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Estimating the clinical effectiveness of cognitive behavioural therapy in the clinic: Evaluation of a CBT informed pain management programme

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Abstract

Randomized controlled trials and meta-analyses provide evidence for the *efficacy* of cognitive-behaviourally informed treatment (CBT) programmes for chronic pain. The current study aims to provide *practice-based evidence* for the effectiveness of CBT in routine clinical settings. Over a 10-year period 1013 pain patients were accepted into a 4 week in-patient pain management programme. Data from more than 800 patients was available at pre-treatment and at one month post-treatment and for around 600 patients at pre-treatment and at 9 months follow-up. Measures reported in this analysis were pain experience and interference, psychological distress (depression and anxiety), self-efficacy, catastrophizing, and walking. Change from pre-treatment to post-treatment and follow-up was assessed with conventional statistical tests, the computation of effect sizes and by the reliable change index (RCI) and clinically significant change (CSC) methodology. These analyses provide evidence of statistical improvement at post-treatment and follow-up and the RCI/CSC methodology suggested that between 1 in 3 and 1 in 7 (depending on the outcome measure) achieved clinically significant gains. There was also evidence that a small percentage of patients (1–2%) reliably deteriorated during the period of treatment. The limitations in the inferences that can be drawn from this study and of the methodology are discussed. A case is made for the application of benchmarking methods using data from RCTs in order to more fully evaluate practice and to generate better quality practice based evidence.

Keywords: Clinical effectiveness; Cognitive behavioural therapy; Reliable change index; Clinically significant change

1. Introduction

The practice of evidence based medicine is espoused by many governments and health care organisations. The aims of evidence based medicine include the allocating of effective treatment in a timely and efficient manner and, increasingly in socially regulated health care systems, managing access to scarce resources. The basis of evidence based medicine (EBM) are high quality randomized controlled trials (RCTs) and integration of their results through systematic review and meta-analysis [41,42]. Psychologically based treatments for chronic pain as a generic condition, or for specific diagnostic groups where pain is a significant symptom and problem e.g. rheumatoid and osteo-arthritis, have developed over 40 years; many RCTs and several meta-analyses attest to treatment efficacy under controlled conditions in comparison with both wait list and control treatments [12,27,44].

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While RCTs and meta-analysis have been used to establish the *efficacy* of psychological treatments they do not necessarily provide evidence of *effectiveness:* whether the treatment provides a measurable beneficial effect when delivered to patients in other service contexts [4]. Generalising from RCTs to other contexts is problematic where there is less control over, for example, selection and recruitment of patients, implementation of treatment to a manualized standard, or checks on the adherence and delivery of the therapeutic protocol [55]. What is required is evidence from clinical practice, i.e. practice-based evidence such as that described by Barkham and Mellor-Clark [4], for the *effectiveness* of treatment. These authors and others argue that a model of research into efficacious and effective treatment should be based on a cycle in which evidence based practice (EBP) informs clinical practice which then generates evidence and questions (practice-based evidence) for testing under more controlled conditions of EBM.

The aim of this article is twofold: It seeks to generate evidence from routine clinical practice for the effectiveness of a cognitive behavioural pain management programme and in doing so it identifies issues concerning the way in which the majority of RCTs in this field measure and report outcomes. Most trials of psychological treatments use continuous measures and the subsequent analyses focus on differences between group means at the end of treatment (suitably controlled for pre-treatment differences and other confounds) that are evaluated with conventional inferential statistics (P values). Aside from the fact that P values are sensitive to sample size, the test statistics are not generally referenced to any external criterion. This methodology is not useful for evaluation of treatment where there is no control group, as is typical in clinical practice. In these situations, pre- and post-treatment differences may be computed but provide no information about the clinical significance of changes. In the current study we employed reliable change index (RCI)/clinically significant change (CSC) methodology [29,30] to evaluate a 4 week in-patient CBT rehabilitation programme for chronic pain.

2. Methods

The data reported in this study were collected as part of routine procedure by the clinic. The data were available in an anonymised database. Permission to access and interrogate the database using an explicit protocol was given by the relevant UK NHS Trust research ethics committee.

2.1. Overview of sample and data collection

Between 1989 and 1998, 2041 patients attended a publicly funded (UK National Health Service) pain management service. The service is a specialist tertiary one that receives referrals from other pain clinics, general practice, orthopaedic and other specialist services from around the UK. Primary assessment was made by anaesthetists and clinical psychologists. The exclusion criteria were: inability to speak English, inability to climb stairs, current major psychiatric disorder (active psychosis, severe depression with high risk of suicidal attempt), suitable for further medical treatments following examination, pain duration less than one year, current opioid misuse (either chronic illegal opioid use or in a methadone maintenance programme). Patients were required to meet two of the following inclusion criteria: widespread disruption in non-work and/or work activity due to pain, habitual overactivity leading to increased pain, use of high levels pain medication with little reported benefit, high affective distress score, unnecessary use of medical aids, high levels of pain behaviour. Patients completed a package of assessments (see below) administered by assistant psychologists and others who were not part of the treatment team. During the period 1989–1998, several treatment options were trialled including 2 and 4 week programmes with in-patient and out-patient options. This article reports the outcomes for patients who attended a 4 week long in-patient programme and provided data at baseline (pre-treatment). Data were collected pre-treatment, one month post-treatment (post-treatment) and at 9 months follow-up (follow-up). There is variation in the number of data points available for each of the measures for two reasons: attrition at post-treatment and follow-up, and because over the 10-year period the programme occasionally changed measures, supplementing or replacing measures as they were improved. The sample sizes varied between 833 for pre-treatment/post-treatment comparisons and 527 for pre-treatment/follow-up comparisons.

2.2. Programme description

Williams et al. (1999: p.60) [57] have previously described this programme as follows: "The unit was staffed by a consultant anaesthetist, two clinical psychologists, a physiotherapist, an occupational therapist, a senior nurse, and a secretary/administrator. The program was based on the work of Fordyce [20], Keefe and colleagues [23,47], and Turk et al. [53] and incorporated operant and cognitive behavioural principles in all aspects. No other active treatments (such as nerve blocks or acupuncture) were offered once patients were accepted for the program. Treatment was carried out in hospital premises with hostel-type accommodation for in-patients who lived independently outside program hours and returned home at weekends. The in-patient programme was carried out over four weeks, four and a half days per week.

The program consisted of the following components, all supported by written materials: education concerning pain, disuse, drugs, and sleep; exercise routines for fitness, flexibility and muscle minimum strength, increasing gradually on a quota system; goal setting across all activities with quota increases and activity-rest scheduling (pacing); psychology sessions to improve problem solving, change maladaptive behaviours and to maintain those changes, with cognitive techniques to identify unrealistic and unhelpful thoughts and beliefs, and to challenge and change them; drug reduction applied to all pain-related drugs which had neither achieved analgesia nor improved function, with the usual aim of abstinence by discharge; applied relaxation; relapse prevention and planning