Journal of Psychosomatic Research 84 (2016) 37–43

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

Developmental study of treatment fidelity, safety and acceptability of a Symptoms Clinic intervention delivered by General Practitioners to patients with multiple medically unexplained symptoms

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ARTICLE INFO

Article history:
Received 14 October 2015
Received in revised form 11 March 2016
Accepted 12 March 2016

Keywords:
Medically unexplained symptoms
Observational study
Intervention
Primary care

ABSTRACT

Background: There is a need for primary care interventions for patients with multiple medically unexplained symptoms (MUS). We examined whether GPs could be taught to deliver one such intervention, the Symptoms Clinic Intervention (SCI), to patients. The intervention includes recognition and validation of patients' symptoms, explanation of symptoms and actions to manage symptoms.

Methods: We conducted an uncontrolled observational study in Northeast Scotland. GPs were recruited and received two days of structured training. Patients were identified via a two stage process (database searching followed by postal questionnaire) and received the SCI intervention from a GP in their practice.

Treatment fidelity was assessed by applying a coding framework to consultation transcripts. Safety was assessed by examining changes in patient symptoms (PHQ-15) and checking for unexpected events. Acceptability was primarily assessed by patient interview.

Results: Four GPs delivered the SCI to 23 patients. GPs delivered all core components of the SCI, and used the components flexibly across the consultations and between patients. They spent more time on recognition than either explanation or actions components. 10 out of 17 patients interviewed described feeling validated, receiving useful explanation and learning actions. 9 out of 20 patients (45%) reported an improvement in PHQ-15 of between 3 and 8 points. Patients who reported the most improvement also described receiving all three components of the intervention.

Conclusions: GPs can be taught to deliver the SCI with reasonable fidelity, safety and acceptability, although some items were inconsistently delivered: further training would be needed before use.

1. Introduction

Persistent physical symptoms which cannot be adequately explained by organic disease, so-called medically unexplained symptoms (MUS), are a common and important cause of ill health and healthcare use. MUS are extremely common in patients attending general practitioners [1]. While the majority of symptoms are self-limiting and mild, approximately 2% of adults experience repeated and persistent MUS which are associated with impaired quality of life [2] and increased healthcare demand [3] which many doctors have limited skills to address [4].

Despite the title, most MUS can be adequately explained in terms of biological and psychological processes. Several models have been proposed with recent interest focusing on the neurobiological model of central sensitisation [5]. Processes of symptom generation may be affected by past or recent emotional events and by tendencies to worry about or be demoralised by symptoms. A number of classifications have been proposed for multiple MUS though none is in widespread use outside of specialist practice. The most recent, DSM-5 Somatic Symptom Disorder [6], includes the experience of multiple symptoms, and while it no longer requires that symptoms are unexplained by disease, it does stipulate that they must be accompanied by excessive concern, worry or help-seeking.

While there is evidence for modest effectiveness of psychological interventions for MUS in specialist settings [7], there is currently no strong evidence for effectiveness of treatment for patients with multiple MUS in primary care. Our earlier Cochrane systematic review found no benefit from very brief interventions but raised the possibility that moderately intensive interventions — approximately two hours of consultation time — might have value [8]. We recently developed the Symptoms Clinic Intervention (SCI) — a GP with Special Interest intervention for patients with multiple physical symptoms — as a moderate intensity intervention to be delivered by a specially trained primary care physician [9].

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http://dx.doi.org/10.1016/j.jpsychores.2016.03.008
0022-3999/

The SCI is based on the premise that patients with symptoms value the following: being listened to and understood; constructive explanations which make sense of their symptoms; and support in living with their symptoms [10–12]. It builds on the reattribution model [13] in three ways – by using more time (similar to other moderate intensity interventions [14]), by expanding the language of explanations for symptoms, specifically avoiding simple psychosomatic causal links [4,15,16], and by emphasising management of symptoms as problems in their own right with direct impacts on quality of life.

An earlier pilot trial had indicated potential benefit from the SCI [9]. We conducted this study as step on the route to a definitive evaluation of the SCI in a randomised controlled trial. In it we aimed to teach the SCI to a new group of GPs, then evaluate their delivery of this intervention to patients under observation. In reporting the study we have selected the outputs for reporting according to the IDEAL [17] model for intervention development (in this case the study could be considered primarily as stage 2a Development). As such, the emphasis in this manuscript is on the delivery of the intervention and the outcomes focus on procedural fidelity, safety, and basic acceptability to patients. This study did not aim to generate generalisable data about efficacy.

In this report we concentrate on three questions: (1) Did GPs deliver the intervention with sufficient fidelity? (2) Was delivery "safe" i.e. were short term outcomes in the direction expected with no unintended consequences? (3) Was the intervention acceptable to patients in terms of satisfaction and absence of complaint?

2. Methods

2.1. Study design

This was an observational study designed to assess whether, after training, GPs could deliver the Symptoms Clinic Intervention to patients with multiple medically unexplained symptoms in their practices. Appropriate permissions were obtained from the NorthEast Scotland Research Ethics Services (14/NS/1014).

2.2. Symptoms Clinic Intervention

The SCI comprises a structured series of three or four consultations over a period of approximately six-eight weeks by a GP. The SCI is comprised of four key elements: *Recognition*, *Explanation*, *Action* and *Learning*. The first consultation lasts around 50 min and focuses on *Recognition*, which centres on eliciting and actively listening to the patient's description of their illness and its consequences on daily living. Successful recognition aims to validate the individual, may have "healing potential" in itself [18] and is important for improving symptom appraisal and active coping behaviour. In the latter part of this first consultation, and in the subsequent shorter (15–20 min) consultations, there is a focus on negotiating *Explanations* for symptoms in terms of biological and psychological mechanisms [15] and adaptations and proposing *Action* in terms of symptom control and management techniques which are coherently linked to the explanation. Throughout the consultations the doctor and patient reflect and *Learn* what makes sense and is helpful. A range of consultation techniques linked to these components were presented at the training days and were detailed in a training manual (available on request from corresponding author) that all GPs received; GPs were encouraged to use those techniques that they thought appropriate on a case-by-case basis.

2.3. Study participants

2.3.1. GPs

We recruited GPs from Northeast Scotland by mail, followed by personal contact from the research team. Initial training was conducted in a group setting over two days and comprised a mixture of didactic teaching, discussion and role play. The training sessions were led by the study investigators and were designed to provide GPs with information about symptoms and the experience of multiple ("medically unexplained") symptoms and practical training on the key components of the SCI (detailed above). Participating GPs also received two sessions of follow up training, delivered on a one-to-one basis. These follow-up sessions were designed to allow GPs to raise any concerns related to their delivery of the intervention or about particular patients during the course of the study.

2.3.2. Patients

We used the same practice database search strategy as the pilot trial of the SCI [9] to systematically identify adults aged 18 or over with multiple symptoms using a combination of diagnostic and referral criteria. The criteria were (a) at least one diagnostic code indicative of a functional somatic syndrome (e.g. tension headache, chronic fatigue syndrome, irritable bowel syndrome) in the electronic record; (b) at least two referrals for diagnostic investigation or specialist opinion in the preceding three years. These criteria were developed following an epidemiological study which showed that patients with repeated referrals and MUS had significantly impaired quality of life and increased healthcare costs [2,19]. As practice searches were conducted after recruitment and training of the GPs, we needed to relax the patient criteria in two practices in order to invite sufficient patients. In one practice, few syndrome diagnoses were coded: we therefore included patients meeting the referral criteria and with functional syndrome diagnoses recorded elsewhere in the records. In the other (a rural practice), coded diagnoses were present but the GPs reported actively seeing patients for extra appointments rather than referring: we permitted patients to be included who did not meet the specialist referral criteria. Within each practice, patients were sequentially invited in batches until 6 patients for that practice had been recruited or all potential patients had been invited.

Participating GPs screened the list of identified patients to exclude patients in whom symptoms were likely to be due to, or confounded by, other conditions (e.g. cancer, diabetes, rheumatoid arthritis); who required significant assistance with daily living (as such patients were likely to require more intensive treatment than that provided); were currently undergoing active multidisciplinary rehabilitation or psychological treatment; or for whom participation would be inappropriate (e.g. recent bereavement or complaint about treatment). Remaining patients were sent an invitation letter from the practice with information about the study, the Patient Heath Questionnaire-15 (PHQ15) [20] which was used as a screening measure, and a reply form. Respondents whose PHQ15 was ≥10 (indicative of at least moderate MUS), were contacted by phone to discuss the study further and to again check the exclusion criteria (see above). Those who met the inclusion criteria and who were interested in taking part in the study completed enrolment. This consisted of giving written informed consent and self-completion of baseline outcome measures immediately before their first SCI consultation.

2.4. Data collection

2.4.1. Qualitative data

GPs audio-recorded the SCI consultations for subsequent analysis. Patients were also asked to participate in a brief follow-up interview approximately two weeks after their final SCI appointment. This semi-structured interview explored patients' perceptions of the consultations, the explanations discussed for their symptoms, and the actions negotiated to reduce the impact of symptoms on daily living. These interviews were carried out over the telephone by a member of the research team, audio-recorded and transcribed.

2.4.2. Outcome measures

Patients completed the PHQ-15, PHQ-9 measure of depressive symptoms [21], GAD-7 [22] measure of anxiety and EQ-5D-5L [23]