Considerations of Assessment of Long Term Pain and Function

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Disclosures

- Consulting
  - Pfizer, Tonix, Theravance, Zynerba, Samumed, Aptinyx, Daiichi Sankyo, Intec, Regeneron, Teva, Lundbeck

- Research support
  - Pfizer, Cerephex, Aptinyx

- Litigation – testified against opioid manufacturers in State of Oklahoma

Potential measures of long term outcomes
Think of pain as more of a state, function as a behavior

- Subjective PROs
  - Pain intensity
  - Pain interference
  - Functional status (disease specific vs generic)

- Objective assessment of performance based measures e.g. a walk, stair, climb or chair-stand test

- Objective activity measured by actigraphy

- TJR

- Some combination of above

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Relationship Between Self-report and Objective Physical Function

- How strong is the relationship between self-report and objective measures of physical function in healthy individuals or in individuals with disease?

- In studies that directly compare self-report and objective measures of physical function or functional status, what are the self-report measures really measuring?

- Should we expect a strong relationship between self-report and objective measures? Lessons from other domains

- Given the differences between self-report and objective measures, which is the "right" measure?

Not very

- If we use actigraphy as the current gold standard for measuring activity or function in real life settings . . .
  - There is a consistently poor relationship (r = 0 - .40) between average activity levels and measures of functional status or activity.[1-4]
  - There is a strong trend towards these relationships being stronger (albeit still rather weak) when the objective measure is compared to *activity* measures vs. *functional status* measures.

1) Kashikar-Zuck, et. al.   Arthritis Care and Research 2013, 2) Chandonnet et. al. PLoS One 2012, 3) Ferriolli et. al. J Pain and Symptom Management 2012. 4) Evenson et. al. J Phys Act Health 2012.
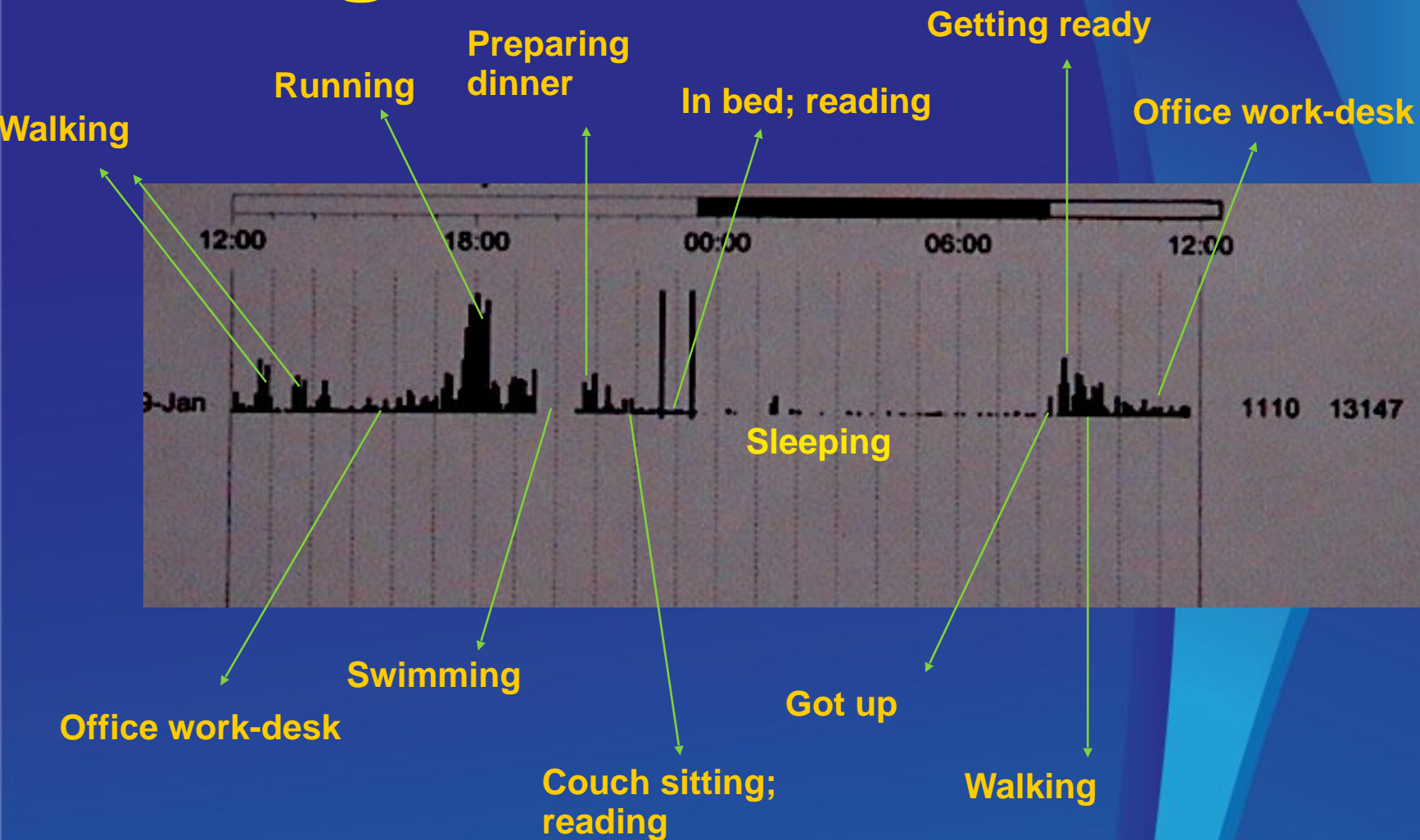
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Relationship between symptoms, self-reported, and objective measures of activity, in fibromyalgia

- Patients with FM have amongst the lowest self-reported functional status of any chronic illness

- This parameter has been very difficult to improve in interventional studies

- How is self-reported activity related to:
  - Objective measures of activity
  - Specific symptoms

Kop et. al. Arthritis Rheum 2005
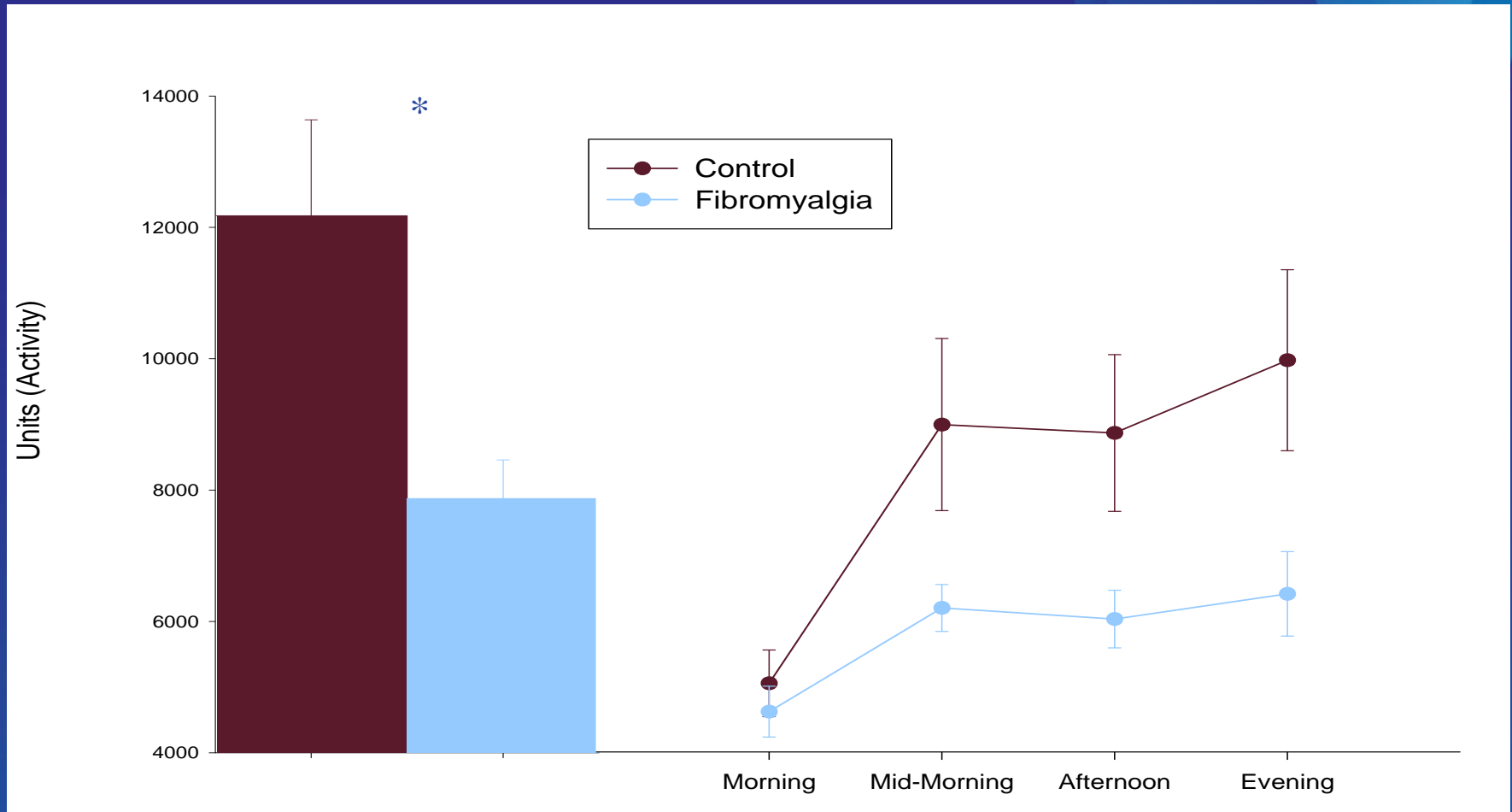
Actogram I

Results – Objective Activity

- *Average* daytime and nighttime activity levels were nearly identical in the patient and the control groups (p=ns).

	Daytime	Nighttime	PCS
Patients	1456±429	147±156	*36*
Controls	1445±556	152±107	*56*

Peak Activity

- *Peak* activity was significantly lower in the FM patient group relative to the control group ($p=0.008$).
  - 7870 ± 3223 vs. 12178 ± 7862 activity units

- *Variability* of peak activity was also significantly different between groups
  - Levene's test on SDs, $p=0.001$

Average and Diurnal Peak Activity Levels of Fibromyalgia Compared to Controls

*p<0.05; Error Bars=SEM

Assessment of Pain and Activity in a Placebo-Controlled Crossover Trial of Celecoxib in Osteoarthritis of the Knee

- RCT in OA (n=47) to examine how to better differentiate active treatment from placebo

- The WOMAC pain subscale was the most responsive of all five pain measures.

- Pain–activity composites resulted in a statistically significant difference between celecoxib and placebo but were not more responsive than pain measures alone. However, a composite responder defined as having 20% improvement in pain or 10% improvement in activity yielded much larger differences

Assessment of Pain and Activity in a Placebo-Controlled Crossover Trial of Celecoxib in Osteoarthritis of the Knee

- The most responsive actigraphy measure was peak activity, with a between-group difference of 91.9 counts/min (P = 0.090); mean activity and total activity did not approach statistical significance.

- Actigraphy was more responsive than the WOMAC function scale, possibly due to lower placebo responsiveness.

Trudeau et. al. Pain Practice 2014

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Self-report vs. Objective Measures of Other Domains

- **Sleep**
  - Correlation between multiple PSG measures and multiple self-report measures in sleep apnea patients ranges from r = .01-.24, mean r = .09.[1]
  - Correlations between self-report and PSG measures in insomnia r = .05 - .36.[2]

- **Memory/cognition**
  - Very poor relationship between subjective measures and objective performance based measures in both healthy individuals, and individuals with mild TBI, but there is a modest relationship between subjective measures and mood measures.[3,4]

1) Weaver, Arch Otolaryngol Head Neck, 2004. 2) Bastien et. al. Sleep Medicine 2001. 3) Schliesher J Clin Exp Neuropsych, 2011. 4) Spencer et. al. JRRD, 2010.

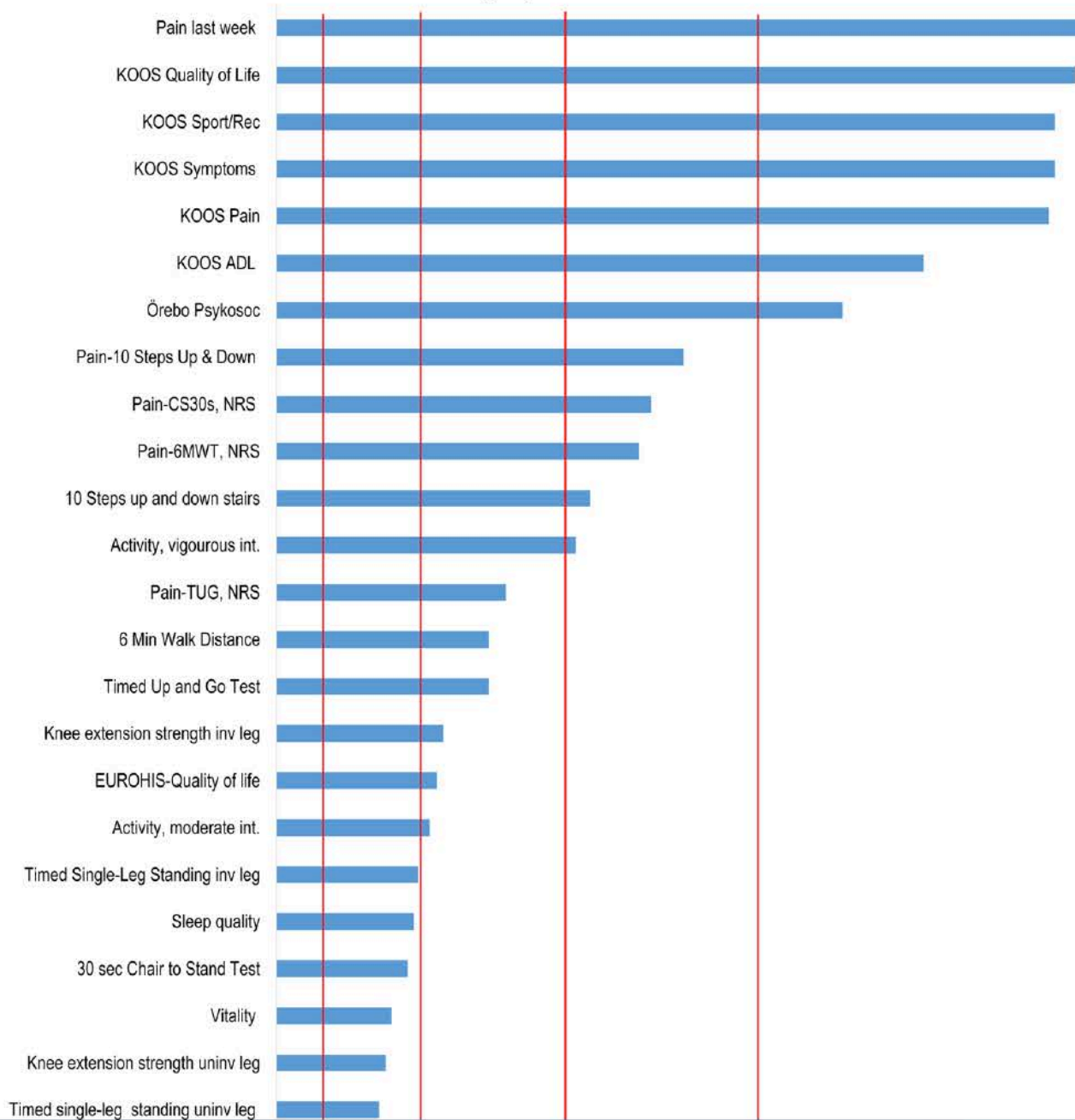**RESEARCH ARTICLE**   **Open Access**

Relative difference among 27 functional measures in patients with knee osteoarthritis: an exploratory cross-sectional case-control study

K. Vårbakken[1,2*], H. Lorås[3], K. G. Nilsson[4], M. Engdal[5] and A. K. Stensdotter[1,2]

Functional measures with KOA
Ranked between-group effect sizes in cases and controls

Measure
Pain last week
KOOS Quality of Life
KOOS Sport/Rec
KOOS Symptoms
KOOS Pain
KOOS ADL
Örebo Psykosoc
Pain-10 Steps Up & Down
Pain-CS30s, NRS
Pain-6MWT, NRS
10 Steps up and down stairs
Activity, vigourous int.
Pain-TUG, NRS
6 Min Walk Distance
Timed Up and Go Test
Knee extension strength inv leg
EUROHIS-Quality of life
Activity, moderate int.
Timed Single-Leg Standing inv leg
Sleep quality
30 sec Chair to Stand Test
Vitality
Knee extension strength uninv leg
Timed single-leg standing uninv leg

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