A nighttime photograph of a city skyline, likely Seattle, with numerous skyscrapers illuminated and their lights reflecting on the water in the foreground. The sky is dark, and the overall scene is lit with warm, golden-yellow light from the city lights.

Effects of Cognitive Behavioral Therapy for Co-Morbid Insomnia and Pain

Michael V. Vitiello, PhD

Professor of Psychiatry & Behavioral Sciences,

Gerontology & Geriatric Medicine, and Biobehavioral Nursing

Co-Director, Center for Research in Management of Sleep Disturbances

Co-Director, Northwest Geriatric Education Center

University of Washington, Seattle WA

Presentation Objectives

- **Describe the nature of sleep/pain relationships.**
- **Describe the evolving understanding of the impact of sleep on pain.**
- **Describe the results of Lifestyles, a RCT designed to examine whether improving sleep in a pain population (osteoarthritis) with co-morbid insomnia results in improved pain.**



Early Observation of Sleep Pain Relationships

“In studying the effect of sleep loss...by the use of the Von Frey test hairs, we studied six subjects, and, whereas the cutaneous sensitivity to touch remained unchanged, that to pain showed a progressive increase (lower thresholds) during the period of wakefulness in every one of the eleven selected points on the face and hands.”

Sleep and Wakefulness p. 223

Nathaniel Kleitman, 1934



Sleep and Pain

- **Chronic pain is associated with:**
 - **Increased nighttime sleep-related complaints**
 - » Vitiello et al., 2004
 - **Increased daytime sleep-related complaints**
 - » Vitiello et al., 2004
 - **Increased likelihood of napping**
 - » Foley et al., 2007
 - **Increased nighttime awakenings from sleep**
 - » Ohayon and Roth, 2003
 - **Increased difficulty returning to sleep after waking.**
 - » Ohayon and Roth, 2003

Sleep and Pain: Questions of Directionality

- **Historically it has been assumed that sleep disturbance was secondary to pain.**
- **The current view is that insomnia is typically co-morbid with pain.**
- **A growing body of data suggests that insomnia can lead to or worsen pain.**
- **Emerging data also suggest that improving sleep may improve co-morbid pain.**

Sleep and Pain

- **Disturbed sleep may maintain/exacerbate pain and related dysfunction.**
 - Haack, Sanchez, Mullington, *Sleep* 2007;30:1145-52.
 - Smith, et al., *Sleep* 2007;30:494-505.
 - Rohers, et al., *Sleep* 2006;29:145-51.

Sleep and Pain

- **Three recent studies have examined the day-to-day predictive relationships between sleep and pain in chronic pain populations:**
 - **Counter-intuitively**, these studies report that, while measures of nighttime sleep quality predict next day pain, pre-sleep pain does not predict subsequent sleep quality.
 - Lewandowski et al., *Pain* 2010; 151:220-225.
 - Tang et al., *Sleep* 2012; 35(5):675-687.
 - Buchanan et al. *J Clin Sleep Med* 2014 (in press, JC-053-14)

Sleep and Pain

- **A recent systematic review of sleep/pain interactions concluded that sleep disturbance is a stronger predictor for the development and maintenance of chronic pain, rather than vice versa, which suggests that improving sleep in chronic pain populations may improve pain outcomes.**
 - **Finan, Goodin and Smith. The association of sleep and pain: An update and a path forward. Journal of Pain. 2013; 14(12):1539-1552.**

Sleep and Pain

- **Several small intervention trials have evaluated CBT-I in diverse pain populations:**
 - **Currie et al., 2000. CBT-I improved sleep but not pain compared to a waitlist at post-treatment and 3-mo among 60 chronic pain patients.**
 - **Edinger et al., 2005. CBT-I improved sleep but not pain, and sleep hygiene improved pain but not sleep compared to usual care at post-treatment in a sample of 47 fibromyalgia patients.**
 - **Jungquist et al., 2010. CBT-I improved sleep and pain relative to a contact control at post-treatment in 28 patients with mixed chronic neck and back pain.**

Sleep and Pain in Osteoarthritis

- **~25% of the older adult population experiences chronic OA pain and co-morbid insomnia.**
- **Co-morbid pain and insomnia have significant negative impact on physical function and quality of life.**
- **Other adverse consequences may include depression, fatigue, impaired cognitive function and increased healthcare utilization and costs.**

CBT-I Improves both Sleep and Pain in Older Adults with Co-morbid Osteoarthritis and Insomnia

Vitiello et al., Cognitive Behavioral Therapy for Insomnia Improves Sleep and Decreases Pain in Older Adults with Co-morbid Insomnia and Osteoarthritis.

Journal of Clinical Sleep Medicine 2009; 5(4): 355-362.

- **CBT-I improved immediate and long-term sleep in OA patients with co-morbid insomnia.**
- **CBT-I reduced both immediate and long-term pain in these patients, without addressing pain.**
- **Improving sleep in OA patients with co-morbid insomnia may be “analgesic”.**
- **The likely reciprocal effects of pain dysfunction and sleep disturbance offer a compelling rationale for integrated management of these disorders.**

Lifestyles - Cognitive Behavioral Therapy for Arthritis Pain and Insomnia in Older Adults

M.V. Vitiello, S.M. McCurry and M. Von Korff, Co-PIs

- Specific Aim – Will a novel cognitive-behavioral intervention that targets both pain and sleep yield substantially improved sleep, pain, and functional outcomes versus a state-of-the-art cognitive-behavioral intervention that targets pain alone and an education only control in older adults with OA pain and co-morbid sleep disturbance.

Supported by AG031126

Lifestyles - Cognitive Behavioral Therapy for Arthritis Pain and Insomnia in Older Adults

- 367 older adults with co-morbid OA and insomnia.
- Randomized to three groups: Education Only Control (EOC), CBT-Pain (CBT-P), CBT-Pain/Insomnia (CBT-PI), each of six weekly 90-minute sessions.
- Sleep, pain, function, affect and cognition assessed at pre and post-treatment and 9 and 18 months.
- Subjects recruited from an HMO, allowing treatment delivery in primary care clinics and changes in health care utilization and costs to be assessed.

Lifestyles Treatment Protocols

Von Korff et al., Group Behavioral Interventions for Co-Morbid Chronic Pain and Insomnia in Primary Care: The Lifestyles Cluster Randomized Trial Design.

Contemporary Clinical Trials 33(4):759-68, 2012.

- EOC – Non-directive pain and sleep education with no implementation components.
- CBT-P – Pain education, physical activation, goal setting, relaxation, activity pacing and cognitive redirection.
- CBT-PI – Standard CBT-I techniques added to the CBT-P intervention components.

All treatments were group format lead by a single pair of MH professionals (MA & PhD).

Lifestyles Study Sample

McCurry et al., Frequency of Co-morbid Insomnia, Pain, and Depression in Older Adults with Osteoarthritis: Predictors of Enrollment in a Randomized Treatment Trial.

Journal of Psychosomatic Research, 2011, 71(5):296-9.

	<u>EOC</u>	<u>CBT-P</u>	<u>CBT-PI</u>
N	123	122	122
Age	73.1 (8.0)	73.0 (8.4)	73.2 (8.1)
% Women	75.6	80.3	79.5
3MSE	93.1 (5.4)	94.0 (4.8)	93.3 (4.4)
GDS	7.0 (5.6)	6.6 (4.5)	6.5 (5.1)
% Chronic illness	49.6	49.2	59.8
Insomnia Severity	11.5 (5.1)	11.8 (4.7)	11.2 (5.2)
Pain Severity	4.1 (1.5)	4.3 (1.6)	4.6 (1.5)

Lifestyles Conclusions

- Lifestyles interventions were all perceived as comparably credible.
- Subject retention was high: post-treatment = 96.7%, 9-mo = 92.9%., 18-mo = 88.9%
- CBT-PI significantly improved ISI and SE relative to EOC over 9-mo.
- CBT-PI significantly improved ISI relative to CBT-P, while both improved SE relative to EOC, over 9 mo.

Lifestyles Conclusions

- Pain Severity and AIMS were not significantly reduced by any Lifestyles intervention over 9 mo.
- An a-priori planned subgroup analysis of subjects with higher baseline pain (PS ≥ 5), revealed a similar pattern of results.
- At 18 months no outcome measure differed significantly from baseline in any of the three treatment arms, even among persons with severe baseline pain.

Lifestyles Conclusions

- **Lifestyles results support the durability of an integrated CBT-PI intervention for reduction of insomnia symptoms through 9 months among individuals with co-morbid OA pain, regardless of severity.**

» Vitiello, et al. *J American Geriatrics Society* 61(6):947-956, 2013.

- **Sustained (18 month) treatment effects for any outcome were not statistically significant and did not support the benefits of an integrated sleep and pain intervention over sleep-focused treatment.**

Lifestyles Strengths and Caveats

- **Strengths:**

- A large population-based study sample with frequent and multiple co-morbidities beyond insomnia and OA .
- Treatment delivered at patients' primary care clinics.
- A highly credible attention control condition.
- Excellent subject retention.
- Moving from testing efficacy to effectiveness.

- **Limitations:**

- Regression to the mean from screen to pre-treatment.
- Higher than expected ICCs which limited analytic power.
- CBT-PI may have diluted CBT efficacy to improve sleep?

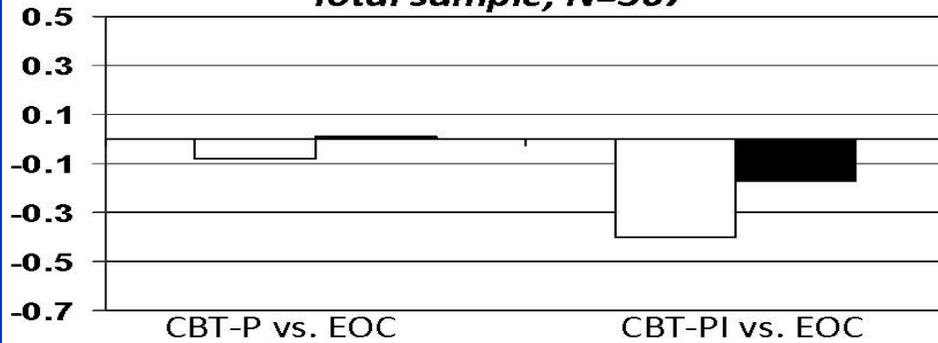
Lifestyles – Lessons Learned

McCurry, et al. Who Benefits from CBT for Insomnia in Primary Care? Longitudinal Results from the Lifestyles Trial. *Sleep*. 37(2);299-308, 2014.

- **Lifestyles may have been underpowered.**
- **Inspection of effect sizes of the primary outcomes for the full study sample, as well as two sub-samples (high baseline pain severity, high baseline pain and insomnia severity), raise questions about the true nature of the study outcome.**

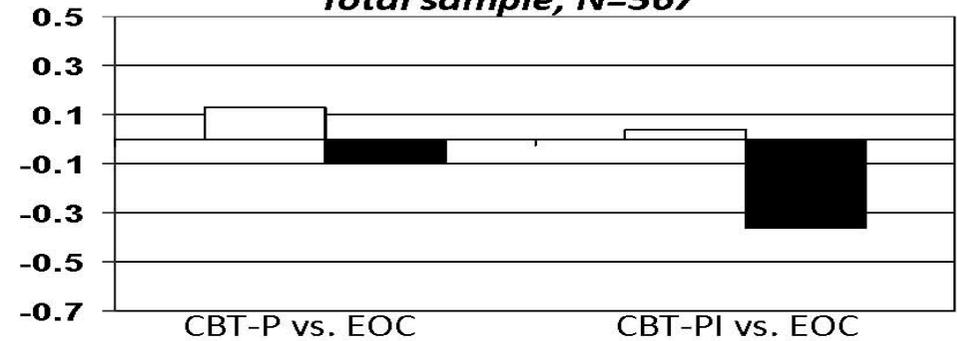
Insomnia Severity Index

Total sample, N=367

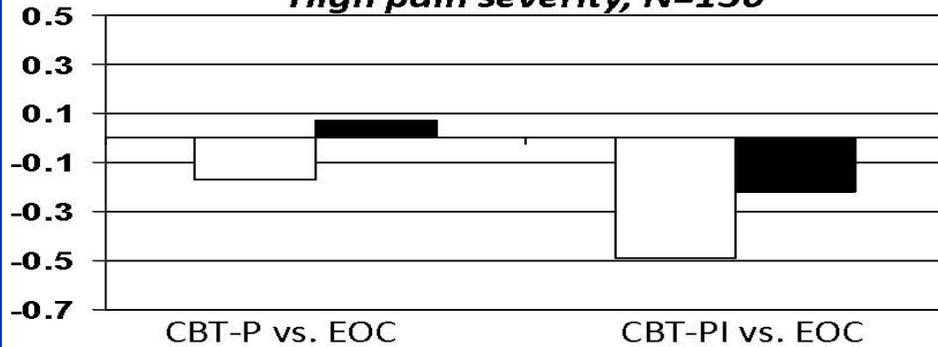


Pain Severity

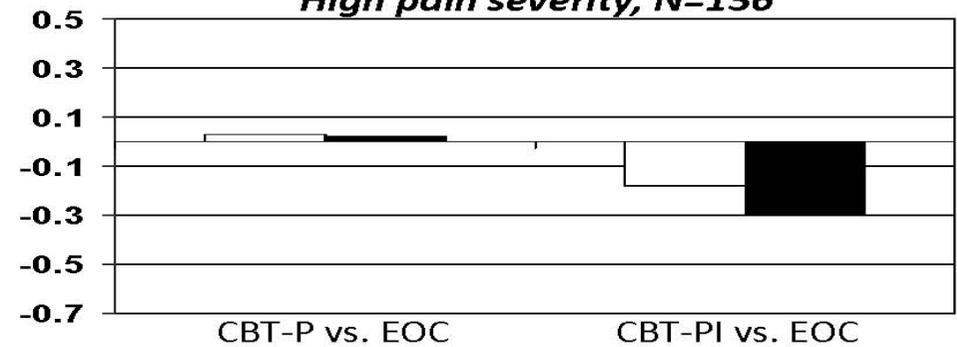
Total sample, N=367



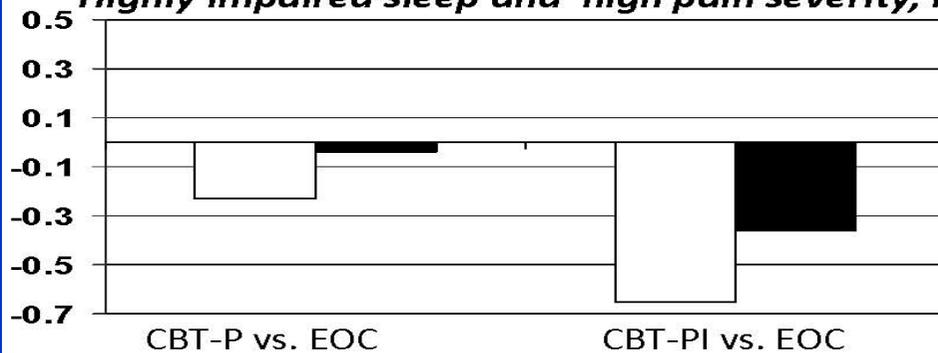
High pain severity, N=136



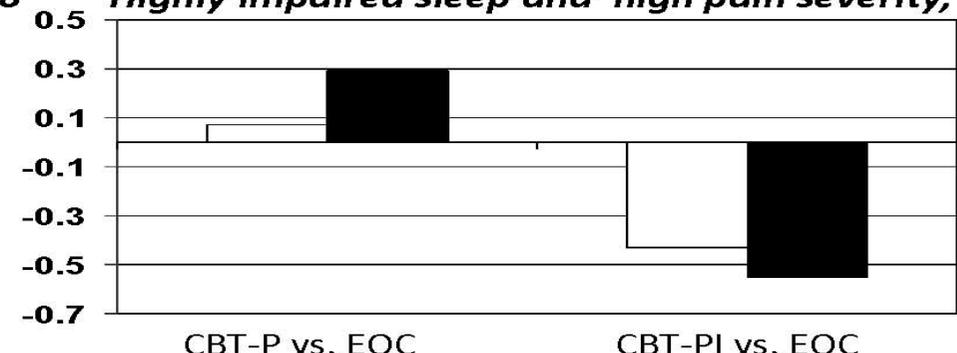
High pain severity, N=136



Highly impaired sleep and high pain severity, N=98



Highly impaired sleep and high pain severity, N=98

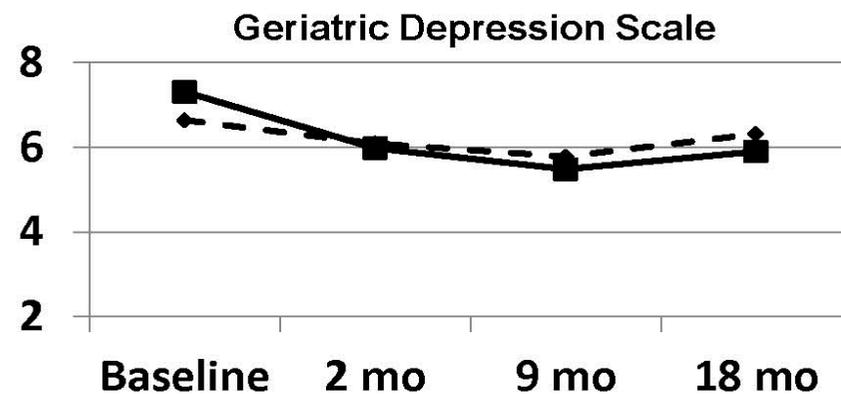
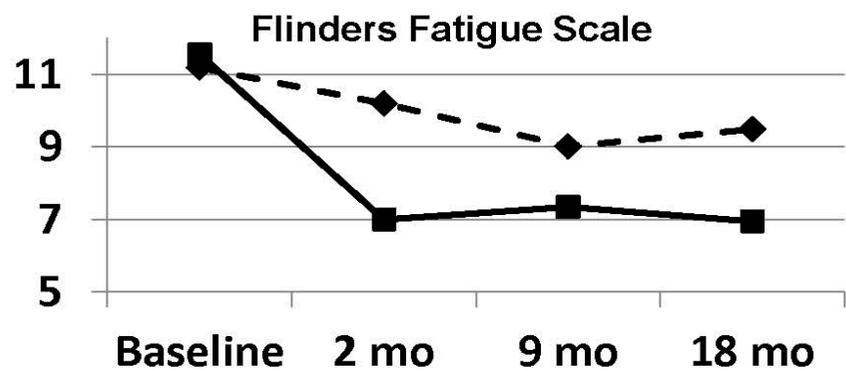
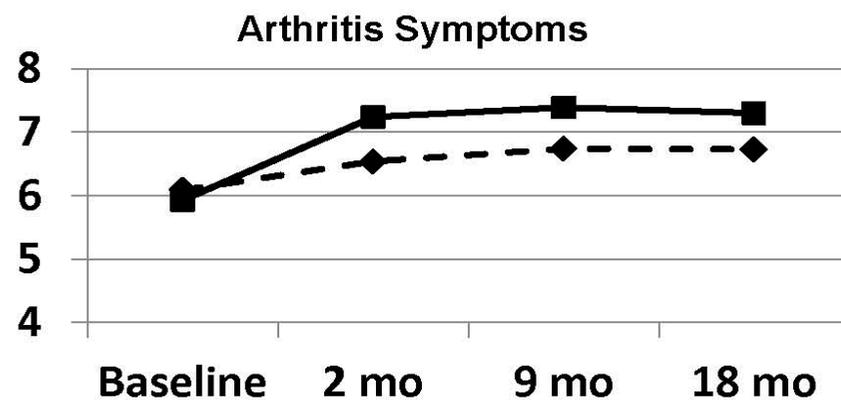
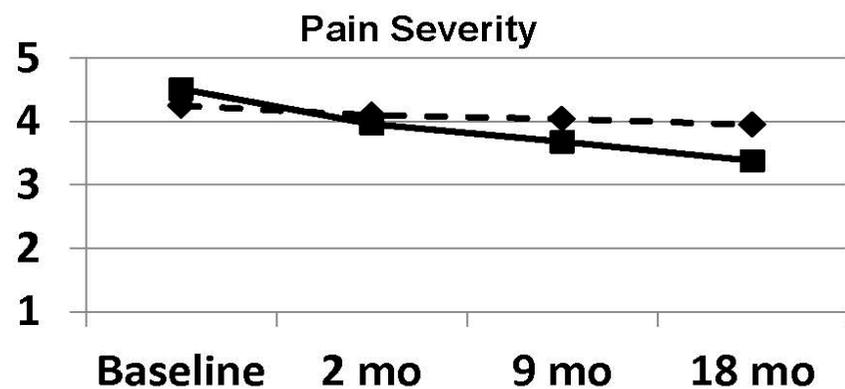
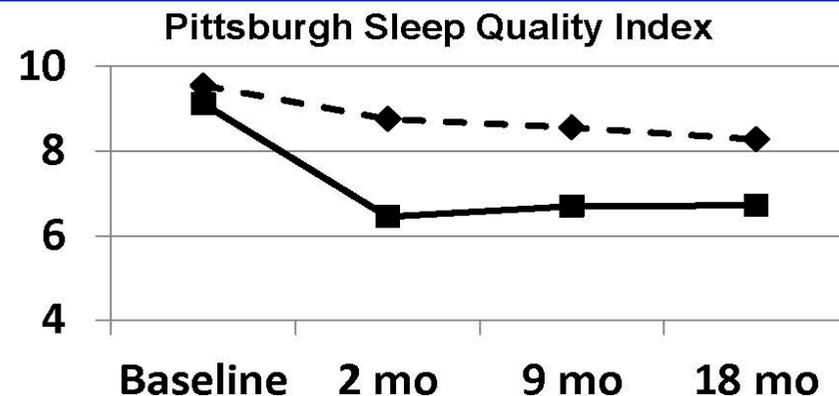
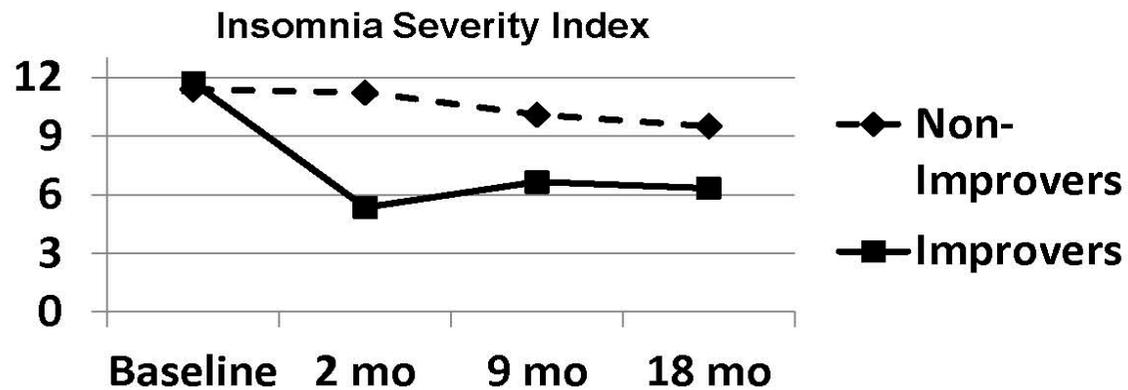


Over 9 months 18 months

Lifestyles – Sleep Improvers Analysis

Vitiello et al. Short-Term Improvement in Insomnia Symptoms Predict Long-term Improvements in Sleep, Pain and Fatigue in Older Adults with Co-Morbid Osteoarthritis and Insomnia. *Pain* (2014), doi: <http://dx.doi.org/10.1016/j.pain.2014.04.032>.

- We compared Lifestyles subjects whose sleep improved (a baseline to post-treatment $\geq 30\%$ decrease in ISI, N=131) regardless of treatment versus those who did not (N=223).
- Sleep improvers showed significant, sustained improvements in ISI (P<.001), PSQI (P<.001), Flinders Fatigue Scale (P<.001).
- Sleep improvers also showed significant, sustained improvements in Pain Severity (P<.001), and Arthritis Symptoms (P<.001), but not in catastrophizing or depression.



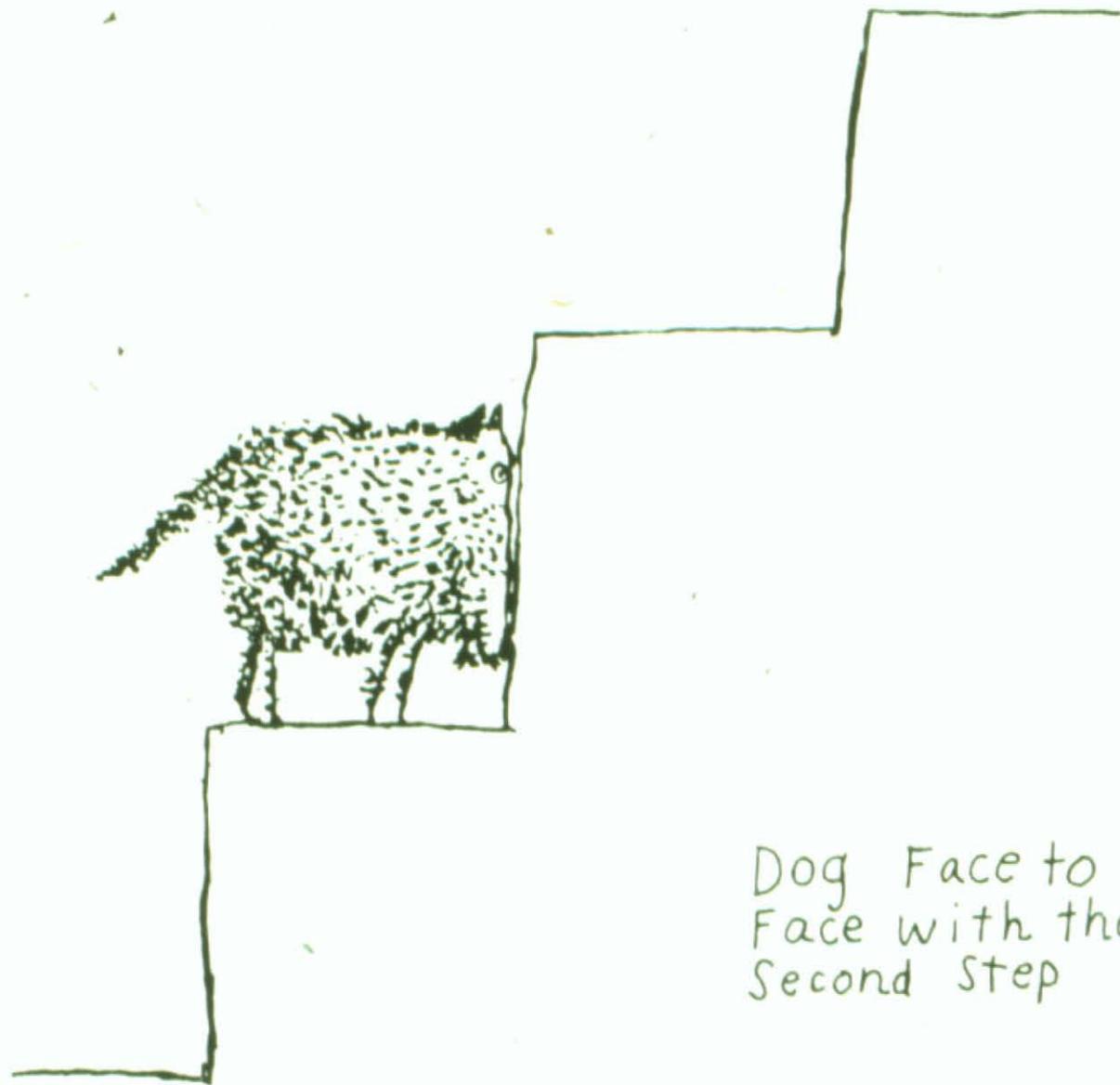
Lifestyles – Sleep Improvers Analysis

Vitiello et al. Short-Term Improvement in Insomnia Symptoms Predict Long-term Improvements in Sleep, Pain and Fatigue in Older Adults with Co-Morbid Osteoarthritis and Insomnia. *Pain* (2014), doi: <http://dx.doi.org/10.1016/j.pain.2014.04.032>.

- We also compared Lifestyles subjects whose pain improved short-term (a baseline to post-treatment $\geq 30\%$ decrease in Pain Severity, N=65) regardless of treatment versus those who did not (N=289).
- Pain Improvers showed significant sustained improvement in Pain Severity ($p < .001$) and marginal improvement in Arthritis Symptoms ($p = 0.05$)
- Pain Improvers failed to show significant sustained improvement in Insomnia Severity or fatigue and only marginal improvement in sleep (PSQI) ($p = 0.046$) and depression (GDS) ($p = 0.04$).

Lifestyles Final Conclusions

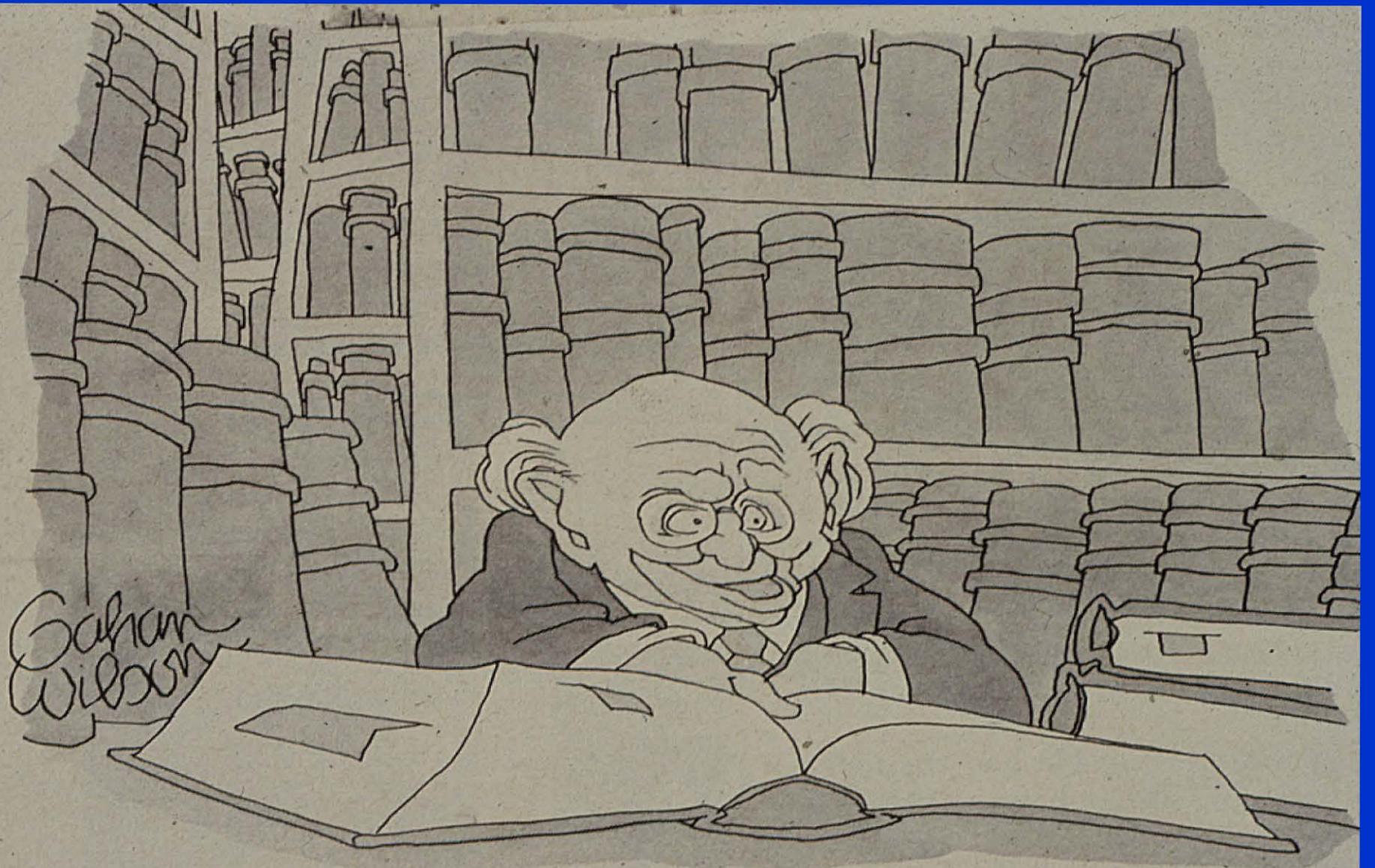
- **The overall pattern of Lifestyles findings suggests that successful treatment of sleep disturbance in OA with co-morbid insomnia may yield benefits for reduced pain over the long-term, contingent on achieving robust and sustained improvements in sleep.**
- **However, the jury is still out on the impact of improved sleep on chronic pain in older OA patients in particular and pain populations in general.**
- **Appropriately powered RCTs to definitively test this sleep/pain relationship remain to be done.**



Dog Face to
Face with the
Second Step

Lifestyles 2: AG031126, Cognitive Behavioral Therapy for Arthritis Pain and Insomnia in Older Adults.

- **RCT in 270 OA patients aged 60+ with persistently elevated pain and insomnia severity from a primary care population in a statewide health plan.**
- **Individual telephone-based CBT-I vs. telephone-based EOC.**
- **Pre-treatment, post-treatment (2 months) and 9- and 18-month follow-ups will assess pain, sleep, fatigue, mood and quality of life.**
- **Intervention cost-effectiveness will be evaluated.**



"By God, for a minute there it suddenly all made sense!"

Lifestyles Collaborators

- **Susan M. McCurry, PhD – Co-PI**
- **Michael Von Korff, ScD – Co-PI**
- **Susan M. Shortreed, PhD – Co-I**
- **Laura D. Baker, PhD – Co-I (Lifestyles 1)**
- **Benjamin Balderson, PhD – Co-I (Lifestyles 1)**
- **Bruce D. Rybarczyk, PhD – Consultant (Lifestyles 1)**
- **Francis J. Keefe, PhD – Consultant (Lifestyles 1)**
- **Charles M. Morin, PhD – Consultant (Lifestyles 2)**
- **Research staffs of the NW Research Group on Aging (NWRGA), University of Washington and the Group Health Research Institute (GHRI), Seattle, WA.**
- **Supported by the NIA (AG031126)**

