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

RUNNING HEAD: GPs' delivery of the Symptoms Clinic Intervention

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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 North East 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 symptom (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.

Keywords: medically unexplained symptoms, observational study, intervention, primary care

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].

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?

Methods

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.

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 minutes 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 minute) 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.

Study Participants

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.

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 Health 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.

Data Collection

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.

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] questionnaires at baseline and again approximately two weeks after their final appointment (6-10 weeks after baseline for patients having 3-4 appointments). The final questionnaire pack was returned by post to the research team. The PHQ-15, PHQ-9 and GAD-7 were chosen to permit comparison between this study and the pilot trial. Additionally, patients completed a 7-point Patients' Global Impression of Change measure (PGIC), as well as a Client Satisfaction Questionnaire (CSQ) at follow-up.

Data analysis

Fidelity of intervention delivery

We classified consultation content using a checklist in order to examine whether the trained GPs delivered the key components of the SCI. We developed the content checklist by thematically coding the consultation transcripts from the previous pilot trial. The content checklist comprised detailed codes grouped into *Recognition*, *Explanation*, and *Action* clusters, representing three parts of our underlying model. The fourth part of the model, *Learning*, was always linked to either *Explanation* or *Action* so was not coded separately. An additional *Other* cluster was used for coding non-core

components of the intervention (e.g. social chit-chat, description of the study, etc.). Table 1 lists the specific content items by category.

For each consultation we measured time spent on each content item. As codes sometimes overlapped or ran in parallel, we listed all codes occurring in each 5 minute segment of the consultation and divided the time equally between them, rather than try to partition time more specifically.

Safety of delivery

The purpose of this study was not to statistically compare outcomes with other studies but to check that the direction of change was as anticipated. For PHQ-15, EQ-5D, PHQ-9 and GAD-7 we calculated means and standard deviations at baseline and follow-up. We examined the transcripts of consultations and interviews for evidence of patients reporting unexpected events or unintended consequences. In the previous pilot trial, the mean reduction in PHQ-15 was 3.2 points. While there are no published minimally clinically important differences for this measure, in the pilot trial a change of 3 or more points was associated with an improvement of between one and two levels on the Patient Global Impression of Change suggesting that this change is likely to be clinically meaningful.

Acceptability of the Intervention

We analysed the content of the follow-up interviews using a framework approach focusing on three components: *recognition* - whether patients felt listened to and validated, whether patients received useful *explanation* of their symptoms, and whether they had learned new *actions* to manage symptoms (or reinforced existing ones). Two investigators repeatedly read the transcripts and discussed features which indicated whether these had been achieved or not. Both then independently graded each interview to assess the presence or absence of each of the three components and resolved differences by discussion. We also assessed the number of patients who rated the intervention positively and negatively on the CSQ.

Results

Recruitment & Participation

We approached 76 practices. Eleven GPs from nine practices expressed initial interest. Five of these GPs were able to schedule their work to allow them to take part in the study and complete the training. Two GPs withdrew from the study following training due to changes in personal circumstances and a sixth was recruited, giving a total of four GP participants. Three of the four GPs who delivered the intervention to patients in their practices were female and had more than 15 years' experience of general practice. The remaining, male, GP had less than 5 years post-training experience. Practices ranged in size from 5574 to 16814 registered patients and were in rural / semi-rural towns in Northeast Scotland. Although GPs saw patients from their own group practice, the intervention was not typically delivered in the context of a long-term GP-patient relationship: only one patient regarded the trained GP as a familiar doctor.

We aimed for GPs to deliver the intervention to six patients in their practices; this sample size was chosen to demonstrate fidelity to the SCI. The searches identified a total of 180 patients (21-89 per practice), 11 of whom were excluded by the participating GPs prior to invitation. In practices with low rates of coding or referrals, GPs identified seven additional patients who met entry criteria. Of

the 176 potential patients, 137 were invited from the four practices, of whom 59 returned the expression of interest form and PHQ-15 screening measure (43%). Forty-four of these patients were eligible based on their PHQ-15 score (75% of interested patients). We scheduled enrolment appointments with 24 patients on a first come basis; however, one did not attend their appointment and 23 patients therefore enrolled in the study. All enrolled patients attended their first SCI appointment and 18 (78%) received three or four appointments in total. This is shown in detail in Figure 1.

Patient Characteristics

Patient ages ranged between 24 and 78 (mean = 51.3, standard deviation 12.7) and 21 (91%) were female. Eleven were currently employed, 5 were retired, 3 were unemployed or unable to work, 3 were at home and one was a student. Main reported limiting symptoms (up to 2 per patient, grouped according to recently proposed categories [24]) were general (fatigue, dizziness, headache etc.) 15; musculoskeletal, 14; gastro-intestinal, 6; cardiopulmonary, 4; mental (depression, stress), 3 and not specified, 4.

Patients' baseline measures are shown in Table 2. Eleven patients had PHQ-15 scores indicative of medium somatic symptom severity (score of 10-14) at baseline, while 12 patients had a score indicative of high somatic symptom severity (score ≥ 15). Based on baseline GAD-7 and PHQ-9 scores, over half of patients (n=14) had mild to severe anxiety, 11 patients had mild-moderate depressive symptoms and five had more severe depressive symptoms. Medical case notes were not reviewed and we did not attempt to determine whether these patients had formal clinical diagnoses of anxiety or depression.

Intervention Fidelity

Figure 2 illustrates the average time per patient that was allocated to the components of the intervention, separated by initial consultation and total subsequent follow-up consultations. As expected, the majority of the initial consultation was spent on *Recognition*, with little explanation or symptom management. Two of the GPs chose to use the entirety of the first consultation to listen to the patients' accounts of their illnesses and build rapport, and did not bring *Explanation* or *Action* into the first consultation. In the follow up consultations, GPs spent more time on the *Explanation* and *Action* components, including suggesting and reviewing symptom control strategies. Although the manual included techniques for challenging unhelpful beliefs about symptoms, GPs used these infrequently.

Intervention Safety – Outcome measures

We collected outcome measures for 20 (87%) patients. This data is summarised in Table 2. Despite postal and telephone reminders, we were unable to collect follow-up questionnaires for the remaining three patients. 14 out of the 20 patients reported at least one level of improvement out of seven on the Patient Global Impression of Change measure.

The mean PHQ15 change was broadly equivalent to those reported in the pilot trial, however there was considerable variation between individuals (range -8 to +6 (negative scores indicate improvement): 5 patients reporting an improvement of 6 or more points and 4 of 3-4 points. 5 patients reported no change; the one worse score was the same as at initial screening, but higher than at entry. The three patients with very high baseline scores (≥ 20) showed no change in PHQ15.

We found no major unexpected changes in physical or mental health. One patient developed worsening sciatica on a background of non-specific back pain and was referred to a spinal surgeon,

another developed new, possibly cardiac, symptoms and was referred to a cardiologist. In both cases there was nothing from the consultation transcripts to suggest serious medical conditions were overlooked,

Intervention Acceptability - patient interviews & satisfaction

We held follow-up interviews with 17 (74%) patients. Table 3 contains example quotes relating to recognition, explanation, and symptom management with short interpretive comments. Recognition included not just the GP listening more, but being perceived as understanding the patient better. Explanations were described as being accepted as new information which was required to be integrated with existing knowledge and experience. No patient described explanations in terms of transforming their knowledge and some challenged or rejected explanations in contests of authority [25]. Relatively few patients described GPs suggesting ways of managing symptoms beyond simple pacing or graded activity, although some described learning and adopting new symptoms management strategies. In two cases, recommendations for graded activity and simple pacing were interpreted as un-original, unrealistic, or as implying laziness.

From the interviews we assessed 13 patients as reporting recognition and 4 not. Of those reporting recognition, explanation was clearly or implicitly described by 10. All the patients with PHQ-15 improvements of 6 or more points and for whom there was an interview described all three of recognition, explanation and symptom management at interview.

Patients rated the SCI positively on the CSQ. All 20 patients who completed the CSQ rated the care they received as good or excellent; 4 indicated that it had not helped them to deal with their problems more effectively.

Discussion

Summary of Main findings

The training resulted in GPs being able to deliver the SCI with reasonable fidelity, although there was room for improvement in explanation and action components. 10 out of 17 interviewed patients perceived the intervention as delivering all three core components and 9 out of 20 reported an improvement in PHQ-15 of between 3 and 8 points. The study found no safety concerns with the intervention, which was acceptable to the majority of participants. This demonstrates that the SCI can be delivered, but that future training will need to be longer than 2 days and include more work, especially on explanation and action components.

Strengths and limitations

This study used a previously developed pathway for identifying potential participants and this resulted in the intervention being delivered to patients who had multiple MUS with moderate to moderately severe symptoms (most patients had a PHQ15 score between 10 and 20). None of the GPs trained in this study had prior experience of interventions for MUS.

The issue of fidelity to treatment is important in delivering consultation interventions but is challenged by the heterogeneity of patients with multiple MUS which is seen in practice and the array of possible components within the SCI. Careful classification, and timing of the use of, intervention components meant that we were able to map use of key components, even when the exact content varied to match the individual patients. The allocation of components to 5 minute blocks of time introduced some imprecision, but it permitted sections of consultations where several

components overlapped to be coded simply; given the overall length of the intervention, minor details on timing are unlikely to have been important. The tools for mapping content can be used in future studies of the SCI to ensure fidelity to the overall model.

We found some deviation from the intended SCI model in that some doctors used the whole first consultation for information gathering and rapport building rather than proposing explanations. While this may have slightly reduced the potential for benefit, their patients kept subsequent appointments. In contrast, one GP often moved quite quickly to proposing explanation and action within the first consultation and this appeared to be associated with lower satisfaction, less adherence to follow up and less improvement in symptoms at follow up. Two potential concerns with the delivery of the intervention in this study are that, unlike CBT, there was relatively little challenging of patient beliefs and there were relatively few examples at interview of actions which patients had taken and put into practice. Given the importance of challenge or exposure during treatment and of consolidating behaviour change, these aspects will require additional focus in future intervention development and training.

The study raises a number of issues regarding future trials and generalisability of this intervention. Firstly the lack of change in PHQ-15 in all three patients whose baseline value was above 20 suggests an upper threshold of severity for this moderate intensity intervention. Secondly in this study only 2 (9%) were male. Data from other studies suggest that approximately 35% of the target population are male [2] so this raises questions about identification or acceptability. However, in our previous study of the same intervention [9] 11/32 (34%) participants were male so we suspect that the low level of participation in males in this study was the result of either local contextual factors or differences in coding by GP practices which influenced the search strategy. Overall 37/137 (27%) invited patients were eligible and willing to participate (although places were only available for 23), which we regard as sufficient to indicate that if the intervention was available and recommended in routine practice it would be generalisable.

We were limited by circumstances of practice size and time, a relatively small number of patients, and to short follow up. As expected, the yield of computer searches, and with it the number of potentially eligible patients, varied between practices. In a trial, the effects of such uncontrollable variation would be limited by randomisation of individual patients within practices, however this was not a controlled study and so is not suitable for making generalisable conclusions about outcomes. As we were committed to recruiting patients from the GPs' own practices for this study we needed to relax the entry criteria around coded diagnoses and referrals but would avoid this in a definitive trial.

Relationship to other research

The SCI is a moderately intensive intervention and as such is similar to the extended treatment model described in two European trials [14,26] but very different from attempting treatment within the constraints of routine 10 minute consultations. In many ways the intervention was similar to the enhanced medical consultation model used as a control intervention in a recent trial of psychodynamic interpersonal therapy[27], however the SCI also includes specific explanation components which are not present in other interventions; unlike the enhanced medical consultation the SCI appears to have a clinically meaningful effect on reported symptoms (mean change in PHQ15 of 3 points for SCI compared to <1 for enhanced medical consultation).

Support for the importance of explanation comes from a recent review of the effects of emotional and cognitive reassurance in primary care studies [28], which showed that to be effective

reassurance must contain cognitive components – such as explanation. One other treatment model has emphasised explanations [29]. However this used a limited repertoire of explanations in relation to stress and stress hormones – whereby emotional distress was experienced as physical symptoms mediated through stress biology [30]. In contrast, the SCI does not require emotional distress for causation, rather it permits it to be included as a consequence, cause or mediator- or even left out completely if the patient wishes – without invalidating the model. We believe that the high rates of acceptance of explanations and willingness to move on to symptom control indicate the acceptability of the explanations within the SCI.

Implications for practice, policy and research

GPs currently lack the confidence and skills to manage medically unexplained symptoms effectively [4] and specialist services rarely achieve more than temporary reassurance for patients by excluding disease [31]. Additionally, previously developed brief approaches for GPs within ordinary consultations, have been found to be ineffective [8]. The Symptoms Clinic Intervention is a constructive and generalisable alternative which has the potential to substantially reduce patients' symptoms and their impact on daily living and subsequently on healthcare use. Studies are now needed to test its medium to long term effectiveness in reducing symptoms and to examine the potential for savings due to reduced demand for disease centred diagnostic investigations and treatments.

Conclusion

The Symptoms Clinic Intervention is a promising intermediate care intervention for patients with multiple medically unexplained symptoms / somatic symptom disorder. GPs can be taught to deliver it with reasonable fidelity, safety and acceptability; further training would will need to be longer than that used here and focus more on symptom explanation and management.

Conflict of Interest

The authors declare no conflict of interest.

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References

1. Taylor RE, Marshall T, Mann A, Goldberg DP. Insecure attachment and frequent attendance in primary care: a longitudinal cohort study of medically unexplained symptom presentations in ten UK general practices. *Psychol Med* 2012;42:855-864.
2. McGorm K, Burton C, Weller D, Murray G, Sharpe M. Patients repeatedly referred to secondary care with symptoms unexplained by organic disease: prevalence, characteristics and referral pattern. *Fam Pract* 2010;27:479-486.
3. Verhaak PF, Meijer SA, Visser AP, Wolters G. Persistent presentation of medically unexplained symptoms in general practice. *Fam Pract* 2006;23:414-420.
4. Olde Hartman TC, van Rijswijk E, van Dulmen S, van Weel-Baumgarten E, Lucassen PL, van Weel C. How patients and family physicians communicate about persistent medically unexplained symptoms. A qualitative study of video-recorded consultations. *Patient Educ Couns* 2013;90:354-360.
5. Bourke JH, Langford RM, White PD. The common link between functional somatic syndromes may be central sensitisation. *J Psychosom Res* 2015;78:228-236.
6. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. Washington, DC: American Psychiatric Association 2013.
7. Van Dessel N, Den Boeft M, van der Wouden Johannes C, Kleinstäuber M, Leone Stephanie S, Terluin B, et al. Non-pharmacological interventions for somatoform disorders and medically-unexplained physical symptoms (MUPS) in adults. 2014.
8. Rosendal M, Blankenstein A, Morriss R, Fink P, Sharpe M, Burton C. Enhanced care by generalists for functional somatic symptoms and disorders in primary care. *Cochrane Database of Systematic Reviews* 2013;10:CD008142.
9. Burton C, Weller D, Worth A, Marsden W, Sharpe M. A primary care symptoms clinic for patients with medically unexplained symptoms: pilot randomised trial . *BMJOpen* 2012;2:000513.
10. Dowrick CF, Ring A, Humphris GM, Salmon P. Normalisation of unexplained symptoms by general practitioners: a functional typology. *Br J Gen Pract* 2004;54:165-170.
11. Giroldi E, Veldhuijzen W, Mannaerts A, Van Der Weijden T, Bareman F, Van Der Vleuten C. "Doctor, please tell me it's nothing serious": An exploration of patients' worrying and reassuring cognitions using stimulated recall interviews. *BMC Family Practice* 2014;15.
12. Salmon P, Dowrick CF, Ring A, Humphris GM. Voiced but unheard agendas: qualitative analysis of the psychosocial cues that patients with unexplained symptoms present to general practitioners. *Br J Gen Pract* 2004;54:171-176.
13. Gask L, Dowrick C, Salmon P, Peters S, Morriss R. Reattribution reconsidered: narrative review and reflections on an educational intervention for medically unexplained symptoms in primary care settings 1. *J Psychosom Res* 2011;71:325-334.

14. Blankenstein AH, Van dH, Schilte AF, de Vries D, Zaat JO, Andre KJ, et al. Development and feasibility of a modified reattribution model for somatising patients, applied by their own general practitioners. *Patient Educ Couns* 2002;47:229-235.
15. Burton C, Lucassen P, Aamland A, Hartman TO. Explaining symptoms after negative tests: towards a rational explanation. *J R Soc Med* 2015;108:84-88.
16. Burbaum C, Stresing AM, Fritzsche K, Auer P, Wirsching M, Lucius-Hoene G. Medically unexplained symptoms as a threat to patients' identity? A conversation analysis of patients' reactions to psychosomatic attributions. *Patient Educ Couns* 2010;79:207-217.
17. McCulloch P, Cook JA, Altman DG, Heneghan C, Diener MK, IDEAL Group. IDEAL framework for surgical innovation 1: the idea and development stages. *BMJ* 2013;346:f3012.
18. Lind AB, Delmar C, Nielsen K. Searching for existential security: A prospective qualitative study on the influence of mindfulness therapy on experienced stress and coping strategies among patients with somatoform disorders. *J Psychosom Res* 2014;77:516-521.
19. Burton C, McGorm K, Richardson G, Weller D, Sharpe M. Health care costs incurred by patients repeatedly referred to secondary care with medically unexplained symptoms: a case control study. *J Psychosom Res* 2012;72:242-247.
20. Kroenke K, Spitzer RL, Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. *Psychosom Med* 2002;64:258-266.
21. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-613.
22. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-1097.
23. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-1736.
24. Budtz-Lilly A, Fink P, Ornbol E, Vestergaard M, Moth G, Christensen KS, et al. A new questionnaire to identify bodily distress in primary care: The 'BDS checklist'. *J Psychosom Res* 2015.
25. Wileman L, May C, Chew-Graham CA. Medically unexplained symptoms and the problem of power in the primary care consultation: a qualitative study. *Fam Pract* 2002;19:178-182.
26. Larisch A, Schweickhardt A, Wirsching M, Fritzsche K. Psychosocial interventions for somatizing patients by the general practitioner: a randomized controlled trial. *J Psychosom Res* 2004;57:507-514.
27. Sattel H, Lahmann C, Gundel H, Guthrie E, Kruse J, Noll-Hussong M, et al. Brief psychodynamic interpersonal psychotherapy for patients with multisomatoform disorder: randomised controlled trial. *Br J Psychiatry* 2012;200:60-67.
28. Pincus T, Holt N, Vogel S, Underwood M, Savage R, Walsh DA, et al. Cognitive and affective reassurance and patient outcomes in primary care: a systematic review. *Pain* 2013;154:2407-2416.

29. Aiarzaguena JM, Grandes G, Gaminde I, Salazar A, Sanchez A, Arino J. A randomized controlled clinical trial of a psychosocial and communication intervention carried out by GPs for patients with medically unexplained symptoms. *Psychol Med* 2007;37:283-294.
30. Aiarzaguena JM, Gaminde I, Clemente I, Garrido E. Explaining medically unexplained symptoms: Somatizing patients' responses in primary care. *Patient Educ Couns* 2013;93:63-72.
31. Rolfe A, Burton C. Reassurance After Diagnostic Testing With a Low Pretest Probability of Serious Disease: Systematic Review and Meta-analysis. *JAMA Intern Med* 2013;173:407-416.

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Table 1, Symptom Clinic Intervention (SCI) component categories and items used to check content of audio-recorded SCI consultations

Category	Item description
Recognition <i>Doctor hears, seeks to understand and validates patient experience. Doctor recognises symptoms as within area of authority.</i>	<ol style="list-style-type: none"> 1. Active listening to patient's account 2. Elicits / discusses patient's perspective of their health/symptoms 3. Elicits / discusses patient's mental state (past or present) or coping style 4. Elicits / discusses impact of symptoms on daily life & activities 5. Elicits / discusses impact of symptoms on social and emotional aspects of life 6. Elicits / discusses thoughts and feelings about previous tests and treatment 7. Elicits / discusses patient's ideas on symptom triggers/patterns/warning signs
Explanation^a <i>Doctor explains symptoms in terms of adaptive or other processes.</i>	<ol style="list-style-type: none"> 1. Proposing and negotiating 1st explanation 2. Proposing and negotiating 2nd explanation 3. Proposing and negotiating 3rd or more explanation 4. Checks how explanation is received
Action <i>Doctor proposes and negotiates symptom management strategies.</i>	<ol style="list-style-type: none"> 1. Elicits information about current action to manage symptoms / impact 2. Proposes new action to manage symptoms / impact 3. Negotiates new specific tasks relating to lessening impact of symptoms 4. Reviews actions to manage symptoms / impact 5. Challenges thoughts / attitudes / beliefs / diagnostic labels
Learning <i>Doctor & patient reflect on use of explanation and action in practice.</i>	Reliable discrete codes for this were difficult to develop. Learning appeared as part of both explanation and action and is included in item 4 of each of these.

^a Explanation items do not include detailed explanation content as this was coded using a separate explanation taxonomy

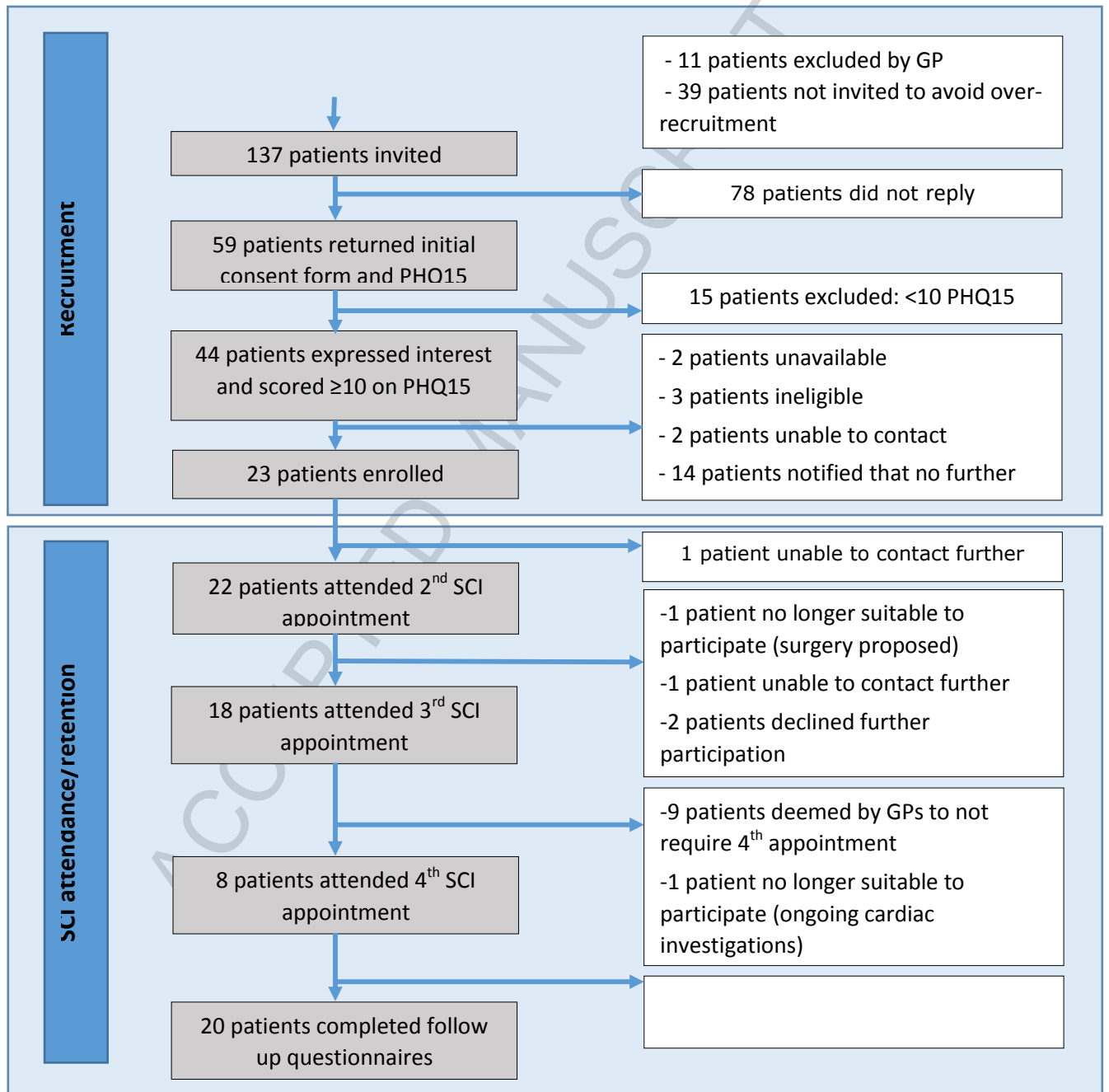


Figure 1, Recruitment and retention of patients from participating practices

180 patients from computer search + 7 from hand search

Table 2 Baseline measures for all enrolled patients; baseline and follow up measures for those who completed outcome measures

	All Enrolled Patients (N=23)		Patients who Completed Outcome Measures (N=20)			
	Baseline		Baseline		Follow up	
	Mean	SD	Mean	SD	Mean	SD
<i>PHQ-15</i> ^a	15.83	(4.46)	15.80	(4.72)	12.95	(6.45)
<i>EQ5D-5L Index</i> ^b	0.49	(0.26)	0.51	(0.25)	0.48	(0.30)
<i>EQ5D-5L Health Today</i> ^c	53.57	(16.46)	54.10	(17.34)	61.35	(25.33)
<i>PHQ-9</i> ^d	10.22	(6.03)	9.85	(5.52)	8.95	(6.94)
<i>GAD-7</i> ^e	7.13	(5.83)	6.55	(5.47)	5.05	(5.62)

^a Patient Health Questionnaire-15 measure of symptom severity

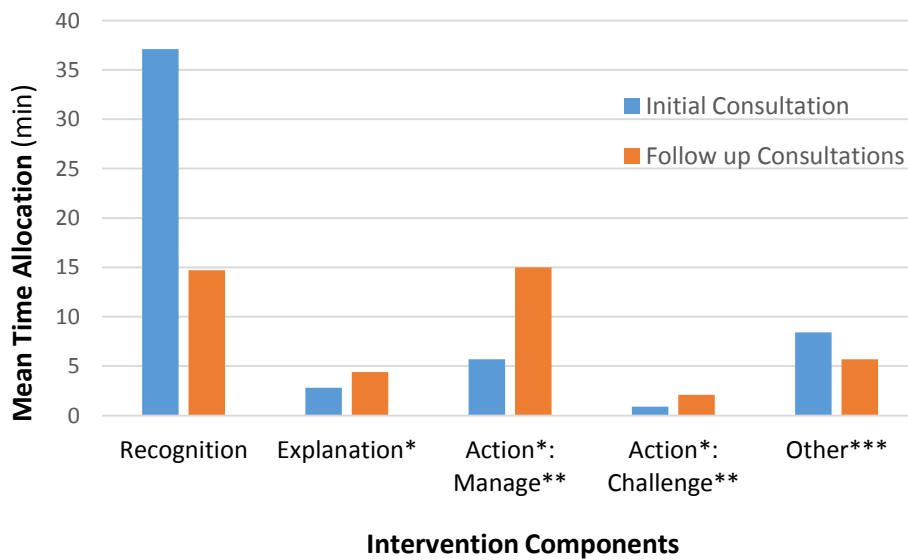
^b EuroQol 5 Dimensions 5 Levels measure of health-related quality of life

^c EuroQol 5-Dimensions 5Levels visual analogue scale of perceived health

^d Patient Health Questionnaire-9 measure of depressive symptoms

^e Generalised Anxiety Disorder Questionnaire-7

Figure 2, Mean time in minutes allocated to intervention components in the initial consultations and during total follow up consultations per patient



* Learning is included with Explanation and Action rather than reported separately

** Manage refers to discussion of specific actions to manage symptoms; Challenge refers to addressing patient's unhelpful thoughts/attitudes/beliefs about their symptoms

***Non-core components, e.g. study description, consultation admin, social chit-chat

Table 3, Example quotations from follow up patient interviews (with commentary) grouped by component of the Symptoms Clinic Intervention

Example Quotations	Comments
<p>Recognition</p> <p>I'd found someone who actually listened to me, it was Dr F obviously, and she's very helpful and she seemed to understand what I was talking about ... she seemed to understand what was going on. P614</p> <p>Because you get that extra time to express yourself, somebody genuinely wants to listen to help you that you don't usually feel that often from GP appointments, and yeah, you tend to get to the root of the problem and the cause. I would definitely recommend it. P423</p> <p>I thought that it was really good. I thought it really, really helped just sort of being able to talk over everything and having someone that bit more trained in sort of long term conditions, like, who actually knew sort of more in depth what they were talking about. P143</p>	<p>Participants used emphatic speech to describe the doctor listening (e.g. "genuinely wants to listen"). They described feeling understood by the doctor, and in the third example particularly, the understanding appears to include medical understanding of the condition as well as empathic understanding of the patient's predicament.</p>
<p>Explanation</p> <p>... if you don't know what fibromyalgia is and why it's occurring and all the different aspects of it, you wonder what the heck's happening to you, so if you can get somebody to say 'well that's because of that' I think it helps you deal with the problem. It's always better to know what you're dealing with. P606</p> <p>Because, as I say, it gave me an insight, a more understanding in what was going on with my body and what the outcome is likely to be, [the relaxation technique suggested by GP] is sort of... not necessary but it helps you, you know, even just the understanding of what's going on is mind settling.P614</p> <p>I think I had already quite a good understanding of my conditions and the symptoms that I have. I really didn't feel that I got anything new in that respect. I understood the concept of the clinic and I understood where the rationale was coming from, but I didn't feel that it particularly met my own symptoms and conditions. P418</p>	<p>Participants described explanation as providing new information which they integrated with information they already held. Information was described as having a purpose beyond knowledge – either helping deal with a problem or rationalising symptom control techniques.</p> <p>Some patients felt they did not gain new knowledge and were not helped.</p>
<p>Action & Learning</p> <p>'cause it's certainly helped me ... the fact that you can actually do it yourself as well by breathing and doing your muscle relaxation, some people might think 'oh no it doesn't work', it does, but you have to be able to remember that it's there and you're responsible for it. It's not just going to be a sudden quick fix like a pill or something like that, it does take time to get used to breathing and then the muscle relaxation things, but the more you do it the more automatic it seems to become. P126</p> <p>Well, I think it's more about anxiety and getting out and about and trying to exercise more. I didn't find overall that it was terrible helpful in that way except that it has led to other things whereby I can move forward I hope. P145</p> <p>Well that's what I'm saying... how could I put it... I don't know, I felt as if Dr D was maybe thinking I was getting a bit lazy or something like that, you know, which definitely I'm not that type of person, I'm not a lazy person, you know, I felt quite uncomfortable with that. He never actually said that, you know what I mean, but I just felt that within</p>	<p>Behaviour changes were typically described as incremental and modest. Positive accounts included elements of learning (e.g. applying a technique for one situation in another) or of reward through perseverance.</p> <p>More neutral accounts were constructed in a way which acknowledged the possibility of benefit while avoiding self-blame.</p> <p>This negative account indicates that the patient perceived blame in the GP's approach.</p>

myself, you know. P429	
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Highlights

- Experienced GPs were trained to deliver the Symptoms Clinic Intervention to patients
- This developmental study assessed fidelity, safety and acceptability of delivery
- The recognition component received most time, explanation and action received less.
- Patients who benefitted most described receiving all three components.

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