

# **‘It’s helped me to learn to deal with it’: a mixed methods service evaluation of a multicomponent fibromyalgia service**

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## **Abstract**

### **Objective**

*To evaluate the Royal London Hospital for Integrated Medicine (RLHIM) multicomponent fibromyalgia service.*

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### **Methods**

*Mixed methods approach consisting of the completion of validated quantitative outcome measures (Patient Health Questionnaire-9; Generalised Anxiety Disorder-7; Pain Catastrophising Scale; Patient Self-Efficacy Questionnaire) pre- and post-treatment to explore the impact of treatment; and qualitative focus groups with patients at their follow-up appointments to explore patients’ experiences and perspectives on the service.*

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### **Results**

*138 fibromyalgia patients attended the RLHIM group fibromyalgia service during the period of the evaluation. Baseline scores demonstrate that patients were significantly impaired pre-treatment according to all outcome measures. At the end of the course of treatment, scores for all outcome measures showed clinically and statistically significant improvements. These improvements were maintained at both 6- and 9-month follow-up appointments. Qualitative analysis indicated that those participating valued the multicomponent treatment approach, and perceived the service as having a positive impact on their fibromyalgia and overall quality of life, enabling patients to effectively manage their condition.*

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### **Conclusion**

*Patients attending the RLHIM multicomponent fibromyalgia service appear to have demonstrable improvements in presenting symptoms, and quality of life. The findings support a multicomponent approach to the treatment of fibromyalgia.*

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### **Key words**

fibromyalgia, mixed methods, service evaluation

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## Introduction

Fibromyalgia is a rheumatological condition characterised by chronic widespread pain and fatigue. The condition is also associated with additional symptoms such as difficulty sleeping, muscle stiffness, headaches, difficulty with mental processing, and bowel disturbances (1, 2). Recent UK National Institute for Health and Care Excellence (NICE) guidelines for fibromyalgia recommend group-based exercise programmes, acupuncture, and/or psychological therapies (cognitive behavioural therapy (CBT) or acceptance and commitment therapy (ACT)) (3). European evidence-based guidelines, such as the German Scientific Medical Societies (AWMF) and the European League Against Rheumatism (EULAR), suggest a multicomponent approach to the treatment of fibromyalgia (4, 5). The most recent AWMF guidelines define multicomponent therapy as “the combination of at least one activating procedure (endurance, strength or flexibility training) with at least one psychotherapeutic procedure (patient education and/or cognitive behavioural therapy)”. Comparison by network meta-analysis of pharmacological versus non-pharmacological therapy in fibromyalgia also favours the latter, with the research concluding that a combination of pregabalin or serotonin and norepinephrine reuptake inhibitors (SNRIs) as pharmacological interventions and multicomponent therapy, aerobic exercise and CBT as non-pharmacological interventions seems most promising for the management of fibromyalgia (6).

The Royal London Hospital for Integrated Medicine (RLHIM) is located within University College London Hospitals (UCLH) National Health Service (NHS) Trust. The hospital has an established multicomponent fibromyalgia service, which is considered a gold standard service by Fibromyalgia Action UK, the leading fibromyalgia patient charity in the UK, with the first author being a member of the charity’s Medical Advisory Board (7). Given there remains a limited amount of research evaluating different fibromyalgia treatments and services to inform clinical guidelines, a mixed methods service

evaluation of the fibromyalgia service at the hospital was conducted to explore patients’ experiences and evaluate treatment outcomes.

## Materials and methods

The service evaluation adopted a mixed methods approach consisting of the completion of validated quantitative outcome measures pre and post treatment to explore the impact of treatment, and qualitative focus groups with patients at their follow up appointments to explore patients’ experiences and perspectives on the service.

### Quantitative component

All patients who were new to the fibromyalgia service at RLHIM and were coming in for their first outpatient session were included in this evaluation. Patients were informed about the evaluation when attending for their first appointment at the hospital. Fibromyalgia patients were asked to complete the following validated outcome measures at their first hospital appointment (baseline), after the completion of their multicomponent treatment, and then again at their 6- and 9-month follow-up appointments. The outcome measures employed in the evaluation included:

- *Patient Health Questionnaire-9 (PHQ-9)*:

This is a 9-question validated instrument to screen for the presence and severity of depression. Scores range from 0 to 27, with scores above 10 being suggestive for the presence of depression; 10–14 for moderate (clinically significant) depression, 15–19 moderately severe, and 20–27 severe depression (8).

- *Generalised Anxiety Disorder-7 (GAD-7)*:

This is a 9-item validated questionnaire to screen for the presence and severity of generalised anxiety disorder. Scores range from 0 to 27, with scores above 10 being suggestive for the presence of generalised anxiety disorder; 10–14 for moderate (clinically significant) anxiety, 15–19 moderately severe, and 20–27 severe (9).

- *Pain Catastrophising Scale (PCS)*:

This 13-item validated scale measures pain catastrophising, an exaggerated

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negative mindset related to pain, which contributes to heightened levels of pain and emotional distress and is a risk factor for chronicity. Scores range from 0–52, with a score of 30 or more being considered to be clinically relevant (10).

- *Patient Self-Efficacy Questionnaire (PSEQ)*:

This is a 10-item validated scale assessing the confidence people with ongoing pain have in performing various activities while in pain. It is scored from 0–60, with higher scores reflecting stronger self-efficacy beliefs. Higher scores (>40) are associated with return to work and maintenance of functional gains, whilst lower scores tend to predict less sustainable gains (11).

An excel dataset was constructed using anonymised data from the fibromyalgia service including all completed outcome measures. Pre and post treatment scores for each outcome measure were analysed. The change in score was calculated for each outcome measure by subtracting each patient's pre-treatment score from their post treatment score. As we were assessing the same patient population at two time points (pre and post treatment) we used the Wilcoxon signed rank test to calculate whether any changes in outcome measure scores were statistically significant.

*Qualitative component*

Three semi-structured focus groups were conducted with a total of 14 patients to explore their experiences of the fibromyalgia service. Focus groups lasted between 30 and 45 minutes, and were conducted by an experienced qualitative researcher [JGH]. Focus groups were conducted at RLHIM when patients attended follow up appointments (6 months following completion of their course of fibromyalgia treatment). The interviewer had no clinical contact with participating patients. Participating patients were provided with written and verbal details of the qualitative evaluation and what participation would entail, and written consent was obtained prior to focus groups commencing. Focus groups were guided by a topic guide, which was updated throughout the evaluation to incorporate emerging themes.

Focus groups were audio recorded and transcribed verbatim. Transcripts were checked for accuracy and anonymised. A constructivist epistemological approach was adopted. The evaluation was approached from the position that “data do not provide a window on reality, rather, the ‘discovered’ reality arises from the interactive process and its temporal, cultural, and structural contexts” (12). Data were analysed inductively (13), using thematic analysis (14). JGH immersed themselves in the data, repeatedly reading the transcripts to understand patients' experiences. Key issues, concepts and themes arising from the data were identified, creating a coding framework. The coding framework was then applied systematically to all the data. The indexed data was then thematically analysed to map the range and nature of phenomena, find any associations and provide explanations.

**RLHIM fibromyalgia group management programme**

Although chronic widespread pain is the hallmark of fibromyalgia, the RLHIM service is not a pain management service but aims to address any of the numerous symptoms which can affect fibromyalgia patients. The service consists of one introductory session which includes some preparatory work for patients to do, followed by 9 x 2.5-hour sessions, with 3 follow-ups at approximately 3, 6 and 9 months. The aim of the programme is to provide positive self-management approaches to reduce the distress associated with fibromyalgia and to improve functioning. The multicomponent service includes pain management, Occupational Therapy including activity management, CBT with elements of Graded Exercise Therapy. Patients can also be referred for physiotherapy, acupuncture and/or dietetic input if required. All patients attending the service have a diagnosis of fibromyalgia (ICD-10 M797) in the absence of significant co-morbidities which impact on pain. Individual sessions can be offered to those patients who are not able to work in groups.

The following topics are covered during the group programme, and are adapted according to the needs of the patients:

*What is Fibromyalgia; Understanding Pain; Medication; Activity Management; Goal/Target Setting; Introduction to CBT; Stress Management; Introduction to relaxation techniques; Sleep; Communication; and Looking Ahead.*

**Results**

138 fibromyalgia patients attended the RLHIM group fibromyalgia service during the period of the mixed methods evaluation. Of these 129 patients completed their baseline outcome measures, and 106 patients also completed their post treatment outcome measures. Fifty patients completed the outcome measures at 6 month follow up, and 43 at 9 months follow up. Three semi-structured focus groups were conducted at patients attending their 6 month follow up, with a total of 14 patients, to explore their experiences of the fibromyalgia service. Patients were seen between February 2011 and July 2019.

*Quantitative data*

The baseline scores demonstrate that patients were significantly impaired pre-treatment according to all scales. For the 129 patients for whom baseline data is available, according to PHQ-9 data 106 (82.2%) were judged as having clinically significant depression pre-treatment. Of these 41 (31.8%) were assessed as having moderate depression (PHQ-9 10–14), 37 (28.7%) as having moderate to severe depression (PHQ-9 of 15–19), and 28 (21.7%) as having severe depression (PHQ-9 of 20–27). In terms of generalised anxiety disorder, at baseline 73 (56.6%) were classified as having clinically significant anxiety. Of these 28 (21.7%) were assessed as having moderate anxiety (GAD-7 of 10–14), 34 (26.4%) as having moderate to severe anxiety (GAD-7 of 15–19), and 11 (8.5%) as having severe anxiety (GAD-7 of 20–27). Fifty-four patients (41.9%) had a clinically relevant PCS score of 30 or more pre-treatment. While 90 patients (69.8%) had PSEQ scores of 30 or lower at baseline, suggesting that these patients lacked confidence in performing activities while in pain.

Mean outcome measure scores pre-treatment were 14.0 for PHQ-9; 11.1

for GAD-7; 25.6 for PCS; and 23.7 for PSEQ. At the end of the course of treatment scores for all outcome measures showed clinically and statistically significant improvements. These improvements were maintained at both 6- and 9-month follow-up appointments (Table I).

*Qualitative data*

All participating patients indicated they were happy with the communication between the hospital and themselves and felt they had received sufficient information prior to starting the fibromyalgia course. Patients indicated that they did not have any expectations for a ‘cure’ for their fibromyalgia from the RLHIM course, rather they wanted to learn techniques which could make their condition ‘more bearable’ (see quotations 1 and 2 in Table II).

For many patients the RHIM course was their first opportunity to meet other patients with the same condition. Patients greatly appreciated the opportunity to share their experiences with other patients with fibromyalgia. For most, hearing other patients with the same condition and symptoms validated their own experiences with the condition. Many highlighted they did not feel judged and that they valued learning in a group setting, which was seen as engendering the sharing of self-management tips from other patients with fibromyalgia (see quotations 3–5 in Table II).

All the patients enjoyed the programme, and highlighted the fact they appreciated the opportunity to receive non-pharmacological approaches for the management of their fibromyalgia. Participating patients perceived all components of the programme as important and valuable to them, with patients not identifying any components of the course which they felt were not beneficial to them. Patients had divergent views on which components of the course were most beneficial for them. In terms of suggestions for improving the course further, patients suggested providing refresher sessions for those who have completed the course to reinforce what they had learned during the course (see quotations 6 and 7 in Table II).

**Table I.** Mean outcome measure data before and after treatment.

Scale	Mean baseline (range; SD)	Mean post treatment (range; SD)	Mean 6 months	Mean 9 months	Mean improvement post treatment	Mean improvement 6 months	Mean improvement 9 months
PHQ-9	14.0 (2-27; 6.4)	9.6 (0-24; 5.4)	9.6	9.8	4.4*	4.4	4.2
GAD-7	11.1 (1-21; 6.1)	7.4 (0-19; 5.0)	7.3	7.4	3.7*	3.8	3.7
PCS	25.6 (2-52; 13.1)	18.5 (0-51; 9.6)	15.8	16.2	7.1*	9.8	9.4
PSEQ	23.7 (3-53; 12.4)	31.8 (8-60; 9.8)	33.8	33.4	8.1*	10.1	9.7

\*Improvements statistically significant at  $p < 0.001$  according to Wilcoxon signed rank tests.

**Table II.** Examples of patient quotes from qualitative focus group

**Expectations of treatment**

1. ‘You kind of want a bit of a miracle don’t you. But there isn’t one, is there? So, yeah, just helpful hints to make it a bit more bearable, I would say.’ [Focus group 2, patient 2]

2. ‘I don’t think anyone was hoping to be cured, because I think we all know that is not curable.’ [Focus group 2, patient 1]

**Group based approach**

3. ‘It made me not feel that I’m the only one who suffers with these symptoms, there are many other people.’ [Focus group 1, patient 2]

4. ‘You don’t feel judged.... I was putting on this poker face, so coming here, I didn’t have to put on that face, I could be honest and say I’m in pain or how I felt.’ [Focus group 3, patient 2]

5. ‘I think it’s the support of the group, you know, and all being sort of offloading and having other people that know how you feel because in your everyday life, nobody else “gets it”.... I think, the support aspect was one of the best aspects for me.’ [Focus group 2, patient 2]

**Multicomponent programme**

6. ‘The acupuncture helped, they really put a lot of needles in.’ [Focus group 1, patient 1]

7. ‘The diary really, really helped me focus on what I really needed to do and things I wanted to do.’ [Focus group 2, patient 1]

**Impact of attending the fibromyalgia course**

8. ‘If the pain improves, then, everything else changes as well.’ [Focus group 1, patient 1]

9. ‘I’m in less pain, I’m happier. I have a special quality of life now. I’m living again, I’d stopped living. I actually had stopped living for a few years and just existing, barely doing anything. Now I’ve things I like to do... I’m healing, I feel like I’m healing I’d say.’ [Focus group 2, patient 3]

10. ‘I have to admit, I found I was happier, I found more helpful ways of doing things, and from the course I was happier and have slightly better quality of life now.’ [Focus group 3, patient 3]

**Patient motivation**

11. ‘From the start of the course, we can see that a lot of people have been dropping off.... whereas, we were more open to listening and to change in our life, some were still stuck in that moment that they didn’t necessarily want to change.’ [Focus group 1, patient 2]

Patients felt the course had enabled them to accept their condition, equipping them with tools to successfully manage their condition going forward. They also frequently indicated that they had accepted greater responsibility for their fibromyalgia and their life in general as a result of attending the course. Patients also indicated that the

course had also led to improvements in their levels of pain, emotional wellbeing, and overall quality of life. In particular, improvements in pain were seen as facilitating improvements in other symptoms and areas of their life. This allowed many of the patients to ‘live again’ after the fibromyalgia had prevented them from doing many valued

activities previously (see quotations 8–10 in Table II).

Interestingly patients perceived the success of the fibromyalgia service as being influenced by how open and motivated they were to changing their life. Those with the greatest motivation and openness to change being perceived as benefitting the most. If patients were perceived as being ‘stuck in the moment’ and not wanting to change, they were deemed as unlikely to benefit from the course. Patients commented that those perceived as not being motivated frequently dropped out of the course before completion (see quotation 11 in Table II).

### Discussion

Fibromyalgia is a long-term chronic condition characterised by widespread pain and fatigue, and difficulty sleeping, muscle stiffness, headaches, difficulty with mental processing, and bowel disturbances (1, 2). The research evidence for effective interventions for fibromyalgia patients is limited, with a dearth of interventions being shown to be effective at alleviating symptoms or improving quality of life in patients (15). As a result, guidelines on how best to manage the condition can be limited in options, with health services attempting to recommend treatments based on limited available evidence. Further research is clearly required to evaluate existing and new approaches to the management of fibromyalgia.

The RLHIM provides a service for fibromyalgia patients which conforms to both current NICE guidelines, as well as European guidelines (3–5). The multicomponent service includes pain management, activity management, CBT with elements of Graded Exercise Therapy, physiotherapy, acupuncture, and dietetic input. Given the limited research evidence for interventions in fibromyalgia it is important for clinical services within the field to evaluate

their treatment outcomes and the perceptions of patients using the service. The present mixed methods evaluation adopted a rigorous methodological approach. The findings suggest a clinical multicomponent service has a demonstrable impact on the severity of fibromyalgia symptoms and improve overall quality of life in patients. It is unfortunate that only 43 patients attended their 9-month follow-up appointment and completed the outcome measures again at this time point (representing just 31% of patients who attended the fibromyalgia service during the evaluation period). We have no data on why patients did not attend their follow-up appointments, however all NHS services experience losses to follow-up, which might be exacerbated in conditions such as fibromyalgia were symptoms such as pain and fatigue might make attendance more difficult. However, from the limited data available, it appears that the benefits from the multicomponent fibromyalgia service are maintained at 9 months post treatment. Qualitative data from focus groups indicate that those participating in the evaluation valued the multicomponent treatment approach, and perceived the service as having a positive impact on their fibromyalgia and overall quality of life, enabling patients to effectively manage their condition. The RLHIM multicomponent fibromyalgia service appears to have demonstrable improvements in patients presenting symptoms, and quality of life. The findings support a multicomponent approach to the treatment of fibromyalgia, and a diagnostic-therapeutic care pathway for the condition (16).

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