



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

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