

**Novel primary care treatment package for patients with Medically Unexplained  
Symptoms – a cohort intervention study**

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***Frank Röhricht<sup>1,2</sup>, Ivan Zammit<sup>1</sup>, & Nina Papadopoulos<sup>1</sup>***

<sup>1</sup>*East London NHS Foundation Trust*

<sup>2</sup>*University of Essex*

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**Address for Correspondence:**

Professor Frank Röhricht, *MD FRCPsych*  
Newham Centre for Mental Health  
East London NHS Foundation Trust  
Glen Road, Cherry Tree Way  
London E13 8SP  
[frank.rohricht@elft.nhs.uk](mailto:frank.rohricht@elft.nhs.uk)  
[frhricht@essex.ac.uk](mailto:frhricht@essex.ac.uk)

## Abstract

### *Background:*

Existing care models for patients with persistent Medically Unexplained Symptoms (MUS) do not adequately address the needs of these patients. New and innovative intervention strategies are necessary to achieve better health and corresponding economic outcomes.

### *Aim:*

To explore the feasibility of implementing a pragmatic care package that provides Primary Care treatment for patients with persistent MUS and to evaluate recruitment, retention and acceptability as well as the potential impact on clinical outcomes and service utilisation.

### *Design and setting:*

Prospective cohort intervention study involving a cluster of GP surgeries providing a “One-Stop-Shop” primary care treatment service.

### *Method:*

The care package included: Identification, Assessment, Engagement, Psychoeducation and a choice of Group Interventions (Mindfulness Based Stress Reduction/MBSR and Body Oriented Psychological Therapy/BOPT). Baseline and follow-up data on somatic symptom levels (PHQ-15), health-related quality of life (SF-36, EQ-5D) and service utilisation was analysed.

### *Results:*

145 patients were referred and assessed for eligibility, 93 included in the study. Participants engaged well with different components of the care package and gained significant improvements in somatic symptom levels with corresponding increases of quality of life ratings and a reduction in health care utilisation (GP contacts and referrals to specialist services) as well as associated health care costs.

### *Conclusion:*

The primary care treatment package can be successfully implemented in primary care at a relatively low cost and easily adopted into routine care. The body-oriented approach is well accepted by clinicians and patients. Controlled trials should be conducted to test the efficacy of treatment package.

### *Keywords:*

Primary health care, Medically Unexplained Symptoms, Body Oriented Psychological Therapy

247 words

### How this fits in

MUS are complex presentations, common in primary care and pose a significant burden to patients, clinicians and society due to a high level of unmet healthcare needs. GPs play an important role in assessment, engagement and sign-posting for treatment. Take-up amongst MUS sufferers through traditional referral systems and response rates for talking therapies are known to be low. The results of this feasibility study suggest that this novel embedded primary care package can be easily implemented and that it provides an alternative and potentially cost-effective and clinically relevant pathway.

### Introduction

Patients with Medically Unexplained Symptoms (MUS, also labelled Bodily Distress Syndrome in newer classification systems, [1-2]) complain of physical symptoms that cannot be explained adequately or sufficiently by organic pathology, causing distress and functional impairment. Whilst the causes remain unknown the medical practitioner can diagnose MUS only per exclusion, but research has demonstrated a high level of diagnostic accuracy [3]. The fundamental assumption is that the complaints are not exclusively physical or mental in nature and origin, but complex presentations that cannot be assigned to single causative factors [4].

Persistent MUS (more than 3 months) is highly prevalent and costly to patients, providers and society; patients with MUS often have unmet health needs as a result of their health beliefs, incorrect diagnosis and consequently ineffective treatment despite frequent presentation at primary and secondary care services [5-7]. Previous research emphasised the importance of General Practitioners' ability to provide generic interventions such as positive communication, reassurance and specific advice [8]; in addition studies found that enhanced primary care with input from specialists works best [9] and that an attitude of diagnostic

openness is important [10]. Flexible treatments with evidence for their efficacy include: reattribution, progressive muscle relaxation, cognitive behaviour therapy [11]. A systematic analysis of non-pharmacological treatments however concluded that the effect sizes in trials evaluating psychological therapies for MUS have been low and that “compared with enhanced or structured care, psychological therapies generally were not more effective for most of the outcomes” [12, page 2]. In addition trials frequently reported that engaging significant numbers of patients in psychological care has been difficult [12].

MUS sufferers require a seamless care pathway and treatment package that is both flexible and multifaceted to meet their individual needs and to foster collaborative relationships [13-14]. Existing standard models have not met the needs necessary to achieve desired health outcomes among this group. It has been suggested that a significant improvement in therapeutic engagement and symptom reduction can be achieved whilst offering a symptom-focused integrative and flexible approach that includes experiential body oriented psychological interventions [15-17].

This cohort study evaluated the feasibility and the potential clinical / cost implications of a novel care package that provides seamless primary care offering identification, assessment, engagement and body oriented interventions to patients with MUS.

The study was aiming to address the following specific research questions:

1. Is it feasible to implement the new care package within a primary care setting (a cluster of GP surgeries) in terms of the practicalities in relation to patient and health professional engagement?
2. To what extent do patient’s symptoms (psychological and physical complaints/distress) and their corresponding subjective quality of life change whilst receiving the care package?
3. What is the potential impact of the care package on service utilization and associated health care cost?

## Methods:

We conducted training sessions for surgery staff on the specific characteristics and requirements of MUS care, engagement strategies for MUS sufferers and to introduce the clinical algorithm for identification of potentially suitable participants (see inclusion criteria). The care package facilitated ongoing clinical dialog between GPs and practitioners who delivered the interventions.

Potentially eligible patients were identified from the primary care electronic database (computerised searches of clinical records, using read codes on somatoform disorder and MUS and specific conditions such as fibromyalgia), clinically by their GPs according to the clinical algorithm and through self-referrals. Following identification all potentially suitable patients were contacted by a member of the care team via telephone contact, letter or direct face to face conversation during routine consultation, obtaining verbal consent for referral to the study; once referred a research assistant arranged for a baseline assessment and consent giving procedures.

### *Inclusion criteria:*

Eligible patients comprised adults aged 18-75 years who met criteria:

- persistent ( $\geq 6$  months) bodily complaints without sufficient explanatory organ pathology (nature AND degree according to GP judgement; using a screening algorithm: pain in different locations, non-specific complaints affecting multiple organ systems, repeated complaints of fatigue or exhaustion, symptoms occur in the context of a stressful lifestyle or stressful life events); at least mild somatic symptom severity on the Patient Health Questionnaire (PHQ-15), represented by a cut-off score of  $>5$  [18].
- and/or all patients with a diagnosis of undifferentiated somatoform disorder DSM-IV (300.81/82) and/or ICD-10 (F45).

*Exclusion criteria:*

- somatisation symptoms attributable to identified physical disease (nature and degree)
- primary diagnosis of anxiety or depressive disorder, psychosis, substance misuse, psychoorganic disorder; and patients considered to be actively suicidal
- insufficient language skills, inability to complete the questionnaires

*Somatic complaints/symptom scores and Health-related quality of life ratings* were collected at baseline and at 4-6 months follow up: Primary Health Questionnaire (PHQ-15), scores of 5, 10, 15, representing cut-off points for low, medium, high somatic symptom severity [18]; Health Survey Form (SF-36, physical and mental components; higher scores indicate a better health status [19]; Subjective quality of life: EQ-5D health score Part 2 VAS (0-100) [20].

The evaluation of group interventions was assessed immediately after participation in the intervention groups, using the Client's Assessment of Treatment Scale [21]; this included quotes from patients as recorded from CAT questionnaires. Two authors (FR and NP) read the free text statements and agreed on most important themes regarding therapeutic benefits.

All participating patients were offered the opportunity to be seen in person for a follow-up assessment and interview by the research assistant; those who did not attend for follow-up received questionnaires (PHQ-15, SF-36 and CAT for self-ratings/assessments) by post.

Service utilisation data was collected from electronic patients' record according to a client service receipt inventory tool tailored for primary care services for the periods of six months prior to participation and six months after the intervention. Health care cost was calculated according to NHS references/unit cost data information, [22]; this included for GP time commitments: surgery consultations, telephone contacts, GP letter, home visits.

*Care package elements/interventions: all participants received individual psychoeducation in respect of their MUS and were offered a choice between two group interventions (in order to allow for a matching of patient preferences with an activity/movement based or mindfulness based intervention – both explicitly utilising body experiences).*

1. Psychoeducation: This was delivered during baseline assessment (60-90 minutes) by a research assistant (psychiatry trainee doctor) and the main aim was twofold: to engage patients and to extend and broaden their understanding of bodily functions; it included information about the predisposing biological vulnerability, low pain thresholds, hyperarousal and “amplifying” somatic styles of coping, perpetuating factors such as focused attention towards distressing bodily sensations (hypervigilance) and re-enforcement as well as stress-tolerance models.
2. Body-Oriented Psychological Therapy (BOPT) offered under the term “Strategies for Better Living Group” (10 weekly sessions 90 mins each): this was delivered by Dance Movement Psychotherapists who were trained to use the manual; the intervention targets patients’ difficulties in acknowledging and expressing emotions and aims to achieve fully embodied ways of relating to somatic symptoms; the therapy identifies alternative behaviours in relation to coping with somatic symptoms, widens exploratory concepts and (bodily) self images towards a more inclusive understanding of the inseparable nature of mental and physical processes, enriches and diversifies negative body images, activates resources (capabilities, bodily strength and creativity) and sets the scene for (bodily, autonomic) self-regulation. The manual for the BOPT intervention and psychoeducation materials have been published together with a TIDieR checklist on [www.mus.elft.nhs.uk](http://www.mus.elft.nhs.uk).
3. Mindfulness Based Stress Reduction (MBSR; 8 weekly sessions 90 mins each): this was delivered as an adapted version of the standard protocol [23] by a certified MBSR instructor. Written materials and audio CDs of guided meditations were provided to

support home practice. MBSR therapy combines meditation, body-awareness techniques and yoga exercises to enhance coping with distressing bodily symptoms such as pain; techniques taught included body-scan, mindfulness of breath / body / feelings / thoughts / emotions and mindful movement. Session themes 1-8: Introduction to MBSR; handling stress, dealing with barriers; the power of being present; living all of your moments; learning about our stress reactions and how we deal with pain and other physical symptoms; coping with stress: using mindfulness to respond instead of react; thoughts are not facts; life style choices – how can I best take care of myself; keeping your mindfulness alive.

### Statistical analysis

We conducted descriptive statistics, reported recruitment and retention figures and compared initial and follow-up characteristics (somatic symptom levels, health related subjective quality of life and service utilisation) of the participants. All values were expressed as mean  $\pm$  SD. Paired samples t-tests were conducted to analyse differences in outcome variables (calculation of 95% confidence intervals; the significance level for hypothesis testing was set at 0.05). All statistical evaluations were performed with SPSS Version 24.0 (IBM SPSS Statistics for Windows).

### Results:

Out of 145 referred patients a total of 93 patients with a wide range of MUS conditions who fulfilled the inclusion criteria were included for participation to receive the care package. The information regarding study recruitment data / process is summarised in the CONSORT diagram flow chart in Figure 1.

Figure 1 in here

*Participants demographic and clinical characteristics (N=93, some data missing):*

Mean age 48 years (21-75); Female 76 (81.7%), Male 17 (18.3%); Ethnicity: White British 17 (18.3%), White other Caucasian 7 (7.5%), Afro-Caribbean 6 (6.5%), Black African 10 (10.8%), Indian 11 (11.8%), Pakistani 16 (17.2%), Bangladeshi 23 (24.7%), other 3 (3.2%).

The majority of patients (N=59, 63.4%) were unemployed, and patients reported receiving state benefits as follows (N=): State retirement 6, Statutory sick pay 9, Working tax credit 9, Housing benefit 41, Council tax benefit 35, Disability living allowance mobility component 12 and Care component 10, Incapacity benefit 5, Income support 20. Most patients (N=68, 73.1%) confirmed that they received family support in relation to their health problems; the mean number of hours was reported as 19 per week (varying from 1-84 hours).

The data for PHQ-15 on somatic symptoms from questionnaires was completed for all participants at baseline (mean total score 17.8, sd 5.7 indicating significant severity) and at follow-up by 44 patients. Baseline scores indicated high levels of somatic symptom severity; 74 patients rated the level of associated problems (an inability to do work, take care of things at home, or get along with other people) as “extremely severe”. Most patients presented with multiple MUS, the most frequently reported complaints were chronic/generalised aches and pains, headaches, back pain, nausea and fatigue; specific conditions such as Irritable Bowel Syndrome and Fibromyalgia were included. Comparative results are summarised in table 1.

Table 1 in here

*Further analysis of patients who participated in the group interventions:*

For the group of 61 patients who accepted to participate in the group intervention (N=44 chose BOPT, N=17 chose MBSR, the number of sessions attended varied between 1-10 (maximum offered), mean: 2.4 sessions.

Comparing outcomes for those who attended a minimum of five sessions (N=24), better outcomes on all measures (symptom levels, quality of life scores and service utilisation) was observed, the results however did not reach statistical significance. Client's assessment of treatment scores obtained from 36 patients who participated in the group intervention demonstrated good satisfaction levels with the group programme (mean scores across all questions 6-7/10); the question "Has treatment/care here been helpful for you?" had the best response with a mean rating of 8.9/10. The majority of these patients (77%) answered that they would want to attend more sessions if offered to them. Themes from free text comments regarding benefits from intervention were identified as follows: shared understanding of problems with other patients, better coping with symptoms, learning new skills, feeling accepted with problems, symptomatic relief, empowerment, learning how to help myself.

#### *Cost analysis:*

Health care expenditures were calculated as resulting from service utilization according to data from GP electronic files, comparing health care costs for the patients in the study sample over a period of six months prior to the baseline assessment with a six months period after being enrolled in the study project. Non-health care costs associated with the health condition include social care costs, the secondary costs resulting from family/friends who provide support and (even though not only and primarily as a result of the MUS health condition) to a certain extent also the costs to the wider economy in terms of unemployment rates and state benefits paid. No changes in unemployment rates or access to state benefits were observed; neither did the hours of family/friends support reduce from baseline to follow-up. NHS unit costs as per standard documentation are listed for all services that were included in the analysis in table 2. The cost reduced by £ 367 per patient over six months.

Table 2 in here

The care pathway elements can all be delivered by senior psychological therapists, trained to deliver the body oriented treatments (BOPT and MBSR) and to conduct assessment / engagement and psychoeducation sessions; optionally this can be supported by sessional input from liaison psychiatrists. Based upon study figures, we calculated the costs to run and administer the care pathway based upon a full time post (including salary, on-cost, office space and equipment) as about £57k per annum. At minimum/maximum capacity with 5-12 participants per group this provides for 250 treated patients (35% drop-out rate from 400 referrals); cost per patient £228.

### Discussion:

#### *Summary:*

This study explored the feasibility and evaluated outcomes of a novel primary care treatment package (“one-stop-shop”) for patients with Medically Unexplained Symptom disorders, provided in one geographical cluster of GP surgeries in East London.

The results of this uncontrolled open study suggest that the majority of patients referred to the care pathway (about 2/3) could be successfully engaged; this included a high percentage of patients from black and ethnic minority backgrounds. The majority of participants chose the body oriented intervention group. Those who received the care package reported significant reductions in self-reported symptom levels and corresponding improvements in their health related subjective quality of life.

The two factors that may best explain the changes in this study are the body oriented approach and the delivery of all components at primary care level. The care package utilised an approach that can be characterised as “meeting the patients at home”, acknowledging that the nature and degree of their somatic complaints must be engaged with on a somatic level across all steps of the care pathway without challenging patients explanatory beliefs. The

results suggest that not just one single component of the care package (assessment / engagement, psychoeducation, intervention) seems to account for the changes observed in this study. Once engaged, patients benefited independent of the quantity of therapeutic inputs and the choice of interventions. Given the preliminary nature of the findings, this needs to be addressed in subsequent controlled efficacy studies.

*Strengths and limitations:*

In this study, emphasis was laid upon GP engagement; the care pathway was developed and implemented in close collaboration with primary care colleagues and included a set-up phase providing practitioners with specific training in addition to raising awareness and fostering a better understanding of patients' difficulties. It is particularly encouraging to see that the described symptom changes were reported for patients with high baseline scores alongside improved subjective quality of life ratings and significant reductions in health service utilization as well as corresponding cost. Given the short-term nature of the intervention significant changes of other social expenditures were not observed. Estimating the potential cost-benefits of the care package, the cost associated with the delivery of the treatment elements has to be taken into account.

This was not a controlled trial and different designs are required to detect treatment effects, but results suggested clinically meaningful changes; patients were able to choose a group intervention based upon their preference in accordance with the main notion of the care pathway. Data on symptom levels at follow-up could only be obtained by half of the sample and results may therefore be biased towards those who had better outcomes. Health care utilization data however was collected from electronic records and therefore available for all participants.

### *Comparison with existing literature*

The findings are in line with previous studies that explored health benefits of body oriented psychological therapy for MUS [24], somatoform disorders [16, 25] and specific psychosomatic disorders [26-28].

Evidence-based approaches at primary and secondary care level are few for MUS patients [8,10]. The relative paucity of randomised controlled trials for specific treatments of MUS is partially explained by heterogeneous patient characteristics and difficulties engaging them in any systematic form of psychological (talking) therapies [11]. Data from a nationwide UK pathfinder project conducted by NHS England indicated low uptake across 12 sites, low attendance rates and only one clinical site demonstrated benefits with symptoms reductions [29].

### *Implications for research and/or practice:*

The existing evidence gap and the fact that most patients who experience persistent MUS are regarded as difficult to treat, require research that addresses the efficacy of enhanced care models with mixed method methodologies. Integrative and collaborative care pathway models that are firmly embedded within enhanced primary care practice seem to have advantages over traditional referral systems. Psychological interventions for patients with somatisation problems should be delivered as intrinsic components of wellbeing strategies; resource- and body oriented approaches [15, 30] as well as empathic support and symptom-immanent explanations [31] seem to be better accepted by MUS patients than talking therapies and more likely to promote better health outcomes.

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### Ethical approval:

Ethical approval was granted by the Health Research Authority Research Ethics Committee Yorkshire & The Humber - Bradford Leeds, REC reference number 14/YH/1038. All patients who participated provided written informed consent.

### Competing interests

No competing interests.

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