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Health related quality of life changes in somatising patients after individual versus group cognitive behavioural therapy: A randomized clinical trial

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ABSTRACT

Objective: To assess changes in health related quality of life after a cognitive behavioural program for patients diagnosed with abridged somatization disorder in primary care.
Method: A multicentre, randomized, parallel group, controlled trial was designed. 168 patients were recruited from 29 primary health care centres in Spain and were randomly assigned to one of the three study arms: treatment as usual improved with Smith's norms, individual cognitive behavioural treatment, and group cognitive behavioural treatment. Health-related quality of life was assessed using SF-36 Health Survey.
Results: Individual cognitive behavioural treatment achieves greater changes in health related quality of life than group cognitive behavioural therapy and treatment as usual. Improvement in health related quality of life was fully observed at 12 month, and partially at 6 months. The modality of intervention interacts with time in all dimensions except for Physical functioning and Vitality. Patients who received individual cognitive behavioural therapy treatment had better scores in Physical and Mental health summary measures at 12 month follow-up.
Conclusions: Individual cognitive behavioural treatment is the most effective way to improve health related quality of life in abridged somatization disorder patients, and its effects are sustained over time. Also, regardless of the type of intervention, physical functioning improves compared with treatment as usual.

Introduction

Medically unexplained physical symptoms (those physical symptoms that remain unexplained after proper physical and laboratory tests) are common in primary care. At least 33% of all somatic symptoms presented to primary care physicians have been classified as medically unexplained [1], and appear to be related to a physical disorder in only 50% to 60% of cases [2]. One out of six patients has medically unexplained physical symptoms that lead to significant limitations in daily life [3]. These symptoms cause the same or more degree of morbidity and impairment in health related quality of life as medically explained physical symptoms [4–9].

Medically unexplained symptoms are the defining feature of somatoform disorders as they were in the DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders). Undifferentiated somatoform disorder which has less restrictive diagnostic criteria than somatization disorder, is considered one of the most common somatoform disorder with a prevalence rate of 22% in primary care settings. Two groups of researchers [10,11] have suggested alternative categories for sub-threshold somatization using less restrictive criteria and less extensive symptomatology than DSM-IV-TR standards for full somatization disorder. In this regard, Escobar et al. [12] proposed the label "abridged somatization", to be applied to men experiencing 4 or more unexplained physical symptoms or to women with 6 or more symptoms.

There is increasing interest in HRQoL as a measure of response to psychotherapy because it includes not only symptoms, but also physical, mental and social functioning as well as role performance. Thus, assessment of HRQoL may provide a more comprehensive

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evaluation of treatment response than one based solely on improvement in somatic symptoms.

The aim of our study is to assess the efficacy of a cognitive behavioural intervention program on HRQoL of patients with abridged somatization disorder in primary care.

Method

Design

A multicentre, randomised, parallel group, controlled trial was designed. Patients were randomly assigned to one of the three study arms: General Practitioner (GP) treatment as usual (TAU) improved with Smith's norms [13] (control group); individual CBT (intervention group 1); group CBT (intervention group 2). The protocol of this study was previously published. This trial follows the Consolidated Standards of Reporting Trials (CONSORT) recommendations for randomized, controlled trials [15].

Setting and study sample

Patients were recruited from 21 primary health care centers in Spain. GPs recruited patients until the required sample was completed, without a quota assigned for each centre. The inclusion criteria were: (1) age 18 to 65 years; (2) fulfill Escobar's criteria of Abridged Somatization Disorder (SSI 4,6); (3) stable course and pharmacotherapy over the previous month; (4) have signed informed consent; and (5) be able to understand and read Spanish. Patients were excluded if they have (1) any primary psychiatric diagnosis other than somatization disorder; (2) severe personality disorder that could prevent an adequate implementation of the protocol for evaluation and/or intervention; (3) inability to attend intervention sessions; and (4) refusal to participate. Data collection began in March 2008 and ended in June 2010.

More detailed design settings and study sample of this trial have been described elsewhere [14,16], which explain the effectiveness of CBT reducing number and severity of somatic symptoms.

Randomization, treatment arms, implementation and masking of the study groups

GPs from the health centres involved in the study who suspected a patient could fulfil abridged somatization disorder criteria [17] administered a screening questionnaire, the Othmer and DeSouza test [18,19] to determine whether the patient met the inclusion criteria. Patients who fulfilled these criteria were interviewed, within the next 10 days, by a member of the research team for diagnostic confirmation (baseline). Cases were considered of patients who had a diagnosis of abridged somatization disorder using the Standardized Polyvalent Psychiatric Interview or SPPI [20].

After informed consent for trial participation was signed, patients were assigned to the three experimental conditions: individual CBT, group CBT or TAU. Each patient was allocated to one of both CBT intervention groups or to the TAU group by means of a computer-generated random number sequence. The allocation was carried out by an independent person, belonging to REDIAPP (Research Network on Preventive Activities and Health Promotion), who was not involved in the study, and patients didn't know what condition they were allocated for. CBT treatment was administered by two psychologists (SM, NB). Different investigators ran the psychological assessment in order to guarantee that they were masked to participants' treatment conditions(RM, ELN). GPs were also kept blinded to intervention as patients were asked not to reveal to them their treatment condition.

To deal with dropouts, we used Last Observation Carried Forward (LOCF) as imputation method for two reasons: it allows the examination of trends over time, and minimizes the number of participants eliminated from the analysis.

Intervention

Control group or standardized recommended treatment for somatization disorder in primary care (Smith's guidelines): standardized letter to the GP with Smith's norms that includes: 1. Provide brief, regularly scheduled visits. 2. Establish a strong patient–physician relationship. 3. Perform a physical examination of the area of the body where the symptom arises. 4. Search for signs of disease instead on relying of symptoms. 5. Avoid diagnostic tests and laboratory or surgical procedures. 6. Gradually move the patient to being "referral ready".

Experimental or intervention group: implementation of the protocol developed by Escobar [21,22] that includes ten weekly 90-min sessions. Patients were assessed at 4 time points: baseline, post-treatment, 6 and 12 months after finishing the treatment. The CBT intervention mainly consists of two major components: cognitive restructuring, which focuses on reducing pain-specific dysfunctional cognitions, and coping, which focuses on teaching cognitive and behavioural coping strategies. The program is structured as follows. Session 1: the connection between stress and pain. Session 2: identification of automated thoughts. Session 3: evaluation of automated thoughts. Session 4: questioning the automatic thoughts and constructing alternatives. Session 5: nuclear beliefs. Session 6: nuclear beliefs on pain. Session 7: changing coping mechanisms. Session 8: coping with ruminations, obsessions and worrying. Session 9: expressive writing. Session 10: assertive communication.

There were two different treatment conditions following the same protocol, individual and group formats, and a third condition for TAU. Differences between both groups were the number of participants (8 to 10 patients for the group intervention) and session length (an hour for the individual form and two hours for group therapy sessions). Because this psychotherapy program is strongly structured and patient participation is emphasized and focused on the task, the interactions among the patients are limited. Groups started the intervention program after randomization and allocation had assigned an appropriate cohort of at least 8 patients to the group. Patients were assessed at 4 time points: baseline, post-treatment, 6 and 12 months after finishing the treatment.

Measurements

The Standardized Polyvalent Psychiatric Interview (SPPI) [20]. It is a semi-structured psychiatric interview designed by our group to diagnose psychiatric morbidity in primary care settings. It was built on the Clinical Interview Schedule and is intended to evaluate patients in a multiaxial system: psychopathology, including duration and severity of disorder; somatic disturbance; social problems and social support: and pre-morbid personality. It generates DSM-IV and ICD-10 psychiatric diagnosis. If the overall score of any of these sections is equal to or greater than 2, it is considered a "psychiatric case". We used the Spanish adaptation of somatic symptoms module to elicit medically unexplained physical symptoms and to diagnose somatoform disorders.

The Othmer and DeSouza test [18] was used as a screening tool. It is a procedure by which the clinician can assess the presence of somatization disorder by asking for the presence of seven symptoms, three of which must be present for a preliminary diagnosis of somatization disorder. The Spanish validation (García-Campayo, 1996) reported 88% sensitivity, 78% specificity, and 80% positive predictive value with a threshold of three symptoms [23].

The 36-Item Short-Form Health Survey (SF-36) [24] consisting of 36 items included in long-form measures developed for the Medical Outcomes Study. The SF-36 includes one multi-item scale that assesses eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. The Spanish validation of SF-36 has good psychometric properties [25].