



Measuring sleep and activity is valuable for pain studies

Actiwatch Spectrum PRO solution

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The Philips Actiwatch Spectrum PRO is a wrist-worn device that provides objective measurements of sleep and daytime activity, and collects real-time, patient-reported responses for two subjective questions (e.g. pain and fatigue levels). This collection of data can be valuable in the overall interpretation of pain studies. The following questions and answers help to explain why sleep and activity data are so important, and why the Actiwatch Spectrum PRO is a very appropriate solution for your pain study needs.

Q. Why are activity and sleep important dimensions of pain?

Individual measurements of sleep and activity can be very helpful for fully understanding each patient's pain experience. Pain affects sleep and activity,^{1,2} and both sleep and activity affect pain sensitivity.^{3,4} The relationship is both reciprocal^{1,5} and complex because there are:

- many types of pain, and
- many ways to **quantify** sleep and activity^{6,7}

Low back pain,⁸ fibromyalgia,⁹ diabetic peripheral neuropathy,¹⁰ burns,¹¹ rheumatoid arthritis,¹² and osteoarthritis¹³ have all been shown to have an adverse effect on sleep. Some of these pain types:

- **decrease total sleep time**¹⁴ and
- others just **increase sleep disturbance**⁸

The distinction is an important one in understanding a patient's overall experience.

Q. Why is it important to evaluate activity and sleep data when interpreting pain study results?

It is important to measure sleep and activity to prevent misinterpretation of the results of pain studies.

For example, if a patient reports a decrease in pain related to an activity, it could be due to the positive effects of treatment or just an overall decrease in activity.

Conversely, the lack of change in a self-reported pain score could lead investigators to believe that the treatment was ineffective when in fact the drug was so effective in reducing pain that the patient was able to increase the activity level to get back to their original level of pain tolerability.¹⁵

Similar problems in interpretation can occur if sleep quality is not measured. An underlying sleep problem could be an important factor contributing to a patient's pain and could conceivably mask the positive effect of pain therapy.³ It is also possible that:

- therapy, such as a pain drug, could induce a sleep problem as a side-effect that could impact the study results or
- improved sleep quality could lower pain scores¹⁶

Q. Why is actigraphy an efficient method for collecting sleep data in pain studies?

Polysomnography (PSG) is the gold standard technology for assessing sleep.⁷ It is objective, but it is also expensive and limited to just a few nights of data collection which can impede its ability to document sleep problems that don't occur every night. The polysomnography testing process can also interfere with sleep, especially on the first night¹⁷ and could have an adverse effect on pain scores the following day.¹⁸

Patient-reported sleep questionnaires are low cost, can be used for multiple nights, and likely do not interfere with sleep. However, they are imprecise and subjective, which may be:

- an **asset** if subjective sleep assessment is the therapy target, or
- a **liability** if the goal is to detect changes in small Phase II or pilot studies.

Unlike questionnaires, where the endpoints are limited to the specific questions asked, **actigraphy data can be analyzed in many ways** including estimation of PSG endpoints such as:

- total sleep time,
- wake after sleep onset, and
- sleep efficiency⁷

More direct endpoints such as movement during the night^{19,20} and circadian rhythms can also be evaluated.²¹

Q. Why is actigraphy an efficient method for collecting daytime activity data in pain studies?

Actigraphy is the **only objective assessment** of daytime activity that can be used throughout the day, regardless of a subject's activities. Patients' responses to questionnaires are subjective and imprecise. Subjects often have a strong tendency to overstate true activity intensities.²² As with sleep data, daytime activity data can be analyzed in many ways to not only detect activity means and peaks, but to detect time spent at different activity levels,²³ daily activity patterns, and circadian rhythms.^{21,24}

Q. What advantages does the Actiwatch Spectrum PRO have over stand-alone methods?

Actiwatch Spectrum PRO can provide both objective assessments of sleep and activity, and subjective assessments of pain. Although many pain studies require patient-reported outcomes that contain more than two questions, the Actiwatch Spectrum PRO **provides subjective response scores for two questions** in real-time. These scores can be used independently of a questionnaire, or to help validate the subject's responses to the questionnaire.

The Actiwatch Spectrum PRO is always worn on the wrist, thus facilitating data collection opportunities. It can be programmed with an audible and/or a vibrating reminder to prompt the subject to enter data on a predetermined schedule.

Q. How can the Actiwatch Spectrum PRO and Philips Respironics' actigraphy services team help meet my study needs?

Feedback from patients and professionals indicate that the Actiwatch Spectrum PRO is easy to wear and simple to use. The challenge is to:

- make sure the devices get to the sites and patients at the right time,
- collect the data in a regulatory-compliant method and analyze the data properly in order to deliver the relevant endpoints

Philips Respironics' actigraphy services team can simplify this complex process. We have worked with all of the top ten pharmaceutical companies – supporting over 60 trials in more than 27 countries over the past 15 years – to provide the protocol endpoints with minimal inconvenience to the sponsor.

Conclusion

Inclusion of the Actiwatch Spectrum PRO for pain protocols, along with support of Philips Respironics' actigraphy services team, may help minimize the risk of missing critically important information about your patient. It may also help increase the likelihood of receiving maximum value from the data through optimal protocol design, efficient study execution, accurate data collection, and precise data analysis.

Footnotes

- ¹ Smith MT, Haythornthwaite JA. How do sleep disturbance and chronic pain inter-relate? Insights from the longitudinal and cognitive-behavioral clinical trials literature. *Sleep Medicine Reviews* 8: 119-132, 2004.
- ² Ellingson LD, Shields MR, Stegner AJ, Cook DB. Physical activity, sustained sedentary behavior, and pain modulation on women with fibromyalgia. *J of Pain* 13: 195-206, 2012.
- ³ Haack M, Scott-Sutherland J, Santangelo G, Simpson NS, Sethna N, Mullington JM. Pain sensitivity and modulation in primary insomnia. *Eur. J. Pain* 16: 522-533, 2012
- ⁴ Heneweer H, Vanhees L, Picavet SJ. Physical activity and low back pain: a U-shaped relations? *Pain* 143: 21-25, 2009.
- ⁵ Lautenbacher S, Kunderman B, Krieg J. Sleep deprivation and pain perception. *Sleep Medicine Reviews* 10: 357-369, 2006).
- ⁶ Davis JA, Robinson RL, Le TK, Xie J. Incidence and impact of pain conditions and comorbid illnesses. *J. Pain Res.* 4: 331-345, 2011.
- ⁷ Kushida CA, Chang A, Gadkary C, Guilleminault C, Carrillo O, Dement WC. Comparison of actigraphic, polysomnographic, and subjective assessment of sleep parameters in sleep-disordered patients. *Sleep Medicine* 2: 389-396, 2001.
- ⁸ O'Donoghue GM, Fox N, Heneghan C, Hurley DA. Objective and subjective assessment of sleep in chronic low back pain patients compared with healthy age and gender matched controls: a pilot study. *BMC Musculoskeletal Disorders* 10: 1-9, 2009.
- ⁹ Nacissio PM, Moxham EG, Schuman CE, Gevirtz RN. The contribution of pain, reported sleep quality, and depressive symptoms to fatigue in fibromyalgia. *Pain* 100: 271-279, 2012a.
- ¹⁰ Gore M, Brandenburg NA, Dukes E, Hoffman DL, Tai K, Stacey B. Pain severity in diabetic peripheral neuropathy is associated with patient functioning, symptom levels of anxiety and depression and sleep. *J. Pain Symptom Management* 30: 374-385, 2005.
- ¹¹ Raymond I, Ancoli-Israel S, Choiniere M. Sleep disturbances, pain and analgesia in adults hospitalized for burn injuries. *Sleep Medicine* 5: 551-559, 2004.
- ¹² Nicassio PM, Ormseth SR, Kay M, Custodio M, Irwin MR, Olmstead R, Weisman MH. The contribution of pain and depression to self-reported sleep disturbance in patients with rheumatoid arthritis. *Pain* 153: 107-112, 2012.
- ¹³ Parimi N, Blackwell T, Stone KL, Lui LY, Ancoli-Israel S, Tranah GH, Hillier TA, Nevitt ME, Lane NE; Study of Osteoporotic Fractures Study Group. Hip pain while using lower extremity joints and sleep disturbances in elderly white women: results from a cross-sectional analysis. *Arthritis Care Res* 64: 10701078, 2012.
- ¹⁴ Okura K, Lavigne GJ, Huynh N, Manzini C, Fillipini D, Montplaisir JY. Comparison of sleep variables between chronic widespread musculoskeletal pain, insomnia, periodic leg movements syndrome and control subjects in a clinical sleep medicine practice. *Sleep Medicine* 9: 352-361, 2008.
- ¹⁵ Kindermans HPJ, Roelofs J, Goossens MEJB, Huijnen IPJ, Verbunt JA, Vlaeyen JWS. Activity patterns in chronic pain: Underlying dimensions and associations with disability and depressed mood. *J. of Pain* 10: 1049-1058, 2011.
- ¹⁶ Russell JJ, Crofford LJ, Leon T, Cappelleri JC, Bushmakina AG, Whalen E, Barrett JA, Sadosky A. The effects of pregabalin on sleep disturbance symptoms among individuals with fibromyalgia syndrome. *Sleep Medicine* 10: 604-610, 2009.
- ¹⁷ Le Bon O, Minner P, Van Moorsel C, Hoffman G, Gallego S, Lambrecht L, Pelc I, Linkowski P. First-night effect of the chronic fatigue syndrome. *Psychiatry Res.* 120: 191-199, 2003.
- ¹⁸ Edwards RR, Almeida DM, Klick B, Haythornthwaite JA, Smith MT. Duration of sleep contributes to next-day pain report in the general population. *Pain* 137: 202-207, 2008.
- ¹⁹ Denise P and Bocca ML. Effects of zolpidem 10 mg, zopiclone 7.5 mg and flunitrazepam 1 mg on night-time motor activity. *Europ. Neuro-Psychopharmacology.* 13: 111-115, 2003.
- ²⁰ Peterson BT, Chiao P, Pickering E, Freeman J, Zammit GK, Ding Y, Badura LL. Comparison of actigraphy and polysomnography to assess effects of zolpidem in a clinical research unit. *Sleep Medicine* 13: 419-424, 2012.
- ²¹ Buffum D, Koettters T, Cho M, Macera L, Paul SM, West C, Aouizer B, Dunn L, Dodd M, Lee K, Cooper B, Vara V, Swift P, Miaskowski C. The effects of pain, gender, and age on sleep/wake and circadian rhythm parameters in oncology patients at the initiation of radiation therapy. *J. of Pain* 12: 390-400, 2011.
- ²² McLoughlin MJ, Colbert LH, Stegner AJ, Cook DB. Are women with fibromyalgia less physically active than healthy women? *Med Sci Sports Exerc.* 43: 905-912, 2011.
- ²³ Farr JN, Going SB, Lohman TG, Rankin L, Kasle S, Cornett M, Cussler E. Physical activity levels in early knee osteoarthritis patients measured by accelerometer. *Arthritis Rheum* 59: 1229-1236, 2008.
- ²⁴ Reneman MF, deVries HJ, van den Hengel EJ, Brouwer S, van der Woude LH. Different level, but similar day pattern of physical activity in workers and sick-listed people with chronic nonspecific musculoskeletal pain. *Arch Phys Med Rehabil* 93: 1864-1866, 2012.

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