Suicide Risk Mitigation: Assessing & Managing Comorbidities in Patients wit Chronic Pain

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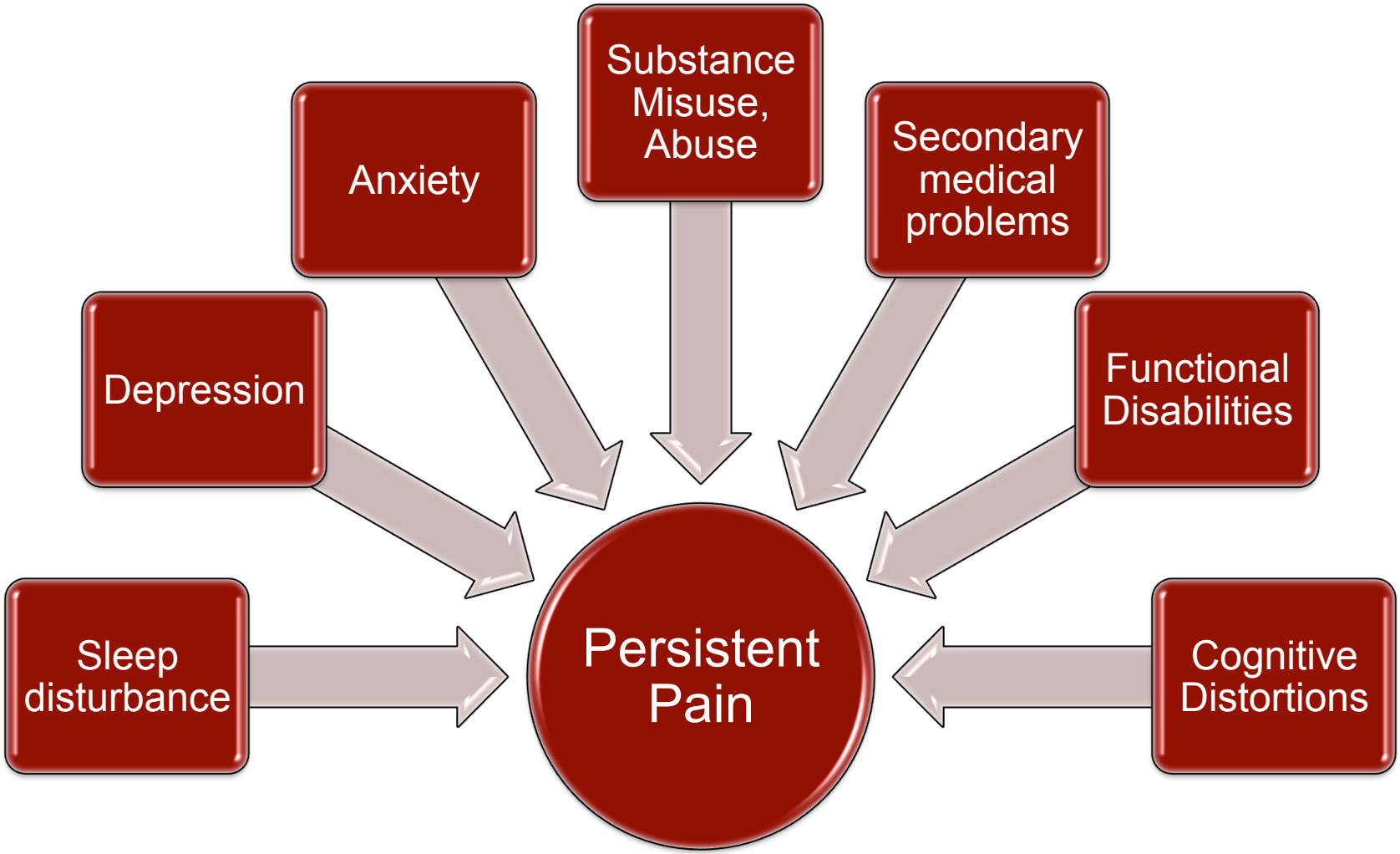
Conflict of interest

- MDC has no conflict of interest related to the topic of this presentation
- This presentation does not contain off-label or investigational use of drugs or products

Learning Objectives

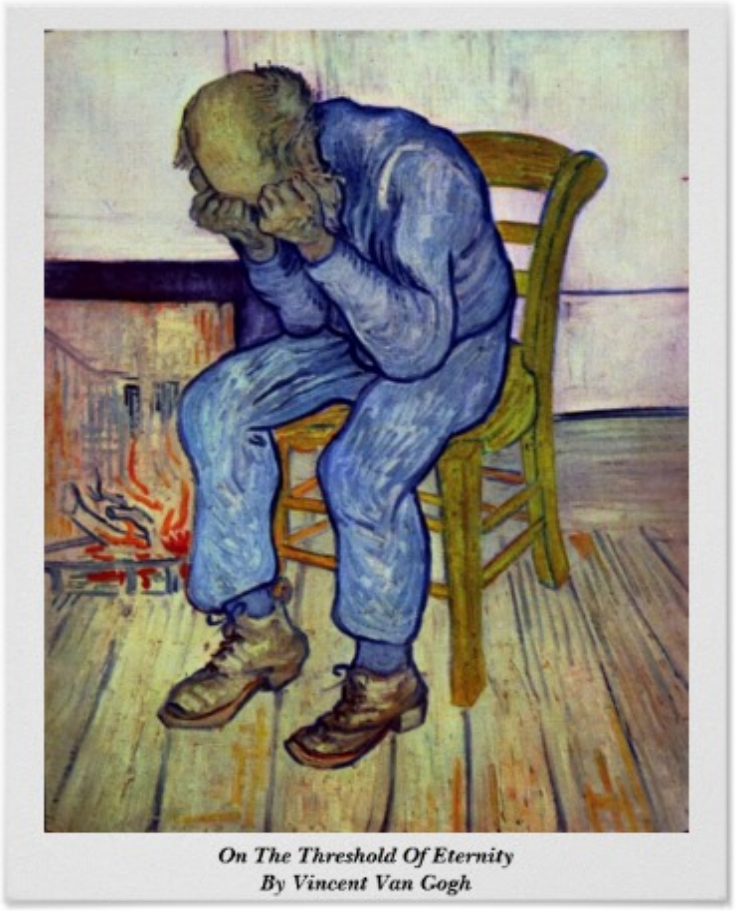
- Describe the common comorbidities associated with chronic pain
- Explain understand the risk/benefit of anti-depressants and benzodiazepines in patients with chronic pain
- Identify non-pharmacologic interventions for treatment of comorbidities in patients with pain


Substance Misuse, Abuse
Anxiety
Secondary medical problems
Depression
Functional Disabilities
Sleep disturbance
Persistent Pain
Cognitive Distortions

Chronic Pain Comorbidites

- Mood Disorders
- Anxiety Disorders
- PTSD
- Sleep Disorders
- Personality Disorders
- Secondary Medical Conditions

Pain, Mood and Anxiety Disorders



On The Threshold Of Eternity
By Vincent Van Gogh

Pain 106 (2003) 127–133

PAIN

www.elsevier.com/locate/pain

Mood and anxiety disorders associated with chronic pain: an examination in a nationally representative sample

Lachlan A. McWilliams[a,b,*], Brian J. Cox[b], Murray W. Enns[b]

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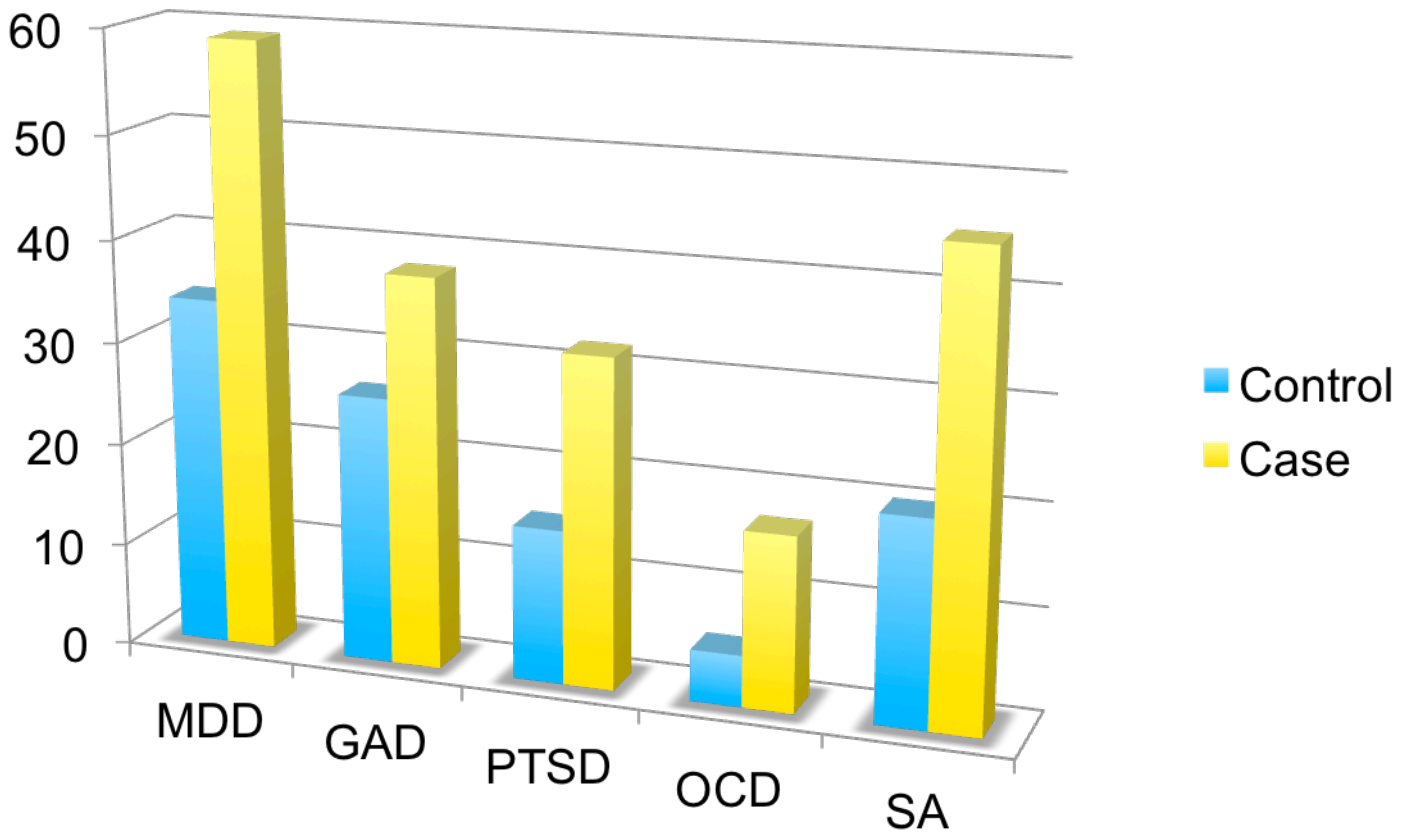
- **National Comorbidity Survey to evaluate the association between chronic pain and common mood and anxiety disorders**
- **Participants (n= 5877) completed the Composite International Diagnostic Interview based on the DSM**

Diagnosis	Number of participants meeting diagnostic criteria (% in parentheses)		Inferential statistics	
	Chronic pain ($n = 382$)	General population ($n = 5495$)	χ^2	p
Any mood disorder	83(21.7)	551(10.0)	32.16	<0.0001
Depression	77(20.2)	510(9.3)	26.53	<0.0001
Dysthymia	20(5.2)	128(2.3)	5.48	<0.01
Any anxiety disorder	134(35.1)	992(18.1)	21.54	<0.0001
Generalized anxiety disorder	28(7.3)	144(2.6)	9.10	<0.005
Panic disorder with or without agoraphobia	25(6.5)	103(1.9)	7.84	<0.01
Simple phobia	60(15.7)	456(8.3)	8.70	<0.01
Social phobia	45(11.8)	428(7.8)	5.91	<0.05
Agoraphobia with or without panic	32(8.4)	182(3.3)	6.52	<0.05
Posttraumatic stress disorder	41(10.7)	182(3.3)	16.29	<0.001

Diagnoses were made using the *Composite International Diagnostic Interview*. Psychiatric diagnostic categories were not mutually exclusive.

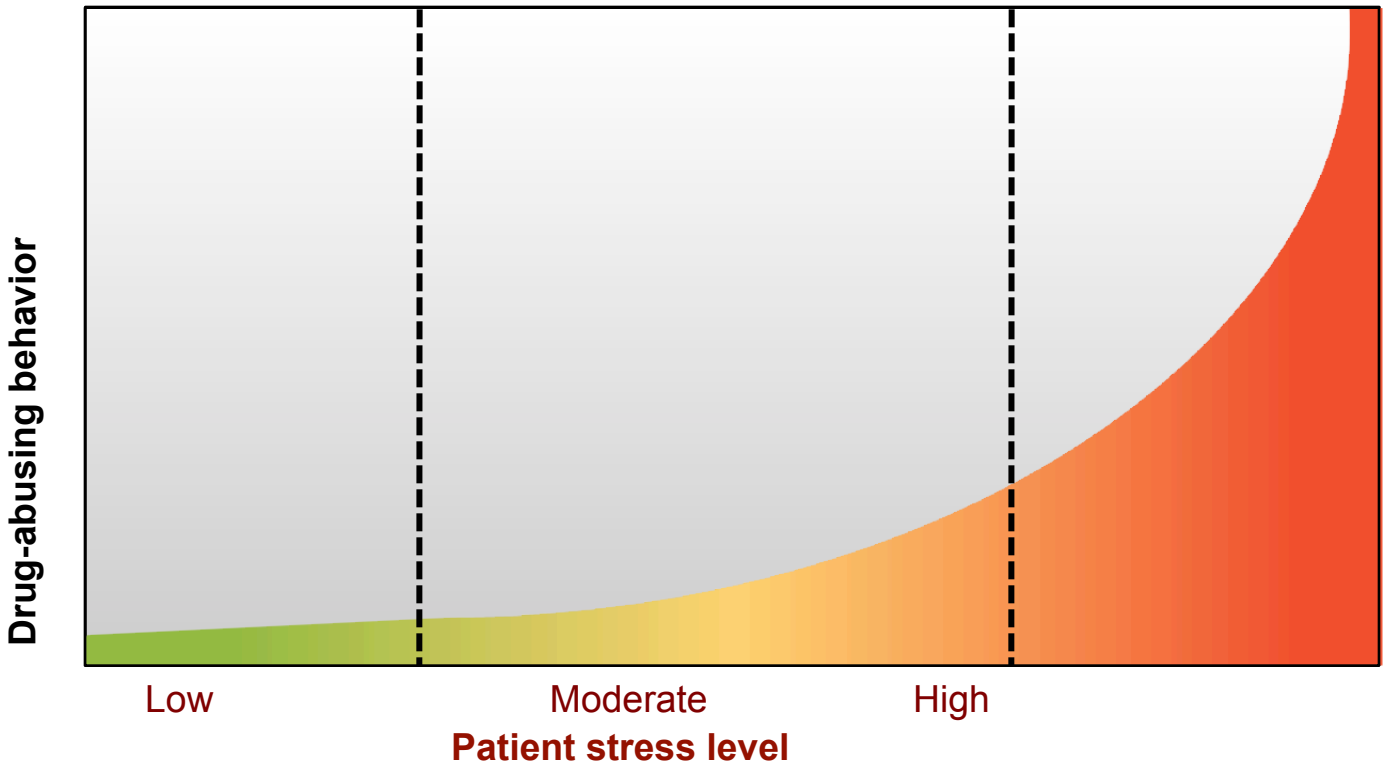
% population (n=1038)



Grant 1RO1DA032776-01 NIDA/NIH PI Cheatle


Pain
Depression
Suicidal Ideation

Level of Abuse in Stressful Environments



Webster LR, Dove B. *Avoiding Opioid Abuse While Managing Pain: A Guide for Practitioners.* North Branch, MD: Sunrise River Press. 2007.

Pain, SI and Sleep Disorders

Suicidal Ideation in Outpatients With Chronic Musculoskeletal Pain

An Exploratory Study of the Role of Sleep Onset Insomnia and Pain Intensity

Michael T. Smith, PhD, Michael L. Perlis, PhD,†‡ and Jennifer A. Haythornthwaite, PhD**

- 51 outpatients with non-cancer chronic pain were recruited and completed the Pittsburgh Sleep Quality Index, the Beck Depression Inventory, and the Multi-Dimensional Pain Inventory. Subjects were classified as suicidal ideators or non-ideators, based on the BDI
- Results indicated that 24% reported suicidal ideation and endorsed higher levels of sleep-onset insomnia, pain intensity, medication usage, pain related interference, affective distress and depressive symptoms
- Step-wise, discriminate function analysis revealed that sleep onset insomnia severity and pain intensity predicted 84.3% of the cases
- *Authors concluded that chronic pain patients who self-report severe and frequent initial insomnia with concomitant daytime dysfunction and high pain intensity were more likely to report passive suicidal ideation, independent of the effects of depression severity*

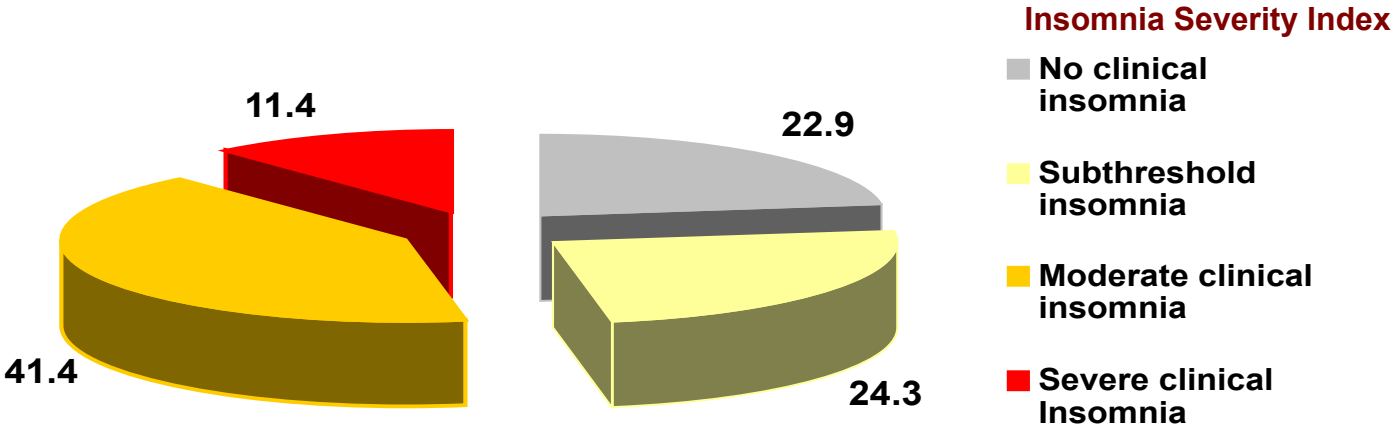
Smith MT, et al Clin J Pain 2004; 20 (2):111-8

Pain and Sleep Disorders

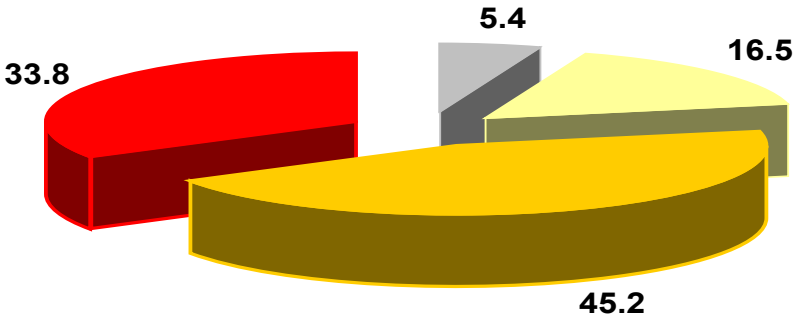
- **Chronic pain is associated with multiple symptoms that may impair a patient's quality of life, including emotional distress, fatigue and sleep disturbance.**
- **Studies have demonstrated that 50% of patients with a number of different chronic pain conditions complain of sleep disturbance, with estimates as high as 70%-88%.**

Cheatle MD, Foster S, Pinkett A, Lesneski M, Qu D, Dhingra L. Assessing and Managing Sleep Disturbance in Patients with Chronic Pain. Anesthesiol Clin. 2016 Jun;34(2):379-93

Pain-insomnia co-occurrence

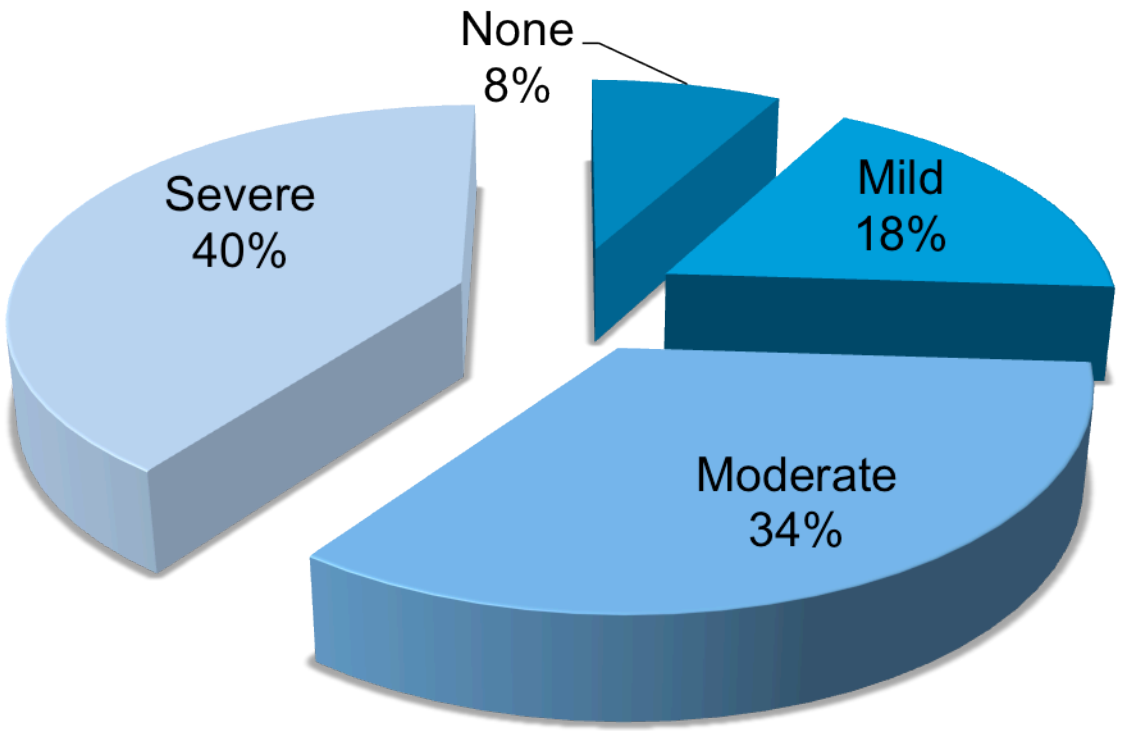


Anaesthetist-led pain clinic
Tang, Wright, & Salkovskis, 2007



National specialist pain management centre
McCracken, Williams, & Tang, 2011

% Population Sleep Disturbance (n= 1180)

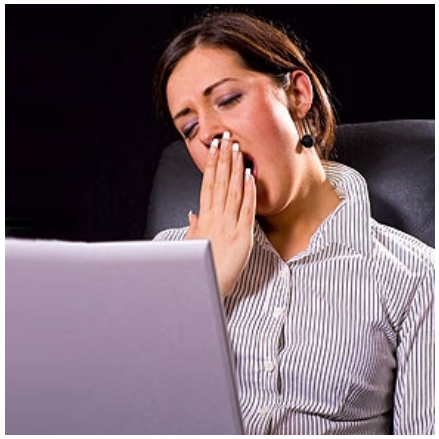


Cheatle M et al "Clinical and Genetic Characteristics of Opioid Addiction in Chronic Pain" 1RO1DA032776-01 NIH/NIDA unpublished data

Untreated or Undertreated Insomnia

Patients with chronic pain and sleep disturbance report:

- **Increased pain**
- **Excessive fatigue**
- **Poorer mood**
- **Higher rates of disability**
- **Increased suicidal ideation**



Experimental Studies

Short term:

- **Sleep deprivation or disruption increases pain & inflammation; dampen mood and pain inhibitory response**

Long term:

- **Development of depression, anxiety, widespread pain, diabetes, hypertension, CHD**

Pain and sleep are bidirectional

Pain and sleep are bidirectional

- Koffel E, Kroenke K, Bair MJ, Leverty D, Polusny MA, Krebs EE. The Bidirectional Relationship Between Sleep Complaints and Pain: Analysis of Data From a Randomized Trial. Health Psychol. 2015 Jun 15. [Epub ahead of print]
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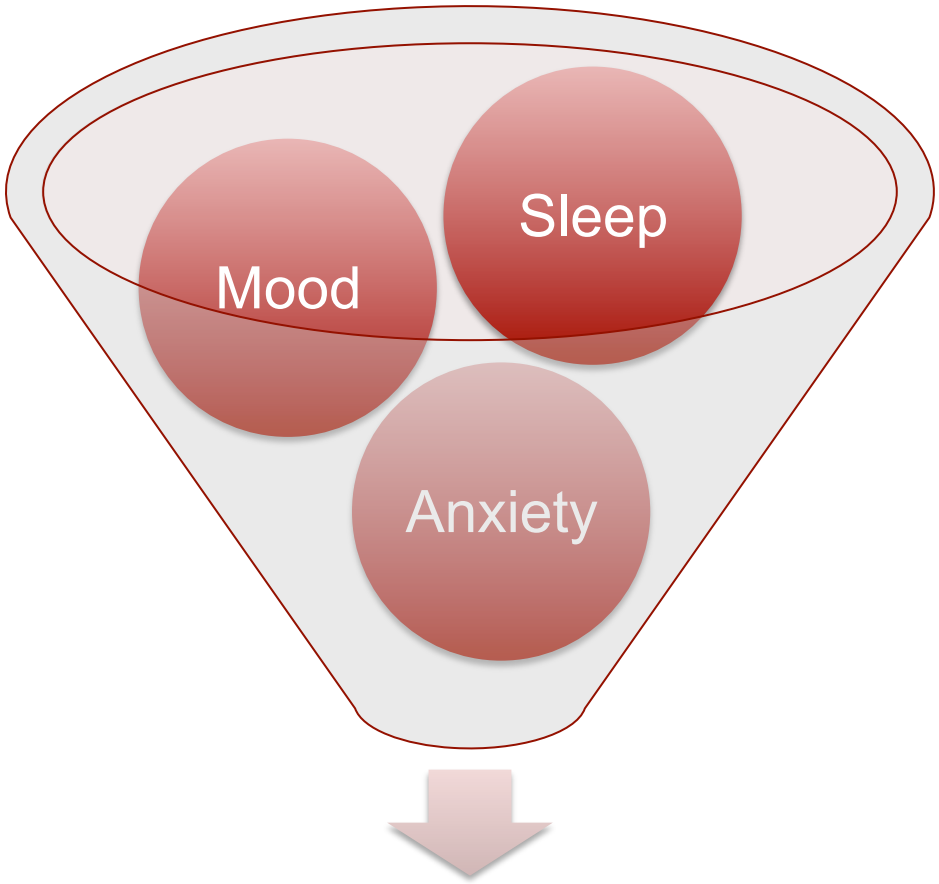
- Chiu YH, Silman AJ, Macfarlane GJ, Ray D, Gupta A, Dickens C, Morriss R, McBeth J. Poor sleep and depression are independently associated with a reduced pain threshold. Results of a population based study. Pain. 2005 Jun; 115(3):316-321.
- Moldofsky H, Lue FA, Eisen J, Keystone E, Gorczynski RM. The relationship of interleukin-1 and immune functions to sleep in humans. Psychosom Med. 1986 May-Jun;48(5):309-18.
- Onen SH, Alloui A, Gross A, Eschallier A, Dubray C. The effects of total sleep deprivation, selective sleep interruption and sleep recovery on pain tolerance thresholds in healthy subjects. J Sleep Res. 2001 Mar;10(1):35-42.
- Boakye PA, Olechowski C, Rashiq S, Verrier MJ, Kerr B, Witmans M, Baker G, Joyce A, Dick BD. A Critical Review of Neurobiological Factors Involved in the Interactions between Chronic Pain, Depression, and Sleep Disruption. Clin J Pain. 2015 May 28. [Epub ahead of print]

Pain and Sleep: Mechanisms of Action

- Reduced pain tolerance
- Pro inflammatory process
- Increased anxiety/lower mood

Mitigating Risk of SI/SB



Increased pain/opioid use/misuse/
risk of SI

Assessment of Mood, Anxiety and Sleep

Mental Health Screening

- BDI-II
- BDI-FS
- Zung Self-Rating Depression Scale
- CES-D
- PHQ-9/PHQ-2
- BAI#
- GAD-7#
- HAS#
- HADS*
- POMS*
- PHQ-4*

Anxiety Scales *Anxiety/Depression Scales

PHQ-4

Over the past few weeks have you been bothered by these problems?	Not at all	Several days	More days than not	Nearly every day
Feeling nervous, anxious, or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ **DATE:** _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems? *(use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
	add columns:	+	+	
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.)	**TOTAL:**			

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?	**Not difficult at all** _____ **Somewhat difficult** _____ **Very difficult** _____ **Extremely difficult** _____

ZT242043

GAD-7

Generalised Anxiety Disorder Scale (GAD-7)

Over the **last two weeks** how often have you been bothered by any of the following problems?
For each question, select the option that best describes the amount of time you felt that way.

In last 2 weeks...	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
1. Feeling nervous, anxious or on edge	○	○	○	○
2. Not being able to stop worrying	○	○	○	○
3. Worrying too much about different things	○	○	○	○
4. Having trouble relaxing	○	○	○	○
5. Being so restless it is hard to sit still	○	○	○	○
6. Becoming easily annoyed or irritable	○	○	○	○
7. Feeling afraid as if something awful might happen	○	○	○	○

Sleep Assessment

- Sleep scales
- Sleep logs
- Actigraphy

Sleep Assessment Scales

Questionnaire	Time frame	# of items
Sleep quality		
Pittsburg Sleep Quality Index	Past month	19
Sleep Questionnaire	Indefinite	59
Sleep Disturbance Questionnaire	Indefinite	12
SF-B	Past 2 weeks	12
Sleep onset		
Nocturnal Sleep Onset Scale	Past 2 weeks	2
General		
Steelman Insomnia Symptom Questionnaire	Past week	13
Athens Insomnia Scale	Past month	8
Pittsburgh Insomnia Rating Scale	Past week	65
Leeds Sleep Evaluation Questionnaire	Indefinite	10

Pittsburgh Sleep Quality Index

- **PSQI consists of 19 individual items used to generate seven composite scores:**
  - subjective sleep quality
  - sleep latency
  - sleep duration
  - habitual sleep efficiency
  - sleep disturbances
  - use of sleeping medication
  - daytime dysfunction
  - 5 to 10 minutes to administer and score
  - Global score can be used to identify presence of sleep disorder

Backhaus J, Junqhanns S, et al.Test-retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. J Psychosom Res. 2002 Sep;53(3):737-40.

Sleep Logs

SLEEP DIARY	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1. What time did you go to bed (lights off)?							
2. Approx how long did it take you to fall asleep?							
3. How many times did you awaken during the night?							
4. Approx how long were you awake each time?	1. 2. 3. 4.	1. 2. 3. 4.	1. 2. 3. 4.	1. 2. 3. 4.	1. 2. 3. 4.	1. 2. 3. 4.	1. 2. 3. 4.
5. What time did you wake in the morning?							
6. What time did you get out of bed?							
7. Approximately how many hours did you sleep?							
8. What medications did you take last night?							
9. Rate the quality of last night's sleep: (1 = excellent, 5 = poor)	12345	12345	12345	12345	12345	12345	12345
10. Avoided naps? (Y/N)							
11. Exercised? (Y/N), When?							
12. Avoided stimulants? (Y/N)							
13. Relaxed before bed? (Y/N), How long?							

Cognitive appraisal/comments:	Please complete in the spaces provided below…
1. _____ (date)	
2. _____ (date)	
3. _____ (date)	
4. _____ (date)	
5. _____ (date)	
6. _____ (date)	
7. _____ (date)	

Actigraphy

CHEST Postgraduate Education Corner
CONTEMPORARY REVIEWS IN SLEEP MEDICINE

Wrist Actigraphy

Jennifer L. Martin, PhD; and Alex D. Hakim, MD

To record sleep, actigraph devices are worn on the wrist and record movements that can be used to estimate sleep parameters with specialized algorithms in computer software programs. With the recent establishment of a Current Procedural Terminology code for wrist actigraphy, this technology is being used increasingly in clinical settings as actigraphy has the advantage of providing objective information on sleep habits in the patient's natural sleep environment. Actigraphy has been well validated for the estimation of nighttime sleep parameters across age groups, but the validity of the estimation of sleep-onset latency and daytime sleeping is limited. Clinical guidelines and research suggest that wrist actigraphy is particularly useful in the documentation of sleep patterns prior to a multiple sleep latency test, in the evaluation of circadian rhythm sleep disorders, to evaluate treatment outcomes, and as an adjunct to home monitoring of sleep-disordered breathing. Actigraphy has also been well studied in the evaluation of sleep in the context of depression and dementia. Although actigraphy should not be viewed as a substitute for clinical interviews, sleep diaries, or overnight polysomnography when indicated, it can provide useful information about sleep in the natural sleep environment and/or when extended monitoring is clinically indicated. ***CHEST 2011; 139(6):1514–1527***

Abbreviations: AASM = American Academy of Sleep Medicine; MSLT = multiple sleep latency test; OSA = obstructive sleep apnea; PSG = polysomnography; SL = sleep latency; SOL = sleep-onset latency; TST = total sleep time; WASO = wake after sleep onset

Risk Assessment for Sleep Disordered Breathing

- **History and physical examination**
  - Assess neck circumference
  - Evaluate throat and nose for restricted airway
- **Obtain a urine drug test to detect nonprescribed benzodiazepines or other CNS depressants**
- **Administer EPWORTH Sleepiness Scale**
- **If patient is candidate for opioid therapy, consider a polysomnogram**
  - Portable at home
  - In a sleep lab

Cheatle, M.D., Webster, L.R. Opioid therapy and sleep disorders: Risks and mitigation strategies. Pain Medicine 16 Suppl 1: S 22-26, 2015.

THE EPWORTH SLEEPINESS SCALE
(To assess risk of Obstructive Sleep Apnea)

Use the following scale to choose the most appropriate number for each situation:-

0 = would never doze
1 = Slight chance of dozing
2 = Moderate chance of dozing
3 = High chance of dozing

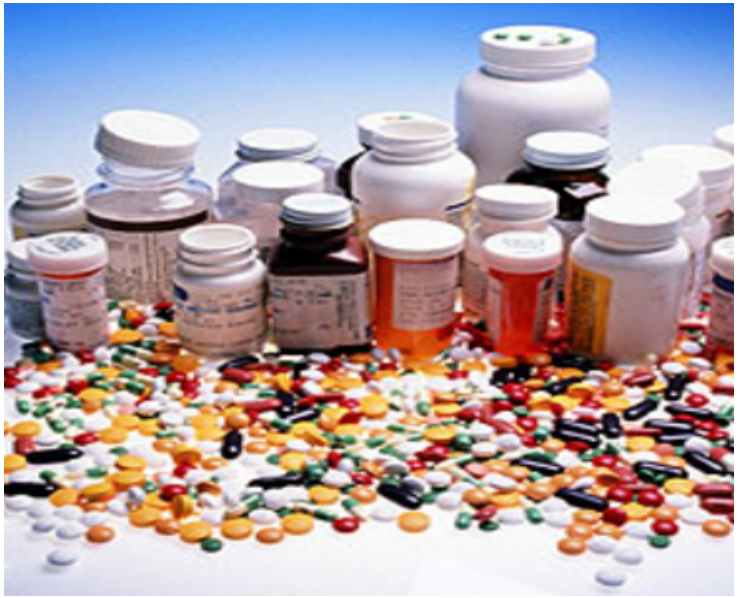
Situation	Chance of dozing
Sitting and reading	
Watching TV	
Sitting, inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	
Total	

Score:

0-10	Normal range
10-12	Borderline
12-24	Abnormal

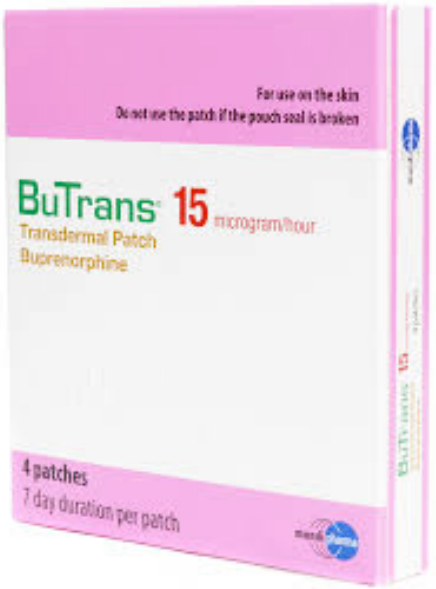
Treatment Approaches

- Pharmacologic



- Nonpharmacologic

Pharmacologic Interventions



Antidepressant medication

- The role of antidepressant medication may relate, in part, to the high prevalence of co-occurring depression in chronic pain
- There is evidence of the analgesic properties of tricyclics and certain SNRIs
- TCAs, SNRIs like opioids are used to modulate descending inhibitory pain pathways

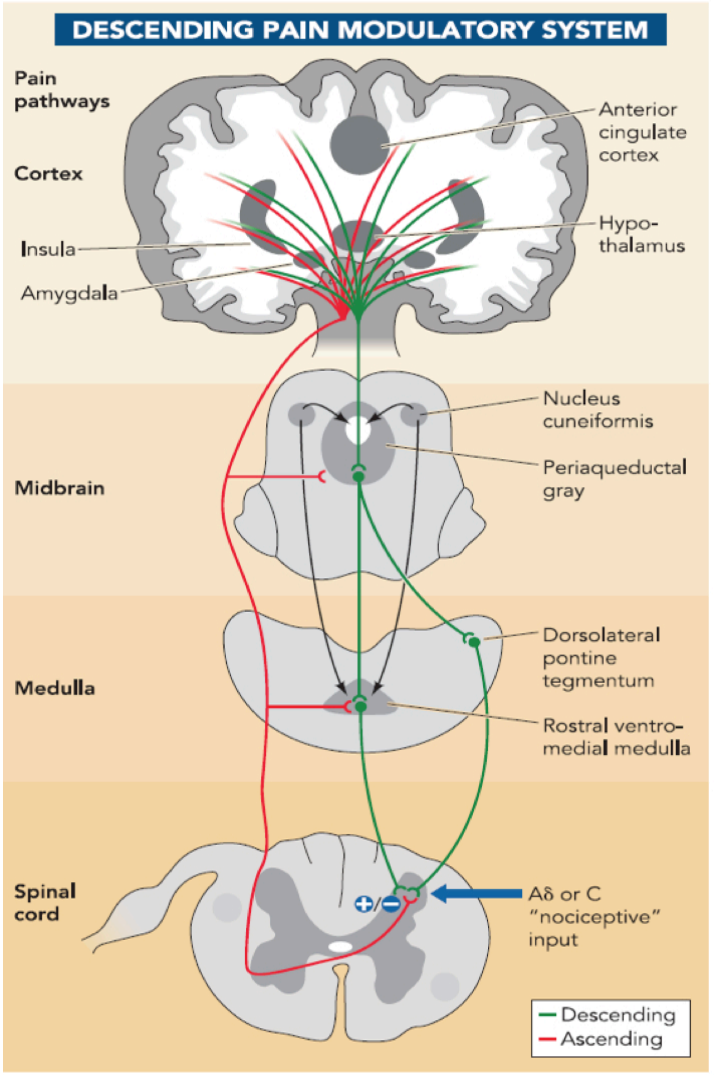


FIGURE 3. The descending pain modulatory system
+/- indicates both pro- and anti-nociceptive influences, respectively.

Jensen *et al. Molecular Pain* 2012, **8**:32
http://www.molecularpain.com/content/8/1/32

MOLECULAR PAIN

RESEARCH Open Access

Patients with fibromyalgia display less functional connectivity in the brain's pain inhibitory network

Karin B Jensen[1,2*], Rita Loitoile[1,2], Eva Kosek[3,4], Frank Petzke[5], Serena Carville[6], Peter Fransson[3], Hanke Marcus[7], Steven CR Williams[8], Ernest Choy[9], Yves Mainguy[10], Olivier Vitton[10], Richard H Gracely[11], Randy Gollub[1,2], Martin Ingvar[3,4] and Jian Kong[1,2]

- **28 matched FM pts compared to 14 healthy volunteers**
- **FM patients required significantly less pressure stimulus to reach a 50/100mm on a VAS**
- **Hypo-connectivity between the rostral anterior cingulate cortex and the amygdyla, hippocampus, and brainstem in healthy volunteers compared to FM patients**
- **Evidence that there is a dysfunction of the descending pain modulatory network**

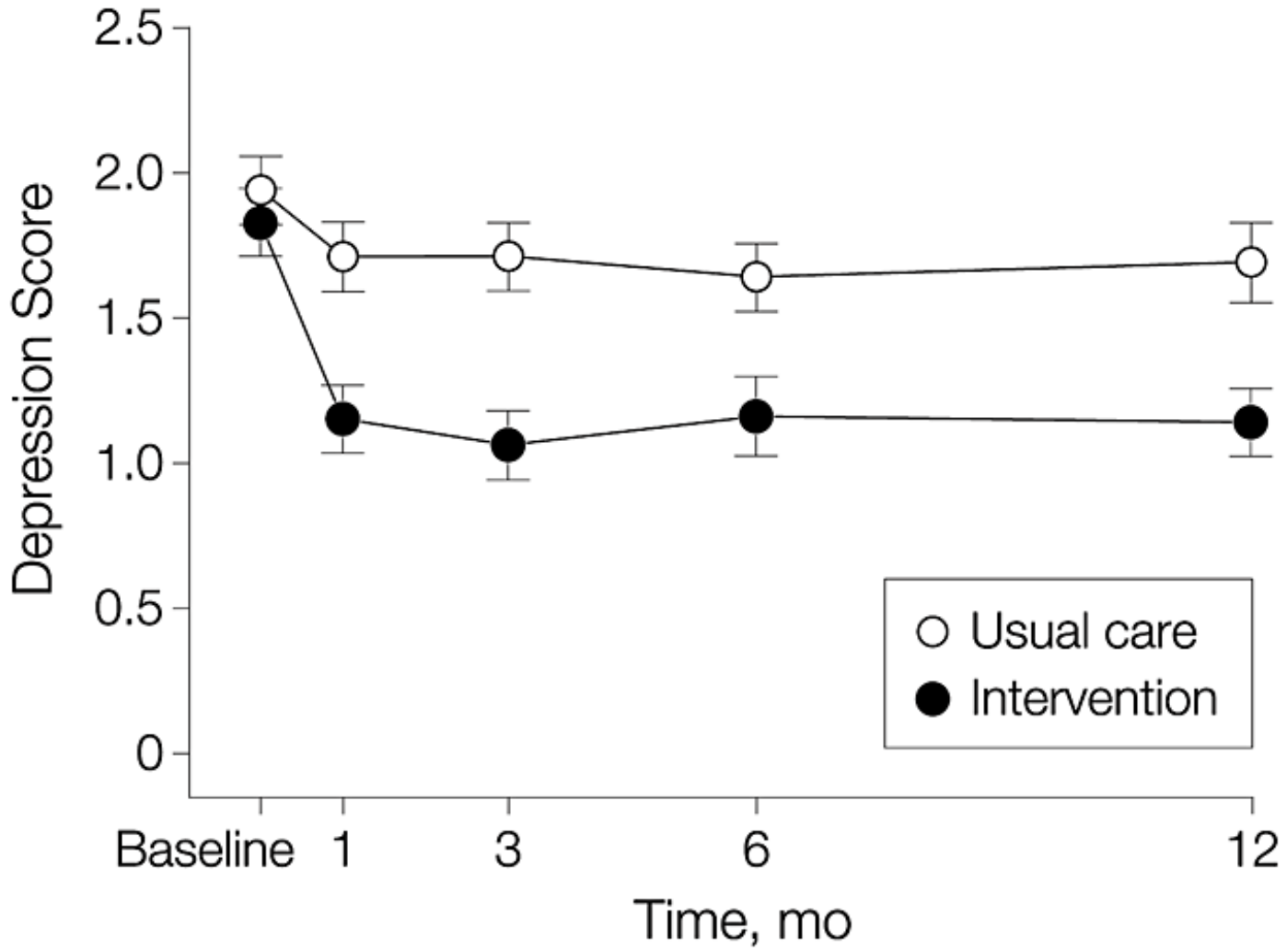
- **Fibromyalgia patients endogenous opioid activity may be elevated at baseline (i.e. already working at full levels and thus can't increase with new pain stimuli)**
  - CSF of FM patients show higher enkephalins compared to controls
  - High Baseline occupancy of opioid receptors in FM patients who have never received exogenous opioids
  - Opioids usually ineffective in most patients with FM
  - Naltrexone-blocking endogenous release of opioids
- **Unlike the opioid system the serotenergic/ noradrenegric system is hypofunctional**
  - Decreased norepinephrine and serotonin metabolites in CSF
  - Efficacy of compounds that raise serotonin and norepinephine may be effective
    - Duloxetine, Venlafaxeine, TCA, ?tramadol
    - Exercise and TENS units help potentiate this descending inhibition

Antidepressant Selection and Dosing

Priorty	Drug	Class	Indications and Precautions	Initial Dose	Possible Increases
1	Venlafaxine (Effexor)	SNRI	Avoid if CV disease, ABN ECG, poorly-controlled HTN	75	150, 225
2	Fluoxetine (Prozac)	SSRI	SSRI of choice	20	30, 40
2	Sertraline (Zoloft)	SSRI	SSRI of choice in patients with CV disease	50	100, 150
3	Citalopram (Celexa)	SSRI	Use if failed with first SSRI	20	30, 40
4	Bupropion (Wellbutrin)	Other	Use if obese, have unacceptable weight gain with other agent, or if sexual AEs reported	200	300, 400
4	Mirtazapine (Remeron)	Other	Use if insomnia a problem; avoid if obese	15	30, 45
5	Desipramine	TCA	Avoid with CV disease, advanced age, ABN ECG, poorly-controlled HTN	25	50, 100

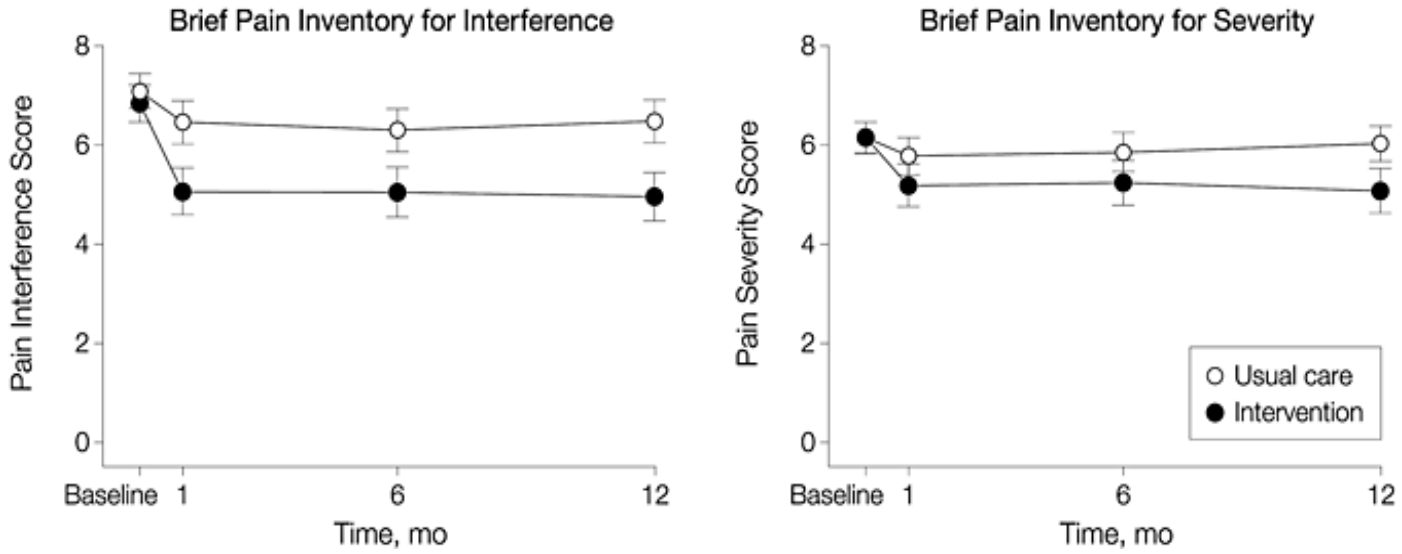
Kroenke K et al JAMA 2009; 301 (20): 2099-110

Mean 20-Item Hopkins Symptom Checklist Depression Scores



Kroenke, K. et al. JAMA 2009;301:2099-2110.

Mean Brief Pain Inventory Scores for Pain Interference and Pain Severity



Kroenke, K. et al. JAMA 2009;301:2099-2110.

How modest is the effect?

Drug	RCT / participants	30% pain reduction (drug vs placebo, %)	Drop out rate due to adverse events, (drug vs placebo, %)
duloxetine	5 / 1,884	46.8 vs 34.0	18.7 vs 10.4
milnacipran	5 / 4,110	36.4 vs 28.1	21.5 vs 11.0
SSRIs	7 / 414	36.4 vs 20.6	9.5 vs 7.0
TCAs	9 / 542	48.3 vs 27.8	5.2 vs 6.5
pregabalin	5 / 3,259	40.0 vs 29.1	19.4 vs 11.0

Arthritis Research & Therapy (2014) 16:201

Progress in Neuro-Psychopharmacology & Biological Psychiatry 75 (2017) 128–134

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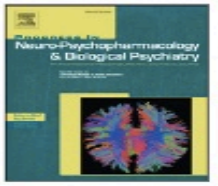


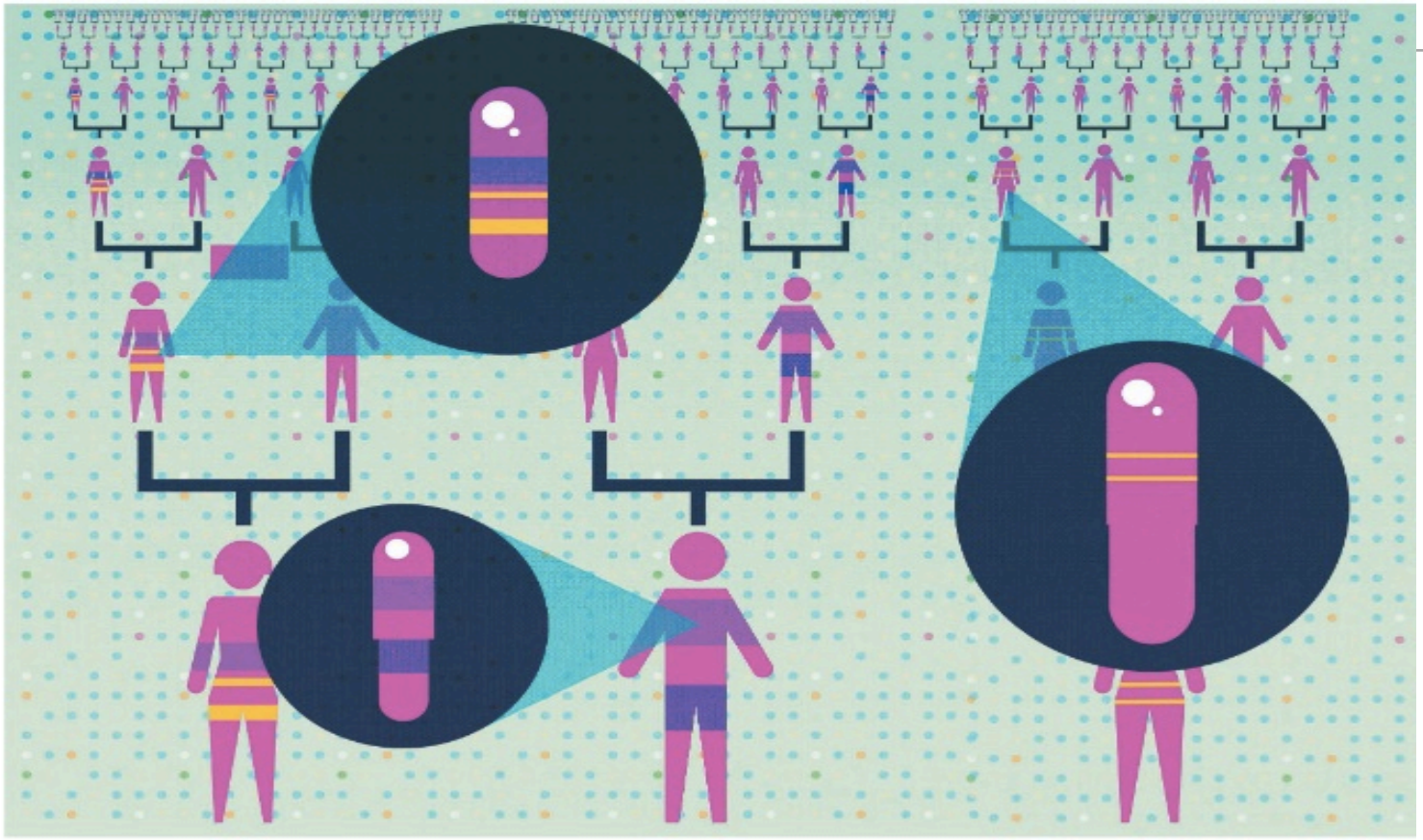
Pharmacogenetics of antidepressant response: A polygenic approach

Judit García-González [a], Katherine E. Tansey [b], Joanna Hauser [c], Neven Henigsberg [d], Wolfgang Maier [e], Ole Mors [f,g], Anna Placentino [h], Marcella Rietschel [i], Daniel Souery [j], Tina Žagar [k], Piotr M. Czerski [l], Borut Jerman [k,m], Henriette N. Buttenschøn [n], Thomas G. Schulze [o], Astrid Zobel [e], Anne Farmer [a], Katherine J. Aitchison [p], Ian Craig [a], Peter McGuffin [a], Michel Giupponi [q], Nader Perroud [r], Guido Bondolfi [s], David Evans [t], Michael O'Donovan [u], Tim J. Peters [v], Jens R. Wendland [w], Glyn Lewis [x], Shitij Kapur [a], Roy Perlis [y], Volker Arolt [z], Katharina Domschke [aa], Major Depressive Disorder Working Group of the Psychiatric Genomic Consortium[1], Gerome Breen [a], Charles Curtis [a], Lee Sang-Hyuk [a], Carol Kan [a], Stephen Newhouse [a], Hamel Patel [a], Bernhard T. Baune [ab], Rudolf Uher [ac], Cathryn M. Lewis [a,*,2], Chiara Fabbri [a,ad,2]

Clinical Pharmacogenetics Implementation Consortium Guideline for *CYP2D6* and *CYP2C19* Genotypes and Dosing of Tricyclic Antidepressants

JK Hicks[1], JJ Swen[2], CF Thorn[3], K Sangkuhl[3], ED Kharasch[4], VL Ellingrod[5,6], TC Skaar[7], DJ Müller[8], A Gaedigk[9] and JC Stingl[10]

Hicks JK, Sangkuhl K, Swen JJ, Ellingrod VL, Müller DJ, Shimoda K, Bishop JR, Kharasch ED, Skaar TC, Gaedigk A, Dunnenberger HM, Klein TE, Caudle KE, Stingl JC. Clinical pharmacogenetics implementation consortium guideline (CPIC) for CYP2D6 and CYP2C19 genotypes and dosing of tricyclic antidepressants: 2016 update. Clin Pharmacol Ther. 2016 Dec 20.



PHARMACOGENETICS

The right drug for you

Personalized prescribing is gaining momentum, but is there enough evidence for it to become standard clinical practice?

Drew L. Pharmacogenics: The Right Drug for You Nature. 2016 Sep 8;537(7619):S60-2.

Evidence-Based Guidelines: Overview

- **There are no clinically significant differences in efficacy, effectiveness, or quality of life among SSRIs, SNRIs, SSNRIs, or other second-generation antidepressants for the treatment of MDD.**
- **There are minor differences only in the incidence and severity of AEs, and mixed evidence of an increased risk of suicide with therapy**
- **Mirtazapine has a faster onset of action; all were the same at 4 weeks**
- **38% of patients did not achieve a treatment response following 6-12 weeks of therapy with the first agent; 54% did not achieve remission**

Ann Intern Med 2008; 149: 725-733

Anxiety Disorders

- **Anxiety disorders are the most commonly diagnosed psychiatric disorders and are highly co-occurring in patients with chronic pain.**
- **Anxiety at times can be so severe that individuals can experience overwhelming fear, avoidance behavior and cognitive distortions that perpetuate anxiety symptoms such that they can not fully engage in other efficacious therapies (for example CBT, PT).**
- **SSRIs and other first-line antidepressant medication treatments may mitigate these maladaptive behaviors and thoughts related to the underlying anxiety disorder, but achieving a therapeutic response can take up to four to six weeks, and oftentimes up to twelve weeks, at a therapeutic dose to evaluate for treatment response.**
- **A time-limited prescription of either a prn or standing dosing of benzodiazepines may be warranted**

- Cheatle, M.D., Shmuts, R. Benzodiazepine and opioid use in patients with chronic pain: balancing risk and benefit. Pain Medicine, 16(2): 219-221, 2015.

- **In waiting for efficacy of these medications the patient would continue to suffer psychiatrically, which in turn will worsen the perception of pain and affect the patient's functionality and quality of life.**
- **A time-limited prescription of either a prn or standing dosing of benzodiazepines may be warranted.**
- **When the antidepressant becomes effective in treating the anxiety symptoms, the benzodiazepine can be discontinued if used prn or tapered if taken as a standing regimen without any major adverse events or risks.**
- **Psychiatrists often call this method of treatment a "benzodiazepine bridge."**

Cheatle, M.D., Shmuts, R. Benzodiazepine and opioid use in patients with chronic pain: balancing risk and benefit. Pain Medicine, 16(2): 219-221, 2015.

Panic Disorders

- **Panic disorder and panic attacks are episodic and intermittent.**
- **Panic and associated sympathetic overdrive could be triggered by uncontrolled pain, and in turn exacerbate pain causing a vicious cycle.**
- **SSRIs and psychotherapy are first-line treatments for this disorder, but some anxiety disorders can be difficult to treat, and in general very high doses of SSRIs are required to achieve remission.**
- **Higher doses of these medications lead to high likelihood of side effects.**

Cheatle, M.D., Shmuts, R. Benzodiazepine and opioid use in patients with chronic pain: balancing risk and benefit. Pain Medicine, 16(2): 219-221, 2015.

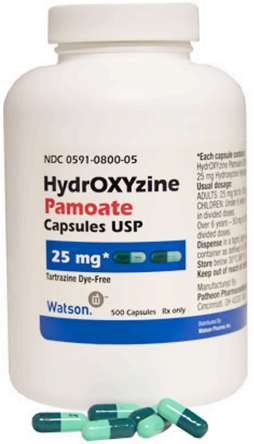
Panic and Benzodiazepines

- **"Rescue medication" would be helpful if their panic disorder and attacks are in partial remission on adequate first-line therapy or they have breakthrough attacks and are otherwise generally well controlled.**
- **Benzodiazepines, in these circumstances, can be helpful when used prn. When used in this manner, the potential for physiologic and psychological dependence is low**
- **Oftentimes when patients with panic disorders have access to rescue medication this eases anticipatory anxiety and reduces the likelihood of having a panic attack.**
- **Employing SSRIs and other first-line therapies (psychotherapy) in combination with as needed benzodiazepines is analogous to the standard practice of prescribing a long acting opioid and other therapies and providing as needed immediate release opioids for breakthrough pain.**

Cheatle, M.D., Shmuts, R. Benzodiazepine and opioid use in patients with chronic pain: balancing risk and benefit. Pain Medicine, 16(2): 219-221, 2015.

Non-Benzodiazepines

- **While benzodiazepines can be very effective in certain cases there are other medications with anxiolytic qualities with low abuse potential and reduced risk for unintentional overdoses when combined with opioids.**
- ***Buspirone* is a medication like the SSRIs can require several weeks to achieve a therapeutic response, but it is generally well tolerated and used often for adjunctive treatment for anxiety, depression, and sometimes sexual dysfunction (especially in women).**
- ***Mirtazepine*, a central alpha-2 agonist, is another antidepressant medication that could be used as monotherapy or adjunctively for depression and anxiety**
- ***Hydroxyzine*, despite the anticholinergic and antihistamine side effect profile, is another medication that could help abort panic and improve sleep.**



Pharmacologic Approaches to Sleep Disorders

- Benzodiazepine and Receptor Agonists (BzRAS)
- Non-benzodiazepine receptor agonists
- Melatonin receptor agonists
- Sedative antidepressants
- Atypical antipsychotic medications,
- Antiepileptic Drugs

Benzodiazepine and Receptor Agonists (BzRAS)

- BzRAS include benzodiazepines (example Temazepam, Triazolam) and a newer class of non-benzodiazepine drugs (for example, Zolpidem).
- This class of drugs binds to GABA-A receptors and induces sedative/hypnotic, amnestic, anxiolytic and anticonvulsant effects.
- Many short term clinical trials show that BzRAS improve sleep quality, sleep latency, wakefulness after sleep onset and total sleep time.
- Most benzodiazepines (excluding Triazolam) have intermediate to long half-life, helping patients fall asleep and stay asleep longer.

Benzodiazepines

- FDA approved benzodiazepines for insomnia include Restoril (Temazepam), Halcion (Triazolam), ProSOM (Estazolam), Doral (Quazepam), and Dalmane (Flurazepam).
- Lorazepam, alprazolam and clonazepam, which are typically used as anxiolytics, are also used off-label for sleep.
- For patients with chronic pain, short-term benzodiazepines may be useful in muscle tension, anxiety, and neuropathic pain, as well as sleep.
- One study found that with long-term use (> 1 year), pain patients using benzodiazepines had no improvement in sleep.

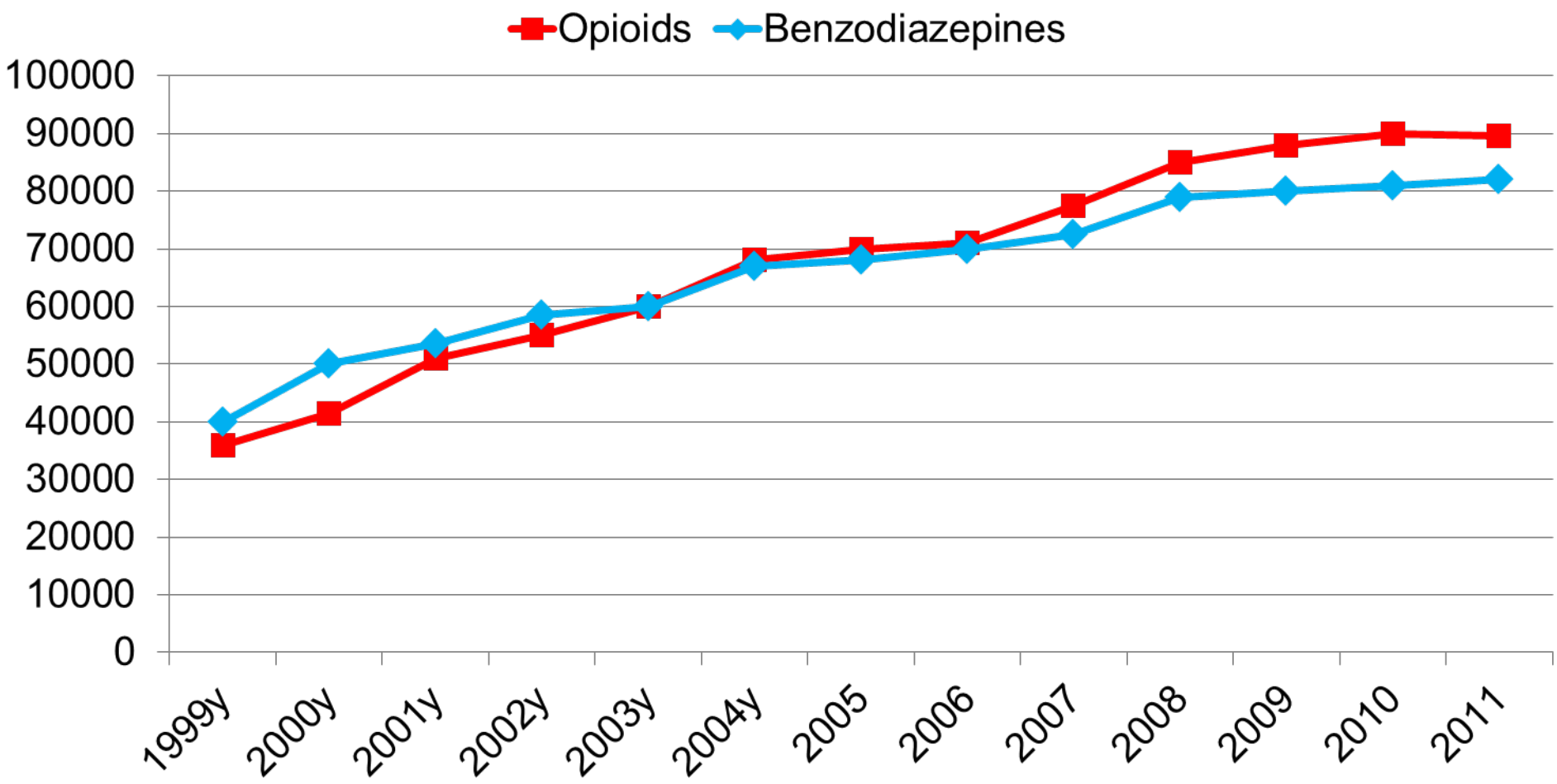
- Benzodiazepines may work well in short-term efficacy trials, but there is a paucity of data on long-term use and there are many documented adverse effects (cognitive impairment, decreased attention, anterograde amnesia).

- Long-term use of benzodiazepines may lead to a depressive symptomatology with cognitive and psychomotor slowing.

- Abruptly discontinuing benzodiazepines may lead to rebound insomnia and there is always a concern of tolerance and dependence, especially in patients with a history of sedative or alcohol abuse.

- Given these multiple safety concerns, benzodiazepines have fallen out of favor as a class of drugs for use in sleep disorders.

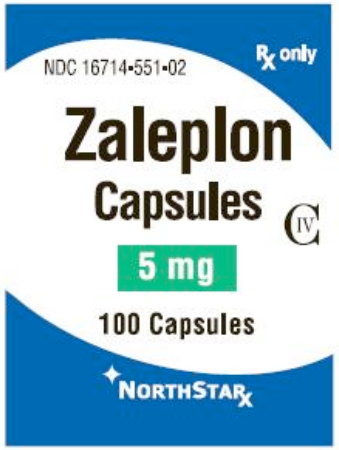
Drug Misuse and Abuse



Spiller HA. What every clinician needs to know about overdoses - poison center surveillance. Presented at: The 2012 National Rx Abuse Summit. April 10 – 12, 2012; Orlando, FL. http://www.slideshare.net/OPUNITE/henry-spiller-edited

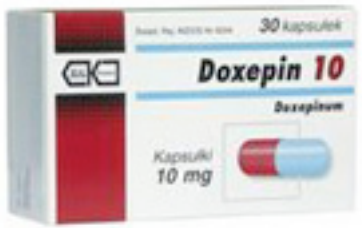
Non-Benzodiazepine Receptor Agonists (NBzRAS)

- Non-benzodiazepine receptor agonists include Ambien (Zolpidem), Sonata (Zalepon), and Lunesta (eszopiclone) are the newest class of FDA approved hypnotics used for insomnia.
- These class of drugs improve sleep latency and have potential for fewer daytime side effects, given their short half-life and receptor binding profile.



- **Zolpidem has become the most prescribed drug for insomnia and, as compared to benzodiazepines, in a double blind placebo controlled study it has shown to remain effective for 8 months of nightly use with no evidence of tolerance or rebound.**
- **Safety trials have demonstrated that there are side effects consisting of sleep eating, sleep walking and sleep driving.**

Antidepressants



Antidepressants

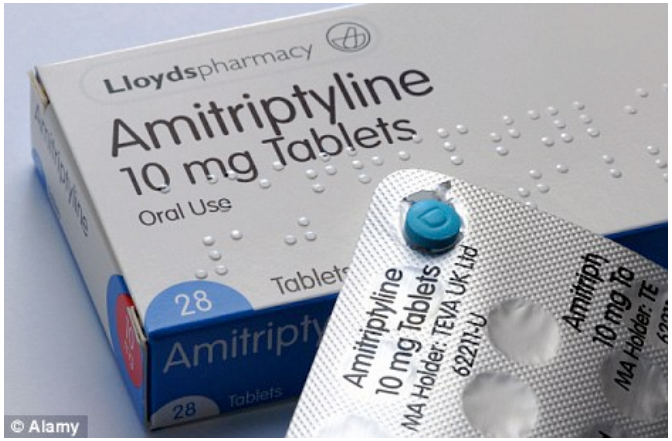
- **Sedative antidepressants, such as tricyclic antidepressants mirtazapine and Trazodone, are useful in treating chronic pain patients with insomnia.**

- **These classes of drugs help to relieve:**
  1. Insomnia
  2. Any associated depression that negatively influences pain perception
  3. The pain condition itself

- **Tricyclic antidepressants have pro-serotonergic, noradrenergic, dopaminergic and sodium channel blocking effects that may account for their efficacy in pain and depression, along with anticholinergic and antihistaminic effects that lead to sedation.**

TCAs

- At standard doses, all tricyclics have shown equal efficacy in treating neuropathic pain; however, they are not all equal in promoting sleep.
- Desipramine and imipramine are less sedating and may disrupt sleep.
- Amitriptyline, nortriptyline, Trimipramine and doxepin, on the other hand, may decrease sleep latency, increase sleep efficiency and increase total sleep time.



Trazodone

- Trazodone is an antagonistic of serotonin type II, histamine and alpha 1 adrenergic receptors and weakly inhibits serotonin reuptake.
- Trazodone exerts most of its hypnotic effects at low doses and works as an antidepressant at higher doses.
- There is some evidence for adjunctive effect when used with pregabalin for pain patients.

Mirtazapine

- Mirtazapine is an antidepressant with sedating qualities due to antagonism of type I histaminergic and serotonin type II receptors.

- At doses 15-30 mg it improves sleep latency, total sleep time and sleep efficiency, and decreases frequency of awakenings. It has also been shown to improve sleep, appetite and mood in cancer patients.

Melatonin Receptor Agonists

- Melatonin receptor agonists include the natural ligand, melatonin, as well as non-melatonin drugs (Ramelteon and Agalomantine).
- Melatonin has been shown to induce sleep by attenuating the wake-promoting impulses in the hippocampus.
- Melatonin is available over the counter and is not FDA approved.
- In 2005 the FDA approved Ramelteon, which is a melatonin receptor agonist, for the treatment of sleep initiation insomnia.

Antipsychotics

- Two of the newer, atypical antipsychotic medications, Seroquel (Quetiapine) and Zyprexa (Olanzapine), have been used off-label for treatment of insomnia.
- Self-reported outcomes and polysomnographic data suggests efficacy in increased total sleep time, slow wave restorative sleep, and decreasing sleep latency.
- At low doses, Seroquel primarily has antihistiminergic properties and is weakly pro-serotonergic .
- It has been known to decrease anxiety and serve as an adjunctive to antidepressant medication.
- These medications may cause significant weight gain and cardiac conduction abnormalities, such as prolonged QT interval, and a low risk of movement disorders, such as tardive dyskinesia.

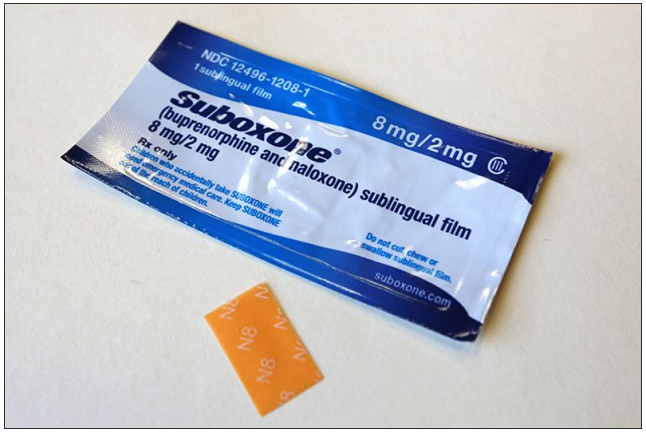
AEDs

- Gabapentin and pregabalin often used to treat chronic pain conditions with comorbid insomnia.
- In multiple studies of patients with neuropathic pain and fibromyalgia, self-reported sleep outcomes suggest positive effects on sleep latency and wakefulness after sleep onset, as well as increased deep sleep.
- Both have adjunctive effects on depression and anxiety.
- Pregabalin showed increased efficacy in promoting sleep in patients with diabetic neuropathy, compared to amitriptyline in a recent study.
- Adverse effects include dizziness, next day sedation, GI symptoms and peripheral edema.

Over the Counter Medications

- Most of the OTC aids contain first generation antihistamines (diphenhydramine and doxylamine).
- Patients may quickly develop tolerance to these agents.
- There are no controlled studies demonstrating efficacy for > than 3 weeks in treatment with insomnia.
- Antihistamines may cause next-day sedation and impaired cognitive function and should be used with caution in the elderly.

Buprenorphine Formulations



Buprenorphine Formulations

- Buprenorphine was developed by UK-based Reckitt & Colman Products and released in the United Kingdom in 1978.
- That same year, a clinical study determined that buprenorphine could be helpful in reducing cravings of pure opioids in patients with an opioid abuse disorder.
- Then, a separate study published in 1982 demonstrated that buprenorphine offered excellent analgesia with a blunted abuse liability.

- **Buprenorphine is a partial agonist at the mu-opioid receptors and an antagonist at the kappa receptors.**

- **Mu-opioid receptor activity produces the analgesic effects of buprenorphine, while a strong affinity for the kappa receptors render them inactive.**

- ***Buprenex***
  Buprenex was released in 1985 in the United States as an injectable formulation of buprenorphine. Buprenex is approved for the relief of moderate to severe pain. This formulation is also used off-label for the treatment of opioid withdrawal in heroin-dependent hospitalized patients.
- ***Bunavail, Suboxone, and Zubsolv***
  The buprenorphine transmucosal film is formulated in conjunction with naloxone. This medication is indicated for the treatment of opioid use disorders and is used for heroin or other opioid use disorders, both for induction and maintenance therapy
- ***Subutex***
  Subutex is a sublingual tablet formulation of buprenorphine approved for the treatment of opioid use disorders, with a particular focus on the induction phase of treatment. It has also been used off-label successfully for the treatment of chronic pain

- ***Belbuca*** **is the newest formulation of buprenorphine available as a buccal film and indicated for the management of pain requiring around-the-clock, long-term opioid treatment not adequately controlled with alternatives.**
- ***Transdermal buprenorphine*** **is a 7 day patch indicated to control of moderate to severe chronic pain**
- ***CAM2038*** **is an investigational buprenorphine subcutaneous injection product being developed as once-weekly and once-monthly formulations for all treatment phases of opioid addiction, from initiation through maintenance.**

Clinical Considerations

PAIN® 154 (2013) 345–349

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Topical review

Suicidality associated with antiepileptic drugs: Implications for the treatment of neuropathic pain and fibromyalgia

Anthony Pereira [a], Michael J. Gitlin [b], Robert A. Gross [c], Kelly Posner [d], Robert H. Dworkin [a,c,*]

[a] Department of Anesthesiology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA
[b] Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA, USA
[c] Department of Neurology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA
[d] Department of Psychiatry, Columbia University, and New York State Psychiatric Institute, New York, NY, USA

- **Results were conflicting and inconsistent regarding increased risk of suicide with Rx of AEDs possibly due to variability in research designs, controls, comparison groups and sample size and measures of SI/SB.**
- **Authors concluded that in spite of the limitations, the literature reviewed suggests that the risk of suicidality should be assessed in patients with neuropathic pain, fibromyalgia or other pain conditions being considered for AED therapy**

PAIN® 155 (2014) 2471–2475

PAIN®

www.elsevier.com/locate/pain

Topical review

Suicidal ideation and behavior associated with antidepressant medications: Implications for the treatment of chronic pain

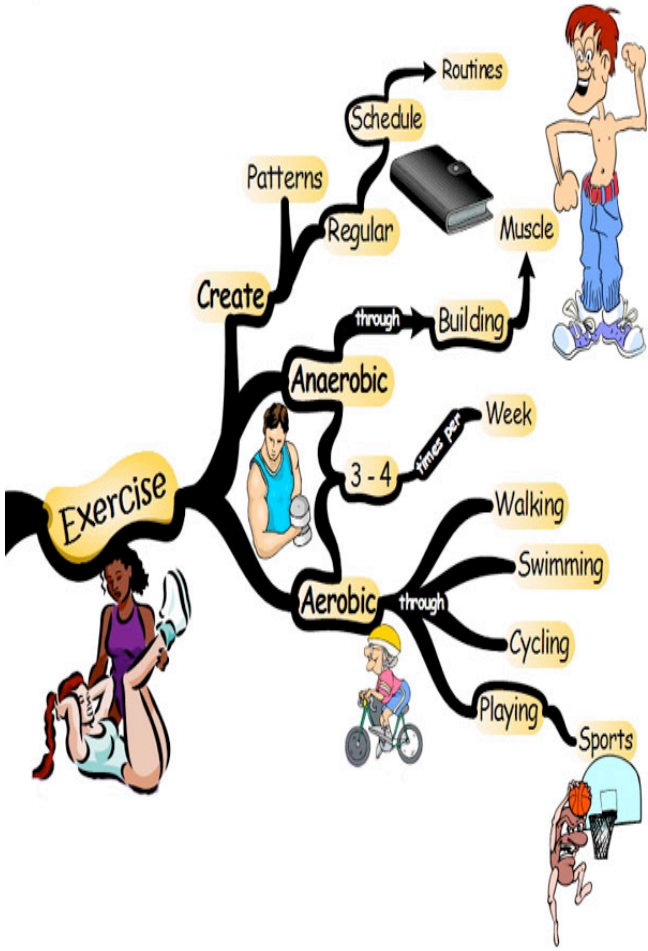
Anthony Pereira [a], Yeates Conwell [b], Michael J. Gitlin [c], Robert H. Dworkin [a,*]

[a] Department of Anesthesiology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA
[b] Department of Psychiatry, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA
[c] Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA, USA

- **The FDA expanded warnings of increased risk of SI/SB for all antidepressants**
- **In the studies reviewed there were no differences between antidepressants and risk of SI/SB**
- **Results of studies reviewed were inconsistent and conflicting due to methodological limitations and variability between studies**
- **Authors concluded that assessment of risk for SI/SB should be standard practice in pain population especially patients initiating antidepressant therapy and in patients between the ages of 18-25.**

Exercise, Pain, Depression and Anxiety

- Exercise not only can enhance the release of endogenous opioids (endorphins) thus reducing the use of prescription opioids, but can also reduce the mortality and morbidity related to major health conditions.
- Recent data from randomized studies suggest that aerobic exercise also significantly improves function and quality of life in patients with chronic low back pain.
- Exercise has proven to be a potent anxiolytic as it both blunts the body's response to cortisol and increases brain serotonin levels; epidemiological studies have shown that exercise both prevents anxiety disorders and effectively treats them



Heldt, S.A., et al., *Hippocampus-specific deletion of BDNF in adult mice impairs spatial memory and extinction of aversive memories.* Mol Psychiatry, 2007. 12(7): p. 656-70. Wipfli, B.M., C.D. Rethorst, and D.M. Landers, *The anxiolytic effects of exercise: a meta-analysis of randomized trials and dose-response analysis.* J Sport Exerc Psychol, 2008. 30(4): p. 392-410.

CBT/ACT

Cognitive Behavioral Therapy

- CBT focuses on maladaptive thought patterns (catastrophizing) and behaviors (kinesiophobia) that occur frequently in patients with CNCP
- The objective of CBT is to guide the patient in recognizing and reconceptualizing his/her personal view of pain, identifying their role in the process of healing and promoting the patient being proactive rather than passive, and competent rather than incompetent
- CBT include specific skill acquisition (relaxation therapy, stress management, cognitive restructuring) followed by skill consolidation and rehearsal, and relapse training (Turk, Flor, 2006)

Psychological therapies for the management of chronic pain (excluding headache) in adults

Amanda C de C Williams[1], Christopher Eccleston[2], Stephen Morley[3]

[1]Research Department of Clinical, Educational & Health Psychology, University College London, London, UK. [2]Centre for Pain Research, The University of Bath, Bath, UK. [3]Leeds Institute of Health Sciences, University of Leeds, Leeds, UK

Contact address: Amanda C de C Williams, Research Department of Clinical, Educational & Health Psychology, University College London, Gower Street, London, WC1E 6BT, UK. amanda.williams@ucl.ac.uk. ucjtamw@ucl.ac.uk.

Editorial group: Cochrane Pain, Palliative and Supportive Care Group.
Publication status and date: Edited (no change to conclusions), published in Issue 2, 2013.
Review content assessed as up-to-date: 10 September 2012.

Citation: Williams ACDC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database of Systematic Reviews* 2012, Issue 11. Art. No.: CD007407. DOI: 10.1002/14651858.CD007407.pub3.

THE COCHRANE COLLABORATION

Efficacy/Effectiveness

- **Objective: To evaluate the effectiveness of psychological therapies for chronic pain (excluding headache) in adults, compared with treatment as usual, waiting list control, or placebo control, for pain, disability, mood and catastrophic thinking**

- **Data collection and analysis: Forty-two studies met our criteria and 35 (4788 participants) provided data. Two authors rated all studies.**

- **Main Results: CBT is effective in altering mood and catastrophising outcomes, when compared with treatment as usual/waiting list, with evidence that this is maintained at six months.**

- **Authors Conclusions: CBT is a useful approach to the**

Cognitive behavioural therapies for fibromyalgia

Kathrin Bernardy[1], Petra Klose[2], Angela J Busch[3], Ernest HS Choy[4], Winfried Häuser[5]

[1]Department of Pain Medicine, BG University Hospital Bergmannsheil GmbH, Ruhr University Bochum, Bochum, Germany. [2]Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen, Germany. [3]School of Physical Therapy, University of Saskatchewan, Saskatoon, Canada. [4]Section of Rheumatology, Department of Medicine, Cardiff University School of Medicine, Cardiff, UK. [5]Department of Psychosomatic Medicine and Psychotherapy, Technische Universität München, München, Germany

Contact address: Winfried Häuser, Department of Psychosomatic Medicine and Psychotherapy, Technische Universität München, Langerstr. 3, München, D-81675, Germany. whaeuser@klinikum-saarbruecken.de.

Editorial group: Cochrane Musculoskeletal Group.
Publication status and date: New, published in Issue 9, 2013.
Review content assessed as up-to-date: 4 September 2013.

Citation: Bernardy K, Klose P, Busch AJ, Choy EHS, Häuser W. Cognitive behavioural therapies for fibromyalgia. *Cochrane Database of Systematic Reviews* 2013, Issue 9. Art. No.: CD009796. DOI: 10.1002/14651858.CD009796.pub2.

THE COCHRANE COLLABORATION

Efficacy/Effectiveness

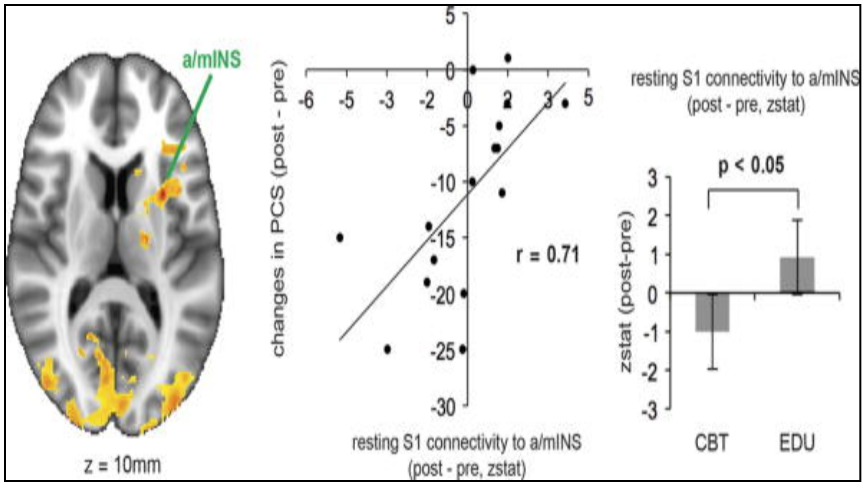
- **Objective: evaluate the effectiveness of CBT for FM**
- **Main Results: 23 studies met inclusion criteria with a total of 2031 patients included. CBT was superior to controls in pain reduction, reducing negative mood and reducing disability both at end of treatment and at 6 month follow up**

Biological Substrates of CBT on Pain

- **16 high catastrophizing patients with fibromyalgia were randomized into a group that received a 4 week course of CBT or a control group that received only fibromyalgia education material.**
- **Resting state fMRI evaluated functional connectivity between key pain processing brain regions at baseline and post-treatment.**

Lazaridou, A., et al., *Effects of Cognitive-Behavioral Therapy (CBT) on Brain Connectivity Supporting Catastrophizing in Fibromyalgia.* Clin J Pain, 2017. **33**(3): p. 215-221.

- **Results revealed that catastrophizing correlated with increased resting state functional connectivity between S1 and anterior insula.**
- **The CBT group demonstrated a larger reduction in both pain and catastrophizing as compared to the control group at the 6-month follow-up and reduced resting state connectivity between S1 and anterior/medial insula at post-treatment and these changes were associated with concurrent treatment-related reduction in catastrophizing.**
- ***The authors concluded that CBT via reducing catastrophizing helps normalize pain-related brain responses***



ACCEPTANCE AND COMMITMENT THERAPY

- Acceptance and Commitment Therapy (ACT) is a form of CBT that is a directive and experiential type of therapy based on rational frame theory. The goal of ACT is to experience life mindfully and reinforce psychological flexibility.
- The core processes of ACT include:
  - -Contact with the present moment
  - -Self-as-context
  - -Defusion
  - -Acceptance
  - -Values
  - -Committed action
- There are 5 randomized control trials on the use of ACT in chronic pain demonstrating efficacy in improving mood and function.

Behaviour Research and Therapy 49 (2011) 748–755

Contents lists available at ScienceDirect

Behaviour Research and Therapy

journal homepage: www.elsevier.com/locate/brat

Acceptance and values-based action in chronic pain: A three-year follow-up analysis of treatment effectiveness and process

Kevin E. Vowles [a,b,c,d,*], Lance M. McCracken [c,d], Jane Zhao O'Brien [c,d,e]

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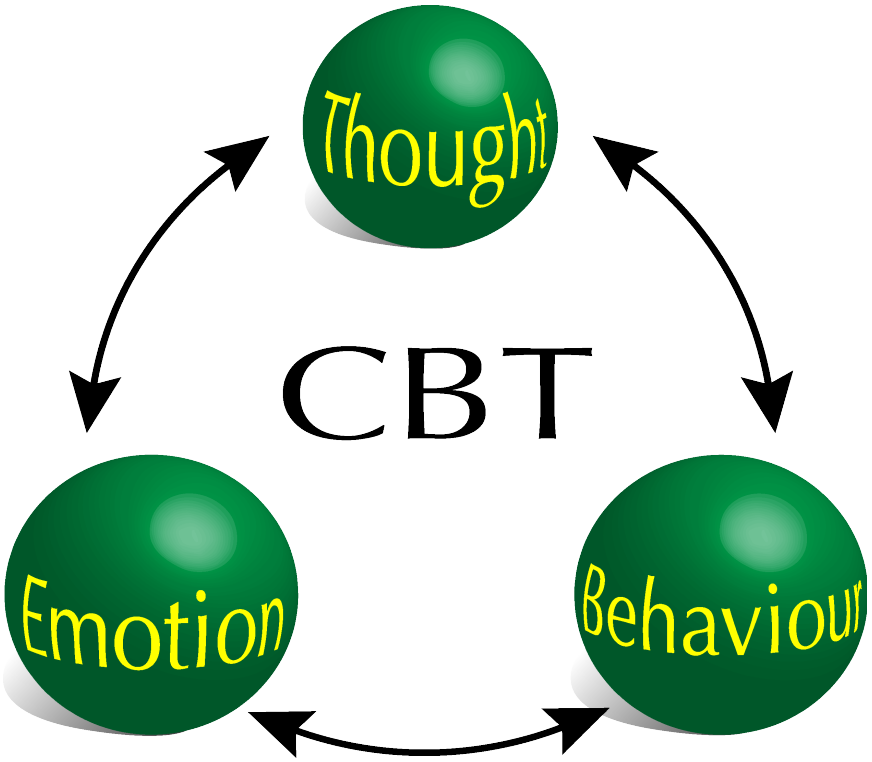
[b] Primary Care Sciences Research Centre, Keele University, UK
[c] Bath Centre for Pain Services, Royal National Hospital for Rheumatic Diseases NHS Foundation Trust, Bath, UK
[d] Centre for Pain Research, University of Bath, Bath, UK
[e] School of Psychology, University of Newcastle Upon Tyne, Newcastle Upon Tyne, UK

- **171 subjects with chronic MSK completed a course of ACT**
- **At a three year f/u 68% of the cohort noted improvement in key outcomes including pain-related anxiety, physical and psychosocial disability and depression**

CBT



Cognitive Behavioral Therapy for Insomnia

- **CBT-I has been demonstrated to be equally effective or even superior to pharmacotherapy in patients with chronic primary insomnia.**

CBT-I cont'd

- **CBT-I consists of:**
  - Psychoeducation about sleep and insomnia
  - Stimulus control
  - Sleep restriction
  - Sleep hygiene
  - Relaxation training
  - Cognitive restructuring

Research Article

The Durability of Cognitive Behavioral Therapy for Insomnia in Patients with Chronic Pain

Carla R. Jungquist,[1,2] Yolande Tra,[3] Michael T. Smith,[4] Wilfred R. Pigeon,[2,5] Sara Matteson-Rusby,[2] Yinglin Xia,[6] and Michael L. Perlis[7]

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- **This was a parallel-group, randomized, single blind trial of CBT-I with a contact/measurement control condition**
- **Twenty-eight subjects with chronic neck and back pain were randomized into the 2 groups.**
- **Results revealed that patients who received CBT-I had significantly improved sleep and these patients maintained a statistically and clinically improved total sleep time even 6 months after treatment ended, despite the persistence of moderate to severe pain**

Sleep Disord. 2012;2012:679648.

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Shorter communication

Hybrid cognitive-behaviour therapy for individuals with insomnia and chronic pain: A pilot randomised controlled trial

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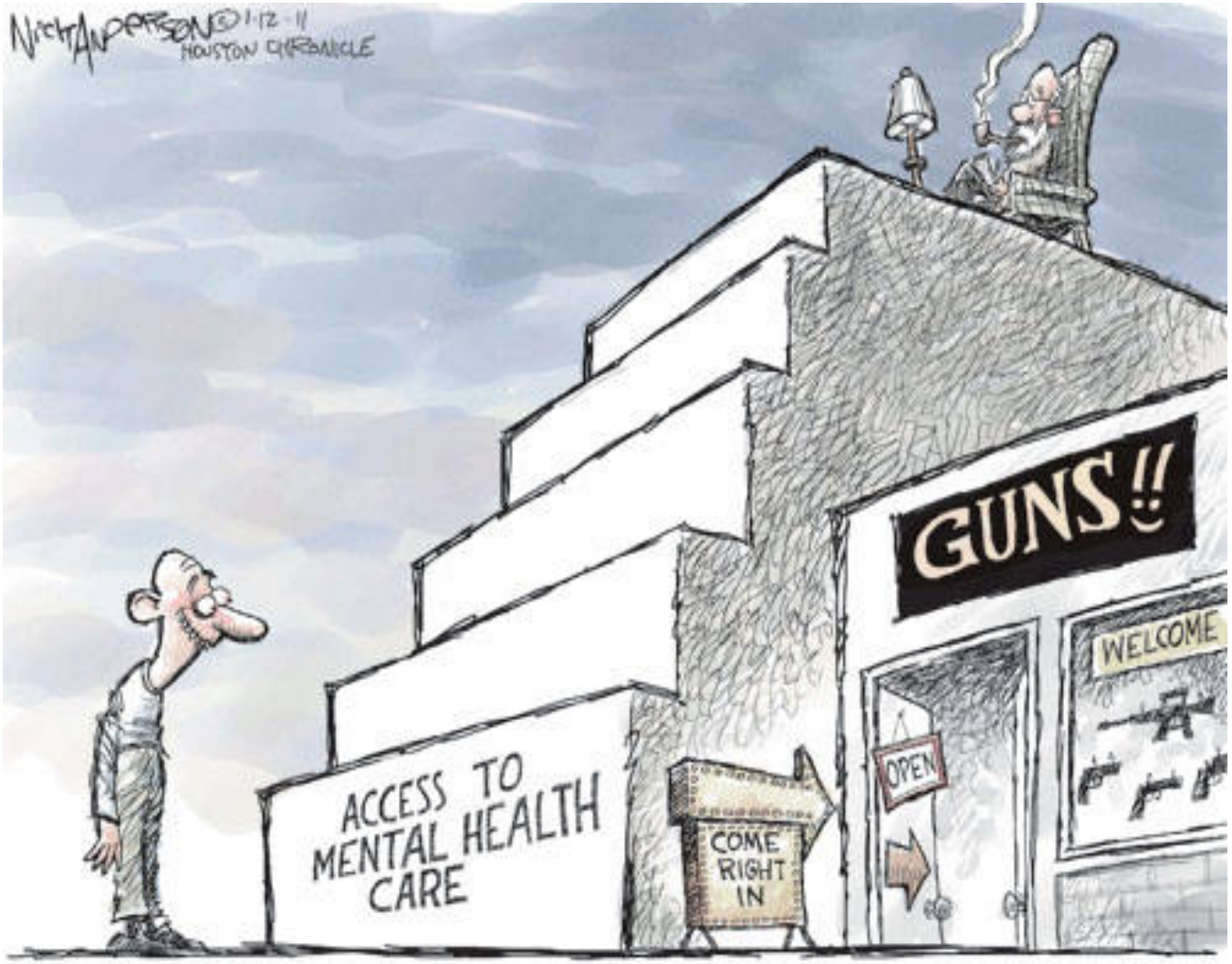
- **An RCT design comparing a Hybrid CBT P-I to a monitoring control group**
- **Compared to symptom monitoring, the hybrid intervention was associated with greater improvement in sleep at post-treatment. Although pain intensity did not change, the Hybrid Group reported greater reductions in pain interference, fatigue and depression than the Monitoring Group. Changes associated with the hybrid intervention were clinically significant and durable at 1- and 6-month follow-ups.**

Barriers to Receiving CBT/ACT

- **Pain is typically inadequately treated in primary, secondary and tertiary care settings**
- **Psychological interventions, in particular, are underutilized**
- **Factors accounting for underutilization of psychological treatment for pain include:**
  - Financial
  - Environmental (lack of transportation or providers in the geographic region)
  - Patient attitude (stigma) associated with receiving psychological care'
  - Healthcare system barriers

Access Issues



Interventions

- **Office-based interventions**
  - Training non-BH staff on CBT etc
  - Antidepressant therapy/pain self-management program

    Kroenke et al 2009
- **E-health**
  - Computer-assisted CBT
  - Telemedicine
  - Smartphone Apps

Computer-Assisted Interventions

Article

Computer-Assisted Delivery of Cognitive-Behavioral Therapy for Addiction: A Randomized Trial of CBT4CBT

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Samuel A. Ball, Ph.D.

Steve Martino, Ph.D.

Charla Nich, M.S.

Theresa A. Babuscio, M.A.

Kathryn F. Nuro, Ph.D.

Melissa A. Gordon, B.A.

Galina A. Portnoy, B.S.

Bruce J. Rounsaville, M.D.

Objectives: This study evaluated the efficacy of a computer-based version of cognitive-behavioral therapy (CBT) for substance dependence.

Method: This was a randomized clinical trial in which 77 individuals seeking treatment for substance dependence at an outpatient community setting were randomly assigned to standard treatment or standard treatment with biweekly access to computer-based training in CBT (CBT4CBT) skills.

Results: Treatment retention and data availability were comparable across the treatment conditions. Participants assigned to the CBT4CBT condition submitted significantly more urine specimens that were negative for any type of drugs and tended to have longer continuous periods of abstinence during treatment. The CBT4CBT program was positively evaluated by participants. In the CBT4CBT condition, outcome was more strongly associated with treatment engagement than in treatment as usual; furthermore, completion of homework assignments in CBT4CBT was significantly correlated with outcome and a significant predictor of treatment involvement.

Conclusions: These data suggest that CBT4CBT is an effective adjunct to standard outpatient treatment for substance dependence and may provide an important means of making CBT, an empirically validated treatment, more broadly available.

(Am J Psychiatry 2008; 165:881–888)

Conclusions

- Mood, anxiety and sleep disorders are common comorbidities to chronic pain
- Each condition separately can cause additional suffering and impact QOL and can increase the risk of SI/SB
- Only a comprehensive approach to assessment, monitoring and treatment will effectively manage these conditions and reduce the risk of SI
- Access to efficacious therapeutics needs to be addressed and non-traditional delivery systems further developed.

THANK YOU !!

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