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International, multidisciplinary Delphi consensus recommendations on non-pharmacological interventions for fibromyalgia

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ABSTRACT

Objectives: To develop evidence-based expert recommendations for non-pharmacological treatments for pain, fatigue, sleep problems, and depression in fibromyalgia.
Methods: An international, multidisciplinary Delphi exercise was conducted. Authors of EULAR and the Canadian Fibromyalgia Guidelines Group, members of the American Pain Society and clinicians with expertise in fibromyalgia were invited. Participants were asked to select non-pharmacological interventions that could be offered for specific fibromyalgia symptoms and to classify them as either core or adjunctive treatments. An evidence summary was provided to aid the decision making. Items receiving >70% votes were accepted, those receiving <30% votes were rejected and those obtaining 30-70% votes were recirculated for up to two additional rounds.
Results: Seventeen experts participated (Europe (n = 10), North America (n = 6), and Israel (n = 1)) in the Delphi exercise and completed all three rounds. Aerobic exercise, education, sleep hygiene and cognitive behavioural therapy were recommended as core treatments for all symptoms. Mind-body exercises were recommended as core interventions for pain, fatigue and sleep problems. Mindfulness was voted core treatment for depression, and adjunctive treatment for other symptoms. Other interventions, namely music, relaxation, hot bath, and local heat were voted as adjunctive treatments, varying between symptoms.

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Conclusions: This study provided evidence-based expert consensus recommendations on non-pharmacological treatments for fibromyalgia that may be used to individualise treatments in clinical practice targeting the diverse symptoms associated with fibromyalgia.

Introduction

Fibromyalgia is a common condition characterised predominantly by chronic widespread pain, fatigue, non-restorative sleep, and cognitive dysfunction.[1] It impacts on the patients' health and quality of life (QoL), and on their significant others and presents a significant presents a large health economic burden.([2,3]) Non-pharmacological interventions are often recommended as first-line treatment for fibromyalgia.[4] However, there are currently no recommendations on which non-pharmacological intervention(s) to offer for the initial management of the different symptoms associated with fibromyalgia, and, which of these to prioritise as core treatments. For instance, the EULAR Guidelines recommended a management approach tailored to each patient's symptoms, however, they recommended symptom specific management only for patients that have failed to respond to initial treatment comprised of patient education, graded physical exercise, with or without other non-pharmacological therapies.[4] For a busy clinician, it is important to know which non-pharmacological intervention(s) to offer for each of the different manifestations of fibromyalgia, as the predominant symptom(s) vary between individuals.[5] As for other conditions, personalising treatment is recommended as a way for improving outcomes in fibromyalgia.[6]

Thus, the objective of this study was to develop an evidence-based multinational expert consensus on the non-pharmacological treatments that could be recommended for common fibromyalgia symptoms, specifically, pain, fatigue, sleep and depression that were ranked as the top four symptom domains for fibromyalgia by an Outcome Measures in Rheumatology Clinical Trials (OMERACT) working group,[7] and to classify them as core and adjunctive treatments. This was based on expert consensus along with the results of our recent systematic review and meta-analysis.[8]

Methods

A three-stage Delphi exercise was designed. Potential panel members were selected from the author list of international fibromyalgia guidelines,([4,9,10]) and experienced clinicians in the field of fibromyalgia. Any medical or health care professional e.g., rheumatologist, general practitioner (GP), physiotherapist, nurse, psychologist, or occupational therapist etc. that participates in care of people with fibromyalgia or an active researcher in the field were eligible to participate.

The Delphi survey was emailed to experts. A virtual or in-person meeting was not organised to avoid the potential for bias due to the influence of more dominant members. They were asked to consider both the research evidence from a recent systematic review and meta-analysis,[8] and their experience of treating people with fibromyalgia with non-pharmacological treatments in terms of efficacy, availability, acceptability, costs, patient preferences and, to decide if they would recommend each treatment for pain, fatigue, sleep, and depression in people with fibromyalgia.

Emails were sent separately to each expert to allow panel members to maintain anonymity. The first-round survey was emailed on 18th August 2019 with responses requested within two weeks. After one week, a reminder e-mail was sent. If, after the reminder, a participant did not complete the survey, they were excluded from subsequent rounds. In the first round, participants were asked to provide their professional background, experience of managing fibromyalgia, and primary professional role. They were also asked to select interventions that could be offered to people with fibromyalgia, and to rate them as either core or adjunctive treatment for each of the four main symptoms. Additionally, experts could suggest additional treatments in the first round of the Delphi exercise. These were circulated in subsequent rounds. The results of meta-analysis, including effect size (ES) and 95% confidence interval (CI) of each intervention for each symptom were provided to summarise current research evidence.[8] The Delphi survey questionnaire used in the first, second, and third rounds is included in the online supplemental material.

Items that received more than 70% votes were accepted, those that received less than 30% votes were rejected and those obtaining between 30-70% votes were recirculated in the second and third rounds. The results of earlier rounds of voting were provided to the panel at subsequent rounds. Interventions accepted for managing fibromyalgia were classified as core if they were recommended as core intervention by at least 50% of the experts, otherwise they were classified as adjunctive.

Patient and public involvement (PPI): At the end of the expert consensus, two patients with fibromyalgia were invited to evaluate and comment on the results from the patient perspective.

Results

Of 48 invited experts, 19 responded to the invitation and 17 agreed to participate in the Delphi exercise, providing a range of academic and clinical participants. There were seven rheumatologists, two physiotherapists, one pain specialist, one psychologist, one nurse and five other health-care professionals. Respondents were from Europe (n = 10), North America (n = 6), and Israel (n = 1). Response and completion rates for the 17 participants were 100% in each round.

In the first round, experts suggested the following interventions: determination to build well-being/happiness, dietary modification, goal setting, hot bath and local heat, orthotics, pacing, periods of relaxation/enjoyment, postural training, stress management, and sleep hygiene (healthy sleep habits such as avoiding caffeine, nicotine and alcohol, regular exercise, and reducing bedroom noise [11]).

After three rounds of voting, 13, 10, 11, and 10 interventions were recommended to be used for pain, fatigue, sleep, and depression, respectively (Table 1). On the other hand, 14, 17, 16 and 18 interventions were not supported for management of pain, fatigue, sleep and depression, respectively. Five interventions for pain, one for fatigue,

Table 1
Accepted non-pharmacological interventions and percentage of agreement for pain, fatigue, sleep, and depression. Proportion of experts supporting each intervention for different symptoms in fibromyalgia.

Interventions	Pain	Fatigue	Sleep	Depression
Aerobic exercise	94%	94%	88%	94%
Education	94%	94%	88%	76%
Sleep hygiene	94%	100%	100%	76%
Cognitive behavioural therapy	94%	88%	88%	88%
Stress management	94%	88%	94%	88%
Mind-body exercise	94%	88%	76%	82%
Strengthening exercise	88%	71%	NR	NR
Periods of relaxation/enjoyment	88%	NR	76%	76%
Goal setting	82%	76%	NR	71%
Hot bath and local heat	82%	NR	71%	NR
Mindfulness	82%	76%	76%	71%
Pacing	82%	76%	82%	NR
Flexibility exercise	71%	NR	NR	NR
Music	NR	NR	76%	NR
Determination to build well-being/ happiness	NR	NR	NR	71%

NR: not recommended.

four for sleep and one for depression did not achieve consensus on whether they should be used or not.

Of the interventions suggested by experts in round one: determination to build well-being/happiness, goal setting, hot bath and local heat, pacing, periods of relaxation/enjoyment, stress management, and sleep hygiene were recommended for at-least one symptom. Results of each round of Delphi exercise are reported in Supplementary Tables 1, 2, 3, and 4.

Aerobic exercise, education, sleep hygiene and cognitive behavioural therapy (CBT) were supported as core treatments for all symptoms. Other interventions, including music, periods of relaxation/enjoyment, use of hot bath and local heat, achieved consensus as adjunctive treatments for some symptoms. Fig. 1 indicates the classification of accepted interventions for pain, fatigue, sleep and depression as core or adjunctive in a treatment strategy for fibromyalgia. The detailed classification of interventions as core or adjunctive can be found in Supplementary Figures 1, 2, 3, and 4.

The PPI representatives agreed with the results from the expert consensus. In addition, they suggested that interventions should be prescribed based on the individual's past experiences with treatments, as the patient's perspective is important for treatment adherence. They highlighted the importance of self-management and programs for management of flare-up.

Discussion

This Delphi exercise recommended 13 non-pharmacological interventions for pain, 10 for fatigue, 11 for sleep, and 10 for depression. These interventions were classified as either core or adjunctive based on expert opinion. This may provide a framework for an individualised non-pharmacological treatment plan for fibromyalgia according to the predominant patient symptoms.

Suggested interventions by the Delphi panel for any fibromyalgia symptoms were mainly exercise, education and psychological treatments such as CBT and mindfulness (a meditation technique that aims to bring someone's attention to the present moment experience [12]). These results align with recent guidelines on fibromyalgia and with management of other chronic painful diseases. The EULAR guidelines(4) recommend graded physical activity with or without other non-pharmacological treatments such as hydrotherapy and acupuncture as first and second line treatment options for all patients with fibromyalgia, respectively. Similar, recommendation in the Canadian and American Pain Society guidelines do not advise on which treatments to offer for the different predominant symptoms of fibromyalgia.([9,13]) These guidelines recommend that the management of fibromyalgia should include consideration of utilising both non-pharmacological and pharmacological interventions.

These evidence-based expert-opinion recommendations suggest that patient education, promotion of sleep hygiene, aerobic exercise, and CBT should be considered as core interventions for all symptoms of fibromyalgia. Among exercise types, mind-body exercises that combine body movement, mental focus and controlled breathing such as tai chi, qigong, and yoga were recommended for pain, fatigue, and sleep; flexibility exercise for pain alone; and strengthening exercise for pain or

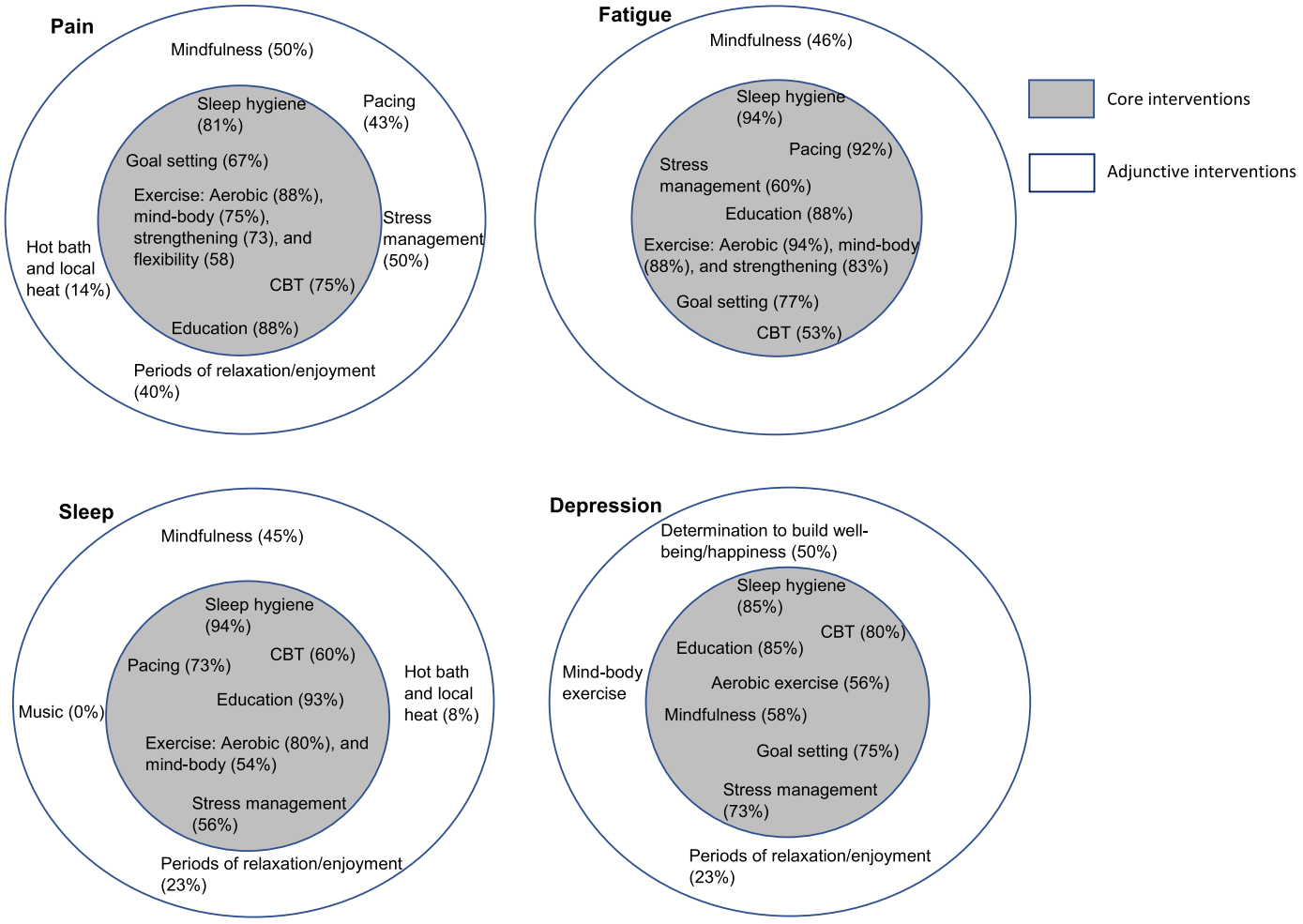

Fig. 1. The classification of accepted non-pharmacological interventions as core or adjunctive for pain, fatigue, sleep and depression. The proportion of experts recommending each intervention as core is shown in parentheses.

fatigue. These results suggest that exercise activity should be tailored to the individual patients' characteristics, as exercise may increase pain for up to 30% of patients with fibromyalgia due to defective pain modulation.[14] Stress management was recommended as core intervention for fatigue, sleep, and depression while pacing was recommended as core intervention for sleep and fatigue. The distinction between recommending an intervention as either core or adjunctive is artificial and is a means of advising clinicians to prioritise offering interventions. However, these decisions should be embedded in shared decision making and an intervention from the adjunctive category may be trialled first, depending on patients' past treatment experiences, patient preference and clinicians' opinion. Indeed, the combination of interventions have been shown to increase their efficacy in fibromyalgia,[15] chronic low back pain,[16] and osteoarthritis.[17]

Even though interventions such as aerobic exercise or CBT were recommended core interventions for all outcomes, they could be difficult to implement. This study will highlight their importance and encourage the health care professionals to utilise available strategies to promote adherence. This may involve the practitioner in providing more patient support and education on the potential benefit from these interventions. Our recommendations may mean that more patients and their health care providers seek CBT in tax-payer, insurance or privately funded healthcare systems.

Rejected interventions were mainly complementary and alternative medicines (CAMs) that had low effect size.[8] On the other hand, some interventions with reported significant improvements such as acupuncture, balneotherapy or weight loss(8) were not recommended. A possible explanation for this may be lack of access to these interventions, cost considerations or potentially unconscious bias against this kind of intervention by members of the Delphi panel who were predominantly physicians. A study assessing cross-cultural differences in GPs' attitudes towards CAM indicated that many GPs in Germany and the United Kingdom are prejudiced against using them and concerned about its availability.[18] Similarly, despite the large effect of balneotherapy,[8] it was rejected by the Delphi panel. We asked them to vote for interventions based not just on research evidence, but also on their knowledge and experiences in terms of acceptability, availability, cost, etc. There are likely differences across continents regarding the cultural acceptance and availability of treatments such as balneotherapy or acupuncture.[19] Therefore, some of these other considerations may have led to its rejection.

The Delphi exercise was not extended beyond the third round despite acupuncture, balneotherapy, determination to build well-being/happiness, dietary modification, massage, music, postural training, strengthening exercise, and weight loss interventions being neither rejected nor accepted for certain predominant symptoms in the management of fibromyalgia. This decision was taken *a priori*, however, it seems justified as the proportion of experts recommending each intervention remained similar in the second and third round of voting.

There are several strengths of this study. First, this Delphi exercise included a multidisciplinary and international group of academics and clinicians, many having participated in international fibromyalgia guideline development groups. All participants completed the three rounds of the Delphi exercise. Recent meta-analysis results were given in summary form, and they were asked to vote by considering research evidence, their knowledge and experience of treating patients with fibromyalgia, and patient preferences. A very comprehensive non-pharmacological intervention list was presented, and the survey also allowed panel members to suggest any other non-pharmacological intervention for each symptom. Two PPI representatives were also involved in interpreting the results and providing patient perspectives to the findings.

However, there were several limitations in this Delphi exercise. First, the panel members of the Delphi exercise were predominantly physicians. This may have caused a biased perspective towards some interventions. Second, some interventions were grouped together: for example, electrotherapy included several modalities such as laser, TENS etc., and music intervention referred to listening to any type of music either therapeutic or for pleasure. Third, effect sizes of the interventions were provided to the participants based on our research findings. This may have introduced a social desirability bias. Even though we reminded experts to use research evidence, clinical experience and patient preferences, participants might have become more influenced by the provided research evidence summary. Fourth, anxiety, that is another common symptom in fibromyalgia, was not assessed in this study. Finally, we included a limited number of patient representatives.

Conclusion

Personalising treatment for fibromyalgia using a targeted symptom approach has been suggested as a way to improve outcomes for patients.[6] This Delphi exercise has reached agreement on a set of core and adjunctive non-pharmacological interventions for the four different major symptoms of fibromyalgia, specifically pain, fatigue, sleep and depression. Clinicians may find this useful as an aid to shared decision-making and treatment choices with patients as part of an individualised management plan.

Contributors

All authors were involved in drafting, revising and approved the final version of the manuscript. Substantial contributions for study conception and design, data analysis and interpretation were made by BK, AA, WZ, MD and all authors for the acquisition of study data. FA, JCB, DB, DC, LJC, MAF, VG, RDG, EK, GJM, CN, NJR, SR, JAPS, AT, DCT, and DW were members of the Delphi panel.

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Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information.

Patient consent for publication

Not applicable.

Ethics approval

Not applicable.

Declaration of Competing Interest

FA reports grants/contracts from BMS, Celgene, Novartis and Sandoz; consulting fees from AbbVie, Biogen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer and Sanofi-Aventis. LC reports grants/contracts from NIH/NIAMS; participation on a data safety monitoring/advisory board for NIH/NIAMS; a leadership/fiduciary role with American College of Rheumatology. MAF reports expert testimony for the plaintiff and the defendant; leadership/fiduciary role with Health Canada, Australian Centre for Cannabinoid Clinical and Research Excellence, Arthritis Foundation US, Canadian Rheumatology Association, American College of Rheumatology abstract committee. EK reports royalties/licenses for studentlitteratur and liber; consulting fees from Eli Lilly; leadership/fiduciary role with IASP Terminology Task Force and IASP ICD-11 Task Force. SR reports grants/contracts from General Nursing Council Trust, Haywood Foundation and CRN. JAPS reports grants/contracts from Pfizer; payment/honoraria from Eli Lilly and Amgen; participation on a

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.semarthrit.2022.152101.

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