical exercise
PICO	Population Intervention Comparison Outcome
PSM	Pain self-management program
PTSD	Posttraumatic stress disorder
RBT	Respondent behavioural therapy
RCT	Randomised controlled trial

REA	Rapid evidence assessment
SIGN	Scottish Intercollegiate Guidelines Network
TAU	Treatment as usual
TBI	Traumatic brain injury
US	United States
VA	Veterans Affairs

Executive Summary

- Chronic pain (sometimes known as persistent pain) is defined as a pain that has persisted beyond the normal healing time, approximately three months, despite efforts to treat the original cause[1]. It has been associated with reduced well-being, impaired work functioning and disability, as well as showing high comorbidity with depression, anxiety, posttraumatic stress disorder (PTSD), substance abuse and insomnia.

- Chronic pain has prevalence rates in community epidemiology studies for adults ranging between 11% and 44% depending on the severity of pain, age and gender. Prevalence rates are higher amongst military samples, with one study finding nearly 50% of a sample of United States (US) veterans seeking Veterans Affairs (VA) healthcare, reported regular pain[2].

- In 2007, the total cost of chronic pain in Australia was estimated at $34.3 billion, or nearly $11,000 per person with chronic pain.

- The aim of this rapid evidence assessment (REA) was to examine the efficacy of psychological or multi-modal interventions (including a psychological component) for adults with chronic pain.

- The interventions included in this review fell into four categories: cognitive behavioural therapy (CBT), multidisciplinary pain management programs (MPMPs) mindfulness-based therapies, and behavioural therapies [respondent behavioural therapy (RBT) and operant behavioural therapy (OBT)].

- Four key domains were used in the assessment of pain outcomes: pain intensity, physical functioning, emotional functioning and patient rating of overall improvement.

- The literature search identified a relevant, high quality set of guidelines titled “Management of chronic pain: A national clinical guideline”. These guidelines utilised the Scottish Intercollegiate Guidelines Network (SIGN) methodology (from here onwards referred to as the ‘SIGN Guidelines’).

- An additional literature search was conducted to identify randomised controlled trials (RCTs) published post-publication of the SIGN Guidelines (2012-2014). Studies were included in the review if they included an adult population, reported on one of the four pain domain outcomes (pain intensity, emotional functioning, physical functioning

and patient rating of overall improvement) and utilised a psychological or multi-modal intervention.

- The findings of the SIGN Guidelines were taken together with the findings of the post-SIGN RCTs. The RCTs were assessed for quality of methodology, risk of bias, and quantity of evidence, and the consistency, generalisability and applicability of the findings to the population of interest. These assessments were collated to determine an overall ranking of level of evidence support for each intervention.

- The ranking categories were 'Supported' –clear, consistent evidence of beneficial effect; 'Promising' – evidence suggestive of beneficial effect but further research required; 'Unknown' – insufficient evidence of beneficial effect; 'Not supported' – Clear, consistent evidence of no effect or negative/harmful effect.

- Thirty-one RCTs met the inclusion criteria for this REA. The majority investigated the effectiveness of CBT (n=18). Seven studies investigated mindfulness-based interventions, five studies investigated MPMPs and one study investigated RBT. Overall, the quality of the studies was generally high, with very few poor quality studies.

- Based on the findings of the SIGN Guidelines in combination with the post-SIGN Guidelines literature, rankings were made for each of the interventions included in this review. The key findings were that:

    - The evidence for CBT in treating chronic pain in adults received a 'Supported' ranking.
    - The evidence for MPMP in treating chronic pain in adults received a 'Promising' ranking.
    - The evidence for mindfulness-based interventions in treating chronic pain in adults received a 'Promising' ranking.
    - The evidence for RBTs (a form of behavioural therapy) in treating chronic pain in adults received a 'Promising' ranking.
    - The evidence for OBTs (a form of behavioural therapy) in treating chronic pain in adults received an 'Unknown' ranking.

- The findings of this REA suggest that CBT has the strongest evidence base for the treatment of chronic pain in adults. While other psychological interventions are gaining momentum, there remains a need for these interventions to be tested against the established treatment of CBT.

Introduction

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”[3]. Pain can develop as a result of tissue damage from an acute injury (e.g. back strain) or disease (e.g. pancreatitis), or damage to the nervous systems or both (e.g. spinal cord injury). Following injury, most people recover and the associated acute pain typically subsides in the ensuing weeks and months. Chronic pain is defined as a pain that has persisted beyond the normal healing time, approximately three months, despite efforts to treat the original cause[1]. Chronic pain is a debilitating problem associated with significant psychological and social difficulties including reduced well-being, impaired work functioning and disability, as well as mental health problems[4-6]. Comorbid psychiatric conditions such as depression, anxiety, posttraumatic stress disorder (PTSD), substance use and insomnia are noted to be highly prevalent in people presenting with chronic pain and reported to be two to seven times greater than those observed in the general population[7-9].

Prevalence rates of chronic pain are difficult to assess however, and estimates vary widely ranging anywhere between 11% and 44% depending on the severity of pain, age and gender[7]. In a recent national survey of Australian general practice[10], it was found that approximately 19% of the patients reported experiencing chronic pain, while the Australian Bureau of Statistics estimated that in 2007-2008 around one in ten (9%) of Australians have experienced chronic pain in the four weeks prior to interview[11]. The total cost of chronic pain in Australia in 2007 was estimated at $34.3 billion, or nearly $11,000 per person with chronic pain[12]. Prevalence rates of chronic pain are even higher in military samples, with one study finding that nearly 50% of a large sample (N=685) of US veterans who sought VA healthcare in 1997 reported regular pain[2]. Rates as high as 82% have been reported in veterans who previously screened positive for potential TBI[13].

Chronic pain is a broad category encompassing a multitude of different pain conditions classified on the basis of location, cause, neurophysiology or body system involved[14]. The most commonly reported pain conditions in the national survey of Australian general practice patients were osteoarthritis (48%) and back problems (29%)[10]. Similarly, back pain and headaches are the most common pain symptoms reported by US veterans[13] and musculoskeletal problems are the most common reason for medical discharge in the British armed forces[15].

Quite often a resolution of chronic pain is unlikely and consequently treatment of chronic pain concentrates on management of the symptoms associated with pain, in the face of pain that may persist. In practice, a number of different interventions have been developed to assist with pain management including psychological, pharmacological, surgical, rehabilitative, somatic, complementary and alternative. In the past decade there has been growing recognition of the psychosocial factors that increase vulnerability to chronic pain, and a shift towards focusing on psychological interventions that may address some of these vulnerabilities. The aim of the current review was to examine the efficacy of psychological interventions and multi-modal interventions that include a psychological component, for the treatment of chronic pain. This REA focused on those categories of psychological and multi-modal therapies that are most commonly used to treat chronic pain in adults, and which were identified as being of most relevance to DVA. Specifically, the REA examined literature relating to the efficacy of cognitive behavioural therapy (CBT), multidisciplinary pain management programs (MPMPs), mindfulness-based interventions and behavioural therapy. Each of the included categories of intervention are described in more detail in the section below.

Psychological interventions

Cognitive behavioural therapy (CBT) is defined as a type of psychological therapy that focuses on the relationship between cognitions, behaviours, and emotional responses[16]. CBT targets cognitions, behaviour and reasoning styles of a person experiencing chronic pain. Particular types of CBT interventions that may be used to treat the underlying mechanism of chronic pain include graded exposure, graded activity and cognitive therapy. In graded exposure, the objective of the treatment is the extinction of fear responses through exposure therapy and modification of unhelpful thoughts. The client and the therapist collaborate to identify negative thinking patterns arising in relation to movements that may lead to further damage or injury and the client is supported in recognising and evaluating these as they occur to identify new, more constructive thoughts. Graded activity concentrates on reinforcing and increasing activity and replacing problematic pain behaviours with more helpful healthy behaviours. Cognitive therapy concentrates on modifying cognitions such as catastrophizing about re-injury or the triggering of pain, beliefs about nature of pain and ability to control pain, and improving coping skills (self-efficacy) and expectations about recovery[17].

Multidisciplinary pain management programs (MPMPs) are a type of multi-modal intervention that address multiple complexities experienced by a person with chronic pain[18]. There is variability between different MPMPs, but the treatment usually addresses one or more biological, psychological, social and occupational factors that contribute to chronic pain problems. As such the treatment is usually directed by multiple disciplines and may include psychologists, physiotherapists, physicians, occupational therapists or social workers. There are no standardised guidelines on what constitutes multidisciplinary treatment of chronic pain. Interventions vary widely and may include education, physiotherapy, CBT, complementary and alternative approaches, occupational and environmental interventions[18].

Mindfulness-based interventions are a group of treatments that focus on helping the individual reconsider relationships between thoughts, feelings and current experience by redirecting attention to the present moment and maintaining a non-judgemental stance towards the actual experience of pain[19]. That is, in contrast to standard psychological treatments like CBT, the individual's symptoms are not the focus of treatment. Mindfulness-based interventions are becoming increasingly recognised as an alternative intervention for chronic pain[20]. In this review, three types of mindfulness-based interventions are explored, and while it is recognised that they differ in important ways, they are grouped together under this umbrella term due to the fact that mindful process are at their core. The first type of intervention is known as mindfulness based interventions (MBIs). MBIs are interventions that are concerned with shifting awareness, focusing on the present and maintaining a non-judgemental stance towards the experience of pain. The second is known as mindfulness based stress reduction (MBSR). MBSR is a specific, structured group-based program that incorporates yoga exercises and mind-body education[20]. Proponents of MBSR identify yoga as helpful in treating some of the mechanical aspects of pain, such as tight muscles that contribute to pain. The third of these mindful based interventions is known as acceptance and commitment therapy (ACT). ACT is a structured therapy that utilises a mindfulness-based approach but also focuses on the experience and willingness to experience pain, while neutralising unhelpful thoughts and re-engaging in activities[21].

Behavioural therapy that focuses on treatment of chronic pain includes respondent behavioural therapy (RBT) and operant behavioural therapy (OBT)[22]. RBT views the chronic pain as a cause and result of muscular tension. The treatment therefore focuses on modifying the physiological response system to pain by reducing the muscular tension. The specific types of RBTs include progressive muscle relaxation, applied relaxation and electromyographic (EMG) biofeedback. In contrast, OBT is based on the notion that

unhelpful behaviour can be reinforced either by the individual themselves or by their environment and thus becomes a chronic problem. As such, OBT focuses on removal of positive reinforcement of pain and promotion of healthy behaviours[23].

Pain intervention outcomes

In the past, evaluating the efficacy of interventions for the treatment of chronic pain has been problematic. Criticism in the literature has pointed to the fact that even when interventions are effective in reducing pain intensity, other aspects of emotional and physical functioning may not improve[24]. To overcome these limitations and to support a better evaluation of interventions, a standardised approach to pain outcome measures was developed and recommended by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT). Four key pain domains were recommended for the assessment of pain outcomes[25]: pain intensity, physical functioning, emotional functioning and patient rating of overall improvement. These domains are commonly used by pain researchers to identify when a pain intervention has resulted in a meaningful improvement for the patient. An intervention is considered to have meaningfully improved patient outcomes, when significant positive effects are found on at least two of the aforementioned domains[22]. For the current REA, this standard was also applied, with an intervention considered to be efficacious if significant positive changes were found on at least two of the four key pain domains.

As stated above, the aim of this review was to examine the efficacy of the most commonly used psychological and multi-modal interventions for the treatment of chronic pain in adults. The interventions that were identified as being of most relevance to DVA were CBT, MPMPs, mindfulness-based interventions and behaviour therapy. This review included literature on non-malignant pain conditions (e.g. musculoskeletal pain, neuropathic pain, back pain) and non-specific chronic pain Non-malignant conditions were included because they are those where the course of disorder is relatively stable and therefore more amenable to psychological interventions, while malignant conditions tend to become progressively worse. This review does not include literature related to headaches, due to the fact that the chronic pain literature and the headache literature are routinely considered to be separate entities in the research community[26]. This is because the treatments for headache are substantially different to those for other types of chronic pain[26], and therefore it did not make sense to include them in this review.

Method

This literature review utilised an REA methodology. The REA is a research methodology which uses similar methods and principles to a systematic review but makes concessions to the breadth and depth of the process, in order to suit a shorter timeframe. The advantage of an REA is that it utilises rigorous methods for locating, appraising and synthesising the evidence related to a specific topic of enquiry. To make an REA rapid, however, the methodology places a number of limitations in the search criteria and in how the evidence is assessed. For example, REAs often limit the selection of studies to a specific time frame (e.g. last 10 years), and limit selection of studies to peer-reviewed published, English studies (therefore not including unpublished pilot studies, difficult-to-obtain material and/or non-English language studies). Also, while the strength of the evidence is assessed in a rigorous and defensible way, it is not necessarily as exhaustive as a well-constructed systematic review and meta-analysis. A major strength, however, is that an REA can inform policy and decision makers more efficiently by synthesising and ranking the evidence in a particular area within a relatively short space of time and at less cost than a systematic review/meta-analysis.

Defining the research question

The components of the question were precisely defined in terms of the population, the interventions, and the outcomes using the Population Intervention Comparison Outcome (PICO) framework (refer to Appendix 1). Operational definitions were established for key concepts for each question, and from this specific inclusion and exclusion criteria were defined for screening studies for this REA. As part of this operational definition, the population of interest was defined as adults with chronic pain, the intervention was defined as any psychological intervention or multi-modal interventions that included a psychological component, and the outcome was defined as health outcomes assessed on four recommended[27] key domains: pain intensity, physical functioning, emotional functioning and patient rating of overall improvement. As the literature is well developed in the area of psychological interventions for chronic pain the literature search used for this REA was restricted to studies that employed the highest quality methodological design, a randomised controlled trial (RCT) methodology. An RCT is a quantitative, comparative, controlled experiment in which the effects of intervention(s) are assessed in participants who were randomised to receive the intervention. Comparisons are made with individuals who were randomised to receive standard treatment/practice, placebo or no treatment. Randomisation

requires that all participants have the same chance of being allocated into any of the trial arms and may be conducted via random sequence generation/random number tables/flipping a coin/rolling a dice.

Search strategy

To identify the relevant literature, systematic bibliographic searches were performed to find relevant trials from the following databases: EMBASE, MEDLINE (PubMed), PsychINFO, Cochrane, Clinical Guidelines Portal (Australia), and the National Guideline Clearinghouse (USA). An example of the search strategy conducted in the Embase database appears in the Appendix 2.

Note: The methodology underpinning this REA sought to identify guidelines, meta-analyses or systematic reviews for this particular topic. In searching for guidelines, systematic reviews or meta-analyses, the following procedures were taken in regards to the processing of data sources:

I. Order of precedence: guidelines > meta-analyses > systematic reviews.
II. The most recent guideline, meta-analysis or systematic review was subject to an assessment of quality. If the guideline, meta-analysis or systematic review did not satisfy the quality assessment (i.e. a rating of poor), then the next most recent source was assessed in reverse sequential order (e.g. most recent to oldest) until the quality assessment criteria were met.
III. The guideline, meta-analysis or systematic review that satisfied the quality assessment determined what the cutoff year would be for the primary research articles (e.g. if a meta-analysis was published in 2009, then primary research studies from 2008 and earlier would not be assessed).

Search terms

Search terms specific to chronic pain, psychological interventions and multi-modal interventions were included in searching the Title/s, Abstract/s, MeSH terms, Keywords lists and Chemical: *chronic pain, persistent pain, ongoing pain, psychological intervention, nonpharmacologic, behavi* therapy, cognitive therapy, cognitive behave* therapy, psychotherapy, psychological therapy, multi*modal intervention, multidisciplinary, pain management program*, biopsychosocial, relaxation, biofeedback, mindfulness, meditation, acceptance therapy, commitment therapy, acceptance commitment therapy, psychoeducation, education, randomi*ed control trial, random control trial, randomi*ed controlled trial, RCT, clinical trial, control trial, control study, clinical study*

Paper selection

After conducting searches and identifying any relevant guidelines, systematic reviews or meta-analyses, studies were evaluated according to the following inclusion and exclusion criteria:

Included:
1. Internationally and locally published peer-reviewed research studies 2. Research papers that were published from **1st January 2004** to **8h July 2014** 3. Trials with outcome data that assessed core pain outcome domains 4. Human Adults (i.e. ≥ 18 years of age) 5. English Language
Excluded:
1. Non-English papers 2. Papers where a full-text version was not readily available 3. Validation studies 4. Animal studies 5. Grey literature (e.g. media: websites, newspapers, magazines, television, conference abstracts, theses) 6. No quantitative outcome data reported on pain intensity, physical functioning, emotional functioning or patient rating of overall improvement 7. Papers where the study focus was headache-related pain 8. Non-RCT design

Information management

A screening process was adopted to code the eligibility of papers acquired through the literature search. Papers were directly imported into the bibliographic tool Endnote X5, and then processed using Excel. All records that were identified through the literature search were screened for relevance against the inclusion criteria. Initial screening for inclusion was performed by one reviewer, and was based on the information contained in the title and abstract. Full text versions of all studies which satisfied this initial screening were obtained.

In screening the full-text paper, the reviewer made the decision on whether the paper should be included or excluded, based on the pre-defined inclusion and exclusion criteria. If the

paper met the criteria for inclusion, then it was subject to data abstraction. At this stage in the information management process, 10% of the articles being processed were randomly selected and checked by a second independent reviewer. It was found that there was 100% inter-rater agreement between the two reviewers. The following information was extracted from studies that met the inclusion criteria: (i) study description, (ii) intervention description, (iii) participant characteristics, (iv) primary outcome domain, (v) main findings, (vi) bias and (vii) quality assessment.

Evaluation of the evidence

There were four key components that contributed to the overall evaluation of the evidence. These components were:

- The **strength of the evidence base**, in terms of the quality and risk of bias, quantity of evidence, and level of evidence (study design)
- The **consistency** of the study results
- The **generalisability** of the body of evidence to the target population (i.e. adults)
- The **applicability** of the body of the evidence to the Australian context

The first two components provided a gauge of the internal validity of the study data in support of efficacy for an intervention. The last two components considered the external factors that may influence effectiveness, in terms of the generalisability of study results to the intended target population, and applicability to the Australian context.

Strength of the evidence base

The strength of the evidence base was assessed in terms of the (a) quality and risk of bias, (b) quantity of evidence, and (c) level of evidence.

a) **Quality and risk of bias** reflected how well the studies were conducted, including how the participants were selected, allocated to groups, managed and followed-up, and how the study outcomes were defined, measured, analysed and reported. An assessment was conducted for each individual study with regard to the quality and risk of bias criteria utilising a modified version of the Chalmers Checklist for appraising the quality of studies of interventions (see Appendix 3). Three independent raters rated each study according

to these criteria, and together a consensus agreement was reached as to an overall rating of 'Good', 'Fair', or 'Poor'.

b) **Quantity** of evidence reflected the number of studies that were included as the evidence base for each ranking. The quantity assessment also took into account the number of participants in relation to the frequency of the outcomes measures (i.e. the statistical power of the studies). Small underpowered studies that were otherwise sound may have been included in the evidence base if their findings were generally similar- but at least some of the studies cited as evidence must have been large enough to detect the size and direction of any effect.

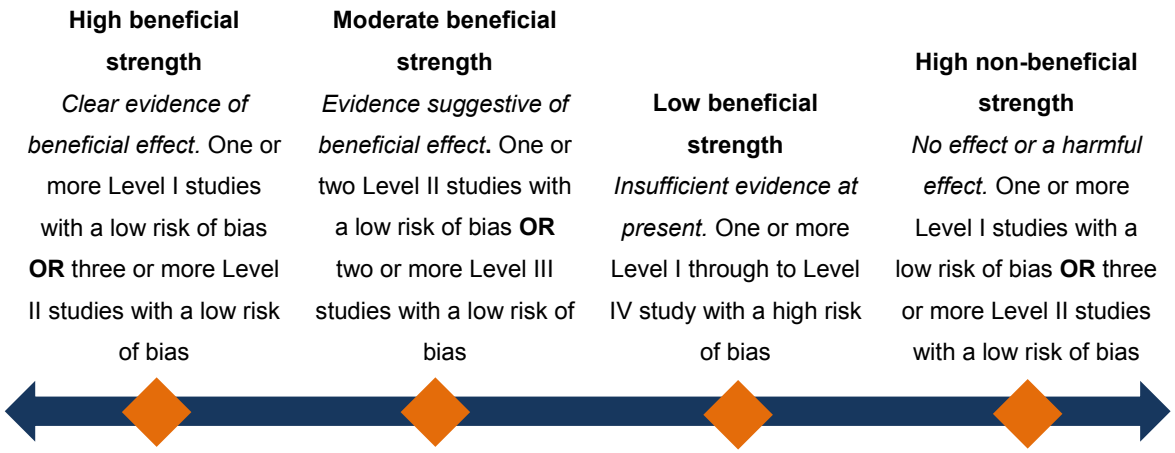
c) **Level of evidence** reflected the study design. The details of the study designs included in this REA, which are covered by a hierarchy of evidence commonly used in Australia[28]:

- Level I: A systematic review of RCTs
- Level II: An RCT

Studies such as pseudo-RCTs (i.e. a trial where a pseudo-random method of allocation is utilised, such as alternate allocation), non-randomised studies (e.g. cohort studies, pre-post studies, case-control studies), and case-series were excluded from this REA. This was due to the fact that a large volume of RCTs were identified in the initial search for this review. RCTs are considered to be studies with high level designs by Australian standards[28]. As such, it was judged to be superfluous to include studies of lower level designs, given the rapid nature of this review.

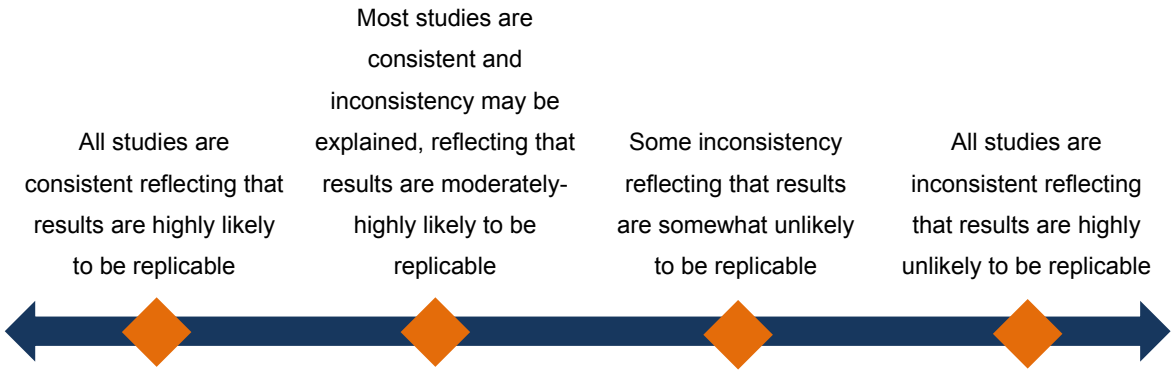
Overall strength

A judgement was made about the strength of the evidence base, taking into account the quality and risk of bias, quantity of evidence and level of evidence. Agreement was sought between three independent raters and consensus about the strength of the evidence based was obtained according to the following categories.



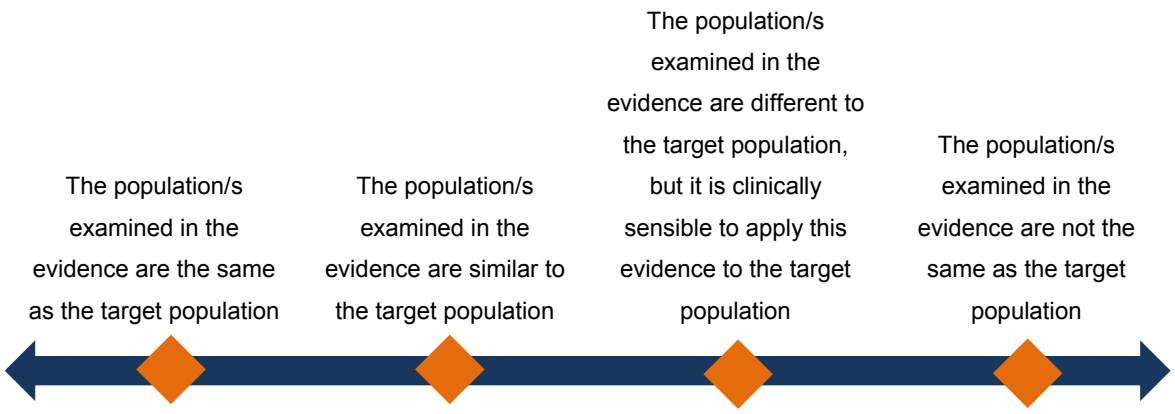
Consistency

The consistency component of the ranking system of the body of the evidence assessed whether the findings were consistent across the included studies (including across a range of study populations and study designs). It was important to determine whether study results were consistent to ensure that the results were likely to be replicable or only likely to occur under certain conditions.



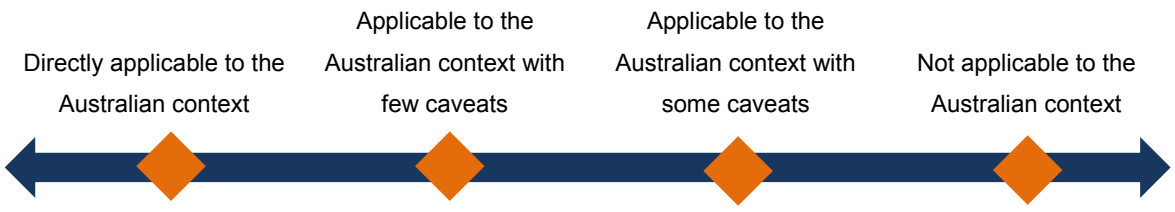
Generalisability

This component covered how well the participants and settings of the included studies could be generalised to the target population. Population issues that might influence this component included gender, age or ethnicity, or level of care (e.g. community or hospital).



Applicability

This component addressed whether the evidence base was relevant to the Australian context, or to specific local settings (such as rural areas or cities). Factors that may reduce the direct application of study findings to the Australian context or specific local settings include organisational factors (e.g. availability of trained staff) and cultural factors (e.g. attitudes to health issues, including those that may affect compliance).



Ranking the evidence

On balance, taking into account the considerations of the strength of the evidence (quantity and risk of bias, quantity of evidence and level of evidence), consistency, generalisability and applicability, the total body of the evidence was then ranked into one of four categories: 'Supported', 'Promising', 'Unknown' and 'Not Supported' (see Figure 1). Agreement on ranking was sought between three independent raters. NOTE: If the strength of the evidence was considered to be low, the next steps of rating consistency, generalisability and applicability were not conducted and the evidence was rated as 'Unknown'.

Figure 1: Categories within the intervention ranking system

SUPPORTED	PROMISING	UNKNOWN	NOT SUPPORTED
Clear, consistent evidence of beneficial effect	Evidence suggestive of beneficial effect but further research required	Insufficient evidence of beneficial effect and further research is required.	Clear, consistent evidence of no effect or negative / harmful effect

Results

The following section presents figures pertaining to the volume of records identified at each stage of the rapid evidence assessment (Figure 2), the country of publication (Figure 3), and the year of publication (Figure 4).

The search identified multiple relevant systematic reviews and guidelines. The guidelines for the treatment of chronic pain in adults: 'Management of chronic pain: A national clinical guideline'[22] (from here onwards referred to as the 'SIGN Guidelines'), was identified as being underpinned by a high quality systematic review and utilised the Scottish Intercollegiate Guidelines Network (SIGN) methodology. In addition to their high quality, they were selected to underpin the current REA because they were the most recently published guidelines (i.e. published in 2013) which specifically examined the management of chronic pain and

covered psychologically-based interventions in a comprehensive way. The systematic review that underpinned the SIGN Guidelines had a data inclusion cut-off of 2012. As such, the literature search period for this REA was reduced to 2012-2014 to capture those studies which were not included in the SIGN Guidelines search. The 2012 studies were cross-checked with the SIGN Guideline studies to ensure they did not overlap (i.e. not counted twice).

From all the sources searched, a further 31 papers met the inclusion criteria and were included in the final REA report. Of the 31 studies, the majority originated from US (16%), Sweden (16%), Australia (13%), Netherlands (10%) and UK (10%). Two studies each were from Norway (7%) and Spain (7%), and the remaining 35% (n=11) comprised one study from each of Belgium, Brazil, Canada, China, Iran, Japan, Turkey. The year of publication for studies that were included in this rapid evidence assessment is presented in Figure 3.

Figure 2: Flowchart representing the number (n) of records retrieved at each stage of the rapid evidence assessment

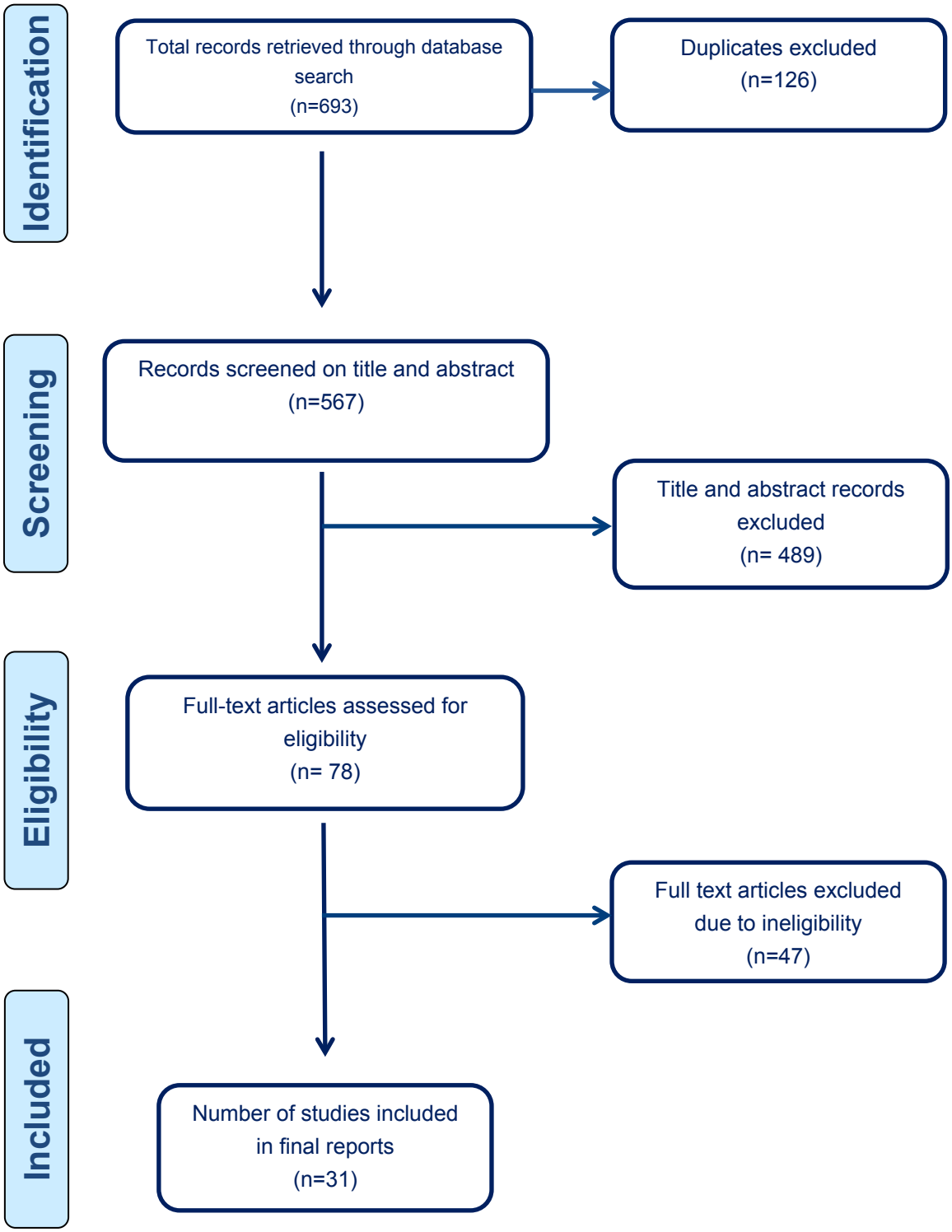


Figure 3. Country of publication of studies included in the rapid evidence assessment

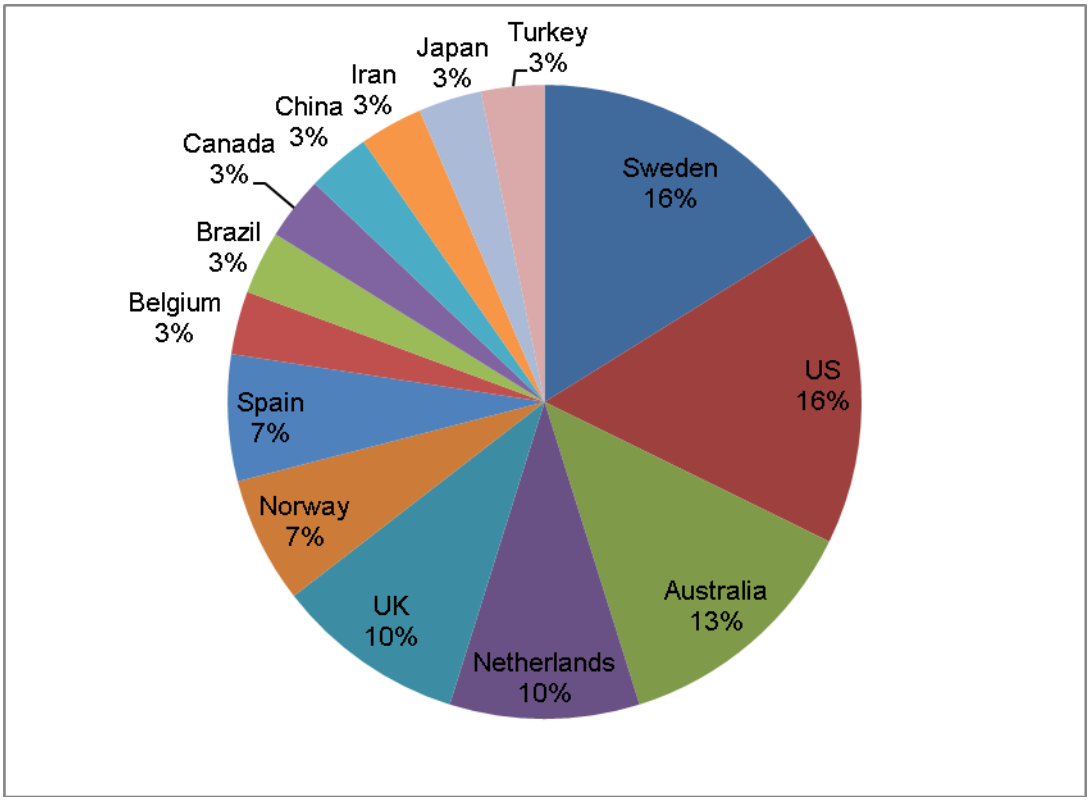
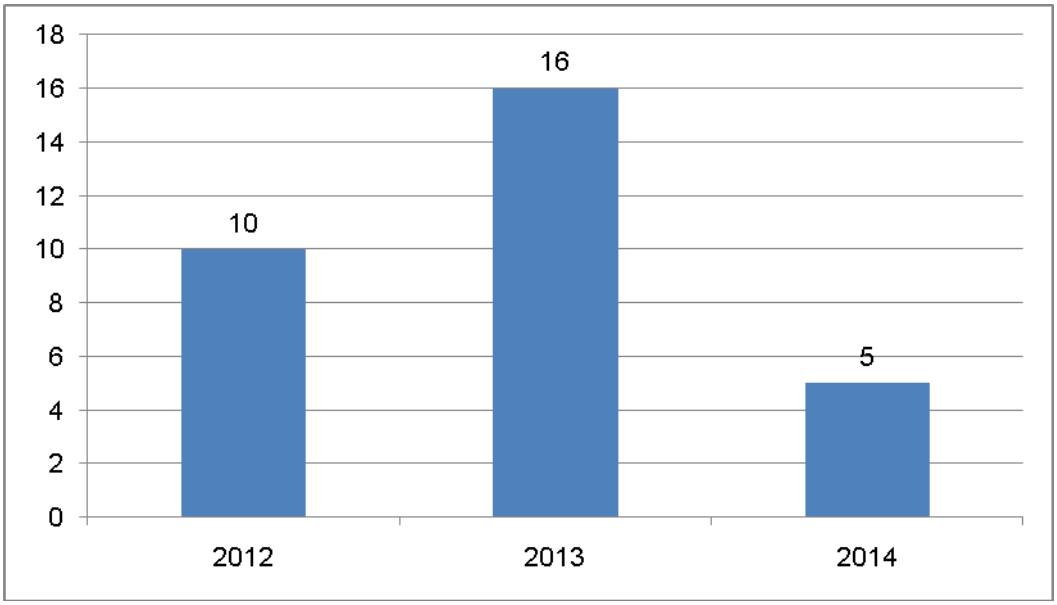


Figure 4. Year of publication of studies included in the rapid evidence assessment



Summary of the evidence

Of the 31 studies identified after the closing date of the systematic review of the SIGN Guidelines (i.e. post-SIGN Guidelines) the largest group of studies (58%, n=18) assessed CBT. Mindfulness-based interventions were assessed in seven studies (23%) and MPMPs were assessed in five studies (16%). There was a single RCT of behavioural therapy (3%). Detailed results for these categories of therapies appear below. Details of the individual study characteristics appear in Appendix 4, with a briefer overview in Appendix 8.

As previously discussed, and consistent with the SIGN Guidelines, an intervention was judged to be superior to the control condition in respect to the treatment of pain if significant differences were found on at least two of the following key domains: pain intensity, physical functioning, emotional functioning or patient rating of overall improvement.

Cognitive Behavioural Therapy (CBT)

The SIGN Guidelines recommend that CBT should be considered for the treatment of adult patients with chronic pain. In a meta-analysis[29] identified in the SIGN Guidelines, CBT was found to be effective in reducing pain intensity but not depression or quality of life. In a systematic review[28] identified in the SIGN Guidelines comparing CBT to treatment as usual (TAU) for chronic orofacial pain, significant improvements in favour of CBT for pain intensity, disability and depression symptoms were identified at three months follow up. Further, the SIGN Guidelines identified that CBT and CBT combined with biofeedback were both effective in reducing the pain intensity, depression and disability and improving quality of life in patients with chronic back pain at post-treatment and short-term follow up[30]. Improvements were also identified in favour of telephone-based and internet-based CBT[31,32].

An additional 18 RCTs examining CBT were published post-SIGN Guidelines (i.e. after the SIGN Guidelines literature search cut-off date, meaning studies that were published from 2012 onwards). Of those, eight studies offered face-to-face individual treatment, seven utilised a group-based approach and three utilised a telecommunication-based CBT approach to the treatment of chronic pain. The results for each of these three modalities are presented and discussed separately in the section below due to the fact that DVA identified an interest in different treatment modalities. Given that the SIGN Guidelines did not make this distinction, and instead considered all modalities of CBT treatment together to formulate their recommendations, the results of the three modalities are combined together with the findings from the SIGN Guidelines to form the basis of the overall ranking for this REA.

The quality of the trials investigating the efficacy of CBT treatments was predominantly good. Study sizes ranged from a small pilot study including 21 participants[33], to a moderate-large scale study including 162 participants[34], with the majority of the rest of the RCTs comprising moderate sample sizes. The risk of reporting bias was considered to be low for the majority of the studies, with most investigators describing appropriate participant randomisation processes and blinding of assessors where relevant. Appropriate statistical analyses were conducted for the majority of studies. In two studies[35,36] relatively high participant drop-out rates (above 25%) were reported, and therefore caution has been exercised in interpreting the results of these two studies.

Face-to-face individual CBT treatment

Eight RCTs that assessed the efficacy of individual face-to-face treatment against waitlist or TAU comparison groups were identified post-SIGN Guidelines, and as indicated above, the majority of these trials were of good quality with low risk of bias. Of the eight, six RCTs [36-41] produced significant treatment effects in favour of CBT on at least two pain domains, while the remaining two RCTs [33,42] were not considered to produce superior pain treatment effects, as significant treatment effects were only found for one pain-related domain.

Of the six RCTs that produced superior pain treatment effects, one RCT[37] assessed the efficacy of 10 weekly 2-hour sessions in a sample of 95 Brazilian adults with musculoskeletal pain. At post-treatment, significant reductions in pain intensity and depression symptoms were reported in favour of the CBT intervention compared to TAU. Significant improvements were also reported on some quality of life subscales including physical limitations, general health state and emotional limitations. Another of these six RCTs [36] involved a small sample of 26 Australian adults with Whiplash-associated disorders and motor vehicle accident related PTSD. Those in the treatment condition received 10 weekly trauma-focused CBT sessions, and reported significantly greater reductions on disability and negative affect compared to those on the waitlist. While there were no improvements reported on pain intensity, significant improvements in favour of the CBT group were reported on some quality of life subscales including physical functioning, bodily pain, general health and social functioning and mental health. Each of the significant treatment effects, except physical functioning, were maintained at 6-month follow-up. In a small RCT[41] 20 US veterans with chronic neuropathic pain were offered up to 11 weekly sessions of CBT. Compared to TAU group, participants in the CBT group reported significantly larger reduction on pain severity and pain interference at post-treatment. The treatment effects were sustained at 4-month

follow-up. There were no significant differences in emotional functioning, as measured by depressive symptoms, between the groups or over time.

For the remaining four RCTs that reported significant treatment effects in favour of individual face-to-face CBT, the CBT interventions was combined with another treatment technique. The first RCT[38] assessed the efficacy of six CBT sessions including hypnosis training against standard therapy in a group of 72 Spanish adults with chronic pain. Significantly greater improvements were reported in pain frequency, intensity and severity, as well as emotional distress for those in the CBT plus hypnosis group. These improvements remained at 9-month follow-up. However, it is important to note that due to the combined nature of the therapy, it is difficult to identify if the significant treatment effects are attributable to the CBT, or the hypnosis component of this intervention. Similar caution is raised in another RCT[39] that assessed the efficacy of a particular form of CBT known as accelerated resolution therapy (ART- a brief exposure-based therapy) against an attention control group in 57 US veterans with chronic pain and PTSD. The ART intervention consisted of two components: imaginal exposure and imagery rescripting and the use of bilateral eye movement. After only two to five individual sessions of ART, participants reported significant improvements in overall pain including pain intensity, pain related impairment and negative affect. However, it is difficult to determine the impact of the imaginal exposure (i.e. verbal or non-verbal recall of the traumatic event while focusing on physiological sensations, thoughts and emotions) and imagery rescripting (i.e. visualising and replacing the imagery and sensory components of the traumatic scene to a positive scene) on treatment outcomes, in comparison to the impact of the bilateral eye movement. The last RCT[40] that combined CBT and another technique was a small trial testing the efficacy of hybrid CBT for insomnia and pain in a group of 24 UK adults experiencing chronic pain and clinical insomnia. Compared to a monitoring group, participants in the CBT group reported significantly greater improvements in pain interference, anxiety and depression, but not pain intensity. The treatment effects were sustained at 1, 6 and 12-month follow-up, however it must be noted that since the intervention targeted both insomnia and pain, it is difficult to determine whether the insomnia focused components of the treatment or the pain focused components had the greatest impact on patient outcomes. Therefore, in all of these four RCTs, it is difficult to identify if the significant treatment affects were attributable to CBT or the additional component of the intervention.

Two RCTs did not find superior outcomes for individual face-to-face CBT, reporting significant treatment effects for only one domain. One of these RCTs was a small pilot study[33] involving 21 US adults experiencing chronic pain and insomnia. This RCT attempted

to determine the effects of combined interventions and stand-alone interventions (CBT for pain, CBT for insomnia, and CBT for pain and insomnia) against a waitlist control. The results indicated that when compared to waitlist control the CBT for pain and insomnia condition produced significantly larger improvements in depression, but not pain. While all three treatment groups experienced some within-group improvements in disability, they were not significantly different when compared to waitlist control. Lastly, when compared with waitlist, none of the treatment groups demonstrated a significant improvement in pain severity, even though the CBT for pain condition demonstrated the largest effects. The last RCT assessed the efficacy of 10-14 sessions of cognitive treatment that targeted illness perceptions against a waitlist control in a group of 156 Dutch adults experiencing chronic lower back pain[42]. The results indicated significant treatment effects for patient-relevant physical activities, but not disability, which the authors attributed to the strong focus of the therapy on patient-relevant physical activities.

Group based CBT treatment

Seven RCTs utilising a group-based CBT treatment for chronic pain in adults[34,43-48] were identified post-SIGN Guidelines. Of these seven trials, four reported significantly greater treatment effects in favour of CBT on at least two pain domains.

A large RCT[44] assessed the efficacy of a group-based CBT-based self-managed pain program (PSM) against two control conditions: exercise attention control (EAC- an conducted for an equivalent period of time, without a therapist's encouragement or a homework requirement) and waitlist control. Participants included 141 older Australian adults experiencing chronic non-specific pain. Both PSM and EAC included eight twice-weekly 2-hour long sessions. At post-treatment significantly greater improvements were reported for the PSM group compared to both EAC and the waitlist control group on measures of disability and pain distress. The treatment effects were sustained at 1-month follow-up. Significant treatment gains for depression symptoms were recorded in favour of PSM post-treatment, however these were not sustained at 1-month follow-up. A second large RCT [34] assessed the efficacy of CBT therapy delivered over 13 weekly 2-hour sessions compared to waitlist. Participants were 162 Dutch adults diagnosed with undifferentiated somatoform disorder or chronic pain disorder. Significant improvements were reported in favour of the CBT group for physical functioning and some of the quality of life indices including bodily pain, social and emotional functioning and physical role functioning post-treatment. However, there were no significant differences in depression or anxiety symptoms between the groups.

An RCT that was conducted in Australia[45] assessed the efficacy of two group-based CBT interventions: CBT plus interceptive exposure and CBT plus distraction. Older adults experiencing chronic pain (N=130) participated in an intensive program, which consisted of daily eight hour group-based CBT treatments delivered over three weeks. At post-treatment significant improvements were found for both interventions on measures of pain intensity, depression and disability, with improvements sustained at 1, 6 and 12-month follow-up. In another medium sized RCT[43], three group-based CBT treatments were compared: multicomponent CBT, multicomponent CBT plus hypnotherapy and standard pharmacological treatment. The moderate sized sample included 93 Spanish adults with fibromyalgia related chronic pain. At post-treatment, participants in both CBT interventions reported significantly larger treatment gains for pain intensity and psychological distress compared to participants in the pharmacological treatment group. The treatment effects were sustained at both 3 and 5-month follow-up. In another smaller RCT[48] female patients (N=43) experiencing fibromyalgia related chronic pain received up to 12 weekly CBT group-based sessions. Significantly larger improvements were once again reported for the CBT group compared to a waitlist condition in subjective impression of clinical improvement and depression and anxiety symptoms. There were no significant differences between the groups in terms of pain intensity.

Significant treatment effects were not found for two of the RCTs. One RCT[46] compared culturally sensitive CBT intervention with culturally sensitive exercise therapy for treatment of non-specific low back pain. Participants included 116 Turkish adult immigrants residing in Switzerland. Both conditions comprised 25 group-based sessions conducted over a six-month period. Only 69% of the total sample completed the treatment. The second smaller RCT[47] included 21 older Swedish adults with chronic pain who were allocated to either a waitlist condition or a treatment consisting of six weekly CBT group-based sessions.

Telecommunication-based treatment

Three RCTs utilised a telecommunication-based CBT approach to treatment. Two RCTs investigated the efficacy of clinician-guided internet delivered CBT (iCBT)[35,49] and the third RCT assessed the efficacy of telephone-delivered CBT[50].

The first RCT[49] investigated the efficacy of iCBT provided in eight online modules and compared against moderated weekly online discussions. Participants included 72 Swedish adults with chronic pain who had previously undergone a multidisciplinary CBT-based rehabilitation program. At post-treatment, significantly greater improvements were found in favour of iCBT for depression and anxiety symptoms and disability. The treatment effects

were sustained at 6-month follow-up. There were no between group differences in pain severity or quality of life. The second RCT[35] assessed the efficacy of iCBT in a group of 62 Australian adults experiencing chronic pain. The participants in the intervention group were provided with five online lessons including telephone and email contact with a therapist on a weekly basis. Significant improvements were reported for iCBT group compared to waitlist on disability, depression, anxiety and pain. These treatment effects were sustained at 3-month follow-up. In the last RCT[50] 101 older US veterans experiencing chronic pain were provided with 12 telephone sessions of either CBT or pain education. Both groups reported significant improvements over time in physical health, mental health, depressive symptoms and pain intensity. Importantly, however, there were no statistically significant differences between the groups at post-treatment or any of the follow-up time points.

Combining results from the three modalities with the SIGN Guidelines findings

When the findings from the SIGN Guidelines were combined together with the additional post-SIGN Guidelines RCTs that covered the three different modalities (i.e. individual, group-based and telecommunication-based CBT), the strength of the evidence base supporting the use of CBT in treatment of chronic pain was judged to be high. The generalisability, consistency and applicability of the RCT's were also strong. The majority of the RCT's were consistent in terms of the direction of their findings, reporting a reduction of pain related symptoms in at least two domains, over the course of the intervention and at follow-up. The studies were conducted in many countries around the world including US, UK and Australia, making the data generalisable to an Australian context. Against the background of recommendations of the SIGN Guidelines to consider the use of CBT, and the good quality, high consistency, high generalisability and applicability of the literature, the use of CBT for the treatment of chronic pain in adults was ranked 'Supported'.

Multidisciplinary pain management programs (MPMPs)

The SIGN Guidelines recommended that the referral to a MPMP, which is a form of a multi-modal intervention, should be considered for patients with chronic pain. The SIGN Guidelines identified one systematic review[51] which suggested that MPMPs were more effective than no treatment control conditions or standard medical treatments for chronic pain. However, two additional systematic reviews[52,53] identified by the SIGN Guidelines found contrasting results with one reporting no treatment effects when MPMP was compared to waitlist or TAU, and the other review finding moderate evidence for efficacy of MPMP

when compared against a waitlist or active treatment for short-term but not long-term pain reduction.

Five additional RCTs that assessed the efficacy of MPMPs were identified post-SIGN Guidelines. One moderate sized RCT assessed the efficacy of combined motivational interviewing and physical exercise therapy (MI+PE) against TAU in a sample of 56 older Chinese adults with musculoskeletal chronic pain[54]. The intervention group received eight weekly group-based sessions with a physiotherapist and registered nurse, while the control group took part in regular activities in the centre. At post-treatment participants in the MI+PE reported a significantly larger reduction in pain intensity, anxiety and depression compared to participants in the control condition. Another moderate/large RCT[55] assessed the efficacy of classification-based cognitive functional therapy (CB-CFT) against traditional orthopaedic manual therapy and exercise in a sample of 121 Norwegian adults with chronic lower back pain. Both groups received 12 weekly sessions with an experienced physiotherapist. At post-treatment, significantly larger improvements in disability, pain intensity and anxiety and depression symptoms were reported for the CB-CFT intervention compared to the control group. These effects were maintained at both 3 and 12-month follow-up.

Of the remaining three RCTs that investigated the efficacy of multi-modal interventions for chronic pain, two offered group-based pain-management treatments while the third offered individual sessions. All three of these RCTs failed to produce superior results for the intervention groups. The first of these RCTs[56] involved a small group (N=33) of Iranian adults with chronic low back pain who were offered a spouse-assisted or patient-oriented MPMP interventions. Both interventions involved seven, weekly 2-hour group-sessions. The results indicated no significant difference in pain outcomes between the two intervention groups and the control group, although significant small to moderate improvements were demonstrated for both groups in terms of disability and pain severity The second RCT[57] involved 62 Canadian adults with chronic musculoskeletal neuropathic pain. Half the participants were offered an early pain management intervention while the other half received delayed intervention. After the treatment of eight weekly 2-hour group-based sessions, there were no differences between the early intervention and control group in terms of quality of life summary scores. Those in the early intervention group did show significant improvements compared to those in the delayed intervention for the social functioning and physical role, and bodily pains quality of life subscales. The third RCT[58] identified in this REA involved a small sample of Japanese adults (N=29) experiencing craniocervical chronic pain and assessed the efficacy of a single session of jaw muscle exercise therapy plus psycho-education or an exercise therapy alone. Both groups were

compared against a pharmacological treatment alone. The results indicated no significant differences in pain intensity between the groups or over time.

The results of this REA show that an increasing number of studies have investigated the efficacy of MPMP published in recent years. However the results of the REA also highlighted some inconsistent findings. While two good quality RCTs found MPMP to be a useful and efficacious treatment of chronic pain, another three RCTs with smaller sample sizes found no evidence to support the superiority of MPMP. This inconsistency might potentially be explained by the variability of the RCT designs (for example, those studies with smaller sample sizes may have had insufficient power to detect treatment effects), and variability of the treatment characteristics. The MPMP studies were considered to be broadly generalisable to adult Australians with chronic pain and considered to be applicable to the Australian context. Against a background of the evidence identified in the SIGN Guidelines and taken together with the additional post SIGN-Guidelines RCTs that were identified, the strength of the evidence base supporting the use of MPMP for treatment of chronic pain in adult populations was ranked 'Promising'.

Mindfulness-based therapies

There was no recommendation by the SIGN Guidelines in regards to the use of mindfulness-based interventions for chronic pain, although the Guidelines did identify relevant literature. The SIGN Guidelines separately identified and reviewed literature related three categories of mindfulness-based therapy known as mindfulness based interventions (MBI), mindfulness-based stress reduction therapies (MBSR) and acceptance and commitment therapy (ACT). In this review, MBI, MBSR and ACT are each discussed separately below. A single overall ranking for mindfulness-based therapies is then formulated, which integrates the SIGN Guidelines findings for MBI, MBSR and ACT, together with the findings of post-SIGN Guidelines RCTs.

In regards to MBI the SIGN Guidelines identified a systematic review[20] which included 10 controlled studies (i.e. both RCTs and pseudo-RCTs) investigating the efficacy of MBI in the reduction of pain and depressive symptoms. The systematic review found that significant improvements were reported in favour of MBI for pain when compared to a control condition, where participants were provided with either education or a massage. However, these differences were not significant when those who received MBI were compared to those who were provided with CBT. Two additional post-SIGN Guidelines RCTs were identified that tested the efficacy of MBI in the treatment of chronic pain. In a moderate/large RCT[59] of US

adults with chronic pain and prescription opioid misuse (N=115), half of the participants received eight weekly group-based sessions of mindfulness oriented recovery enhancement (MORE; an intervention that incorporates mindfulness, cognitive reappraisal skills and positive emotion regulation), while the other half participated in a group-based support group. After treatment, significant differences were reported between the groups in favour of the MORE intervention for pain intensity and functional interferences. These treatment effects were maintained at 3-month follow-up. In the second post-SIGN Guidelines RCT[60] significantly greater improvements in mental health outcomes were reported for UK adults experiencing musculoskeletal chronic pain (N=28) who received an MBI compared to a TAU control group. However, there were no between group differences in terms of pain intensity or physical health. This RCT was also limited by the small sample size and a relatively high drop-out rate from both conditions.

In their review of the literature pertaining to MBSR for the treatment of chronic pain, the SIGN Guidelines identified one meta-analysis[61]. This meta-analysis showed significant small to moderate effects in favour of MBSR therapy for all health outcomes including pain, depression, anxiety, physical well-being and quality of life. When the same meta-analysis considered only RCTs and excluded pseudo-RCTs, the results showed significant effects for pain, depression and physical well-being only. These results may be explained by the fact that when the meta-analysis was restricted to RCTs only, it may have had insufficient power to detect significant effects due to the small number of studies included in the statistical analysis the small sample sizes in each of the included studies. Two additional RCTs identified in the SIGN Guidelines, also failed to show treatment effects for MBSR compared to a control group or an educational program[62,63]. No MBSR studies fitting the inclusion criteria of this REA were identified in the post-SIGN Guidelines literature.

The SIGN Guidelines also reviewed the evidence in regard to ACT. A single moderate/large RCT[64] was identified by the SIGN Guidelines, which examined the efficacy of ACT compared to TAU and CBT. Compared to TAU, no significant differences were found between the groups for any of the health outcomes assessed, while significant improvements in both the ACT and CBT groups were observed across time, compared to TAU in terms of pain interferences, depression, pain-related anxiety, but not in pain intensity, mental and physical functioning. Post-SIGN Guidelines, five additional RCTs were identified that tested the efficacy of ACT in treating chronic pain. Significant improvements were identified in two out of the five RCTs, as indicated by superior results in at least two key pain related domains. The first RCT[65] involved a sample of Swedish adults with fibromyalgia related chronic pain (N=40). Half of the participants received 12 weekly group-based

sessions of ACT, while the other half of participants was put on a waitlist. After treatment, significant differences were reported between the groups in favour of the ACT intervention for pain related disability, mental functioning and depression and anxiety symptoms. The second RCT[66] that identified treatment effects investigated the effectiveness of ACT plus TAU, compared to TAU only. Participants in the ACT intervention group were provided with four 4-hour long group-based sessions. At post-treatment, significant differences were found between the groups in favour of the ACT for depression and overall subjective improvement as measured by a global impression of change scale. At 3-month follow up, those in the ACT group demonstrated lower disability, less depression and significantly higher pain acceptance compared to those participants that only received TAU.

The remaining three RCTs[67] [68,69] examined ACT therapies that utilised telecommunications, but did not find significant improvements for those in the treatment conditions. In the first RCT[67] of Swedish adults with chronic pain (N=76), half the participants participated in seven weekly sessions of clinician-guided internet-delivered ACT, while the other half participated in online group discussions. At post-treatment, significant differences were reported between the groups in favour of internet ACT for depression and anxiety symptoms (i.e. a positive result within the emotional functioning domain). These treatment effects were sustained at 6-month follow-up. However, there were no significant differences for any other key pain related domain. The second large RCT[69] involved Dutch adults experiencing chronic pain (N=238) assessed the efficacy of two interventions: an ACT-based internet-delivered clinician-guided self-help intervention and an internet-based expressive writing intervention. Both conditions were compared to a waitlist control group. At post-treatment, participants in the ACT-based intervention reported larger reductions in pain intensity and pain interference (i.e. within the pain intensity domain) than the participants in the expressive writing intervention. These effects were sustained at 6-month follow-up. However, no significant improvements were shown for those in the ACT-based group in comparison to the waitlist control as both groups improved. In addition, there were no differences between any of the groups for any other key pain related domains. In the last RCT[68] significant differences in emotional functioning were reported in favour of an ACT based smart-phone intervention compared to an attention-placebo control, for a sample of 140 Norwegian adults with fibromyalgia related chronic pain. This effect however was not sustained at 5-month follow-up, and significant results were not found for any other pain related domains.

When the findings from the SIGN Guidelines for MBI, MSBR and ACT were taken together with the additional post-SIGN Guidelines RCTs for these three categories of therapy, the strength of the evidence base supporting the use mindfulness-based therapies for chronic

pain was judged to be sufficient to suggest a beneficial effect for face-to-face individual and group-based treatments, but not those self-managed or delivered over the internet. Although the populations examined in the studies were varied, the studies were considered to be generalisable to adult Australians with chronic pain given that they mostly comprised Western samples. The treatments were considered to be applicable to the Australian context. Against the background of the SIGN Guidelines findings, and the results of the post-SIGN Guidelines RCTs, the use of face-to-face and group-based mindfulness-based interventions for the treatment of chronic pain in adults was ranked 'Promising'.

Behavioural therapies

The SIGN Guidelines examined two specific types of behavioural therapy known as RBT and OBT. RBT includes progressive muscle relaxation and EMG biofeedback, while OBT is based on the notion that unhelpful responses are reinforced either by the individual or their environment. In the section below, RBT and OBT are each reviewed separately. In line with SIGN Guidelines, two separate rankings are then provided for RBT and OBT.

The SIGN Guidelines recommended that RBT should be considered for the treatment of adults with chronic pain on the basis of two systematic reviews[23,70] that demonstrated some evidence that for patients with chronic lower back pain, progressive relaxation was more effective than no treatment in improving pain intensity, disability and functional status, but not depression. There was however no difference between the groups when muscle relaxation was compared to CBT. EMG biofeedback was also reported to be more effective in improving pain and disability but not short-term functional status. In another systematic review and meta-analysis[29] examined in the SIGN Guidelines, self-regulatory treatments defined as biofeedback, relaxation and hypnosis, were found to be more effective than waitlist in reducing pain intensity and depression at post-treatment.

Post-SIGN Guidelines, one RCT[71] was identified that assessed the efficacy of muscle relaxation therapy (a form of RBT) in the treatment of (N=78) Belgian adults with whiplash associated chronic pain. The intervention group received one 20 minute muscle relaxation session and was compared to a group that received one session of acupuncture treatment. The results indicated no significant differences between the groups in pain severity or neck disability. However, those participants in the acupuncture therapy reported greater improvements over time in pain severity compared to the muscle relaxation group.

The SIGN Guidelines also reviewed the use of OBT in the treatment of chronic pain, identifying two systematic reviews[23,70] which demonstrated that compared to waitlist, OBTs

were effective in reducing pain intensity, but not functional outcomes, while the evidence on mood was mixed. Further evidence suggested no treatment benefits for pain intensity when OBTs are compared to exercise therapy alone, cognitive therapy alone or combined behavioural treatments. The SIGN Guidelines therefore recommended that clinicians should be aware of their own behaviour and potential for clinical environments to impact and reinforce unhelpful responses in patients with chronic pain. There were no post-SIGN Guidelines studies investigating OBT that met the inclusion criteria for the current REA

In respect to RBT, taking into consideration the evidence that was provided by the SIGN Guidelines and the single additional post-SIGN Guidelines RCT, the applicability of RBT to an Australian context was considered to be high. Given that the SIGN Guidelines recommended that RBT should be considered for the treatment of chronic pain and a lack of substantial new additional evidence to contradict the SIGN Guidelines recommendation, the use of behavioural therapies for treatment of chronic pain in adults was ranked ‘Promising’.

In respect to OBT, the SIGN Guidelines found that there was evidence demonstrating OBTs produce superior effects for some of the four key pain domains in comparison to waitlist conditions, but not necessarily in comparison to active treatments such as cognitive therapy, showing some inconsistency in the evidence. The applicability of OBTs to an Australian context was considered to be high, and the generalisability of the studies included in the systematic reviews captured by the SIGN Guidelines was considered to be good. However, due to the lack of consistent evidence showing superior effects on at least two pain domains, the use of OBTs for the treatment of chronic pain in adults was ranked ‘Unknown’.

Discussion

The aim of this review was to assess the evidence related to effective psychological or multi-modal interventions for adults with chronic pain. The literature presented in this REA showed that chronic pain is a widely researched area, demonstrated by the large number of RCTs published in the last three years. The reviewed literature also highlighted the large range of pain injuries and pain conditions associated with chronic pain including musculoskeletal pain, neuropathic pain, fibromyalgia-related pain, general chronic pain and specific localised chronic pain. Evaluating such a diverse range of pain conditions and treatment outcomes required the use of a rigorous assessment structure, which was achieved through the use of the IMMPACT system. An intervention was considered to produce superior results if significant change was observed on at least two key pain domains (i.e., pain intensity, physical functioning, emotional functioning, and overall improvement). As a consequence of

such rigorous standards, some interventions were considered to be ineffective, as changes were only demonstrated on one key pain domain (e.g. Pigeon et al, 2012; Siemonsma et al, 2013). Despite this and the heterogeneity that was observed at the individual trial level, there was some strong evidence that demonstrated good treatment effects for all of the psychological interventions.

In particular, this review found strong evidence to support face-to-face and group-based CBT, relative to control conditions such as attention control, TAU or waitlist. Additionally, the evidence also suggested that internet-delivered clinician assisted CBT was effective in treating chronic pain[35,49]. Overall, CBT had the most research support for its use in the treatment of chronic pain in adult populations, with the SIGN Guidelines recommending that it should be considered as a treatment. The efficacy of CBT was also demonstrated across the key pain domains. Within the post-SIGN Guidelines literature alone (n=18 studies), 11 found that CBT was highly effective in improving emotional functioning. Nine also identified that CBT was very effective in improving physical functioning and reducing level of disability, and eight identified that CBT was effective in reducing pain intensity and severity. The applicability and efficacy of CBT was also demonstrated across populations with a variety of pain conditions including populations with lower back pain, musculoskeletal pain, chronic neck pain, fibromyalgia and Whiplash associated disorders. In addition, some results indicated that CBT targeting chronic pain is not only effective in improving chronic pain outcomes, but may also improve other complaints such as PTSD symptoms[36,39] and insomnia[40]. Taken together with the recommendations in the SIGN Guidelines, these findings led the evidence base for the use of CBT for the treatment of adults with chronic pain to be ranked as ‘Supported’.

The recommendations of the SIGN Guidelines suggested that MPMP should also be considered for patients with chronic pain. Several post-SIGN Guidelines studies were identified which investigated the efficacy of MPMP. While a face-to-face MPMP intervention was found to be effective in one trial[55], another trial demonstrated no significant treatment effects[58]. RCTs that utilised group-based treatments[56,57] [54]also provided mixed results. It is worth noting however, that non-significant findings were predominantly observed in trials limited by small sample sizes and that included heterogeneous samples (i.e. samples comprising patients a number of different types of pain conditions). In addition, it is important to note that MPMP treatments are not standardised and as a consequence, it is not clear which components of MPMP contribute to the treatment effects. Therefore, larger studies of sufficient power are needed to investigate whether the trend towards positive results is sustained in non-inferiority trials utilising standardised treatment models and in comparison

with other well established therapies for chronic pain (e.g. CBT). As such, the 'Promising' ranking that was given to MPMP in treating adults with chronic pain and is likely to increase to a 'Supported' ranking if further evidence is produced.

The SIGN Guidelines did not make a recommendation concerning mindfulness based therapies. This may reflect the fact that mindfulness-based therapies represent a relatively new area of research within the field of pain. The SIGN Guidelines did however identify a systematic review that found a significant beneficial effect for MBI[20], and a meta-analysis which showed small to moderate effects in favour of MBSR[61]. In addition, seven post-SIGN Guidelines mindfulness-based therapy RCTs were identified. One moderate/large RCT[59] reported significant treatment effects in favour of mindfulness-based therapies when compared to TAU, while another two good quality RCTs reported significant evidence for group-based ACT over TAU[66] and waitlist[65]. Interestingly, one RCT which examined internet-based ACT found only partial treatment effects[69] while another examining internet-based ACT[67] found no treatment effects when compared to an attention placebo control group. These mixed results may reflect the influence of the different treatment modalities, which may have led to different treatment responses for those who received face-to-face therapy versus those who received internet-based therapy. It is also important to note that non-significant findings were predominantly observed in trials limited by small sample sizes, therefore, large well powered non-inferiority studies are needed to investigate whether positive results are obtained when mindfulness-based therapies are compared to well established therapies such as CBT. The SIGN Guidelines literature taken together with the post-SIGN Guidelines literature led to the use of face-to-face individual and group-based mindfulness-based interventions (but not those that are self-managed or delivered over the internet) to treat adults with chronic pain to be ranked as 'Promising'.

The SIGN Guidelines examined the literature related to two types of behavioural therapies: RBT and OBT. The SIGN Guidelines recommended that RBT, which included muscle relaxation and EMG feedback, should be considered for the treatment of chronic pain in adults. Evidence from systematic reviews that were presented in the SIGN Guidelines demonstrated some treatment effectiveness of muscle relaxation lessening pain intensity, and improving functional status and disability in the short-term. There was, however, no indication that muscle relaxation was effective when compared to CBT. EMG biofeedback was also reported to be effective in improving pain disability but not short-term functional status. A single good quality post-SIGN Guidelines RCT[71] was identified that investigated the effectiveness of muscle relaxation against acupuncture. The results however indicated no significant differences between the groups in pain severity or neck disability, with

improvements noted for both groups. Taking into consideration the evidence that was provided by the SIGN Guidelines and a lack of substantial new evidence to contradict the findings of the SIGN Guidelines, the use of RBTs for the treatment of chronic pain in adults was ranked ‘Promising’.

The SIGN Guidelines did not make a recommendation for OBTs in terms of whether they should be considered as a treatment option. Instead the SIGN Guidelines recommended that clinicians should be aware of their own behaviour and potential for clinical environments to impact and reinforce unhelpful responses in patients with chronic pain. The evidence considered by the SIGN Guidelines suggested that OBTs were effective in reducing pain intensity, but not functional outcomes, while the evidence on mood was mixed. There were no post-SIGN Guidelines OBT studies that met the inclusion criteria for this REA. Due to the lack of consistent evidence showing superior effects on at least two pain domains, the use of OBTs for the treatment of chronic pain in adults was ranked ‘Unknown’.

It is important to note that there were less studies included in the behavioural therapy literature pool (which comprised RBTs and OBTs) compared to other interventions (e.g. CBT). Only one trial on behavioural therapy that met inclusion criteria was published in the three-year period post-SIGN Guidelines (relative to 18 in CBT), which may indicate that the field is moving away from examining these types of interventions. This would make sense given CBT incorporates a strong behavioural component (which often includes progressive muscle relaxation) and may therefore supersede interventions that limit themselves to a behavioural only approach.

Finally, while this REA was not designed to determine comparative efficacy between therapies it was certainly clear that CBT had the largest evidence base supporting its use. This suggests that in the future, non-inferiority studies should be conducted testing new and emerging psychological interventions against CBT. For example, additional non-inferiority studies are needed to determine whether the general trend towards positive results for MPMP, mindfulness-based interventions and behavioural therapies (in the form of RBTs) are sustained. This REA did not identify any studies that tested MPMP, behavioural or mindfulness-based therapies against interventions with strong evidence bases, such as CBT, and further research is needed to address this important research gap.

Implications

The results of this REA suggest that there is sufficient evidence to indicate that CBT should be made available to adults with chronic pain. The SIGN Guidelines made recommendations

to also consider MPMPs as a treatment for chronic pain in adult populations, which is supported by the findings of this REA. As noted above non-inferiority trials comparing MPMP, mindfulness-based and behavioural interventions with CBT should be a research priority. Given the heterogeneity of the pain conditions and pain domains studied, it is important that direct comparisons of treatments are made within populations with the same chronic pain condition. In addition, the exact component(s) of therapies or the specific combinations that are most effective remain unknown. For example, MPMP needs to be standardised and tested more rigorously. Further dismantling studies are also needed to determine which components of the multi-modal interventions are most effective in treating adults with chronic pain.

Although there is some uncertainty around the efficacy of individual treatment components, the improvements in chronic pain across different modalities demonstrated for the CBT interventions (i.e., face-to-face, group-based and telecommunication-based) indicate that the treatment itself is fairly adaptable and effective in several modes. This may prove to be very useful for clients who are remotely located from service providers, limited in mobility, and have a varying range of treatment preferences. However, this was not systematically explored therefore these findings should be taken cautiously and re-assessed in light of future studies.

Limitations of this rapid evidence assessment

The findings from this REA should be considered alongside its limitations. The first set of limitations refers to the 'rapid review' process, which imposed some restrictions on our methodology. These limitations included: the omission of potentially relevant papers that were published prior to or after the defined search period; the omission of non-English language papers; and reference lists of included papers were not hand-searched to find other relevant studies. Similarly, although we did evaluate the evidence in terms of its strength, consistency, and generalisability, these evaluations were not as exhaustive as in a systematic review methodology nor did it use a meta-analysis methodology to combine or synthesise the results in a statistical way. We made a qualitative judgement based on the level of evidence about the certainty of our estimates of prevalence.

A second set of limitations results from the fact that this REA utilised previously published treatment Guidelines, with the literature search for this review conducted from the period of time after the SIGN Guidelines data cut-off. Thus, if the SIGN Guidelines missed any important studies, this review would also not have included these studies. In addition, the

recommendations within this review are based on the literature search from 2012 and the recommendations by the SIGN Guidelines. However, the evidence included in the SIGN Guidelines and as such the accuracy of their recommendations was not reviewed or assessed. Nonetheless, the SIGN Guidelines covered psychologically-based interventions and were the most recently published systematic review that utilised a well-developed and publicised methodology.

Lastly, the information presented in this REA is a summary of information presented in available papers. We recommend readers source the original papers if they would like to know more about a particular intervention or study.

Conclusion

The findings of this REA build upon the evidence presented in the SIGN Guidelines, outlining the effective treatments for chronic pain in an adult population. The evidence from this REA was consistent with the SIGN Guidelines, demonstrating strong evidence for efficacy of CBT in the treatment of chronic pain. Specifically, the results of this REA indicated support for the use of face-to-face individual and group-based CBT, but not those that are self-managed or delivered over the internet. Additional data for MPMP and mindfulness-based therapies were identified in the post-SIGN Guidelines literature. Further studies are needed to determine whether the trends for positive outcomes identified for these treatments will remain for larger non-inferiority studies which include evidence-based therapies such as CBT as the comparison condition.

Appendix 1

Population Intervention Comparison Outcome (PICO) framework

This question was formulated within a Population Intervention Comparison Outcome (PICO) framework. Application of a PICO framework helps to structure, contain and set the scope for the research question. Inclusion of intervention and comparison components is dependent on the question asked, and may not be appropriate for all question types.

- **What are effective psychological or multi-modal interventions for adults experiencing chronic pain?**
    - **PICO format:** In adults diagnosed with persistent or chronic pain, which psychological or multimodal interventions are effective for reducing the symptoms pain?

P Patient, Problem, Population	**I** Intervention	**C** Comparison (*optional*)	**O** Outcome *when defining "more effective" is not acceptable unless it describes **how** the intervention is more effective*
Patient: Adults Problem: Chronic pain (excluding headaches)	• Any psychological intervention • Multi-modal interventions that include a psychological component		Changes in: • pain • physical functioning • emotional functioning • self-reported overall improvement

Appendix 2

Example search strategy

The following is an example of the search strategy conducted in the Embase database:

Step	Search Terms	No of records
S1	"chronic pain" or "persistent pain" or "ongoing pain"	49667
S2	chronic pain/	34419
S3	“psychological intervention" or nonpharmacologic or "behavi* therapy" or "cognitive therapy" or "cognitive behave* therapy" or psychotherapy or "psychological therapy" or "multi*modal intervention" or multidisciplinary or "pain management program*" or biopsychosocial or relaxation or biofeedback or mindfulness or meditation or "acceptance therapy" or "commitment therapy" or "acceptance commitment therapy" or psychoeducation or education	1186950
S4	cognitive therapy/ or psychotherapy/ or behavior therapy/	133232
S5	relaxation training/ or meditation/ or mindfulness/ or controlled clinical trial/ or psychotherapy/	477193
S6	psychoeducation/ or education/	319130
S7	"randomi*ed control trial" or "random control trial" or "randomi*ed controlled trial" or RCT or "clinical trial" or "control trial" or "control study" or "clinical study"	3248961
S8	controlled clinical trial/	385695
S9	1 or 2	49667
S10	3 or 4 or 5 or 6	1548494
S11	7 or 8	3248961
S12	9 and 10 and 11	4146
S13	limit 12 to (english language and yr="2012 -Current")	522

Appendix 3

Quality and bias checklist

Chalmers Checklist for appraising the quality of studies of interventions[72]

Completed		
Yes	No	
		1. **Method of treatment assignment**
		• Correct, blinded randomisation method described OR randomised, double-blind method stated AND group similarity documented
		• Blinding and randomisation stated but method not described OR suspect technique (eg allocation by drawing from an envelope)
		• Randomisation claimed but not described and investigator not blinded
		• Randomisation not mentioned
		2. **Control of selection bias after treatment assignment**
		• Intention to treat analysis AND full follow-up
		• Intention to treat analysis AND <25% loss to follow-up
		• Analysis by treatment received only OR no mention of withdrawals
		• Analysis by treatment received AND no mention of withdrawals OR more than 25% withdrawals/loss-to-follow-up/post-randomisation exclusions
		3. **Blinding**
		• Blinding of outcome assessor AND patient and care giver (where relevant)
		• Blinding of outcome assessor OR patient and care giver (where relevant)
		• Blinding not done
		• Blinding not applicable
		4. **Outcome assessment (if blinding was not possible)**

		• All patients had standardised assessment
		• No standardised assessment OR not mentioned
		5. Additional Notes
		• Any factors that may impact upon study quality or generalisability

Appendix 4

Evidence Profile

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
COGNITIVE BEHAVIOURAL THERAPIES								
Andersson et al. (2012)	RCT	Swedish older adults experiencing chronic back or neck pain Mean age 72 (4.60) Male 24%	(I): Cognitive behavioural therapy (C): Waitlist	6 weekly 2hr sessions *(Group based)*	-Pain severity (MPI -Disability (PAIRS) Anxiety and depression (HADS) -Quality of life (QOLI) -Pain intensity (VAS)	n/a	N=11	N=10
In comparison to a waitlist control group, cognitive behavioural therapy was not more effective in reducing pain severity, pain intensity, depression, anxiety or improving quality of life overtime. It was, however significantly more effective than the waitlist condition, in reducing the disability associated with pain.								
Buhrman et al. (2013a)	RCT with 6-month follow-up	Swedish adults with chronic pain who have previously undergone a multidisciplinary CBT-based rehabilitation program Mean age 40.10 (8.94) Male 28%	(I): Guided internet delivered cognitive behavioural therapy (iCBT) (C):Attention control (i.e., Moderated weekly online discussions)	8 weekly online modules *(Clinician guided individual)*	-Clinical overall improvement (CSQ)	-Depression and anxiety symptoms (HADS) -Pain severity (MPI) -Quality of life (QOLI) -Disability (PAIRS)	N=36	N=36

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
Significant differences with small effect sizes[1] were reported between the guided internet delivered CBT (iCBT) and the attention control group, with those that received the iCBT intervention reporting greater improvement at post-treatment on catastrophizing (d=0.16) and diverting attention (d =0.20) . These treatment effects were sustained at 6-month follow-up. Significant differences with small effect sizes were reported between the groups in favour of the iCBT for depression (d = 0.32), anxiety (d = 0.45) and disability (d=0.32) in favour of the iCBT, with improvements remaining at 6-month follow-up. There were no significant differences in pain severity or quality of life between the groups or over time.								
Carmody et al. (2013)	RCT	US older military veterans experiencing chronic pain Mean age (I): 66 (9), (C): 69 (10) Male (I) 96% and (C) 98%	(I): Telephone delivered Cognitive Behavioural therapy (T-CBT) (C):Telephone delivered pain education (T-EDU)	12 telephone sessions over 20 weeks *(Individual)*	-Mental and physical health (SF-12) -Depression (BDI) -Pain intensity (PI)	n/a	N=50	N=51
There were no statistically significant differences between the groups on any of the primary outcomes. There were, however statistically significant improvements over time for both groups in terms of physical health (β=0.16, 95% CI=0.03 to 0.29, p=0.01), mental health (β= 0.05, 95% CI=0.00 to 0.10, p=.04), depressive symptoms (β=0.20, 95% CI=-0.31 to -0.09, p=.0003) and pain intensity (β=0.03, 95% CI=-0.05 to -0.01, p =.0035).								
Castel et al. (2012)	RCT with 3-month and 5-month follow-up	Spanish adults with chronic pain related to fibromyalgia diagnosis Mean age 49.6 (6.8) Male 3%	(I1): Multicomponent cognitive behavioural therapy (CBT) (I2): Multicomponent cognitive behavioural therapy with hypnosis	12 weekly 2hr sessions *(Individual and Group based)*	-Pain intensity (NRS) -Psychological distress (HADS)	n/a	(I1) N=34 (I2) N=29	N=30

[1] Effect size is a quantitative measure that measures the magnitude of the difference between two groups with the proposed degree of difference corresponding to small (e.g. *d*=0.3), medium (e.g. *d*=0.5) or large (e.g. *d*=0.8) effect sizes.

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
			(CBT-H) (C): Standard pharmacological treatment (SPC)					
At post-treatment those in the multicomponent cognitive behavioural therapy (CBT) were found to have significantly lower levels of pain intensity and psychological distress than those receiving standardised pharmacological treatment (SPC). Significant lower levels of pain intensity and psychological stress were also reported for those receiving multicomponent cognitive behavioural therapy with hypnosis (CBT-H). In addition, significantly lower levels of psychological distress were found for those receiving CBT-H compared to those receiving only CBT. Over time, significant reductions in psychological distress were found for those in both CBT and CBT-H, and the effects remained significant at both 3-month and 5-month follow-up. No significant reductions over time were identified for pain intensity.								
Castro et al. (2012)	RCT	Brazilian adults with chronic musculoskeletal pain Mean age (I): 45.9 (8.1), (C): 48.7 (14.3) Male 11%	(I): Cognitive behavioural therapy (CBT) (C): Standard care	10 weekly 2hr sessions *(Individual)*	-Pain intensity (VAS) -Depression and anxiety symptoms (HADS) -Quality of life (SF-36)	n/a	N=48	N=47
At post-treatment, 54% of participants in the CBT group compared to 28.9% of participants in the standard care group reported a significant reduction in pain intensity (RR=1.88; 95%CI 1.11-3.19). Significant reductions in depressive symptoms were reported by participants in the CBT group compared to standard care group, while there were no significant differences reported between the groups on symptoms of anxiety. Significant improvements on quality of life indices were reported by those who received CBT compared to standard care recipients on three of the eight quality of life subscales: physical limitations, general state of health and emotional limitations.								
Dear et al. (2013)	RCT with 3-month follow-up	Australian adults experiencing chronic pain	(I): Clinician guided Internet-delivered cognitive behaviour	5 online lessons delivered over 8 weeks, including	-Disability (RMDQ) -Depression (PHQ-9) -Anxiety (GAD-7)	-Pain (WBPQ)	N=31	N=31

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		Mean age 49 (13) Male 14%	therapy (iCBT) (C): Waitlist	telephone and email contact with clinician on a weekly basis *(Individual and self-managed)*				
Significant improvements were reported for the clinician guided internet-delivered CBT (iCBT) group compared to waitlist control group on disability, depression, anxiety and pain. These improvements corresponded to moderate to large effect sizes for levels of disability (d=0.88), depression (d =0 .66), and average pain (d=0.64), and a small effect size for anxiety (d=0 .38). These treatment effects were sustained at 3-month follow-up.								
Dunne et al. (2012)	RCT with 6-month follow-up	Australian adults with Whiplash-associated disorders and MVA-related PTSD Mean age 32.54 (7.09) Male 50%	(I): Trauma-focused cognitive behavioural therapy (TF-CBT) (C): Waitlist	10 weekly 1 hr sessions *(Individual)*	- PTSD symptom severity (SCID) - Disability (NDI)	- PTSD self-reported symptom severity (PDS, IES-R) -Negative affect (DASS-42) - Quality of life (SF-36) - Pain intensity and negative affect (NRS)	N=13	N = 13
At post-treatment significantly fewer participants in the trauma-focused cognitive behavioural therapy (TF-CBT) met criteria for a PTSD diagnosis compared to the waitlist control group (η_P^2=0.57). In addition greater reductions on disability were found for the TF-CBT group compared to the controls (η_P^2=0.27). Both these improvements were maintained at 6-month follow-up. There were no significant differences in pain intensity recorded between groups or over-time. At post-treatment significant reductions for the TF-CBT group compared to waitlist were recorded for self-reported PTSD, negative affect and four out of eight quality of life subscales (i.e., physical functioning, bodily pain, general health and social functioning and mental health). Each of these effects, except physical functioning, were maintained at 6-month follow-up.								

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
Ferrando et al. (2012)	RCT with 9-month follow-up	Spanish adults with chronic pain related to temporomandibular disorders with muscular diagnosis Mean age (I): 39.57 (13.82), (C): 38.38 (16.57) Male (I) 13%), (C) 9%	(I): Cognitive Behavioural Therapy plus hypnosis (CBT+H) (C): Standard therapy	Six 1hr sessions over 2.5 months *(Individual)*	-Pain frequency (non-standardized) -Pain intensity (PMQ) -Pain severity (MPI) -Emotional distress (BSI-18)	n/a	N=41	N=31
Significant differences with small effects sizes were reported at post-treatment between the cognitive behavioural therapy plus hypnosis (CBT-H) group and standard therapy (ST), with those that received CBT-H intervention reporting greater improvements for pain frequency (effect size = 0.18), pain intensity (effect size = 0.18), pain severity (effect size = 0.15) and emotional distress (effect size = 0.15). The majority of participants in the CBT+H group reported significant clinical improvements in pain frequency (90%), pain intensity (77%) pain severity (83%) and emotional distress (69%). These improvements remained at 9-month follow-up.								
Jensen et al. (2012)	RCT	Swedish adults with fibromyalgia related chronic pain Mean age 45.6 (6.4) Male 0%	(I): Cognitive behavioural therapy (CBT) (C): Waitlist	12 weekly 1.5hr sessions *(Group based)*	-Subjective impression of clinical improvement (PGIC)	-Depression (BDI) -Anxiety (STAI-S) -Pain intensity (VAS)	N=25	N=18
At post-treatment significantly larger improvements were reported for the CBT group compared to waitlist for subjective impression of clinical improvement, depression [F(2, 32) = 8.6, P = 0.001] and anxiety symptoms [F(2, 52) = 3.31, P = 0.044]. There were no significant differences between the groups in pain intensity.								
Kip et al. (2014)	RCT	US veterans with PTSD and chronic pain	(I): Accelerated Resolution Therapy	2 to 5, 1h - 1.25hr sessions	n/a	-Pain (POQ)	N=29	N=28

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		Mean age 41 (12.4) Male 80%)	(ART)(exposure based therapy) (C): Attention control (AC) - (i.e., fitness assessment and planning)	*(Individual)*				
At post-treatment significantly larger treatment effects were reported for the Accelerated Resolution Therapy (ART) compared to attention control group for overall pain (effect size=1.04). In terms of the subscales of the pain measure those in the ART reported greater improvements for pain intensity (effect size=1.81), pain-related impairment in mobility (effect size=0.69) and negative affect (effect size =1.01).								
Nicholas et al. (2013)	RCT with 1-month follow-up	Australian older adults experiencing chronic pain Mean age 73.9 (6.5) Male 37%	(I1): Self-managed pain program (PSM) based on CBT (I2): Exercise attention control (EAC) (C): Waitlist	8 twice-weekly 2hr sessions *(Group based)*	-Disability (RMDQ)	-Pain intensity and distress (0-10 numerical scale) -Depression (DASS-21)	(I1) N=49 (I2) N=53	N=39
At post-treatment significant improvements were reported for the self-managed pain program (PSM) group compared to exercise attention control (EAC) group for measures of disability (d=0.47, 95% CI (0.04–0.89)], pain distress [d= 0.68, 95% CI (0.26–1.11)] and depression [d= 0.51, 95% CI (0.07–0.93)]. At 1-month follow-up, treatment effects were maintained for disability and pain distress. When PSM and EAC interventions were compared to the waitlist condition, similar treatment effects were identified for PSM group on disability [d= 0.76, 95% CI (1.2–0.3)] and pain distress [d=0.56, 95% CI (1.01–0.11)]. There were no significant differences between EAC and waitlist conditions on any of the outcomes. Clinical improvements in physical disability assessment at 1-month follow-up were achieved by 44% of the patients in the PSM group, 22% in the EAC and 20% in the waitlist group.								

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
Nicholas et al. (2014)	RCT with 1, 6 and 12-month follow-up	Australian older adults experiencing chronic pain Mean age (I): 42.05 (12.33), (C): 43.22 (11.08) Male (I): 23%, (C): 26%	(I): CBT plus interoceptive exposure (CBT+IE) (C): CBT plus distraction/ relaxation (CBT+D/R)	Daily 8hr sessions over 3 weeks *(Group based)*	-Pain intensity (MPI) -Depression (DASS-42) -Disability (MRDQ)	n/a	N=66	N=74
At post-treatment significant improvements were found in both CBT plus interoceptive exposure (CBT+IE) and CBT plus distraction/relaxation (CBT+D/R) conditions for pain intensity (CBT+IE d=-0.50; CBT+D/R d=-0.54), depression (CBT+IE d=-0.50; CBT+D/R d=-0.42) and disability CBT+IE d=-0.64; CBT+D/R d=-0.58). These treatment effects were sustained at the 1, 6 and 12-month follow-up.								
Otis et al. (2013)	RCT with 4-month follow-up.	US veterans with chronic neuropathic pain Mean age (I): 62.50 (10.98), (C): 63.38 (11.69) Male 100%	(I): Cognitive-behavioural therapy (CBT) (C): Treatment as usual (TAU)	11 weekly 1hr sessions *(Individual)*	-Pain severity (WHYMPI-PS) -Pain interference -Depression (BDI)	n/a	N=12	N=8
Significant differences were reported between the groups with participants in the cognitive behavioural therapy (CBT) reporting significantly larger reductions on pain severity (B = -.54, 95% CI=-.09 to -.99) and pain interference (B = -.77, 95% CI=-.24 to -1.30) compared to participants in the treatment as usual (TAU) group. These treatment effects were sustained at 4-month follow-up. There were no significant differences in depressive symptoms between the groups or over time.								

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
Pigeon et al (2012)	RCT	US adults experiencing chronic pain and insomnia Mean age 50.7 (8.3) Male 33%	(I1): Cognitive behavioural therapy for pain (CBT-P) (I2): Cognitive behavioural therapy for insomnia (CBT-I) (I3): Cognitive behavioural therapy for combined pain and insomnia (CBT-P/I) (C):Waitlist	10 weekly sessions *(Individual)*	-Pain (MPI) -Depression (CES-D)	-Disability (PDI)	(I1) N=5 (I2) N=6 (I3) N=6	N=4
Compared to the waitlist condition, cognitive behavioural therapy for pain (CBT-P) was not associated with significant improvement on any of the outcomes. Both cognitive behavioural therapy for insomnia (CBT-I) and cognitive behavioural therapy for pain and insomnia (CBT-I/P) however, were associated with reduced depression severity (CBT-I g=1.64; CBT-P/I g=2.99) when compared to the waitlist condition. There were no significant differences in pain or disability between the groups. All groups experienced moderate to large improvements in pain over time (CBT-P g=1.21; CBT-I g=0.83; CBT-I/P g= 0.49), although these were not significantly different compared to waitlist control (g=0.44).								
Siemonsma et al. (2013)	RCT	Dutch adults experiencing chronic lower back pain Mean age (I): 45.6 (12.9), (C): 47.1 (11.1) Male (I) 46%, (C) 40%	(I): Cognitive treatment of illness perception (C): Waitlist	10-14 weekly 1hr sessions *(Individual)*	n/a	-Physical disability (QBPDS) -Patient relevant physical activities (PSC)	N=104	N=52

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
At post-treatment, there were no statistically significant differences between those who received cognitive treatment of illness perception and those on the waitlist in terms of physical disability. However, significant differences were found between the groups in favour of the cognitive treatment of illness perception on measure of patient relevant physical activity.								
Sleptsova et al (2013)	RCT with 12-month follow-up	Turkish adult immigrants with chronic low back pain Mean age (I): 44 (7.4), (C): 43.8 (7.1) Male (I) 30%, (C) 32%	(I): Culturally sensitive cognitive behavioural therapy (Cs-CBT) (C): Culturally sensitive exercise therapy (Cs-ET)	Twenty five 1.5hr sessions over 6 months *(Group based)*	-Physical functioning (SF-36) -Mental functioning (SF-36) -Anxiety and depression (GHQ) -Disability (PDI) -Pain intensity (VAS)	n/a	N=62	N=54
There were no significant differences identified between the groups for physical or mental functioning, anxiety, depression, disability or pain intensity at post-treatment or at 12-month follow-up.								
Tang et al. (2012)	RCT with 1-month and 6-month follow-up	UK adults with chronic non-malignant pain and clinical insomnia Mean age (I): 45.7 (9.3), (C): 51.3 (7.9) Male 10%	(I): Hybrid cognitive behavioural therapy (H-CBT) for insomnia and pain (C): Monitoring group	4 weekly 2hr sessions *(Individual)*	n/a	-Pain intensity (BPI) -Pain interference (BPI) -Anxiety (HADS-A) -Depression (HADS-D)	N=12	N=12
Significant differences were reported between the hybrid cognitive behavioural therapy for insomnia and pain (H-CBT) and the monitoring control group, with those that received H-CBT intervention reporting greater improvements at post-treatment on pain interference (d=1.92) anxiety (d=1.44) and depression (d=0.94). These treatment effects were sustained at 1-month and 6-month follow-up. There were no significant differences in pain intensity between the groups.								
Zonneveld et al. (2012)	RCT	Dutch adults with undifferentiated	(I): Cognitive behavioural therapy (CBT)	13 weekly 2hr sessions	-Physical functioning (SF-36)	-Quality of life (SF-36) -Depression, anxiety	N=84	N=78

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		somatoform disorder or a chronic pain disorder Mean age (I): 46 (38-53), (C): 44 (35-52) Male (I): 20%, (C): 18%	(C): Waitlist	*(Group based)*	-Mental functioning (SF-36)	(SCL-90-R)		
Significant differences were reported between the cognitive behavioural therapy (CBT) and the waitlist condition, with those that received the CBT intervention reporting greater improvements at post-treatment for physical functioning (d = 0.38). There were no significant differences in mental functioning between the groups or overtime. On the secondary outcome measures, significant differences were found between the groups in favour of the CBT intervention on four out of eight quality of life subscales including role functioning physical (d=0.43), bodily pain (d=0.51), social functioning, (d=0.36) and role functioning emotional (d=0.44). There were no significant differences in depression or anxiety symptoms between the groups, or over time.								
MULTIDISCIPLINARY PAIN MANAGEMENT INTERVENTIONS								
Abbasi et al. (2012)	RCT	Iranian adults with chronic low back pain Mean age 45 (10) Males 14%	(I1): Spouse assisted - multidisciplinary pain management programme (SA-MPMP) (I2): Patient-oriented multidisciplinary pain management programme (P-MPMP) (C): Standard medical care (SMC)	7 weekly 2hr sessions *(Group based)*	-Disability (RDQ) -Pain severity (VAS)	n/a	(I1) N=10 (I2) N=12	N=11

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
At post-treatment, there were no significant differences in disability or pain severity between the groups. However, significant small to moderate improvements were noted across all groups on disability (SA-MPMP η^2=0.48; P-MPMP η^2=0.33; SMC η^2=0.43) and for both intervention on pain severity [SA-MPMP η^2= 0.43; P-MPMP η^2=0.27).								
Angeles et al. (2013)	RCT with 6-month follow-up	Canadian adults with chronic musculoskeletal or neuropathic pain Age range 40-59 years Male 37%	(I): Early pain management intervention (EI) (C): Delayed Intervention (DI)	8 weekly 2hr sessions *(Group based)*	-Quality of life – physical and social/emotional functioning - (SF-36)	n/a	N=31	N=32
There were no significant differences between groups in terms of quality of life total score. When quality of life subscales were examined separately, there was a significant difference between the groups for two out of 10 quality of life subscales in favour of the early intervention in role physical (EI: mean change = -15.3; DI: mean change = + 3.4) and bodily pain (EI: mean change=9.2; DI: mean change =-3.9) domains. These treatment effects were maintained at 6-month follow-up.								
Fersum et al. (2013)	RCT with 3-month and 12-month follow-up	Norwegian adults with chronic lower back pain Mean age 42.9 (12.5) Male 51%	(I):Classification based cognitive functional therapy (CB-CFT) (C): Traditional manual therapy and exercise	12 weekly 30-45 min sessions *(individual)*	-Disability (ODI) -Pain intensity (PIRNS) -Anxiety and depression (HSCL-25)	n/a	N=62	N=59
Significantly larger improvements were reported at post treatment for the classification based cognitive functioning therapy (CB-CFT) compared to the traditional manual therapy and exercise control group on disability [mean difference -9.7; 95% CI -12.7 to -6.7], pain intensity [mean difference -2.1; 95% CI -2.7 to -1.4] and anxiety and depression symptoms [mean difference -0.12; 95% CI -0.19 to -0.04]. These treatment effects were maintained at both 3-month and 12-month follow-up.								
Makino et al. (2014)	RCT	Japanese adults experiencing craniocervical chronic	(I1): Exercise therapy plus psychological intervention (ET+PI)	One session on psycho-education and jaw muscle	Pain intensity: (NRS)	n/a	(I1) N=13 (I2) N=13	N=13

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		pain Mean age (I): 53 (27-75), (I): 42 (32-73), (C): 40 (17-66) Male (I) 15%, (I) 46%, (C) 31%	(I2): Exercise therapy (ET) (C): Pharmacological treatment	relaxation				
At post-treatment, there were no significant differences in pain intensity between the groups or over time. At follow-up, there was a significant improvement over time in pain intensity found at T4 (day 70) and T5 (day 98) for exercise therapy plus psychological intervention (ET+PI). There was no improvement noted for the exercise therapy alone or pharmacological control group over time. In addition, at T5 (day 98) there was a significant difference between the groups with participants in the ET+PI intervention reporting significantly lower levels of pain intensity than the other two groups.								
Tse et al. (2013)	RCT	Chinese older adults with chronic musculoskeletal pain Mean age 76.5 (5.9) Male 6%	(I): Motivational interviewing and physical exercise program (MI+PE) (C): Treatment as usual (TAU)	8 weekly 1.5hr sessions *(Group based)*	-Pain intensity (NRS) -Anxiety (STAI) -Depression (GDS-SF) -Functioning (SF-12)	n/a	N=31	N=25
At post-treatment participants in the motivational interviewing and physical exercise program (MI+PE) reported a significant reduction in pain intensity [-1.18, 95% CI (-1.92, -0.45)] and state anxiety [-18.11, 95% CI (-30.72, 5.5)]. There were no significant reductions reported by the treatment as usual (TAU) control group on any of the outcome measures. Comparing the two groups at post-treatment, participants in the MI+PE intervention reported significantly lower pain intensity, depression and anxiety state levels than those in the TAU group.								
MINDFULNESS AND ACCEPTANCE AND COMMITMENT THERAPIES								
Brown and Jones (2013)	RCT	UK adults with chronic musculoskeletal pain	(I): Mindfulness-based pain management	8 weekly 2.5hr sessions	-Mental and physical health (SF-36)	n/a	N=15 at completion	N=13 at completio

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		Mean age (I) 48 (10), (C): 45 (12) Male 33%	program (MBPMP) (C): Treatment as usual (TAU)	*(Individual)*	-Pain intensity (sensory/affective pain) (MPQ)		(pre-treatment N not provided)	n (pre-treatment N not provided)
Those in the mindfulness based pain management program group reported significantly greater improvements in mental health compared to TAU. There were no significant differences reported for physical health between the groups or over time. There was no significant difference between the groups in terms of pain. There was however, a significant difference over time for affective pain in favour of the mindfulness based pain management program group.								
Buhrman et al. (2013b)	RCT with 6-month follow-up	Swedish adults experiencing chronic pain Mean age 49.1 (10.3) Male 41%	(I): Internet delivered acceptance and commitment therapy (I-ACT) (C): Attention placebo (online discussion forum)	7 weekly online modules *(Clinician guided, individual)*	n/a	-Depression and anxiety symptoms (HADS) -Pain severity (MPI) -Quality of life (QOLI) -Disability (PAIRS)	N=38	N=38
At post-treatment, significant differences were reported between the groups in favour of the internet ACT intervention for depression (d =0.18) and anxiety (d = 0.44) symptoms. These treatment effects were sustained at 6-month follow-up. There were no significant differences in pain severity, quality of life or disability between the groups or over time.								
Garland et al. (2014)	RCT with 3-month follow-up	US adults with chronic pain and prescription opioid misuse Mean age 48 (14) Male 32%	(I): Mindfulness Oriented Recovery Enhancement (MORE) (C): Attention placebo (i.e., Support group)	8 weekly sessions *(Group based)*	-Pain severity (BPI) -Functional interference (BPI)	n/a	N=57	N=58

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
At post-treatment, significant differences were reported between the groups in favour of the mindfulness oriented recovery enhancement (MORE) intervention for pain severity (d= 0.50) and functional interference (d = 0.78). These treatment effects were maintained at 3-month follow-up.								
Kristjánsdóttir et al. (2013)	RCT with 5-month follow-up	Norwegian adults with fibromyalgia related chronic pain Mean age :(I) 44.59 (11.13), (C) 43.80 (11.20) Male 0%	(I): ACT based smart phone intervention with diaries and therapist feedback (C): Attention placebo (i.e., Informational Website with self-help pain management material)	*4 weeks smartphone delivered intervention* *(Individual, group based and self-managed)*	n/a	-Pain intensity (VAS) - Emotional functioning (SF-8) -Physical functioning (SF-8) -Emotional distress (GHQ)	N=70	N=70
At post-treatment, significant group differences were reported between the groups in favour of the ACT intervention for emotional functioning (d = 0.63). However, this effect was not sustained at 5-month follow-up. There were no significant group differences reported on pain intensity, physical functioning or emotional distress at post-treatment or 5-month follow-up.								
McCracken et al. (2013)	RCT with 3-month follow-up	UK adults experiencing chronic pain Mean age 58 (12.8) Male 31%	(I): Acceptance and commitment therapy (ACT) plus TAU (C): Treatment as usual (TAU)	Four 4hr sessions over 2 weeks *(Group based)*	-Disability (RMDQ) -Depression (PHQ) -Physical functioning (SF-36) -Pain intensity (0-10 rating)	-Emotional functioning (SF-36) -Subjective improvement (PGIC)	N=37	N=36
At post-treatment, significant differences were found between the groups in favour of ACT for depression (effect size=0.46) and overall improvement. At 3-month follow-up those in ACT demonstrated lower disability (d=0.58), less depression (d=0.59) and significantly higher pain acceptance (d=0.64) in comparison to those in TAU.								
Trompetter et al. (2014)	RCT with 6-month follow-up	Dutch adults experiencing chronic	(I1): Internet-based clinician guided self-help	Nine online modules over 9-12	-Pain interference (MPI)	-Depression and anxiety (HADS)	(I1) N=82 (I2) N=79	N=77

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		pain Mean age (I): 52.9 (13.3), (I): 52.3 (11.8), (C) 53.2 (12) Male (I) 23%, (I) 24%, (C) 25%	intervention based on ACT (I2): Internet-based expressive writing (C): Waitlist	weeks duration (Individual and self-guided)		-Pain intensity (NRS) -Pain disability (PDI) -Positive mental health (MHC-SF)		
At post-treatment significant differences were reported between the groups in favour of ACT based internet self-help intervention compared to internet-based expressive writing therapy for pain interference (d= 0.33) and pain intensity (d=0.23). These effects were sustained at 6 month follow-up. No significant improvement was present for ACT compared to waitlist condition. However there were no differences between the groups at post-treatment when ACT was compared to the internet-based expressive writing or waitlist condition for depression, anxiety, pain disability or positive mental health outcomes.								
Wicksell et al. (2013)	RCT	Swedish adults with fibromyalgia related chronic pain Mean age 45.1 (6.6) Male 0%	(I): Acceptance and Commitment Therapy (ACT) (C): Waitlist	12 weekly 1.5hr sessions *(Group based)*	-Pain related disability (PDI)	-Quality of life (mental and physical functioning)(SF-36) -Depression (BDI) -Anxiety (STAI) -Pain intensity	N=23	N=17
Significant differences with moderate to large effect sizes were reported for those in the Acceptance and Commitment Therapy (ACT) condition compared to waitlist for pain related disability (d=0.75), mental functioning (d=0.84), depression (d=0.44), state anxiety (d=0.51) and trait anxiety (d=0.73). There were no significant differences in physical functioning or pain intensity between the groups.								
BEHAVIOURAL THERAPIES								
Tobbackx et al. (2013)	RCT	Belgian adults with whiplash associated chronic pain	(I): Muscle relaxation (C): Acupuncture	One 20 minutes session	Pain sensitivity	-Neck disability (NDI) -Neck pain (VAS)	N=39	N=39

Authors & year	Design	Sample	Intervention (I) and Comparison (C)	Intervention delivery method, frequency, duration, (delivered to)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Participants randomised	
							I	C
		Mean age 41 (10) Male 28%		*(Individual)*				
Those in the acupuncture therapy reported significantly greater improvements over time in pain sensitivity compared to muscle relaxation group. There were no significant differences between the muscle relaxation group and acupuncture for neck disability or pain severity.								

Appendix 5

Evaluation of the evidence

Type of Intervention	Included Studies
Supported	
CBT	• Andersson et al. (2012) • Buhrman et al. (2013a) • Carmody et al. (2013) • Castel et al. (2012) • Castro et al. (2012) • Dear et al. (2013) • Dunne et al. (2012) • Ferrando et al. (2012) • Jensen et al. (2012) • Kip et al. (2014) • Nicholas et al. (2013) • Nicholas et al. (2014) • Otis et al. (2013) • Pigeon et al (2012) • Siemonsma et al. (2013) • Sleptsova et al (2013) • Tang et al. (2012) • Zonneveld et al. (2012)
Promising	
MPMP	• Abbasi et al. (2012) • Angeles et al. (2013) • Fersum et al. (2013) • Makino et al. (2014) • Tse et al. (2013)
MINDFULNESS AND ACT	• Brown and Jones (2013) • Buhrman et al. (2013b) • Garland et al. (2014) • Kristjánsdóttir et al. (2013) • McCracken et al. (2013) • Trompetter et al. (2014) • Wicksell et al. (2013)
BEHAVIOURAL THERAPIES: RBT	• Tobbackx et al. (2013)
Unknown	
BEHAVIOURAL THERAPIES: OBT	

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