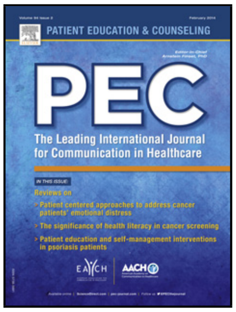

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PII: S0738-3991(17)30648-1
DOI: https://doi.org/10.1016/j.pec.2017.12.002
Reference: PEC 5843

To appear in: *Patient Education and Counseling*

Received date: 31-5-2017
Revised date: 28-11-2017
Accepted date: 5-12-2017

Please cite this article as: Banerjee Anirban, Hendric Paul, Bhattacharjee Purba, Blake Holly.A systematic review of outcome measures utilised to assess self-management in clinical trials in patients with chronic pain.*Patient Education and Counseling* https://doi.org/10.1016/j.pec.2017.12.002

A systematic review of outcome measures utilised to assess self-management in clinical trials in patients with chronic pain

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Highlights

- Self-management is one's ability to manage the condition, treatments, roles and life-styles
- Self-management is recommended in national guidelines for managing chronic pain
- However there is no consensus to measuring self-management in chronic pain
- This systematic review identified 14 diverse measures used to assess self-management
- Multi-dimensional measures are suitable for measuring self-management

ABSTRACT

Objectives: The aim of this review was to identify, appraise and synthesise the outcome measures used to assess self-management in patients with chronic pain.

Methods: Medline, Embase, CINAHL, PsycINFO, the Cochrane Library and Google Scholar were searched to identify quantitative measures used within randomised or non-randomised clinical trials to assess self-management in adults (≥18 years) with chronic pain.

Results: 25 RCTs published between 1998 and 2016 were included in this review. Studies included patients with chronic pain, hip/knee osteoarthritis, rheumatoid arthritis, chronic low back pain, fibromyalgia and chronic fatigue syndrome. Included studies utilised 14 different measures assessing a variety of constructs including self-efficacy (n=19), coping (n=4), empowerment (n=2), pain attitude and management (n=3), self-care (n=1), role behaviour (n=1) and multiple constructs of self-management (n=1). The Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (heiQ) cover different self-management related constructs across the physical, mental and social health domains.

Conclusion: The review identified 14 measures used as proxy measure to assess self-management in patients with chronic pain. These measures have good content and construct validity, and internal consistency. However additional research is required to develop their reliability, responsiveness and interpretability.

Practice implications: Multi-constructs measures (CPCI, heiQ) are suitable assess self-management.

Keywords: self-management, chronic pain, systematic review, outcome measures

1. Introduction

Chronic pain is a common [1,2] and challenging condition associated with high healthcare usage [3] and socioeconomic burden [4,5]. Given the known benefits in reducing pain and disability [6,7], the clinical practice guidelines [8-10] recommend self-management for chronic pain along with other treatments. Self-management (SM) is one's dynamic ability to manage the chronic condition and its treatment, adapt to physical and psychological changes, and adhere to lifestyle modifications [11]. SM involves a number of constructs, which include managing the disease, healthy lifestyle behaviours, changes in social and vocational roles and emotion by solving day-to-day problems, making conscious decisions, using appropriate health and social care resources, forming a good relationship with the health care providers and importantly taking appropriate actions **[12,13],** for example, pacing or increasing physical activity.

Measuring the effectiveness of an intervention to enhance SM (called SM support) in chronic conditions is complex and widely variable [14]. Change in SM in chronic pain is predominantly measured using a wide range of outcome measures for pain, physical functioning, psychological wellbeing and quality of life, which are not designed specifically to measure SM. Different scales are commonly employed to measure SM for example, Arthritis Self-Efficacy Scale [11], Patient Activation Measure (PAM) [15] and the Health Education Impact Questionnaire (heiQ) [16]; however, there is currently no standardised way of measuring SM. National clinical practice guidelines do not recommend the use of any particular scale/ tool for measuring SM [17].

Therefore, the purpose of this systematic review was to identify, appraise and synthesise the range of outcome measures used to assess self-management (SM) in patients with chronic pain- aiming to provide information that will help researchers and clinicians in the selection of the most appropriate tool to assess SM.

2. Methods

The review was conducted following the published protocol [18]. Additionally, Patient Reported Outcome Measure Information System (PROMIS) framework [19], which is based on World Health Organization's physical, mental and social health categories [20], was used in the review to appraise the domains or 'latent traits' targeted by the measures assessing SM. Further, modified Terwee criteria [21] were utilised to summarise the psychometric properties of the included measures. These criteria were developed to provide explicit guidance for assessing the quality of health questionnaires.

2.1. Search strategy

Medline, Embase, CINAHL, PsycINFO, the Cochrane Library (since inception to February 2016) and Google Scholar were electronically searched. The search strategy was developed with a combination of Medical Subject Headings and keywords, using randomised controlled trial (RCT) filters from the Cochrane Back Review Group [22]. Further, the references of selected articles were hand-searched for eligible studies and experts in the area of SM research were contacted for any potential additional unpublished studies.

2.2. Inclusion criteria of studies

Full-text primary research reports (available in English language) of randomised and non-randomised controlled trials were included, where effectiveness of any non-surgical interventions was purposefully measured with quantitative outcome measures to assess SM in adult (more than 18 years with no upper age limit) patients with chronic pain (at least three months duration) (Table 1). Given this review targeted outcome measures used to assess SM, studies reporting outcomes of non-surgical interventions were considered for inclusion, including SM support programmes, educational interventions, physical, psychological, cognitive therapy, cognitive-behavioural therapy, behavioural therapy and their combinations. SM defines individuals' ability to manage chronic pain, its treatments and physical, mental and social changes [11].

2.3. Exclusion criteria of studies

Studies involving participants with carcinoma, episodic pain (including post-surgical pain), traumatic and surgical conditions, substance abuse and addiction, AIDS and end-of-life care conditions (or terminal illnesses) were excluded because of the difference in the nature of pain and variation in the motivational factors associated with self-regulation of pain. Validation and feasibility studies that were not designed to investigate change in SM were excluded in this review. Book chapters, stand-alone abstracts, opinions and correspondence and previous reviews were excluded from the review, as these are not primary research reports. Studies published in languages other than English were excluded due to limited resources and unclear advantage of inclusion of non-English language research reports [23]. As the review aimed at appraising the outcome measures utilised, secondary research reports were excluded to avoid multiple publication bias (Table 1).

Please insert Table 1 about here

2.4. Selection of studies

The Cochrane Handbook [23] and the Cochrane Back Review Group [22] guidelines were followed in the review process. The review findings are reported in keeping with The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [24]. Electronic search yields were imported into an Endnote file. After deleting duplicates, potential studies were screened at two stages- firstly, at brief screening by titles and abstracts, and finally, at detailed screening, by reading full text articles. Articles were screened by two independent reviewers (AB and PB) for inclusion in the review. Any disagreement in study selection were resolved by consensus or by consulting a third reviewer (PH or HB). The reasons for exclusion were reported only at full-text screening stage.

2.5. Risk of bias assessment of the selected studies

Two reviewers (AB and PB) assessed quality of the individual studies using the Cochrane Risk of Bias tool [23]. The Cochrane Risk of Bias assessment tool guides the reviewers to rate selection bias, performance bias, detection bias, attrition bias and reporting bias in ‘low risk’, ‘high risk’ and ‘unclear risk’ categories. Disagreements were resolved by consensus or by consulting a third reviewer (PH or HB).

2.6. Data extraction

One reviewer (AB) extracted study details (type of study, aims and sample size), population characteristics (age, gender, level of education, employment status, condition, symptoms duration), SM outcome measures (name, constructs measured, source and psychometric properties reported in the selected studies) and other outcome measures (for example, pain, disability, disease severity). Further, characteristics of the interventions including SM support programmes (description, mode of delivery, duration and follow-up) were extracted. A second reviewer (PB) verified the extracted data.

Psychometric properties of the included outcome measures were extracted by the first reviewer (AB) from three sources: the individual articles, relevant citations and additional search in Ovid Medline (1996 to present). Extracted psychometric data were verified with the source by a second reviewer (PB) at random 50% of the fields. Psychometric properties of these included measures were reported using a modified criteria following Terwee and colleague [21]. The criterion validity was not assessed in absence of a ‘gold standard’ measure for assessing change in SM. Any disagreement in data extraction was resolved by discussion.

3. Results

3.1. Study selection

A total of 2383 search yields were imported into Endnote, where duplicates were deleted. 1633 reports were screened by title and abstract and 110 reports were selected for full text review. 85 studies were excluded after reading full-text versions (reasons outlined in Table 2) and 25 studies were included in this systematic review. The PRISMA flow diagram is presented in Figure 1. All included 25 studies were RCTs published between 1998 and 2016 and conducted in Western developed countries (USA, Canada, Australia, Germany, Switzerland, Sweden, Norway, Belgium and UK).

Please insert Table 2 about here

Please insert Figure 1 about here

3.2. Risk of bias assessment of the selected studies

The majority of included studies were categorised with ‘low risk' for selection bias, detection bias, attrition bias and reporting bias. However, overall a high risk of performance bias was found in the majority of included studies, as blinding of the personnel and patients were not attempted due to practical reasons in a majority of the individual studies. Baseline differences in the clinical and demographic details among the treatment groups were low risk in the majority of the included studies. Details of the risk of bias assessment are summarised in Figures 2 and 3.

Please insert Figure 2 and Figure 3 about here

3.3. Participants

The sample sizes in the selected studies ranged between 30 [25] and 812 [26]. The participants in the selected studies were patients with hip/knee osteoarthritis and/or rheumatoid arthritis (six studies) [26-31], chronic low back pain (six studies) [32-37], fibromyalgia (two studies) [25,38], chronic fatigue syndrome (one study) [39] and non-cancer chronic musculoskeletal pain (seven studies) [40-46]. The mean age of participants in the individual studies ranged from 39 [42] to 82 years [41]. The average duration of symptoms in the included studies varied from three years [32] to over 13 years [27]. Characteristics of the participants in the included studies are presented in Table 3.

Please insert Table 3 about here

3.4. Interventions

13 of the included studies evaluated the effectiveness of physical activity programmes [32], behavioural interventions [27,33,39,43,45], pain education programmes [25], their combinations [28,35,37,49], and others non-surgical treatments [31,47]. The remaining 12 studies investigated the effectiveness of SM support programmes. The SM programmes were delivered in face-to-face group settings in nine studies [26,29,34,38,40-42,44,48], and online in three studies[30,36,46]. All SM support programmes were carried out at outpatient clinics except one study [50], which was in a specialised inpatient setting. The duration of the programmes ranged from 2.5 hours [34] to 16 hours [44]. The follow-up period in the individual studies ranged from three weeks to 12 months.

3.5. Self-management outcome measures

This systematic review identified 14 different scales used to assess change in SM (Table 4). The majority of the included studies used self-efficacy scales as a proxy measure of SM with other measures for pain, physical function and psychological wellbeing.

Please insert Table 4 about here

3.5.1. Self-Efficacy Scales

Arthritis Self-Efficacy Scale (ASES) was used in six of the included studies [26,27,29-31,38]. The ASES was developed by Lorig and colleague in late 1980s [51] to measure a patient's perceived self-efficacy or confidence to cope with specific arthritis symptoms or activity. This 20-item scale measures three SM constructs: pain self-efficacy (five items), function self-efficacy (nine items) and other symptoms self-efficacy (six items). Each item can be rated on a 10-point scale from '1 (or 10) = very uncertain' to '10 (or 100) = very certain'. This scale has acceptable internal consistency (Cronbach's α 0.82-0.91) and been widely used in patients with osteoarthritis [52].

Self-Efficacy Scale (SES) was utilised in three included studies [28,34,42]. This 11-item scale was developed by using pain and other symptoms subscales of the original ASES. Each item can be rated using a 10-point graphic/ numeric rating for example, '1 (or 10) = very uncertain' to '10 (or 100) = very certain'. The phrase 'arthritis pain' is usually changed according to the specific disease population, for example, 'chronic pain' or 'back pain'. The internal consistency (Cronbach's α 0.82-0.91) has been estimated at 0.76 to 0.90 [42,51].

Pain Self-Efficacy Questionnaire (PSEQ) was used in seven included studies [33,37,44-46,48,49]. This 10-item scale was developed by Nicholas and colleague [53] in the late 1980s to measure a patient's perceived confidence in performing specific activities when living with pain. Each of these items are rated with a 7-point Likert scale where '0 = not at all confident' and '6 = completely confident'. Internal consistency (Cronbach's α 0.82-0.91) was estimated at 0.92 [53].

Chronic Pain Self-Efficacy (CPSE) scale was utilised in one included study [47]. This 22-item scale was developed to measure self-efficacy in patients with chronic pain [54]. Each item can be scored from 0 to 8. The original scale has three subscales: pain management self-efficacy (PSE), coping self-efficacy (CSE) and physical function self-efficacy (FSE) with internal consistency (Cronbach's α) 0.88, 0.90 and 0.87 respectively [54]. The included study used only the PSE subscale.

The Health Related Behaviour Self Efficacy and Body Self Efficacy Scale[55] were used in one included study.[32] These scales have a reported internal consistency (Cronbach's α) of 0.76 and 0.72 respectively [55]. Jason and colleague [39] used a self-efficacy scale with a 5-point Likert scale option (completely disagree to completely agree) modified for patients with chronic fatigue syndrome. This scale has an internal consistency (Cronbach's α) ranging from 0.70 to 0.77 [56].

3.5.2. Coping Scales

The Coping Strategies Questionnaire (CSQ) scale was used in two included studies [31,43]. The original 50-item scale was developed in patients with chronic low back pain. Each item can be rated from ‘0 = never do that’ to ‘6 = always do that’ [57]. This scale measures how frequently the six cognitive coping strategies (ignoring pain, reinterpretation, diverting attention, self-statements, catastrophizing, praying/ hoping) and two behavioural coping (increasing activity and increasing pain behaviour- overt pain behaviours that decrease pain) are used and with two single item questions on how effective each of these coping strategies is in controlling and decreasing pain [58]. Despite the factor instability [59], this scale measures three main constructs: conscious cognitive coping attempts, confidence in controlling and decreasing pain and diverting attention in non-painful activities [58]. Internal consistency of CSQ was estimated between 0.45 and 0.84 [59].

The Pain Coping Inventory (PCI) was utilised in one study [25]. This 34-item scale measures three active coping strategies (transformation, distraction and reducing demands) and three passive coping strategies (ruminating, retreating and resting). Each item can be rated from ‘1 = hardly ever’ to ‘4 = very often’. The PCI is reliable with internal consistency (Cronbach’s α 0.82-0.91) for subscales (in people attending pain clinic) between 0.53 and 0.83 [60].

The 42-item Chronic Pain Coping Inventory was used in one included study [30] along with the ASES. The CPCI was developed and validated in chronic pain population by Jenson and colleague [61,62] to measure cognitive and behavioural coping. The CPCI includes 8 sub-scales: three on illness focused coping: Guarding, Resting, Asking for Assistance; four on wellness focused coping: Relaxation, Task Persistence, Exercises and Stretch, Coping Self-statements; and other coping Seeking Social Support. Items are rated from ‘0 to 7’ as these are used in last one week. This scale provides individual sub-scale scores but does not provide a composite score. This scale is a modified version of an earlier 65-item scale [61]. The 42-item scale demonstrates good reliability and internal consistency (Cronbach’s α) 0.71-0.89 [62].

3.5.3. Pain Attitudes and Management Scales

The Survey of Pain Attitudes (SOPA) scale was used in two included studies [33,41]. This scale has seven subscales: Control, Disability, Harm-exercise (accepts pain means damage and activity can increase damage), Emotion, Medication, Solicitude and Medical Care. Items can be rated with ‘0 = very untrue for me’ to ‘4 = very true for me’. The longer version of the scale [63] has 57 items but a reduced version with 30 items is also available [64]. The original scale has moderate internal consistency (Cronbach’s α 0.71-0.80 for long version [63] and 0.56-0.83 for short version) [64].

The German Pain Management Questionnaire (GPMQ) was used in one included study [35]. This scale consists of 24 items and each item can be rated from ‘1 = do not agree at all’ to ‘6 = fully agree’. This scale has two main domains: a) cognitive strategies consisting of three subscales: action-oriented coping, cognitive restructuring and coping competence and b) behavioural strategies consisting of three subscales: mental distraction, counter activities and relaxation. Each of these subscales can be scored between 4 and 24, where a higher score indicates stronger agreement with the respective coping strategy. The internal consistency (Cronbach’s α) of these subscales range from 0.73 to 0.84 [35].

3.5.4. Empowerment Scales

The Psychological Empowerment Scale (PES) was utilised in one study [36]. This scale was originally developed following the Cognitive Empowerment Model in a workplace setting [65] and later utilised in patients with fibromyalgia syndrome [66]. This scale has four different subscales: meaningfulness, competence, self-determination and impact; each subscale has three items, which can be scored using a 7-point Likert scale from ‘1 = strongly disagree’ to ‘7 = strongly agree’ [36,67]. Each of these subscales has acceptable internal consistency (Cronbach’s α 0.87-0.97) [66]. In the included study, the PES was translated and contextualised for Italian patients with chronic back pain and a similar internal consistency (Cronbach’s α 0.82-0.91) for the translated version was reported between 0.71 and 0.94 [36].

The Swedish Rheumatic Disease Empowerment Scale (SEW-RES-23) was used in one included study [40]. This 23-item scale measures five constructs: goal achievement and overcoming barriers, self-knowledge, stress management, assessing dissatisfaction and readiness to change, and support for caring. Each item can be rated from '1 = strongly disagree' to '5 = strongly agree' and a higher total score indicates better empowerment. The Diabetes Empowerment Scale [68] was translated into Swedish for patients with diabetes [69]. This Swedish scale was later modified and validated in the SWE-RES-23 for patients with rheumatic diseases [70]. The estimated internal consistency (Cronbach's α) ranged from 0.59 to 0.91 for the five sub-scales and 0.92 for the total score [70]. The SEW-RES was used with the Appraisal of Self Care Agency scale in the included study [40].

3.5.5. Other Scales

Appraisal of Self Care Agency Scale (ASA-A) was utilised to assess the self-care ability in one included study [40]. This scale contains 24 questions and each item can be rated from '1 = totally disagree' to '5 = totally agree' [71] with a total possible score between 24 and 120, where higher scores indicate better self-care ability. The Swedish ASA-A has an internal consistency (Cronbach's α 0.82-0.91) of 0.59 [72]. However, the ASA scale rated by caregivers or nurses has higher internal consistency (Cronbach's α 0.77 or 0.87 respectively) [72].

The Social Integration and Support subscale of the Health Education Impact Questionnaire (heiQ) was used in one study [49]. This 40-item scale was purposefully designed for measuring SM and the development was guided by a Programme Logic Model, Concept Mapping and interviewing the stakeholders [73]. This scale consists of eight different independent constructs: Positive and Active Engagement in Life (five items), Health Directed Behavior (four items), Skill and Technique Acquisition (five items), Constructive Attitudes and Approaches (five items), Self-Monitoring and Insight (seven items), Health Service Navigation (five items), Social Integration and Support (five items), and Emotional Wellbeing (six items). The Internal consistency (Cronbach's α) of these sub-scales ranges between 0.70 and 0.89 [73]. Each of the 40 items can be scored on a four point Likert scale from 'strongly disagree' to 'strongly agree'. This scale does not provide a total score. However, the included study [49] used only one of these eight constructs along with PSEQ to measure self-management.

The Inventory of Adult Role Behaviours (IARB) was used in one study [42] to assess self-help along with Self-Efficacy Scale. This 45-item scale [74] includes a modified 22-item Effect Scale [75] and 23 newly developed items on social, family, leisure and personal roles. Each item can be rated with a 100 mm visual analogue scale. This scale has excellent internal consistency (Cronbach's α) 0.84-0.92 [74,75].

3.6. Constructs of the measures

Further, the Patient Reported Outcome Measure Information System (PROMIS) framework [20] was used to evaluate the constructs or sub-scales of the identified SM measures (Table 5). Twelve out of 14 measures did not assess all three domains of the PROMIS. However, the Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (heiQ) cover all three PROMIS domains.

Please insert Table 5 about here

3.7. Psychometric properties of the measures

Psychometric properties of these included measures were summarised (in Table 6) following Terwee and colleague [21]. The content validity was established as positive or intermediate in 10 out of 13 measures and nine measures had high internal consistency (Cronbach's α) between 0.70 and 0.95 with each of the sub-scales and/or the total scores. Only eight measures for construct validity and four measures for reliability had positive or intermediate ratings. Agreement, responsiveness, and floor and ceiling effects had no or negative ratings for all 13 measures. Intermediate quality of interpretability was reported for only two out of 13 measures. These findings highlight, a lack of research in reproducibility, responsiveness and interpretability data for these outcomes. Further, Arthritis Self-efficacy Scale (ASES), Self-Efficacy Scale (SES), Pain Self Efficacy Questionnaire (PSEQ), Chronic Pain Self-Efficacy Scale (CPSES), Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (heiQ) had better psychometric properties than the other included scales (with three or more positive ratings out of eight assessed- in Table 6). Among these six scales CPSES, CPCI and heiQ were developed either for patients with any condition or with chronic pain.

Please insert Table 6 about here

4. Discussion and conclusion

4.1. Discussion

To date, this systematic review identified, synthesised and appraised the outcome measures used to quantify change in self-management (SM) in patients with chronic pain. The present review identified 25 randomised controlled trials with 14 different patient reported measures used to detect change in SM. These 14 measures are quite diverse and measure a variety of underlying constructs including self-efficacy, coping, empowerment and impact on knowledge. This demonstrates a lack of consistency and consensus around the measurement of SM in chronic pain and creates challenges in directly comparing findings of studies assessing SM or related constructs. It is evident that only effects measured by identical instruments can be directly compared.

Our findings are in alignment with a prior systematic review by Boger and colleague [84] on patient reported outcome measures used in SM trials in patients with stroke. Boger and colleague found that multiple measures were used to capture change in SM. They also reported that the majority of their included studies (n=13) measured diverse constructs such as physical function, mood, participation, satisfaction and quality of life, which are not direct measures of SM. In their review, other commonly used proxy measures of SM (such as resource utilization, self-efficacy, locus of control, health behaviours, knowledge and goal attainment) were not frequently measured. However, this is not consistent with our review findings for SM in chronic pain, since the majority of our included studies used self-efficacy scales as a proxy measure of SM.

Studies included in the current review frequently used more than one scale to capture SM, perhaps due to a lack of validated multi-domain SM scales. Theoretically, SM encompasses multiple constructs including; disease and symptoms management, behaviour management, role and emotional management [11] using problem solving and decision making skills, navigating health and care resources and taking appropriate actions (e.g., pacing or increasing physical activity) [12,85]. A recent systematic review on self-management in chronic low back pain has highlighted that the majority of included self-management trials did not disclose or follow a priory theoretical model or framework [85]. Future research should aim to select and follow a theoretical framework for interventions which will inform selection of appropriate outcome measures.

Conceptually, the constructs of SM fall into a range of constructs of the physical, mental and social health domains of Patient Reported Outcome Measure Information System (PROMIS) framework [20]. 12 of 14 measures did not assess all three domains of the PROMIS, which potentially make these measures less effective to detect changes in SM over time. In contrast, the CPCI and heiQ, covering all three PROMIS domains, are potentially more appropriate than scales measuring individual constructs of SM.

Another potential reason for the complexity in measuring SM in chronic pain is a lack of direct biological measures for pain severity [14,86]. In some chronic conditions, direct biological measures are available to detect change in disease severity, for example, HbA1c is commonly used to detect clinical changes in diabetes over time that are indicative of improvements in condition management. A review by Nolte and colleague [14] found outcome measures used in SM trials are mainly perception- or evaluation-based patient reported outcome measures (PROMs), which require the responders to understand the questions, recall and process relevant information to answer and finally to form the response in keeping with the quality of life appraisal model [87]. Nolte and colleague also identified that self-efficacy scales, which are most frequently used in our included studies, have high response shifts with small differences in the effect sizes between intervention and control groups, indicating instability across time. In another review, Miles and colleague evaluated psychometric properties of five commonly used self-efficacy measures (Arthritis Self-Efficacy Scale, Self-Efficacy Scale, Chronic Pain Self-Efficacy Scale and Pain Self-Efficacy Questionnaire) in people with chronic pain [88]. They found these self-efficacy scales to have acceptable internal consistency and construct validity, although indicated further research is required on responsiveness and test-retest reliability of the self-efficacy scales. Their results are in agreement with our own review.

The current review found self-efficacy scales to be the most frequently used to measure change in SM. These scales were developed and validated in patients with arthritis and later modified for populations with chronic pain. Most of these scales are short, quick to administer in the clinic and easy to score [88]. However, these scales can only measure perceived confidence in doing specific things despite the pain; therefore there is a tendency that these are activity-specific and lack universal appropriateness to patients with chronic pain in identifying how patients self-manage. The coping scales measure endorsement and frequency of different cognitive and behavioral strategies used to cope with chronic pain. However, these coping scales fail to capture issues of empowerment or pain management skills.

The Health Education Impact Questionnaire (heiQ) and Chronic Pain Coping Inventory (CPCI) are multi-domain scales cover all three PROMIS domains and had good psychometric properties. The CPCI measures cognitive and behavioural coping in chronic pain and the heiQ measures effect of any educational or SM support programme in all patients. Knowing the heiQ covers eight out of 12 SM related constructs across all three PROMIS domains (Table 5) and with acceptable psychometrics (Table 6) has emerged as an appropriate scale to measure change in SM over time.

4.2. Strength and limitations

This review identified the wide range of measures used to assess change in SM in chronic non-cancer pain. It assessed both the quality of the included studies and the identified measures flowing published quality assessment criteria. The reviewers carried out a thorough search; two independent reviewers conducted the study selection and the quality assessment; and synthesised the majority of validated scales used to measure change in SM. It is possible that articles may have been missed due to the search strategy and selection criteria of the review. Although every effort was made to seek additional information from authors where required, not all attempts of communication with authors were successful. Furthermore, seven abstracts were not available in full text version; and non-English articles were not considered for inclusion.

4.3. Conclusion

This review identified and evaluated the measures used to detect change in SM in patients with non-cancer chronic pain. Included measures are diverse, targeting different SM constructs, highlighting the complexity, inconsistency and lack of consensus in definitions of SM. Despite some evidence on internal consistency, content and construct validity these SM measures significantly lack research in three core psychometric properties: reproducibility, responsiveness and interpretability, which may be prioritised in future research. Whilst single construct scales are more commonly used, they do not cover multiple PROMIS domains which potentially make these measures less effective to detect changes in SM over time. Multi-construct scales (for example, Chronic Pain Coping Inventory and Health Education Impact Questionnaire) are valid, internally consistent and cover multiple PROMIS domains. Future research should aim to gain consensus on constructs of SM, for example using a modified Delphi method; to develop a new multi-domain SM measure for use with patients who have chronic pain; and validating the new and/or existing scales in patients with chronic pain.

Conflict of interest

Authors declare no financial conflicts of interest related to this work.

Acknowledgement/ funding

Anirban Banerjee has been awarded International Vice-Chancellor Scholarship from The University of Nottingham.

Authors would like to convey sincere thanks to the reviewers for their constructive feedback.

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Figure legends

Figure 1: PRISMA Flow Diagram

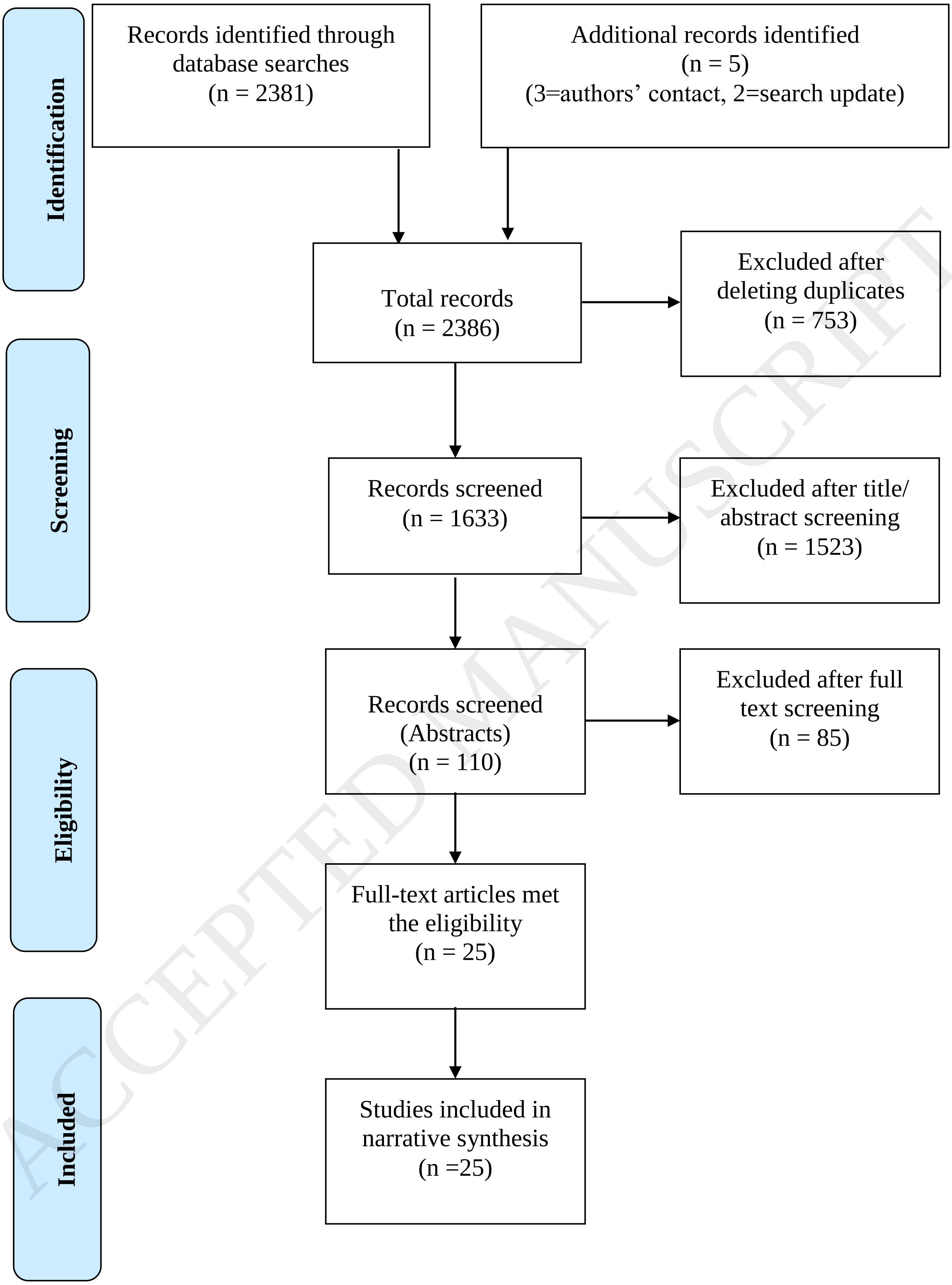
Figure 2: Risk of bias summary: review authors' judgements about each risk of bias item for each included study

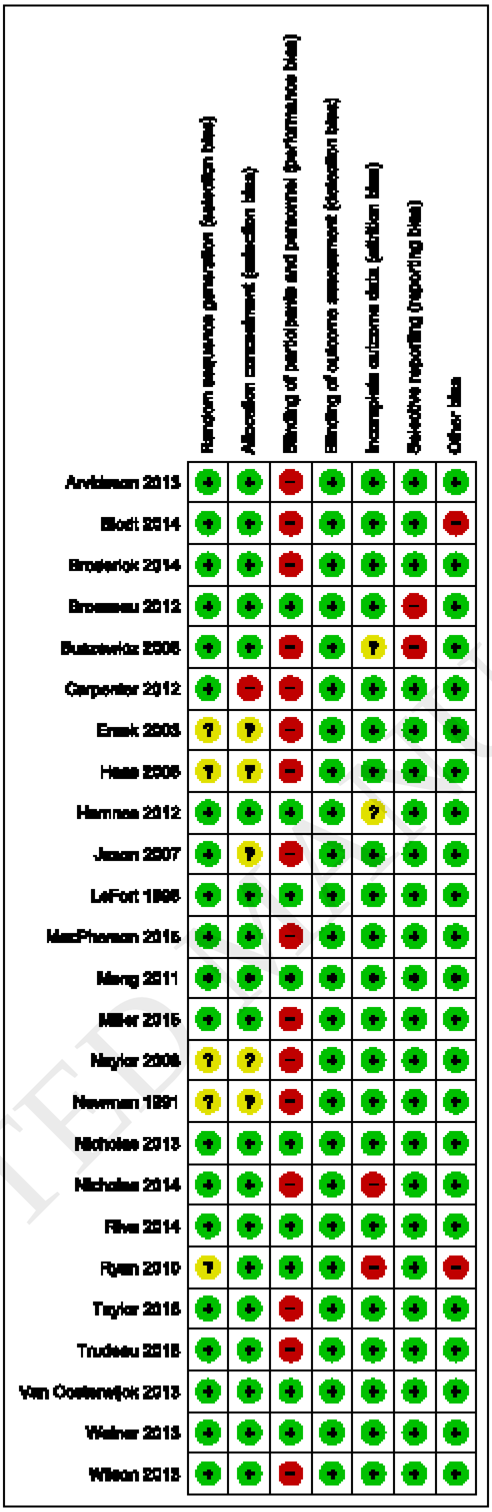
+	**low risk of bias**	?	**unclear risk of bias**	-	**high risk of bias**

Figure 3: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

🟩 Low risk of bias 🟨 Unclear risk of bias 🟥 High risk of bias

Figure 1: PRISMA Flow Diagram





	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Arvidsson 2013	+	+	−	+	+	+	+
Blodt 2014	+	+	−	+	+	+	−
Broderick 2014	+	+	−	+	+	+	+
Brosseau 2012	+	+	+	+	+	−	+
Butkiewicz 2006	+	+	−	+	?	−	+
Carpenter 2012	+	−	−	+	+	+	+
Ernst 2008	?	?	−	+	+	+	+
Haas 2006	?	?	−	+	+	+	+
Hamnes 2012	+	+	+	+	?	+	+
Jason 2007	+	?	−	+	+	+	+
LeFort 1998	+	+	+	+	+	+	+
MacPherson 2015	+	+	−	+	+	+	+
Meng 2011	+	+	+	+	+	+	+
Miller 2015	+	+	−	+	+	+	+
Naylor 2008	?	?	−	+	+	+	+
Newman 1991	?	?	−	+	+	+	+
Nicholas 2013	+	+	+	+	+	+	+
Nicholas 2014	+	+	−	+	−	+	+
Riva 2014	+	+	+	+	+	+	+
Ryan 2010	?	+	+	+	−	+	−
Taylor 2016	+	+	−	+	+	+	+
Trudeau 2015	+	+	−	+	+	+	+
Van Oosterwijck 2013	+	+	+	+	+	+	+
Weiner 2013	+	+	+	+	+	+	+
Wilson 2015	+	+	−	+	+	+	+

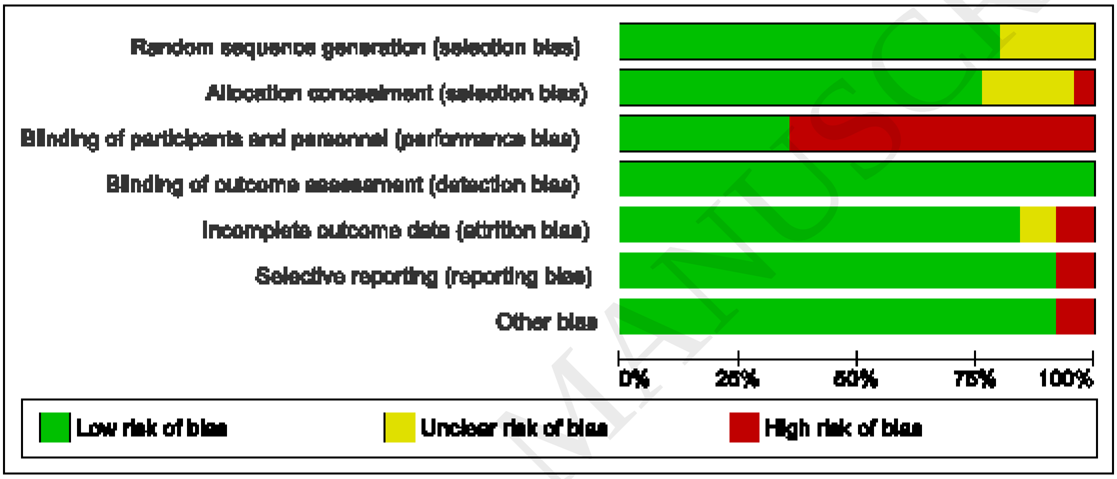

Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding of participants and personnel (performance bias)
Blinding of outcome assessment (detection bias)
Incomplete outcome data (attrition bias)
Selective reporting (reporting bias)
Other bias
0%
25%
50%
75%
100%
Low risk of bias
Unclear risk of bias
High risk of bias

Table 1: Study selection criteria for the systematic review

Selection criteria
Inclusion criteria • Participants: adults (≥18 years) with chronic pain (pain duration ≥ 3 months) • Intervention: any non-surgical interventions • Comparison: any comparisons • Outcome: change in self-management measured using a composite quantitative outcome measure • Studies: randomised and non-randomised controlled trails • Limits: (full-text) research reports available in English language
Exclusion criteria • Observational, validation, feasibility and qualitative studies • Studies including patients with cancer, trauma, surgical and episodic pain; substance abuse and addiction; AIDS and end-of-life care conditions (or terminal illnesses) • Secondary research and multiple publication

Table 2: Reasons for exclusion at the detailed screening stage

Reasons for exclusion	**Number of studies**
Not in chronic pain as defined in the protocol	30
No self-management outcome measure used	16
Not randomised or non-randomised controlled trials	19
Study protocol	05
Secondary analysis or multiple publication	08
No full text available even through interlibrary loan services	07
Total excluded articles at the full-text screening	**85**

Table 3: Characteristics of the included studies

Author, year [reference]	**Total participants (drop out)**	**Conditions**	**Mean symptom duration***	**Mean age***	**Female (%)**	**Attended college or university (%)**	**Unemployed (%)**	**Self-management outcome measures**
Arvidsson 2013 **[40]**	202 (40)	Chronic pain/ fatigue	NR	56.4 (7.2) IG, 55.2 (13.2) CG	71 IG, 73 CG	21 in IG, 25 in CG	NR	Swedish Rheumatic Disease Empowerment Scale; Self-Care Agency Scale
Blodt 2014 **[32]**	128 (14)	Chronic low back pain	2.7 (1.4) IG, 3.2 (1.5) CG	45.7 (10.0) IG, 47.7 (10.8) CG	90.6 IG, 69.8 CG	67.2 IG, 55.6 IG	0	Self-Efficacy Scale
Broderick 2014 **[27]**	256 (27)	Osteoarthritis- knee/hip	13.95 (10.63) IG, 13.59 (9.09) CG	68.00 (8.67) IG, 66.37 (10.26) CG	74.4 IG, 78.9 CG	71.7 IG, 73.1 CG	78.9 IG, 60.3 CG	Arthritis Self-Efficacy Scale, Coping Strategies Questionnaire
Brosseau 2012 **[28]**	222 (100)	Osteoarthritis- knee	10.3 (9.26)	63.4 (8.6)	68.9	72.1	NR	Self-Efficacy- Coping with symptoms, Confidence about doing things
Buszewicz 2006 **[26]**	812 (193)	Osteoarthritis- hip/knee	NR	68.4 (8.2) IG, 68.7 (8.6) CG	63 IG, 63 CG	28 IG, 27 CG	NR	Arthritis Self-efficacy
Carpenter 2012 **[33]**	141 (32)	Chronic low back pain	8.64 (7.84)	42.5 (10.3)	83	54	NR	Pain Self-efficacy Scale, Survey of Pain Attitudes

Author, year [reference]	**Total participants (drop out)**	**Conditions**	**Mean symptom duration***	**Mean age***	**Female (%)**	**Attended college or university (%)**	**Unemployed (%)**	**Self-management outcome measures**
Ersek 2003 **[41]**	45 (6)	Chronic pain	NR	81.9 (range 65-94)	87	75	NR	Survey of Pain Attitudes
Haas 2005 **[34]**	109 (8)	Chronic low back pain	NR	77.2 (7.7)	84.4	23.8	NA	Self-Efficacy Scale
Hamnes 2012 **[38]**	150 (32)	Fibromyalgia	7.03 (7.21) IG, 6.13 (6.53) CG	45.4 (9.4) IG, 49.7 (4.0) CG	92 IG, 100 CG	24 IG, 21 CG	72 IG, 70.8 CG	Arthritis Self Efficacy Scale
Jason 2007 **[39]**	114	Chronic fatigue syndrome	43.8	NR	83.3	90.3	58.3	Self-Efficacy Scale
LeFort 1998 **[42]**	110 (8)	Chronic pain	6.5 (range 1-28) IG, 5.6 (range 1-20) CG	39 IG, 40 CG	74 IG, 75 CG	75 IG, 66 CG	63 IG, 66 CG	Self-Efficacy Scale
MacPherson 2015 **[47]**	517 (89)	Chronic neck pain	6	53.2 (13.8)	69	NR	39.8	Chronic Pain Self-Efficacy Questionnaire
Meng 2011 **[35]**	360 (91)	Chronic low back pain	NR	50.2 (7.6) IG, 49.5 (7.7) CG	65.2 IG, 63.0 CG	18.9 IG, 25.5 CG	9.2 IG, 8.8 CG	German Pain Management Questionnaire
Miller 2015 **[48]**	102 (22)	Chronic pain	10 (median)	53.4 (13.5)	73.5	32 IG, 21 CG	86 IG, 92 CG	Pain Self-Efficacy Questionnaire
Naylor 2008 **[43]**	51 (4)	Chronic musculoskeletal pain	11.5 (9.27)	46 (11.47)	86	70	NR	Coping Strategy Questionnaire

Author, year [reference]	**Total participants (drop out)**	**Conditions**	**Mean symptom duration***	**Mean age***	**Female (%)**	**Attended college or university (%)**	**Unemployed (%)**	**Self-management outcome measures**
Newman 1991 **[29]**	180 (50)	Osteoarthritis, rheumatoid arthritis	12.9 (1.49)	69.0	87.7	IG 59.2 CG 57.6	IG 1.4, CG 0.0	Arthritis Self Efficacy Scale
Nicholas 2013 **[44]**	141 (22)	Chronic pain	6.0 (median)	73.9 (6.5)	63	NR	NA	Pain Self-Efficacy Questionnaire
Nicholas 2014 **[45]**	140 (13)	Chronic pain	5.60 (7.26) IG, 6.48 (7.44)	42.05 (12.33) IG, 43.22 (11.08) CG	51 IG, 55 CG	55 IG, 55 CG	68 IG, 70 CG	Pain Self Efficacy Questionnaire
Riva 2014 **[36]**	51 (0)	Chronic back pain	7.9 (7.2) IG, 9.3 (8.7) CG	44(13.6) IG, 51(14.1) CG	51.9 IG, 50.0 CG	33.3 IG, 12.7 CG	40.7 IG, 41.7 CG	Psychological Empowerment Scale
Ryan 2010 **[37]**	38 (11)	Chronic low back pain	7.6 (7.0) IG, 13.7 (10.2) CG	45.2 (11.9) IG, 45.5 (9.5) CG	70.0 IG, 61.1 CG	NR	NR	Pain Self Efficacy Questionnaire
Taylor 2016 **[49]**	703 (82)	Chronic musculoskeletal pain	85% had pain for 3 years or more	60.3 (13.5) IG, 59.4 (13.8) CG	67	40% ended formal education after 20 years	26 IG, 24 CG	Pain Self-Efficacy Questionnaire, Health Education Impact Questionnaire (Social Integration and Support)
Trudeau 2015 **[30]**	245 (73)	Arthritis and ankylosing spondylitis	NR	49.9 (11.6)	68.4	61.4	8.8	Arthritis Self Efficacy Scale and Self-Management Behaviours

Author, year [reference]	**Total participants (drop out)**	**Conditions**	**Mean symptom duration***	**Mean age***	**Female (%)**	**Attended college or university (%)**	**Unemployed (%)**	**Self-management outcome measures**
Van Oosterwijck 2013 **[25]**	30 (4)	Fibromyalgia	13.0 (6.0) IG, 9.67 (3.83) CG	45.8 (9.5) IG, 45.9 (11.5) CG	80 IG, 93.3 CG	NR	66.7 IG, 53.3 CG	Pain Coping Inventory
Weiner 2013 **[31]**	190 (31)	Osteoarthritis-knee	5.7 (6.4) IG, 6.2 (6.8) IG1, 7.2 (8.3) CG	67.1 (8.9) IG, 65.8 (8.7) IG1, 66.8 (10.4) CG	12.7 IG, 15.6 IG1, 17.5 CG	58.7 IG, 54.7 IG1, 50.8 CG	NA	Arthritis Self Efficacy Scale
Wilson 2014 **[46]**	114 (34)	Chronic pain	NR	49.33 (11.63)	78	51	NR	Pain Self-Efficacy Questionnaire

CG control group, IG intervention group, IG1 other intervention group, NA not applicable, NR not reported, * mean (standard deviation) in years unless mentioned

Table 4: Self-management outcome measures used in the included studies

No.	Name of the instrument (Number of studies which used the instrument)	Number of items	Scoring methods	No of subscales	Administration of the scales	Internal consistency (Cronbach's α) as mentioned in the included/ cited studies
1.	Arthritis Self-efficacy Scale (6)	20	10-point	3	Pen and paper	0.82-0.91
2.	Self-efficacy Scale (3)	11	10-point	1	Pen and paper	0.76-0.90
3.	Pain Self Efficacy Questionnaire (7)	10	7-point	1	Pen and paper	0.92
4.	Chronic Pain Self-Efficacy Scale (1)*	22	9-point	3	Pen and paper	0.87-0.90
5.	Coping Strategies Questionnaire (2)	50	7-point	8	Pen and paper	0.45-0.84
6.	Pain Coping Inventory (1)	34	4-point	6	Pen and paper	0.53-0.83
7.	Chronic Pain Coping Inventory (1)	42	0 to 7 days	8	Pen and paper	0.71-0.89
8.	Survey of Pain Attitudes (2)	30	5-point	7	Pen and paper/ online	0.56-0.83
9.	German Pain Management Strategies (1)	24	6-point	6	Pen and paper	0.73-0.84
10.	Psychological Empowerment Scale (1)	12	7-point	4	Pen and paper/ online	0.87-0.97
11.	Swedish Rheumatic Disease Empowerment Scale (1)	23	5-point	5	Pen and paper	0.59-0.91
12.	Appraisal of Self-Care Agency Scale (1)	24	5-point	1	Pen and paper	0.59-0.87
13.	Health Education Impact Questionnaire** (1)	40	4-point	8	Pen and paper/ telephone	0.70-0.89
14.	Inventory of Adult Role Behaviours (1)	45	100 mm visual analogue scale	2	Pen and paper	0.84-0.92

* Pain Management Self-Efficacy subscale was used in the study. ** Social Integration and Support sub-scale was used in the study

Table 5: Appraisal of the self-management measures following PROMIS framework [19]

No.	Measures	Physical			Psychological				Social				
		Pain behaviours	Pain experience	Pain impact	Psychological stress	Psychological impact	Cognitive function	Self-Efficacy	Social relationships	Social support	Family relationships	Ability to participate	Participation satisfaction
1.	Arthritis Self-efficacy Scale	+	-	+	-	-	-	+	-	-	-	-	-
2.	Self-Efficacy Scale	+	-	+	-	-	-	+	-	-	-	-	-
3.	Pain Self Efficacy Questionnaire	+	-	+	-	-	-	+	-	-	-	-	-
4.	Chronic Pain Self-Efficacy Scale	+	-	+	-	+	+	+	-	-	-	-	-
5.	Coping Strategies Questionnaire	+	-	+	+	+	+	+	-	-	-	-	-
6.	Pain Coping Inventory	+	-	+	+	+	+	-	-	-	-	-	-
7.	Chronic Pain Coping Inventory	+	-	+	+	+	+	-	-	+	-	+	-
8.	Survey of Pain Attitudes	+	+	+	+	+	-	-	-	-	-	-	-
9.	German Pain Management Strategies	+	-	-	+	+	+	+	-	-	-	-	-
10.	Psychological Empowerment Scale	-	-	-	-	+	+	+	-	-	-	-	-
11.	Swedish Rheumatic Disease Empowerment Scale	-	-	-	+	+	+	-	-	-	-	-	-
12.	Appraisal of Self-Care Agency Scale	-	-	+	-	-	-	-	-	-	-	+	-
13.	Health Education Impact Questionnaire	+	-	+	+	+	+	-	+	+	-	+	-
14.	Inventory of Adult Role Behaviours	-	-	+	-	-	-	-	+	+	+	-	-

Table 6: Quality criteria of the identified measures following Terwee (modified) [20]

	Measures (target population)	**Reference/s**	Content validity	Internal consistency	Construct validity	Reproducibility Agreement	Reproducibility Reliability	Responsiveness	Floor and ceiling effects	Interpretability
1.	Arthritis Self-efficacy Scale (Patients with arthritis)	[51,52]	+	+	+	0	?	0	0	0
2.	Self-Efficacy Scale (All patients)	[51,52]	+	+	+	0	?	0	0	0
3.	Pain Self Efficacy Questionnaire (Patients with pain)	[53,76,77]	+	+	+	0	?	0	-	?
4.	Chronic Pain Self-Efficacy Scale (Patients with chronic pain)	[54]	+	+	+	0	+	-	0	0
5.	Coping Strategies Questionnaire (All patients)	[59]	-	-	-	0	0	0	0	0
6.	Pain Coping Inventory (Patients with pain)	[60]	-	-	-	0	-	0	0	0
7.	Survey of Pain Attitudes (Patients with pain)	[63,64,78]	+	-	?	0	0	0	0	0
8.	Chronic Pain Coping Inventory (Patients with chronic pain)	[62,79,80]	+	+	+	0	0	0	0	0
9.	Psychological Empowerment Scale (All patients)	[67,81]	?	+	?	0	0	0	0	0
10.	Swedish Rheumatic Disease Empowerment Scale (Patients with rheumatoid arthritis)	[70]	+	-	-	0	0	0	-	?
11.	Appraisal of Self-Care Agency Scale (All patients)	[72,82]	?	+	-	0	0	0	0	0
12.	Health Education Impact Questionnaire (Patients with chronic conditions)	[73,83]	+	+	+	0	0	0	0	0
13.	Inventory of Adult Role Behaviours (All patients)	[74,75]	-	+	-	0	0	0	0	0

+ = positive, ? = intermediate, - = negative, 0 = no information available; German Pain Management Strategies was not appraised as the paper is not in English