

HELPFUL HINTS FOR TREATING FIBROMYALGIA

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Feb 2017

Awareness of FM has skyrocketed

Due to FDA approval of 3 FM drugs

- **Neurontin/gabapentin** (*never FDA approved for FM*)
 - The drug company was fined \$430 million for off-label marketing. The unprecedented fine came after the epilepsy drug was promoted for “unapproved uses” including migraines and chronic pain (because it was discovered how well gabapentin worked for “nervous system” pain!)
- **Lyrica/pregabalin**-- June 2007 (Pfizer)
- **Cymbalta/duloxetine**— June 2008 (Eli-Lilly)
- **Savella/milnacipran**— January 2009 (Forest/Cypress)

\$ millions were spent by pharmaceutical companies to educate the PUBLIC and PRIMARY CARE PROVIDERS from 2007-2012.

FM became a household word.



Dr. Oz: July 23, 2013

The Disease Doctors Miss Most: Fibromyalgia



Fibromyalgia is a term used to describe:

- A **syndrome** characterized by widespread chronic pain in the body, and is thought related to amplified pain signals in the spinal cord and brain (the central nervous system).
- FM is characterized by:
 - **Hyperalgesia**---amplified, e.g. severe pain.
 - **Allodynia**---the sensation of pain from a milder stimulus, such as touch or pressure.

Fibromyalgia is not primarily a musculoskeletal disorder

- Although FM was originally studied in rheumatology clinics, it has more recently been considered a **nervous system** disorder that creates musculoskeletal pain, along with global pain amplification, physical and mental fatigue.
- Some FM may eventually be considered a *neuroimmune* or *autoimmune* condition.

FIBROMYALGIA CRITERIA (ACR 1990)

Chronic (>3 months)

Widespread Pain (pain in 4 quadrants of body & spine)
and Tenderness (>11/18 tender points)

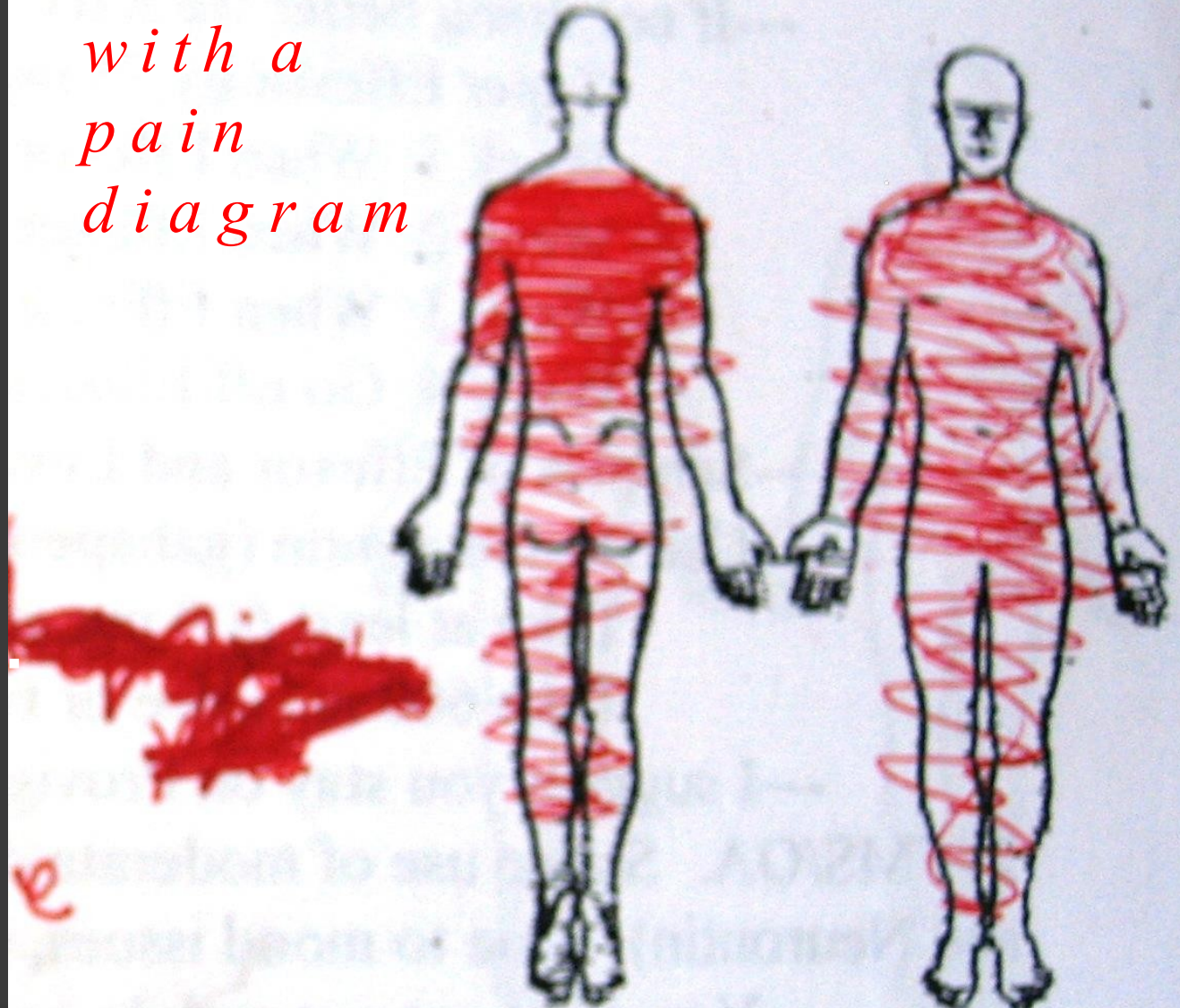
*PAIN= stiffness, achiness, sharp shooting pains...tingling and numbness...light and sound sensitivity...
in muscles, joints, bowel, bladder, pelvis, chest, head...*

**FATIGUE, COGNITIVE and SLEEP disturbances
are described in Wolfe et al but were not required for dx,**

FM
feels like...

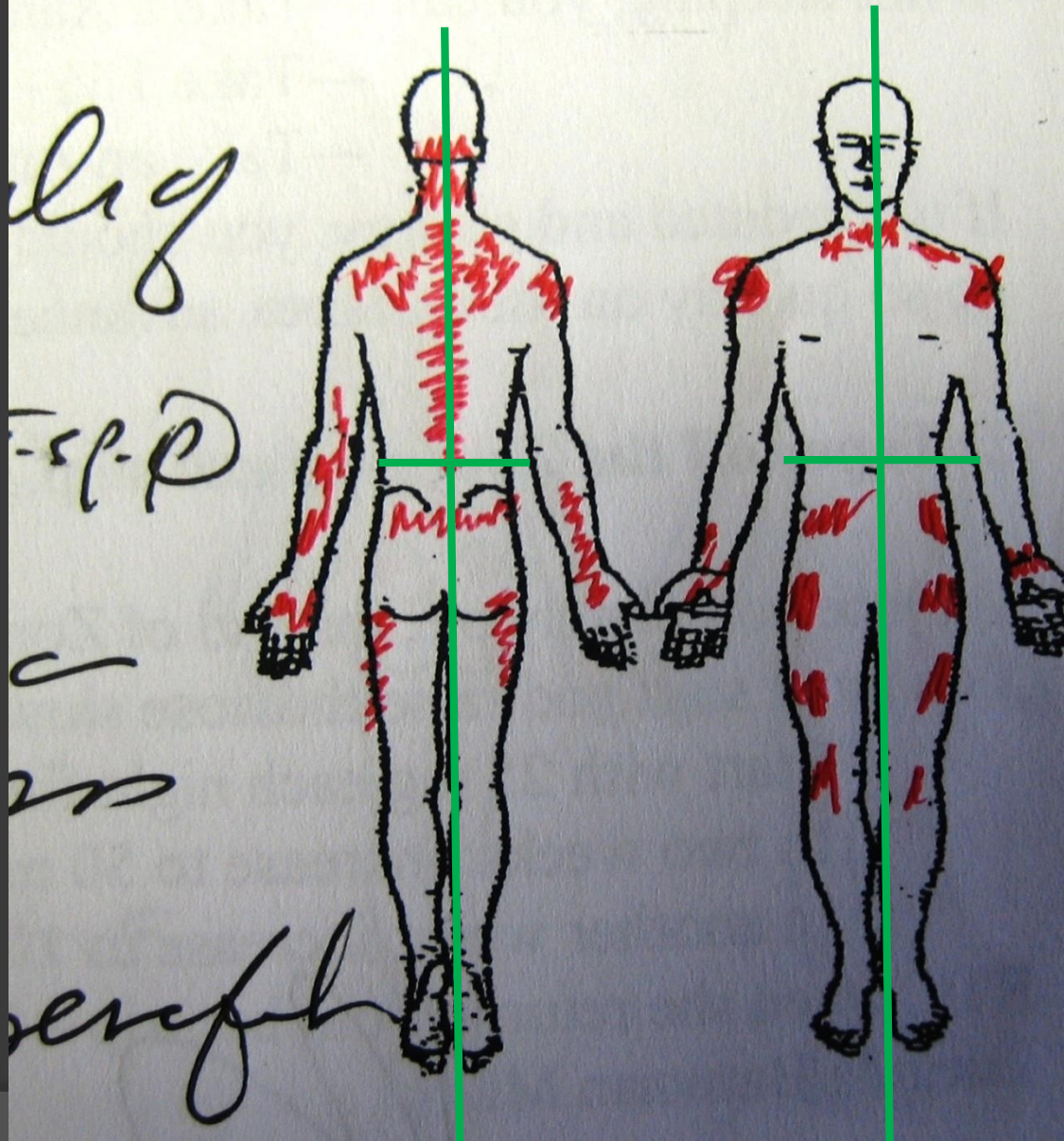
COLOR IN ALL PAIN AREAS IN RED INK

*"See" and "hear"
with a
pain
diagram*



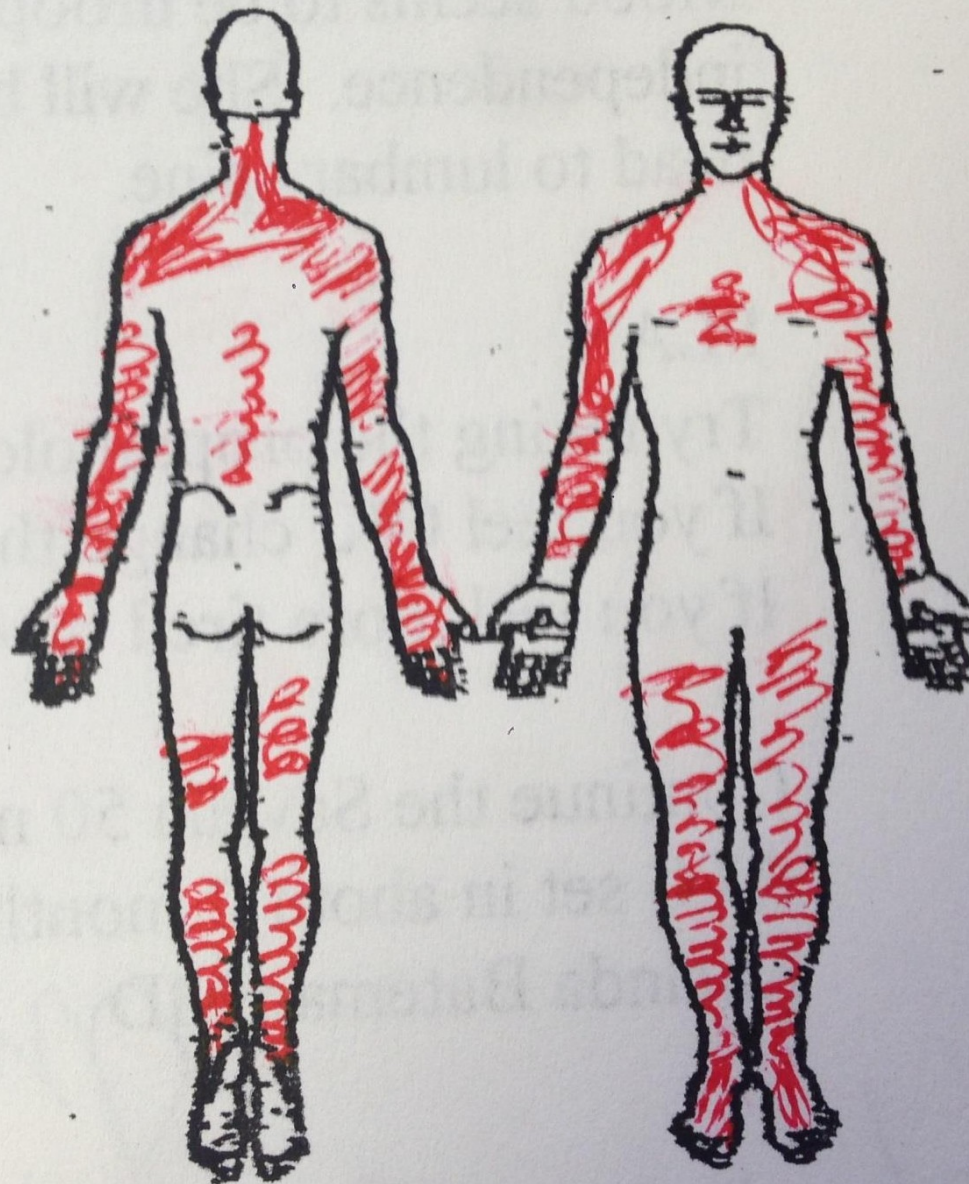
*We use **red pen** to communicate **pain***

COLOR ALL PAIN AREAS IN RED INK



Four
quadrants
and the
spine

COLOR IN ALL PAIN AREAS IN RED INK



pulls a
108
12/10/11

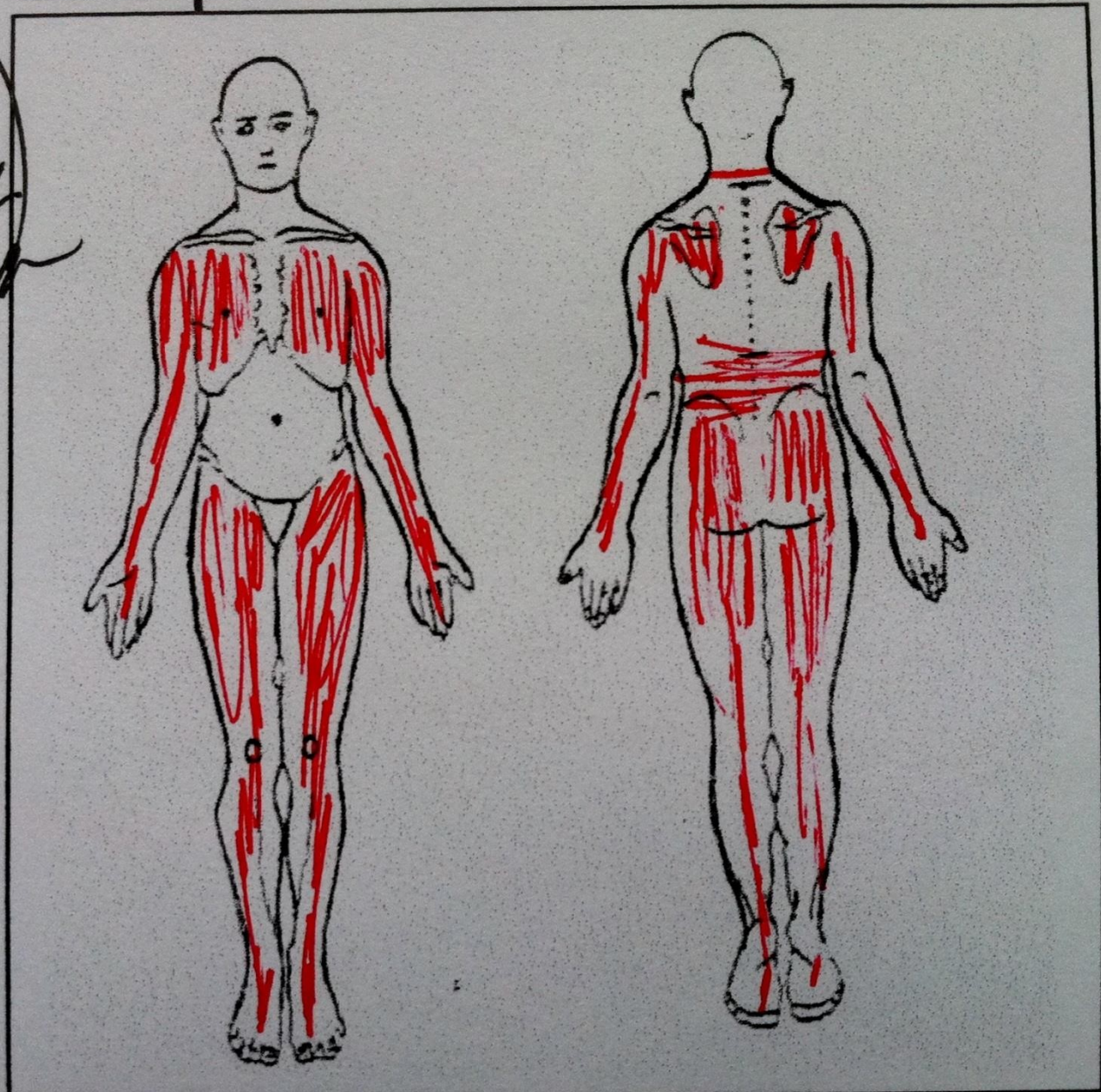
t)

bed 11
3-4h
up jaw
8-830

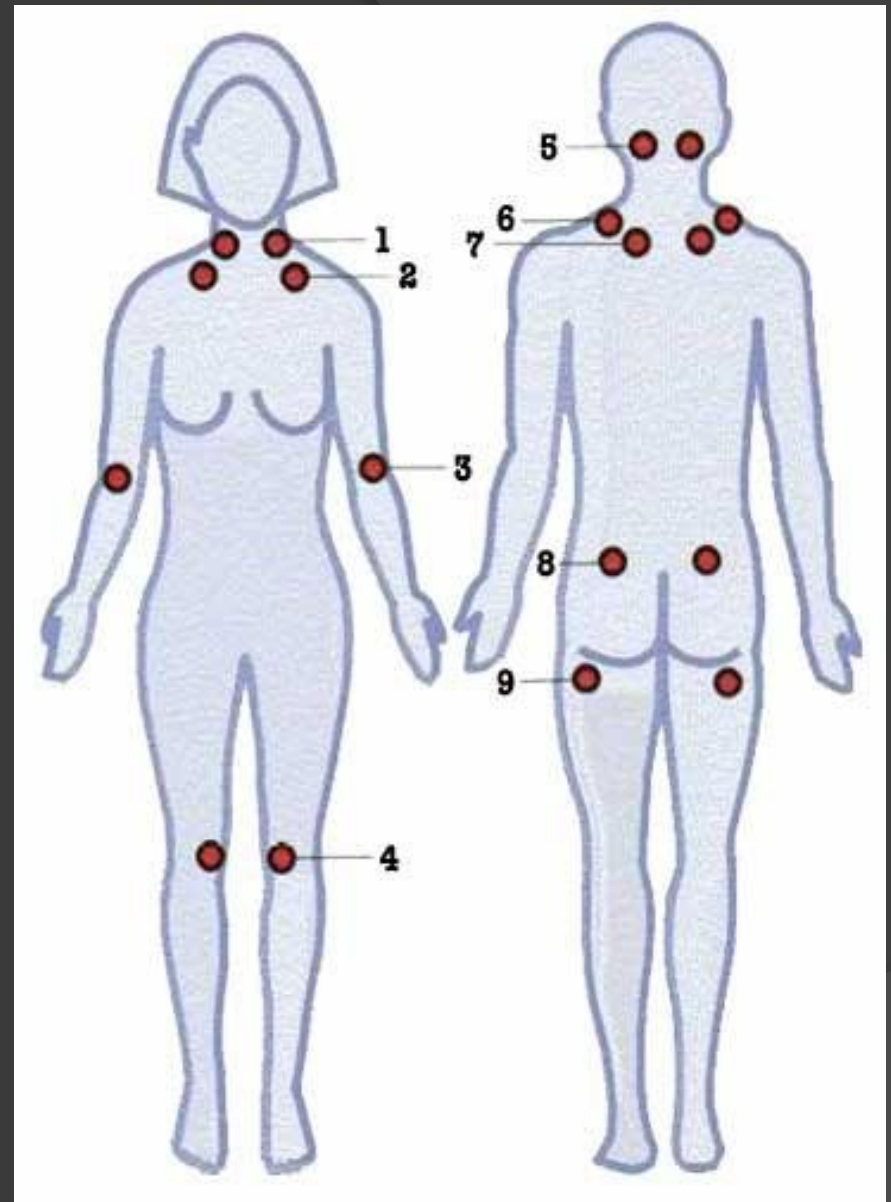
2 13 14 15+

2 13 14 15+
ing in bed)

anor 30
COLOR IN ALL PAIN AREAS IN RED INK



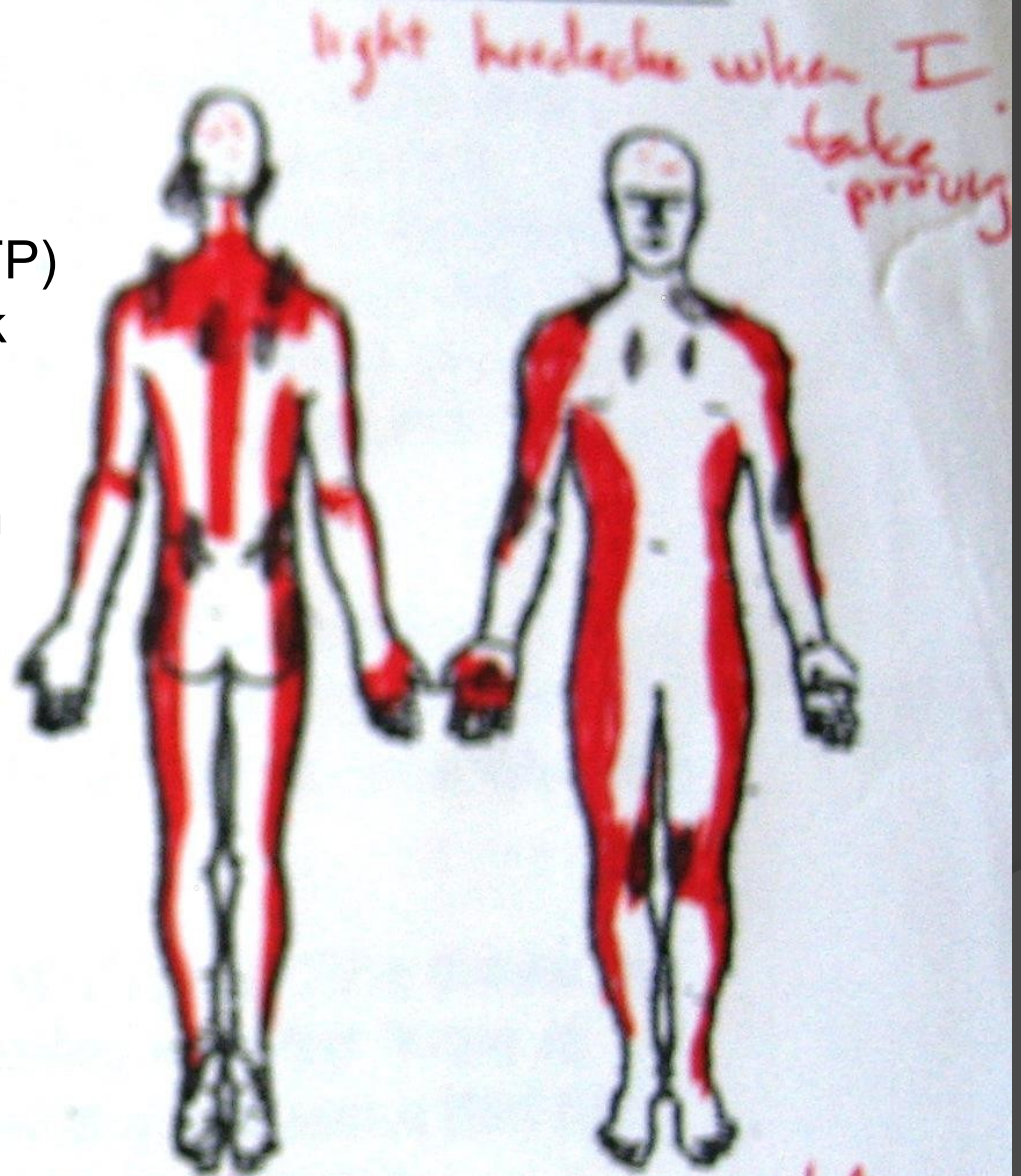
The 1990
ACR FM Criteria
require presence of
at least 11 of the
18 TENDER POINTS
(9 pairs)



Wolfe F, Smythe HA, Yunus MB. The American College of Rheumatology. 1990
Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria
Committee. *Arthritis Rheum.* Feb 1990;33(2):160-72

COLOR IN ALL PAIN AREAS IN RED INK

Tender Points (TP)
drawn in black
by examiner
at time of
physical exam



FM Prevalence (2 studies)

by 1990 ACR Criteria:

2-3% of adults

3-5% of all adult women **0.5-1.6% of adult men**

3,006 persons **Wichita, KS, USA.**

The prevalence of FM:

2.0% of adults both sexes

3.4% of women

0.5% of men

Prevalence increased with age
highest values were in

> 7.0% of women 60 and 79 years

The prevalence and characteristics of fibromyalgia in the general population. Arthritis Rheum. 1995 Jan;38(1):19-28. Wolfe F, et al.

3,395 persons. **Ontario. Canada**

The prevalence of FM:

3.3% of adults both sexes

4.9% of women

1.6% of men

Prevalence rises with age from

1% of women 18-30 to

8% in women 55-64.

The London Fibromyalgia Epidemiology Study: the prevalence of fibromyalgia syndrome in London, Ontario. J Rheumatol. 1999 Jul;26(7):1570-6

Using 1990 ACR FM criteria there are 6-10 million Americans with FM

ALTERNATE "NEW" FIBROMYALGIA CRITERIA (ACR 2010)

1) Widespread PAIN index (WPI)
(0-19 points—see next slide)

7+

or 3-6

2) Symptom Score (SS):

0=none, 1=mild, 2=mod, 3=severe

Chronic fatigue (0-3)

Unrefreshing sleep (0-3)

Cognitive complaints (0-3)

Multisystem complaints (0-3)

Max SS = 12

5+

and 9+

FM

FM

> 3 months in duration and without other apparent explanation

19 PAIN AREAS OF WPI (2010 ACR FM)

neck
chest

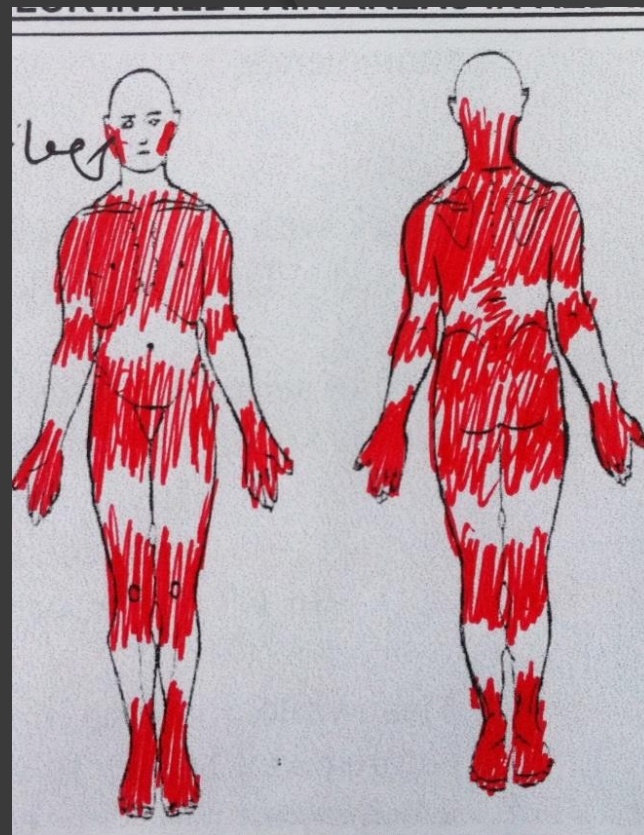
jaw left
shoulder girdle left
upper arm left
lower arm left

right jaw
right shoulder girdle
right upper arm
right lower arm

upper back
abdomen
lower back

hip left
upper leg left
lower leg left

right hip
right upper leg
right lower leg



FM patient clinic chart with pain diagram and symptom scores:

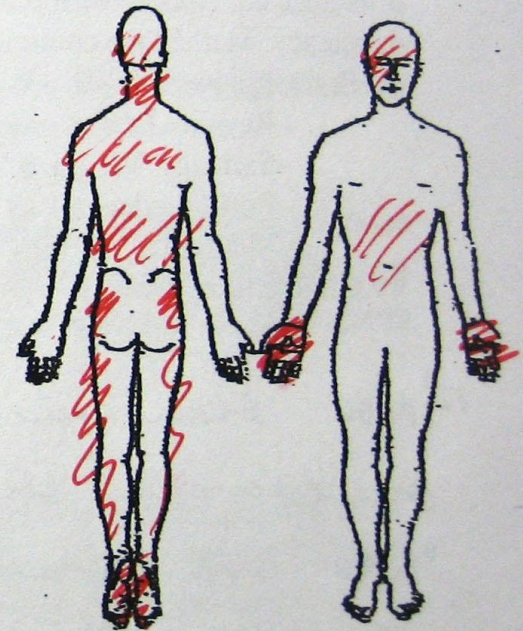
SYMPTOM SCORES

FATIGUE	0	1	2	3	4	5	6	7	8	9	10
DEPRESSION*ANXIETY	0	1	2	3	4	5	6	7	8	9	10
BRAIN FOG	0	1	2	3	4	5	6	7	8	9	10
BODY ACHES	0	1	2	3	4	5	6	7	8	9	10
PAIN	0	1	2	3	4	5	6	7	8	9	10
HEADACHES	0	1	2	3	4	5	6	7	8	9	10
SLEEP PROBLEMS	0	1	2	3	4	5	6	7	8	9	10
INACTIVITY/function	0	1	2	3	4	5	6	7	8	9	10
0= GOOD (least)						10= BAD (most)					

What do you want to discuss or work on today?

- 1) Refills
- 2) Study(?)
- 3) Referral
- 4) Testosterone ?

COLOR IN ALL PAIN AREAS IN RED INK



WPI (pain areas) + **SS** (fatigue, sleep, cognitive, other)

ACR FM 1990 vs 2010?

- Of 1,604 questionnaire participants, 269 were invited to attend the research clinic, and 104 (39%) attended; 32 of these subjects (31%) met ≥ 1 set of fibromyalgia criteria.
- The prevalence of fibromyalgia by:
 - 1990 ACR FM criteria = 1.7%
 - modified 2010 ACR criteria = 5.4%
- The ratio of females to males was:
 - 1990 ACR FM criteria = 13:1
 - 2010 ACR FM criteria = 2:1
- ACR FM 2010 raises prevalence by 3X compared to 1990

The Prevalence of Fibromyalgia in the General Population: A Comparison of the American College of Rheumatology 1990, 2010, and Modified 2010 Classification Criteria. Jones GT, et al. Arthritis & Rheumatology. Volume 67, Issue 2, pages 568–575, February 2015. Published online: 28 JAN 2015

Increased **central sensitivity** and **sympathetic overdrive** are only broadly defined by the 1990 or 2010 ACR Criteria, and the overlap with MECFS criteria is significant

- ❑ Migraine and tension headaches, TMJ/TMD
- ❑ Paresthesia (numbness and tingling)
- ❑ Restless legs syndrome
- ❑ Irritable bowel syndrome, IBS-D, IBS-C
- ❑ Irritable bladder or interstitial cystitis, painful menstruation, pelvic pain, vulvodynia
- ❑ Heart palpitations, sinus tachycardia, low HRV
- ❑ Sicca syndrome (dry eyes and mouth)
- ❑ Light, noise and chemical sensitivities

GENERAL PRINCIPLES OF SUPPORTIVE MANAGEMENT:

1) **Address all other conditions** (complete a good medical work-up)
--i.e. anemia, thyroid, diabetes, sleep apnea, low Vit B12

2) **“Pace”** to prevent symptom escalation (Preventive activity management. Reduce overload)

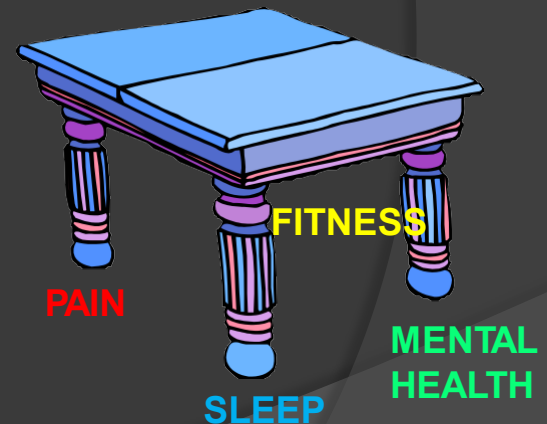
3) **Address the major aspects of illness**

PAIN: reduce severe pain

SLEEP: achieve restorative sleep

MENTAL HEALTH: insight and support

FITNESS: engage in restorative exercise



How do we “address” other conditions that may cause widespread pain, fatigue, disturbed sleep and cognition?

HISTORY and PHYSICAL EXAM

---further investigation of any abnormalities.

Preventive screening tests

---mammogram, pap, colon screen, fasting lipids ...

LABS: CBC, CMP, TSH, ESR (CRP), UA

(+/-) FSH, testosterone, Vitamin B12, Vitamin D, HgA1C

CPK, ANA, RF, hepatitis C, HIV... *based on clinical presentation*

X-ray, CT, MRI: if needed to evaluate pain, joints, spine, brain, etc.

Polysomnography: for daytime sleepiness or unrelieved sleep disruption

Stress testing: to exclude heart and lung disease based on clinical presentation

GI studies: EGD and colonoscopy (celiac disease, Hpylori, inflammatory bowel disease)

There should be careful emphasis on evaluating for other causes of chronic widespread pain/achiness

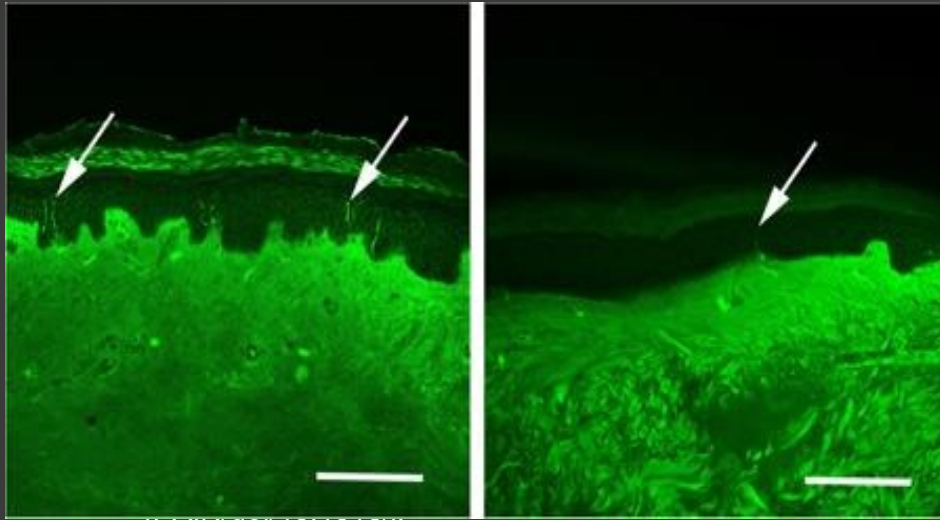
- ❑ Rheumatology conditions: polymyalgia rheumatica, lupus, rheumatoid arthritis, etc.
- ❑ Peripheral and poly-neuropathies
- ❑ Hypothyroidism, hyperparathyroidism, metabolic syndrome
- ❑ Multiple sclerosis
- ❑ “Statin” induced muscle pain (cholesterol drugs)
- ❑ Hepatitis C...and other post-viral syndromes
- ❑ Hyperparathyroidism
- ❑ Toxic exposures...

Some fibromyalgia/FM patients may have unrecognized **SFPN** (small fiber poly-neuropathy) a distinct disease process often missed that can be tested for objectively* and sometimes treated definitively.

*Some controversy: Not always evident on typical neurologic exam or nerve studies.

Pain. 2013 Nov;154(11):2310-6. doi: 10.1016/j.pain.2013.06.001. Epub 2013 Jun 5.
Objective evidence that small-fiber polyneuropathy underlies some illnesses currently labeled as fibromyalgia.
Oaklander AL, Herzog ZD, Downs HM, Klein MM.

SFPN or FM?...or both?



These biopsy samples show significantly reduced density of nerve fibers (white arrows) in the skin of a fibromyalgia patient (right) compared with a healthy volunteer (left). (PAIN/doi/10.1016/j.pain.2013.06.001)

"Until now, there has been no good idea about what causes fibromyalgia, but now we have evidence for some but not all patients. Fibromyalgia is too complex for a 'one size fits all' explanation," says Oaklander, an associate professor of Neurology at Harvard Medical School. "Helping any of these people receive definitive diagnoses and better treatment would be a great accomplishment."

Pain symptoms of SFPN

- ❑ cold-like pain, tingling or a pins and needles
- ❑ burning pain
- ❑ transient electric shock–like pain
- ❑ may worsen during periods of rest and at night

Small nerve fiber neuropathies also may result in autonomic dysfunction and multisystem illness symptoms, including orthostatic intolerance...

- ❑ dry eyes, dry mouth
- ❑ postural lightheadedness, fainting
- ❑ abnormal sweating
- ❑ erectile dysfunction
- ❑ nausea, vomiting, diarrhea, constipation, low appetite
- ❑ difficulty with urinary frequency, nocturia, and/or voiding

Dysautonomia:

32 yo woman 12+ years with FM/CFS, anxiety/depression

Orthostatic Vital Signs/The NASA LEAN Test

Supine 1 minute BP: 118/64 Pulse: 89

Supine 2 minute BP: 116/60 Pulse: 85

Standing straight with shoulder blades against the wall

Standing 0 minute BP: 104/80 Pulse: 85

Standing 1 minute BP: 108/74 Pulse: 119

Standing 2 minute BP: 96/70 Pulse: 116

Standing 3 minute BP: 108/75 Pulse: 123 Arms "tingling"

Standing 4 minute BP: 98/78 Pulse: 120

Standing 5 minute BP: 96/73 Pulse: 123 Lightheaded and dizzy

Standing 6 minute BP: 91/73 Pulse: 125

Standing 7 minute BP: 94/74 Pulse: 122

Standing 8 minute BP: 96/74 Pulse: 122

Standing 9 minute BP: 92/79 Pulse: 126 Increased lightheadedness, nausea

Standing 10 minute BP: 93/80 Pulse: 120 Increased "electrical buzz"

Summary:

SBP -27 mmHg meets criteria for orthostatic hypotension (>20 mmHg decrease)

HR +41 bpm meets criteria for POTS (>30 bpm increase)

SFPN: Normal or near normal physical and neurologic examination

- ❑ Coordination, motor, and reflex examinations will be normal.
- ❑ Light touch, vibratory sensation, and proprioception may be normal
- ❑ May have decreased pinprick, decreased thermal (heat) sensation, or hyperalgesia in the affected region. There may be mildly decreased vibratory sensation
- ❑ EMG and nerve conduction may be normal

SFPN: Skin biopsy is the most definitive test, but not always diagnostic.

- The sensitivity (78%–92%) and specificity (65%–90%) of skin biopsy for diagnosing a small fiber neuropathy is fairly high across all studies, but not always practical or available in a clinical setting.

Mirtapex .125 - ⁶⁻¹² @ HS - pm
 Doxepin 10mg ⁽⁴⁾ - 5 - at HS
 Zolagran 100mg - ⁶ at HS
 Xanax 40mg - ⁶ 1/2 at HS

7. Tizanidine 1/2 4x5xaday
 8. Soma 350 1/2 - 4xaday
 9. ~~After~~ Dex tro methamphetamine
 10. Trazizine and 1/2 @ 11³⁰ 3P = 2d

11. Tizanidine T @ HS
 12. Tizanidine T @ HS
 13.
 14.
 15.

PTOM SCORES	good days or bad days										
SUE	0	1	2	3	4	5	6	7	8	9	10
DEPRESSION*ANXIETY	0	1	2	3	4	5	6	7	8	9	10
FOG	0	1	2	3	4	5	6	7	8	9	10
ACHES	0	1	2	3	4	5	6	7	8	9	10
ACHES or	0	1	2	3	4	5	6	7	8	9	10
PROBLEMS	0	1	2	3	4	5	6	7	8	9	10
IVITY/function	0	1	2	3	4	5	6	7	8	9	10
0= GOOD (least) 10= BAD (most)											

Do you want to discuss or work on today?

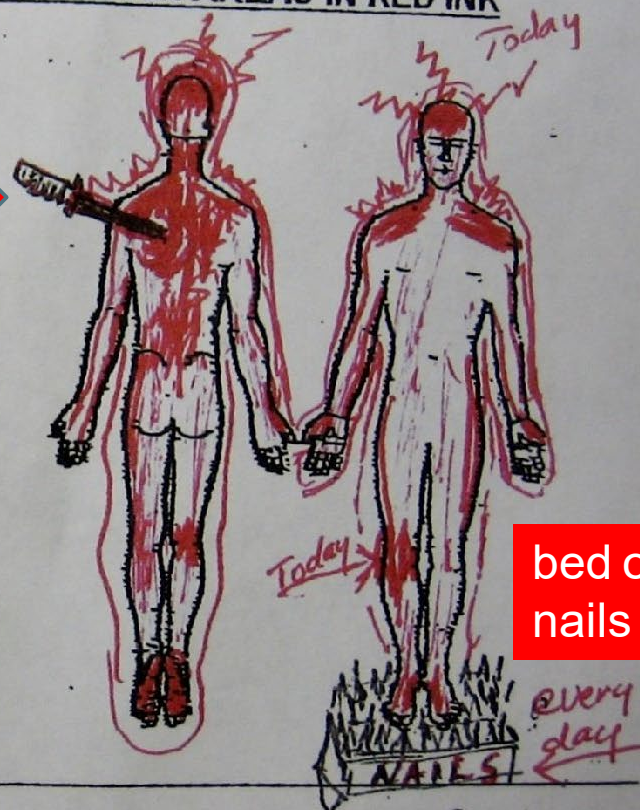
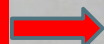
disability
 am real tired of hurting
 keep going and just get behind and behind

AL EXAMINATION:

[REDACTED] has applied for
 disability once & denied.
 She is appealing.

COLOR IN ALL PAIN AREAS IN RED INK

Knife



bed of
nails

COLOR IN ALL PAIN AREAS IN RED INK

~~EVERY~~

Headache

Neck

Shoulders

Arms

Chest

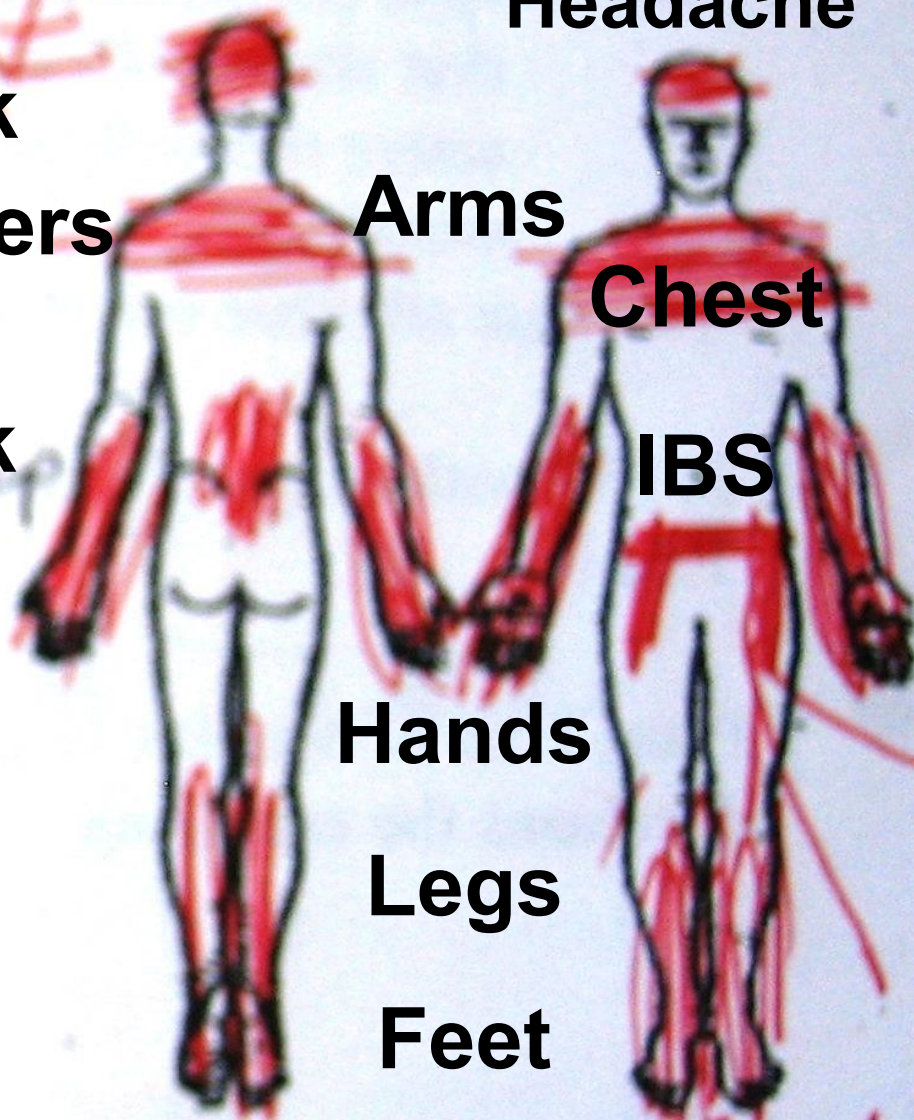
Back

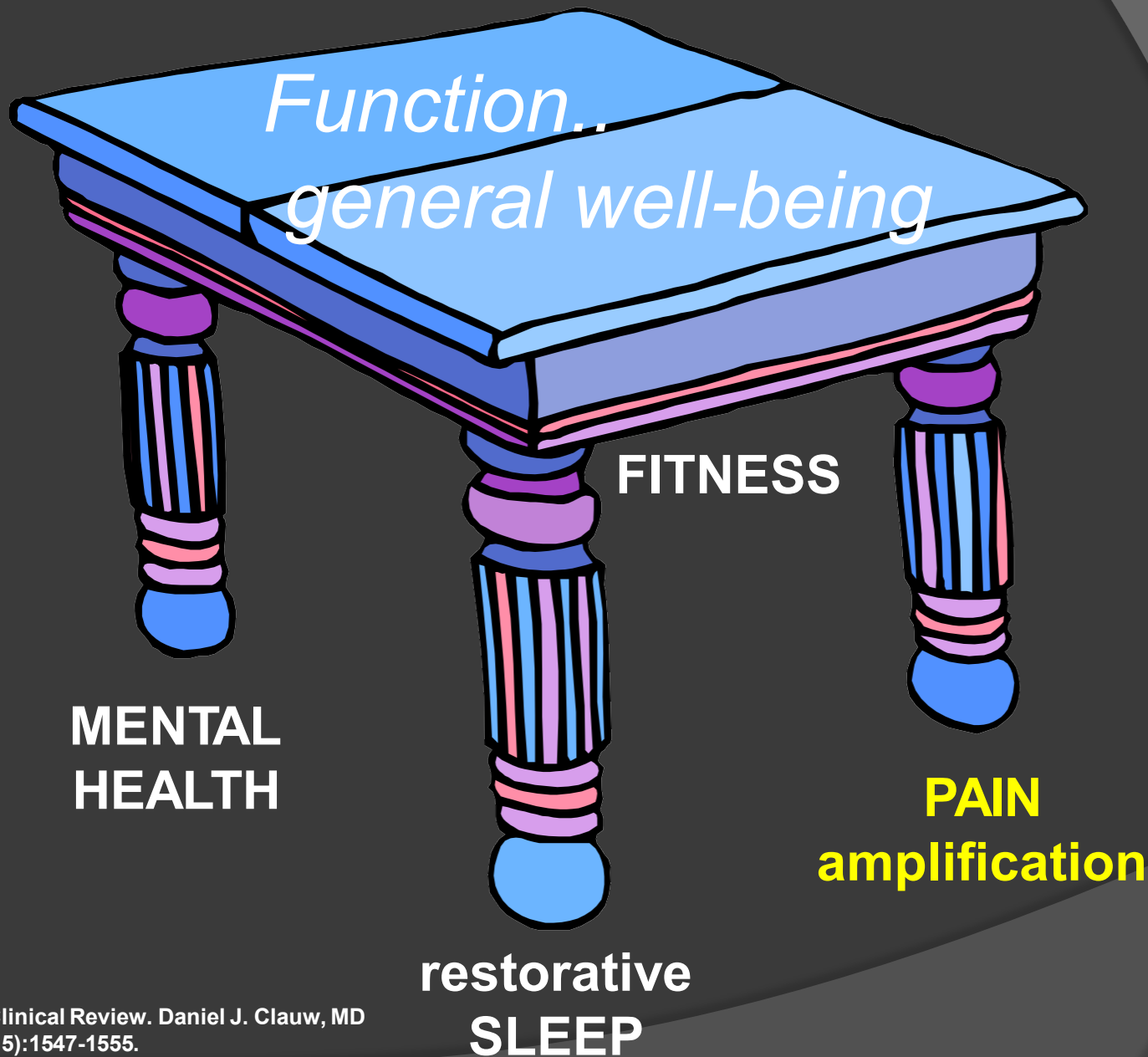
IBS

Hands

Legs

Feet





FM PAIN

- ❑ Mental health: improve situational stressors and coping skills
- ❑ Restorative sleep: Improve quality of quantity of restorative sleep.
- ❑ Physical activity: the right amount
 - ❑ Not too little
 - ❑ Not too much

FM PAIN

Utilize CNS-pain modulating drugs:

- **Drugs (FDA approved) for FM**
 - Anticonvulsant: **pregabalin** (Lyrica)
 - SNRI: **duloxetine** and **milnacipran** (Savella)
- **Drugs (non-FDA approved) used for FM**
 - **gabapentin**
 - Other anticonvulsants: topiramate, zonisamide
 - Low dose TCA: **amitriptyline, doxepin, cyclobenzaprine**
 - SNRI: levomilnacipran, venlafaxine, desvenlafaxine
 - tramadol, opioids
 - **LDN** (low dose naltrexone)...

Treat comorbid pain conditions

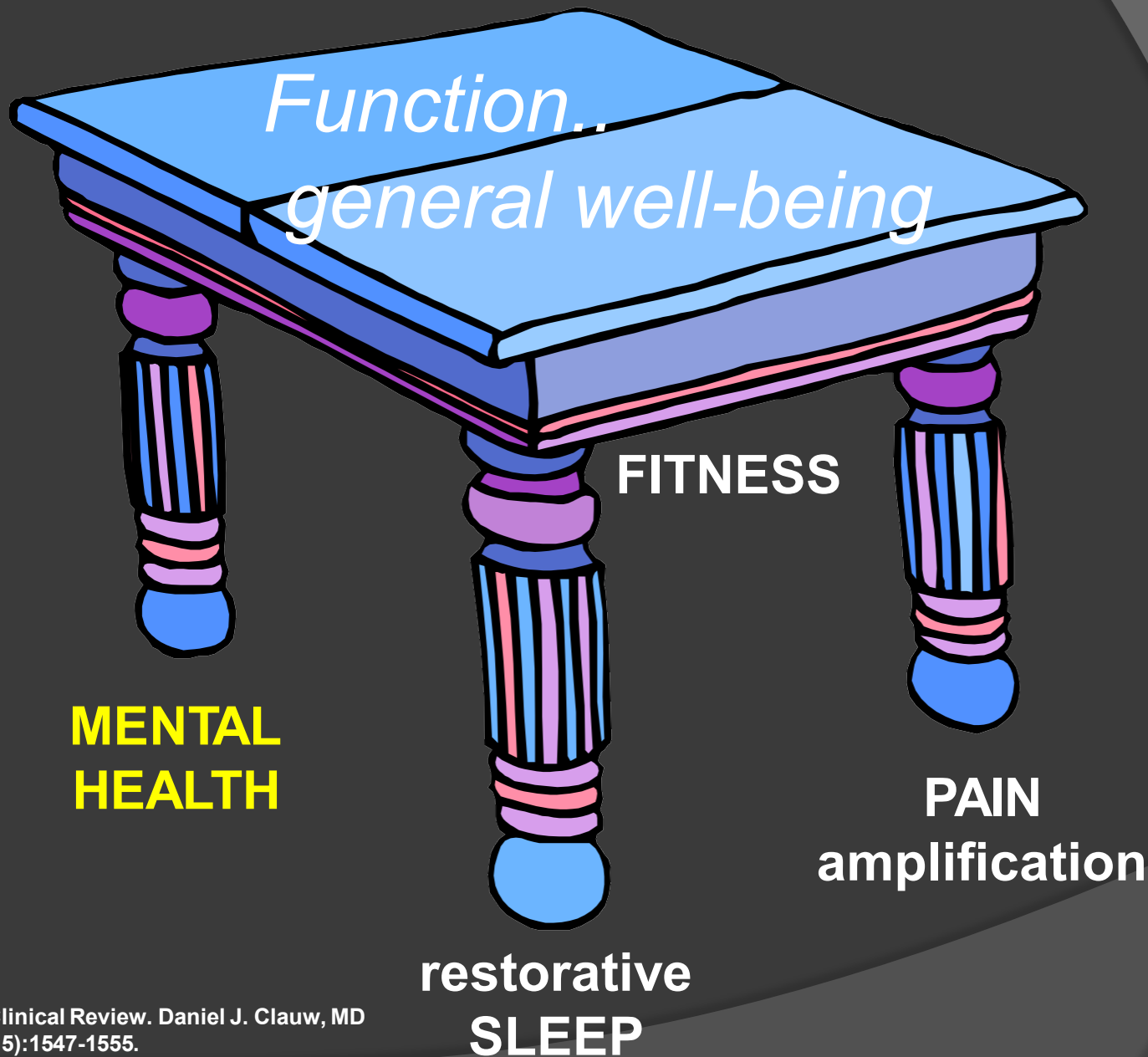
- NSAIDs, celecoxib

LDN (low dose naltrexone)

- naltrexone hydrochloride is an opioid receptor antagonist. FDA approved for treatment of alcohol and opioid dependence (50 mg).
- In very low doses (4.5 mg) LDN may
 - paradoxically decrease pain due an increase in the release of endogenous opioids with transient blockade
 - calm microglial cell activation in the CNS (anti-inflammatory or neuroinflammatory agent)

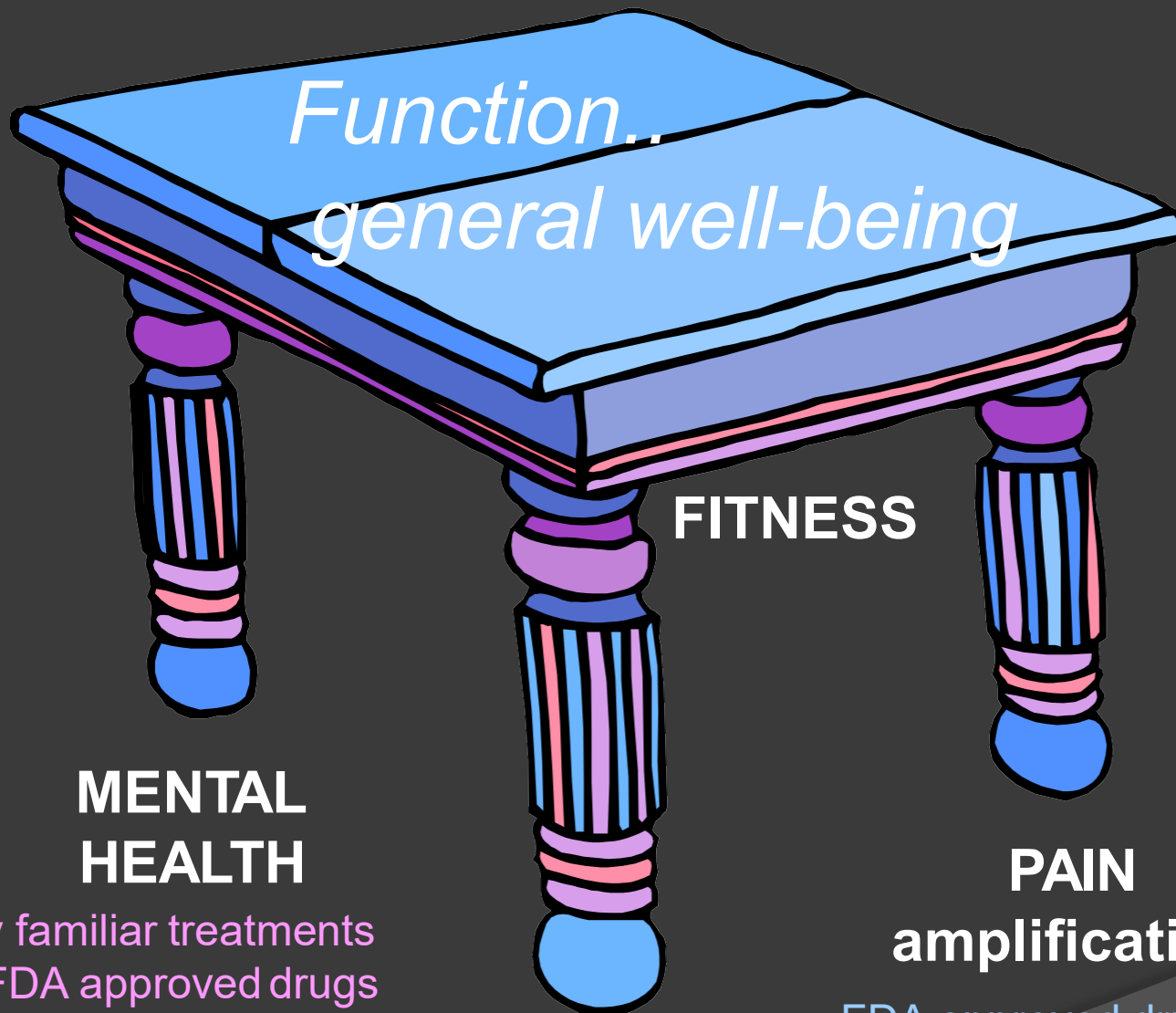
Low-dose naltrexone for the treatment of fibromyalgia: findings of a small, randomized, double-blind, placebo-controlled, counterbalanced, crossover trial assessing daily pain levels. Younger J1, Noor N, McCue R, Mackey S. Arthritis Rheum. 2013 Feb;65(2):529-38. doi: 10.1002/art.37734

The use of low-dose naltrexone (LDN) as a novel anti-inflammatory treatment for chronic pain. Younger J, Parkitny L, McLain D. Clin Rheumatol. 2014 Apr;33(4):451-9. doi: 10.1007/s10067-014-2517-2. Epub 2014 Feb 15. **Review.**



MENTAL HEALTH

- Address any mental health issues whether primary or secondary
- Don't over-treat MH and miss an opportunity to treat the underlying disorders
- Take advantage of anticonvulsants for pain, headaches, sleep, anxiety and bipolar features.



*Function..
general well-being*

FITNESS

**MENTAL
HEALTH**

Many familiar treatments
and FDA approved drugs

**restorative
SLEEP**

**PAIN
amplification**

FDA approved drugs for FM
and many off-label treatments

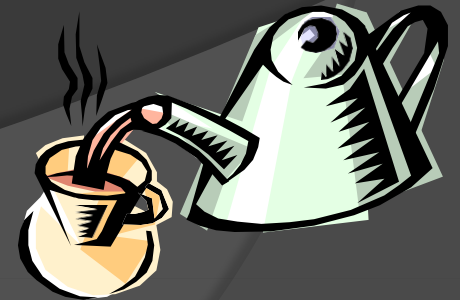
SLEEP

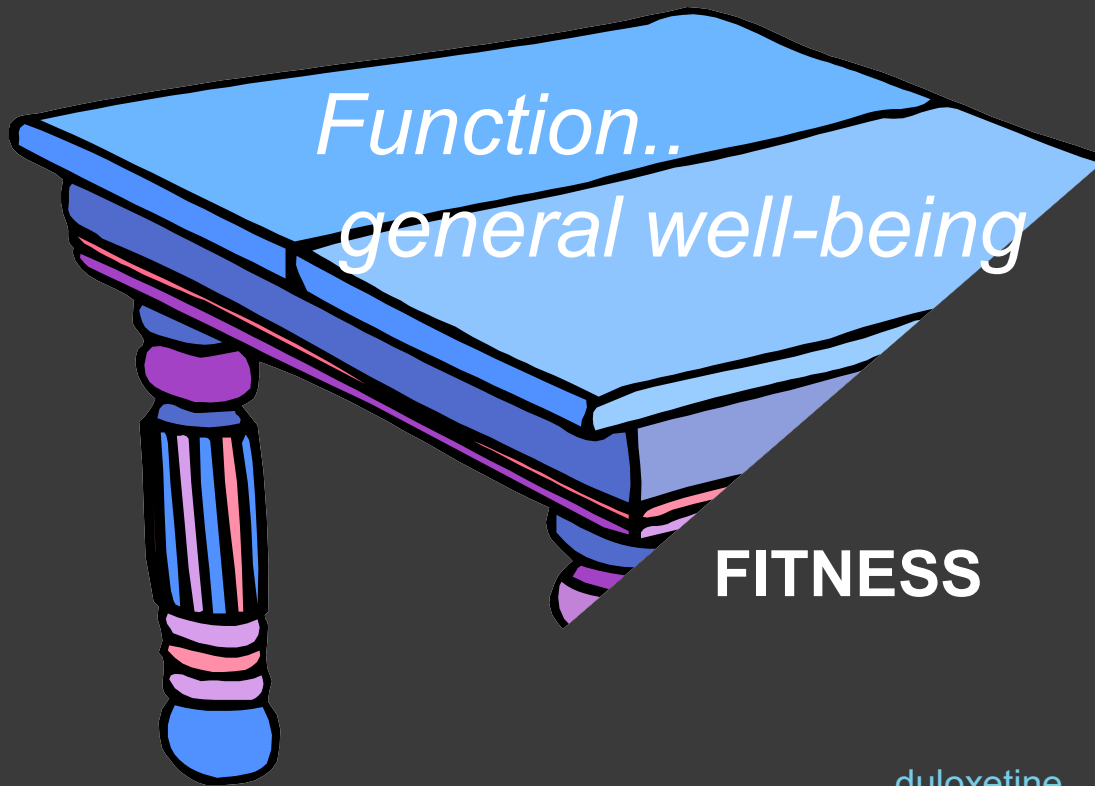
- **Establish good SLEEP HYGIENE**

Set a regular pattern, create a good sleep environment, reduce noise and distractions. Get enough sleep. Don't nap too long. Reserve bed for sleep and intimacy.

- **Avoid DRUGS that disrupt sleep**

Caffeine, decongestants, long acting stimulants, ephedrine





**EMOTIONAL
wellness**

Many familiar treatments
and FDA approved drugs

duloxetine
milnacipran

pregabalin
gabapentin
amitriptyline

PAIN

amplification

FM FDA approved drugs
and many off label treatments

**restorative
SLEEP**

Drugs often used for sleep disturbances:

Longer acting sleep “sustainers” *off-label use for sleep:*

***TCA:** amitriptyline (10-20 mg), doxepin (5-20 mg)

Other antidepressants: trazodone 25-100 mg, mirtazapine 7.5-15 mg

***Anticonvulsants:** gabapentin 300-1200 mg, topiramate 25-100 mg

Benzodiazepines: clonazepam or lorazepam 0.5-1 mg

Atypical antipsychotics: quetiapine 12.5-50 mg, olanzapine 2.5-5 mg

These longer acting drugs may cause “hangover” symptoms the next morning if dosed too high or taken too late in the evening, along with unwanted weight gain or worsen orthostatic intolerance.

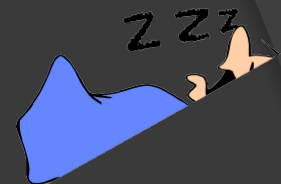
Choose a sleep medication based on comorbid conditions and the nature of the sleep disturbances.

*additional benefits for pain

Drugs often used for sleep disturbances:

Sleep “initiators” or hypnotics

FDA approved for insomnia, not specifically for fibromyalgia



zolpidem 5-10 mg (approx 4 hours, CR 6 hours)

zaleplon 5-10 mg (approx 2 hour duration)

eszopiclone 1, 2 or 3 mg (approx 6 hour duration)

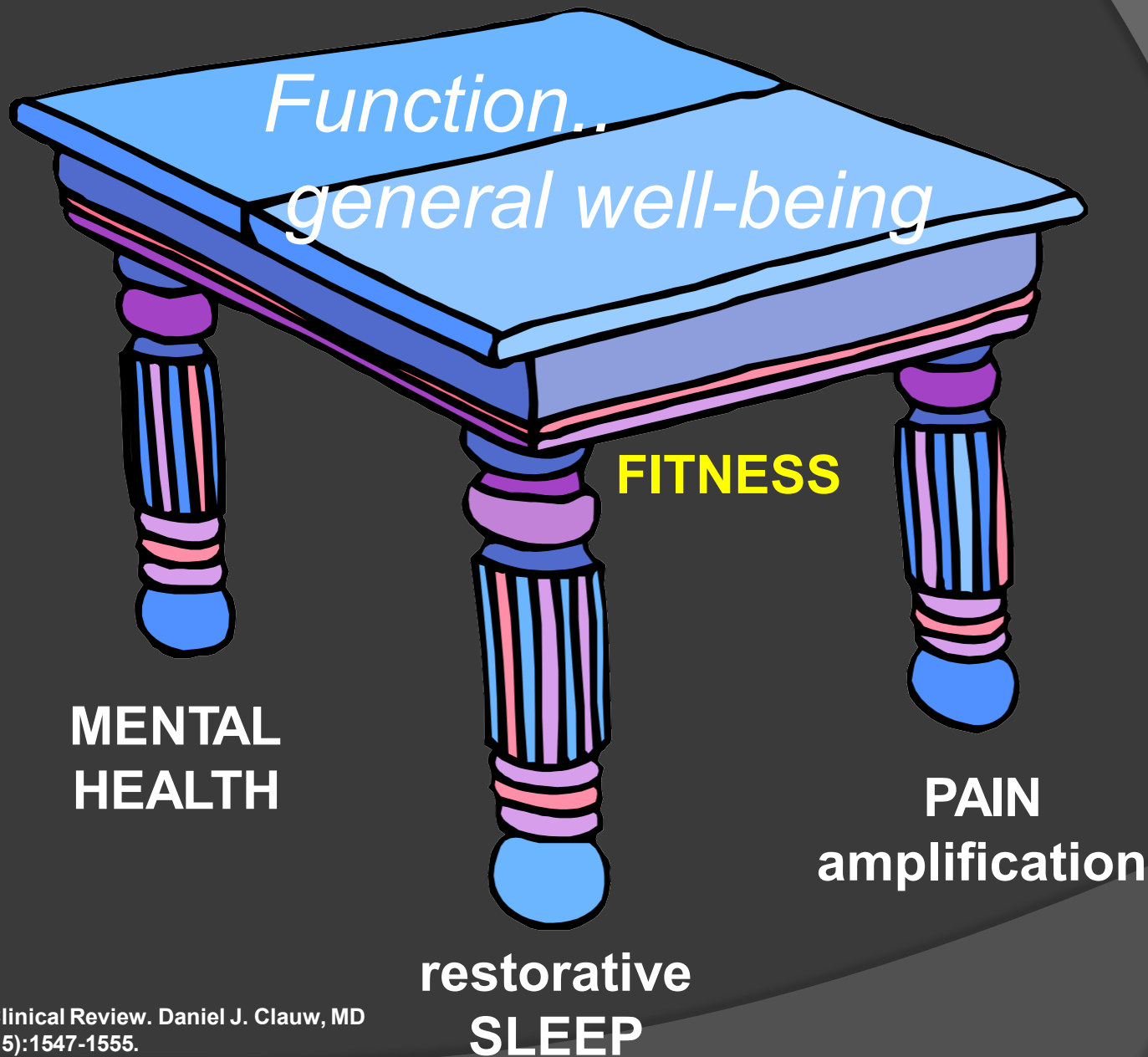
benzodiazepines, ex: *temazepam* 15-30 mg (tolerance/habituation)

- ❑ *Chronic use discouraged, and thus problematic for chronic illness*
- ❑ *Tolerance or dependence and rebound insomnia typically develops.*
- ❑ *Better for sleep initiation than to sustain sleep all night.*
- ❑ *Better for PRN use rather than nightly use*

Drugs often used for sleep disturbances:

***Belsomra/suvorexant**: an orexin receptor antagonist (suppresses wakefulness)

May be in a class of it's own.

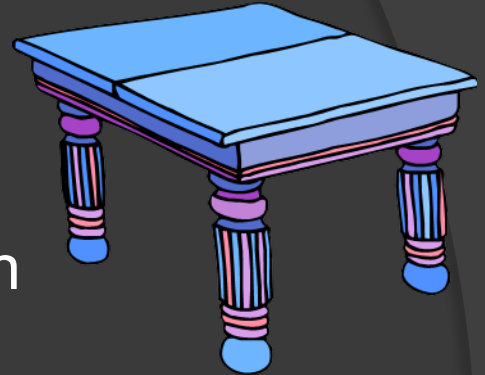


FITNESS

- ❑ Stretching and toning
- ❑ Low impact strength training
 - ❑ Yoga. Pilates. Water aerobics.
- ❑ Low impact low intensity cardio
 - ❑ Walking. Ex bike. Water exercises.
- ❑ Weight awareness.
 - ❑ weight gaining meds too!



Understand and manage the “4 legs of the table”



□ Pain

□ Use drugs effective for the type of pain

- FDA approved for FM: pregabalin, duloxetine, milnacipran
- Non-FDA approved for FM: gabapentin, amitriptyline, cyclobenzaprine, tramadol, LDN
- NON-FM PAIN may need to be considered separately (i.e. osteoarthritis)

□ Sleep disturbances

- Sleep hygiene. Diagnose and treat sleep disorders. Smart medications.

□ Psychological state (mental health)

- Balance. Calm. Optimism. Education. Good stress management.

□ Deconditioning/Fitness

- Restorative exercise: strength, flexibility, low impact aerobic.