Nuovi approcci terapeutici

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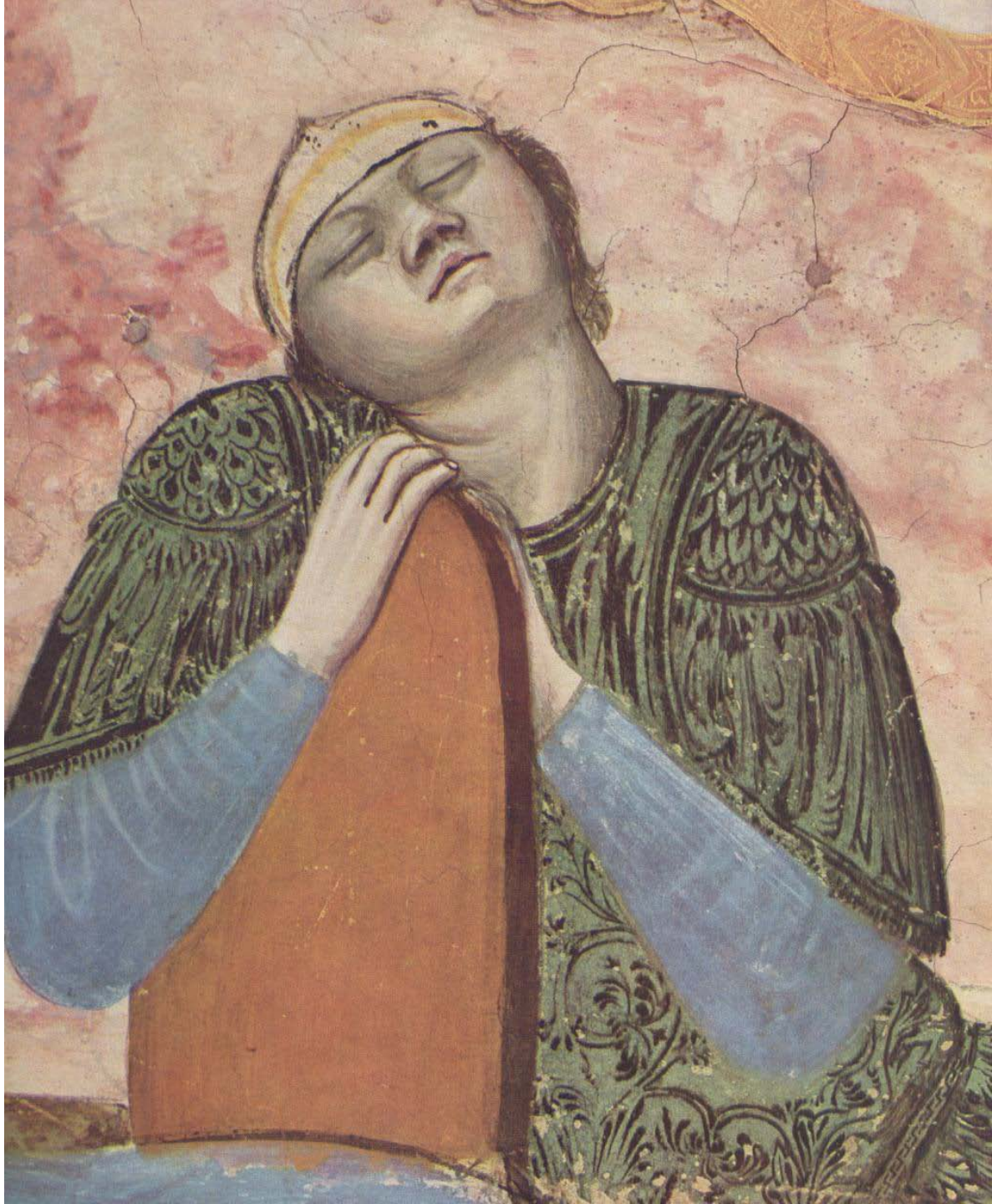
SD Reumatologia A.O.
"G.Rummo"

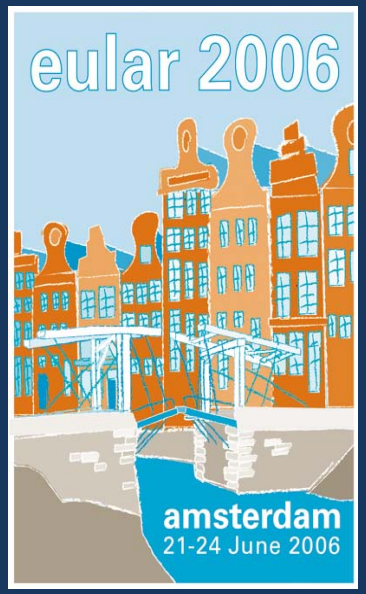
Benevento



Evidenced based Medicine

- Criteri di diagnosi
- Linee guida o Raccomandazioni per la terapia

eular



EULAR Recommendations for the Management of Fibromyalgia Syndrome

Evidence for each recommendation was categorized according to the study design, as previously published (Shekelle et al. 1999).

Category of evidence	Definition
Ia	Evidence for meta-analysis of randomized controlled trials
Ib	Evidence from at least one randomized controlled trial
IIa	Evidence from at least one controlled study without randomization *
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

The strength of each recommendation was then classified according to the following criteria

Strength	Definition
A	Directly based on category I evidence
B	Directly based on category II evidence, or extrapolated recommendation from category I evidence
C	Directly based on category III evidence, or extrapolated recommendation from category I or II evidence
D	Directly based on category IV evidence, or extrapolated recommendation from category II or III evidence

General Recommendations

1

- Full understanding of fibromyalgia requires comprehensive assessment of pain, function, and psychosocial context.
- Fibromyalgia should be recognised as a complex and heterogeneous condition where there is abnormal pain processing and other secondary features.

- Level of Evidence – IV
- Strength - D

General Recommendations

- Optimal treatment requires a **multidisciplinary approach with a combination of non-pharmacological and pharmacological treatment modalities** tailored according to pain intensity, function, associated features such as depression, fatigue and sleep disturbance in discussion with the patient.

- Level of Evidence – IV
- Strength - D

Non-Pharmacological Treatment

- Heated pool treatment with or without exercise is effective in fibromyalgia.

- Level of Evidence IIa
- Strength B

Non-Pharmacological Treatment

- Individually tailored exercise programmes including aerobic exercise and strength training can be beneficial to some patients with fibromyalgia.

- Level of Evidence – IIb
- Strength C

Non-Pharmacological Treatment

- Cognitive behavioural therapy may be of benefit to some patients with fibromyalgia.

- Level of Evidence IV
- Strength D

Non-Pharmacological Treatment

- Other therapies such as relaxation, rehabilitation, physiotherapy and psychological support may be used depending on the needs of the individual patient.

- Level of Evidence – IIb
- Strength - C

Pharmacological

- Anti-depressants
  - Tri-cyclics
  - SSRIs
  - Dual reuptake inhibitors
  - MAO Inhibitors
  - 5HT2/3 antagonists
- Analgesics
  - Systemic & Topical
- Others
  - Pregabalin
  - T3

Effect Size Calculations

Pharmacologic			Non-Pharmacologic		
Intervention	Effect size (95% confidence interval)		Intervention	Effect size (95% confidence interval)	
	Pain	Function		Pain	Function
TCAs	0.663 (1.812)	0.663 (23.239)	Pool based Exercise	0.472 (1.873)	0.498 (14.852)
Dual re-uptake	0.475 (2.18)	Can't calculate	Balneotherapy	1.916 (2.344)	4.147 (21.222)
MAOIs	0.685 (1.561)	Can't calculate	Aerobic Exercise	0.121 (0.839)	0.218 (2.06)
SSRIs	0.607 (1.346)	0.782 (3.414)	Strength training	2.224 (1.232)	1.039 (8.747)
Analgesics (S)	2.013 (1.394)	0.189 (10.549)			
Pramipexole	3.848 (1.711)	3.455 (9.216)			

Pharmacological Treatment

- Tramadol is recommended for the management of pain in fibromyalgia.
- Simple analgesics such as paracetamol and other weak opioids can also be considered in the treatment of fibromyalgia.
- Corticosteroids and strong opioids are not recommended.

- Level of Evidence Ib
- Strength A

Pharmacological Treatment

- Antidepressants: amitriptyline, fluoxetine, duloxetine, milnacipran, moclobemide and pirlindole, reduce pain and often improve function therefore they are recommended for the treatment of fibromyalgia.

- Level of Evidence – Ib
- Strength - A

Pharmacological Treatment

- Tropisetron, pramipexole and pregabalin reduce pain and are recommended for the treatment of fibromyalgia.

- Level of Evidence – Ib
- Strength A

Sodio Oxibato

ARTHRITIS & RHEUMATISM
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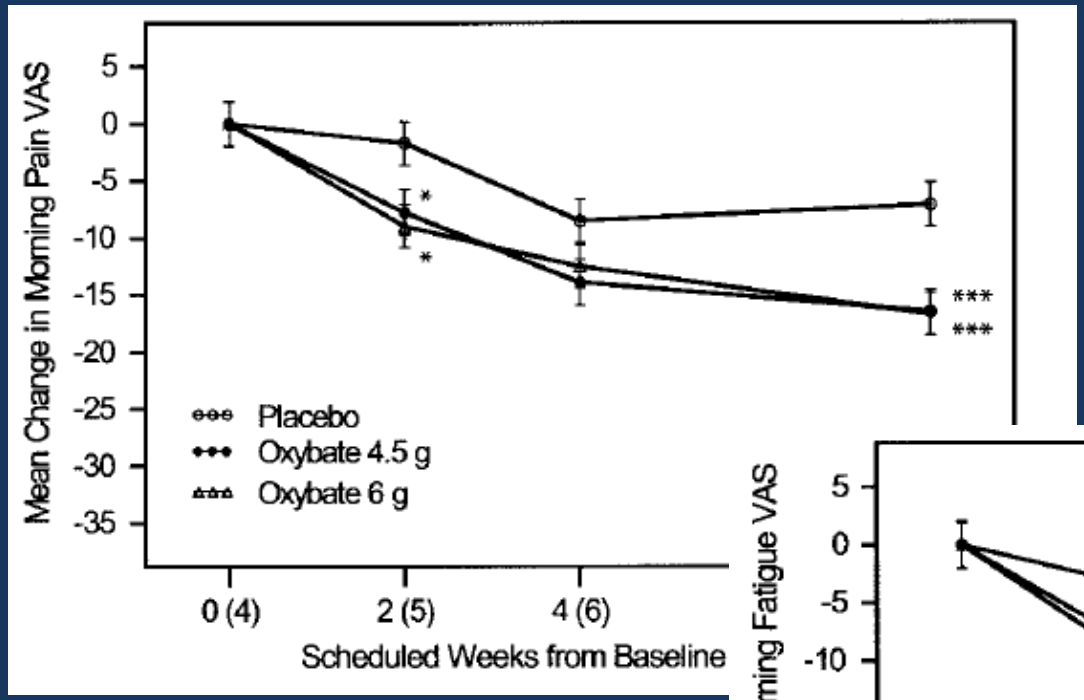
DOI 10.1002/art.24142

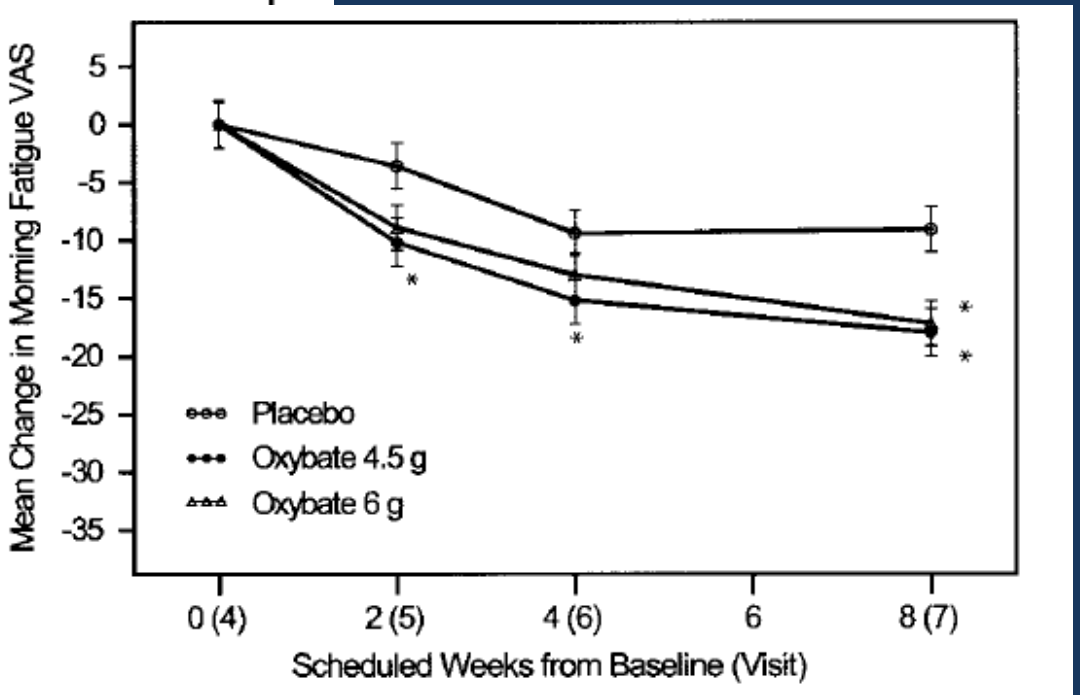
Sodium Oxybate Relieves Pain and Improves Function in Fibromyalgia Syndrome

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Clinical Trial

I. Jon Russell,[1] A. Thomas Perkins,[2] Joel E. Michalek,[1] and the Oxybate SXB-26 Fibromyalgia Syndrome Study Group

Risultati


Mean Change in Morning Pain VAS
5
0
-5
-10
-15
-20
-25
-30
-35
*
*
***
***
Placebo
Oxybate 4.5 g
Oxybate 6 g
0 (4)
2 (5)
4 (6)
Scheduled Weeks from Baseline


Mean Change in Morning Fatigue VAS
5
0
-5
-10
-15
-20
-25
-30
-35
*
*
*
*
Placebo
Oxybate 4.5 g
Oxybate 6 g
0 (4)
2 (5)
4 (6)
6
8 (7)
Scheduled Weeks from Baseline (Visit)

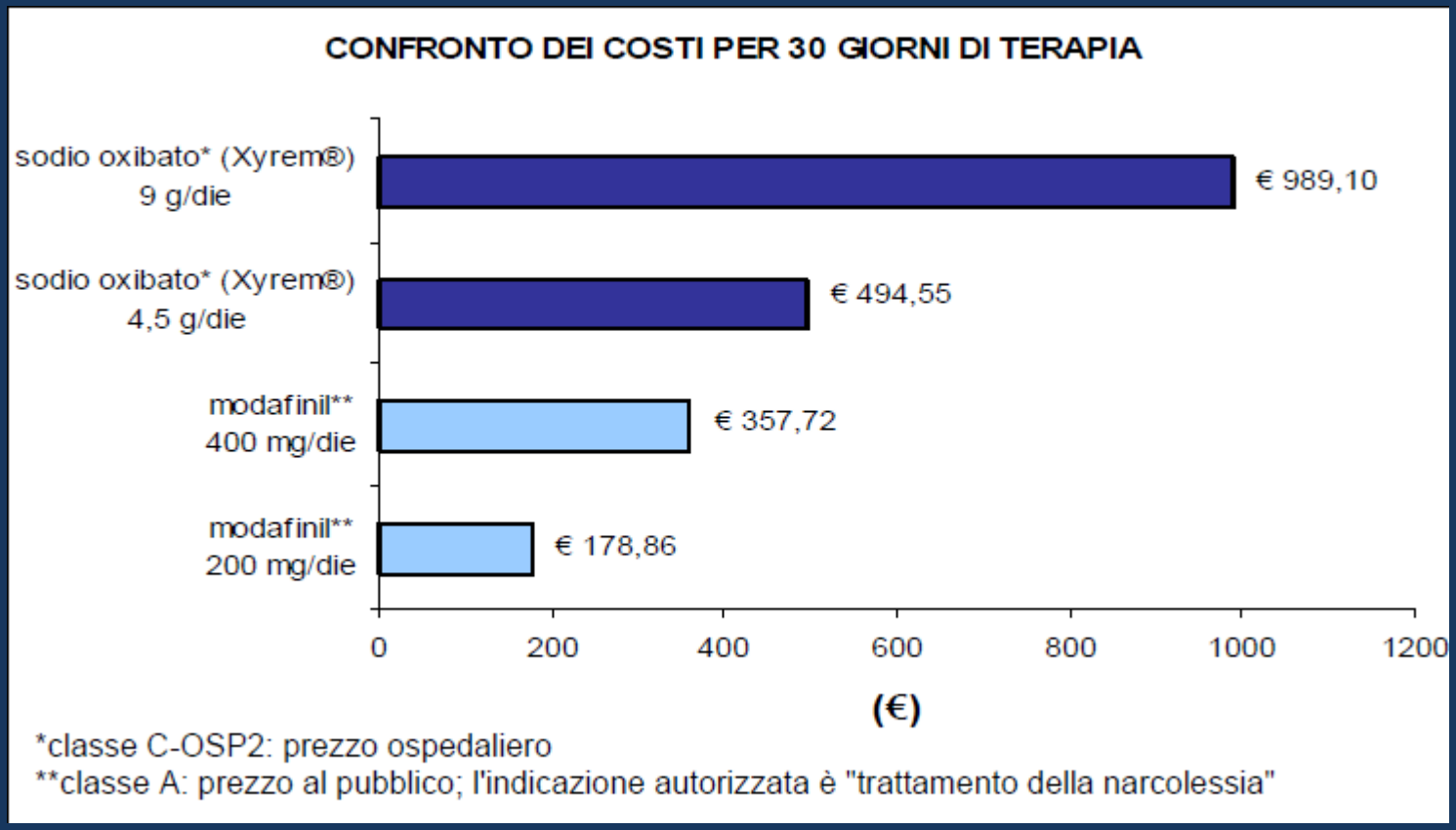
Eventi avversi

Table 3. Adverse events affecting ≥2% of the patients with fibromyalgia syndrome in the all-treated population (n = 192)*

Adverse event	Placebo (n = 65)	Sodium oxybate 4.5 gm (n = 60)	Sodium oxybate 6 gm (n = 67)	*P* versus placebo
Nausea	6 (9.23)	10 (16.67)	19 (28.36)	0.02
Pain in extremity	0 (0)	4 (6.67)	0 (0)	0.009
Nervous system disorders†	9 (13.85)	16 (26.67)	27 (40.3)	0.003
Dizziness	2 (3.08)	5 (8.33)	12 (17.91)	0.01
Restlessness	0 (0)	3 (5)	0 (0)	0.03
Renal and urinary disorders	0 (0)	1 (1.67)	5 (7.46)	0.04
Urinary incontinence	0 (0)	0 (0)	4 (6.0)	0.004

* Values are the number (%) of patients. *P* values were determined by Fisher's exact test (2 degrees of freedom).
† Includes dizziness, headache, paresthesia, and somnolence.

Il profilo rischio/beneficio del farmaco risulta ancora incerto, a causa di 3 punti critici sul profilo di sicurezza che necessitano di essere esaminati ulteriormente: dipendenza, tolleranza, e potenziale d'abuso del farmaco. Inoltre il prezzo non è giustificato alla luce dell'esistenza dell'altra specialità a base di sodio oxibato in commercio ad un prezzo molto inferiore.



INTERNAL MEDICINE

□ ORIGINAL ARTICLE □

Efficacy of Waon Therapy for Fibromyalgia

Kakushi Matsushita, Akinori Masuda and Chuwa Tei

Abstract

Objective Fibromyalgia syndrome (FMS) is a chronic syndrome characterized by widespread pain with tenderness in specific areas. We examined the applicability of Waon therapy (soothing warmth therapy) as a new method of pain treatment in patients with FMS.

Methods Thirteen female FMS patients (mean age, 45.2±15.5 years old; range, 25-75) who fulfilled the criteria of the American College of Rheumatology participated in this study. Patients received Waon therapy once per day for 2 or 5 days/week. The patients were placed in the supine or sitting position in a far infrared-ray dry sauna maintained at an even temperature of 60℃ for 15 minutes, and then transferred to a room maintained at 26-27℃ where they were covered with a blanket from the neck down to keep them warm for 30 minutes. Reductions in subjective pain and symptoms were determined using the pain visual analog scale (VAS) and fibromyalgia impact questionnaire (FIQ).

Results All patients experienced a significant reduction in pain by about half after the first session of Waon therapy (11-70%), and the effect of Waon therapy became stable (20-78%) after 10 treatments. Pain VAS and FIQ symptom scores were significantly ($p<0.01$) decreased after Waon therapy and remained low throughout the observation period.

Conclusion Waon therapy is effective for the treatment of fibromyalgia syndrome.

Key words: fibromyalgia, Waon therapy, thermal therapy

(Inter Med 47: 1473-1476, 2008)
(DOI: 10.2169/internalmedicine.47.1054)

Waon Therapy

Therapy in which the entire body is warmed in an evenly heated dry chamber for 15 minutes at 60 °C that soothes the mind and body. The deepbody temperature increases approximately 1.0-1.2 °C. The soothing warmth effects are sustained by maintaining the warmth at rest for an additional 30 minutes, with fluids corresponding to perspiration being supplied at the end.

RESEARCH Open Access

Effects of acupuncture to treat fibromyalgia: A preliminary randomised controlled trial

Kazunori Itoh*, Hiroshi Kitakoji

Abstract

Background: Acupuncture is often used to treat fibromyalgia (FM), but it remains unclear whether acupuncture is effective. This study aims to evaluate the effects of acupuncture on pain and quality of life (QoL) in FM patients.

Methods: Sixteen patients (13 women and 3 men aged 25-63 years) suffering from FM were randomised into two groups: group A (n = 8) received five acupuncture treatments after the fifth week and group B received ten acupuncture treatments. Outcome measures used in this study were pain intensity (visual analogue scale, VAS) and the fibromyalgia impact questionnaire (FIQ).

Results: After the fifth week, pain intensity (U = 25.0; P = 0.022) in group B decreased and QoL (U = 24.5; P = 0.026) improved compared to group A.

Conclusion: The present study suggests that acupuncture treatment is effective to relieve pain for FM patients in terms of QoL and FIQ.

REVIEW Open Access

Effectiveness of manual therapies: the UK evidence report

Gert Bronfort[1*], Mitch Haas[2], Roni Evans[1], Brent Leininger[1], Jay Triano[3,4]

Abstract

Background: The purpose of this report is to provide a succinct but comprehensive summary of the scientific evidence regarding the effectiveness of manual treatment for the management of a variety of musculoskeletal and non-musculoskeletal conditions.

Methods: The conclusions are based on the results of systematic reviews of randomized clinical trials (RCTs), widely accepted and primarily UK and United States evidence-based clinical guidelines, plus the results of all RCTs not yet included in the first three categories. The strength/quality of the evidence regarding effectiveness was based on an adapted version of the grading system developed by the US Preventive Services Task Force and a study risk of bias assessment tool for the recent RCTs.

Results: By September 2009, 26 categories of conditions were located containing RCT evidence for the use of manual therapy: 13 musculoskeletal conditions, four types of chronic headache and nine non-musculoskeletal conditions. We identified 49 recent relevant systematic reviews and 16 evidence-based clinical guidelines plus an additional 46 RCTs not yet included in systematic reviews and guidelines.
Additionally, brief references are made to other effective non-pharmacological, non-invasive physical treatments.

Conclusions: Spinal manipulation/mobilization is effective in adults for: acute, subacute, and chronic low back pain; migraine and cervicogenic headache; cervicogenic dizziness; manipulation/mobilization is effective for several extremity joint conditions; and thoracic manipulation/mobilization is effective for acute/subacute neck pain. The evidence is inconclusive for cervical manipulation/mobilization alone for neck pain of any duration, and for manipulation/mobilization for mid back pain, sciatica, tension-type headache, coccydynia, temporomandibular joint disorders, fibromyalgia, premenstrual syndrome, and pneumonia in older adults. Spinal manipulation is not effective for asthma and dysmenorrhea when compared to sham manipulation, or for Stage 1 hypertension when added to an antihypertensive diet. In children, the evidence is inconclusive regarding the effectiveness for otitis media and enuresis, and it is not effective for infantile colic and asthma when compared to sham manipulation.
Massage is effective in adults for chronic low back pain and chronic neck pain. The evidence is inconclusive for knee osteoarthritis, fibromyalgia, myofascial pain syndrome, migraine headache, and premenstrual syndrome. In children, the evidence is inconclusive for asthma and infantile colic.

Clin Rehabil. 2010 Apr;24(4):305-18.

A randomized controlled trial of a wellness intervention for women with fibromyalgia syndrome.

Stuifbergen AK, Blozis SA, Becker H, Phillips L, Timmerman G, Kullberg V, Taxis C, Morrison J.
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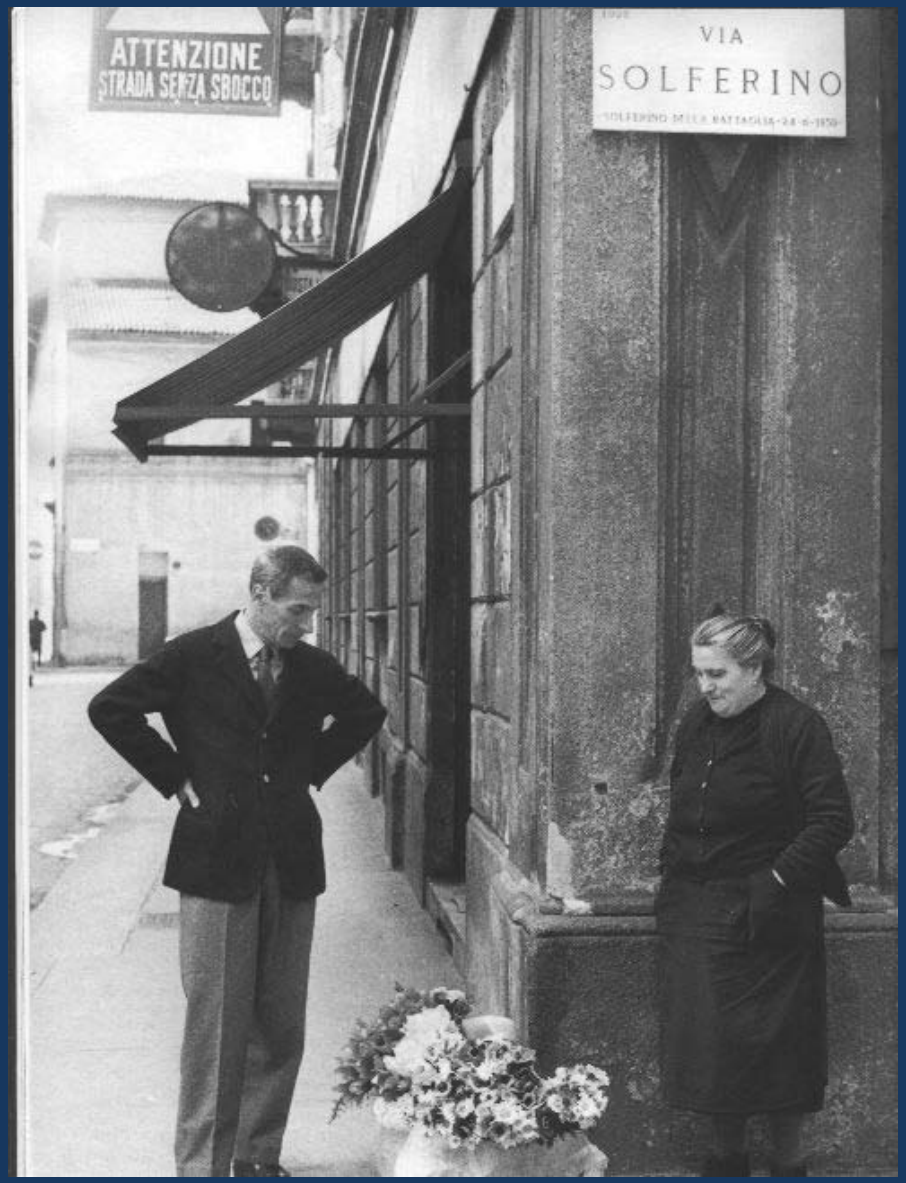
OBJECTIVE: To examine the effects of a wellness intervention, Lifestyle Counts, for women with fibromyalgia syndrome on the level of self-efficacy for health-promoting behaviours, health-promoting activity and perceived quality of life. DESIGN: A randomized controlled single-blinded trial with treatment and attention-control groups. SETTING: Community in the southwestern United States. SUBJECTS: Convenience sample of 187 women (98 treatment, 89 attention control) with fibromyalgia syndrome (mean age = 53.08 years, SD 9.86). INTERVENTION: The two-phase Lifestyle Counts intervention programme included lifestyle change classes for eight weeks, with goal-setting and telephone follow-up for three months. Participants in the attention-control group were offered an equivalent amount of contact in classes on general disease-related information and health education topics and unstructured follow-up phone calls. Participants were followed for a total of eight months after baseline. OUTCOME MEASURES: Self-report instruments measuring self-efficacy for health behaviours, health-promotion behaviours and health-related quality of life (SF-36 and the Fibromyalgia Impact Questionnaire) were completed at baseline, two months (after the classes), five months (after telephone follow-up) and at eight months. RESULTS: Both groups improved significantly ($P<0.05$) over time on the measures of self-efficacy, health behaviours, fibromyalgia impact and quality of life. There were significant group x time interactions for scores on the Health Promoting Lifestyle II subscales of physical activity and stress management. CONCLUSIONS: The Lifestyle Counts wellness intervention holds promise for improving health-promoting behaviours and quality of life of women with fibromyalgia syndrome.

Conclusions

- Many RCTs in fibromyalgia
- Effective treatments for fibromyalgia are available
- Treatment needs to be tailored to the needs of individual patient
- EULAR recommendations for FMS have been developed



"... gli uomini per quanto possano volersi bene, rimangono sempre lontani; che se uno soffre il dolore è completamente suo, nessun altro può prenderne su di sé una minima parte; che se uno soffre, gli altri per questo non sentono male, anche se l'amore è grande, e questo provoca la solitudine della vita."

Dino Buzzati, Il deserto dei Tartari. Rizzoli Ed., 1940