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Review article

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

Anirban Banerjee[a,b,*], Paul Hendrick[a], Purba Bhattacharjee[b], Holly Blake[a]

[a] School of Health Sciences, University of Nottingham, Nottingham, NG7 2HA, UK
[b] Nottingham CityCare Partnership, Nottingham, NG1 6GN, UK

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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 for assessing self-management.
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* Corresponding author at: School of Health Sciences, University of Nottingham, South Block, Queen's Medical Centre, Derby Road, Nottingham, NG7 2HA, UK.
*E-mail address:* Anirban.Banerjee@nottingham.ac.uk (A. Banerjee).

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## 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 (ASES) [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 outcome measures, e.g., 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 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 assess 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).

### 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

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