Actiwatch Spectrum PRO

Records Subjective Pain and Fatigue Scores with High Subject Usability and Adherence

Abstract

Wrist actigraphy has been used to assess daily activity and sleep in many pain studies because sleep and activity are closely related to the patient's experience of pain. In order to provide a more comprehensive assessment of pain, Philips Respironics has developed the Actiwatch Spectrum PRO that allows the patient to enter scores for two different aspects of pain (pain intensity and fatigue) on the device at cued times or spontaneously.

A study in 20 chronic pain patients was conducted to determine the usability and adherence with the patient reported outcomes (PRO) feature of the device during a five-day wearing period. Each subject was asked to enter a pain and a fatigue score in the Actiwatch Spectrum PRO and the same scores in a paper diary when the alarm (sound/vibration) went off four times per day.

The subjects entered pain and fatigue scores on the Actiwatch Spectrum PRO within five minutes of the cue 95% of the time. They also entered scores in the paper diary but they differed from each other 18% of the time. This difference between the Actiwatch Spectrum PRO and paper values could be due to non-adherence ("back filling") with the paper diaries.

The subjects gave favorable scores for the readability (90-95%) and comfort (90%) of the device. The Actiwatch Spectrum PRO provides continuous objective assessments of activity and sleep and contemporaneous recordings of the patient's subjective pain scores with high subject adherence to the protocol.

Introduction

Pain, activity, and sleep are closely related[1,2,3]. Therefore, a comprehensive assessment of pain and the effectiveness of pain therapies would be aided by simultaneous measurements of pain, sleep and activity. Wrist actigraphy provides accurate, precise, and objective measurements of motion that can be used to quantify daily activity and sleep quality[4], but pain is a subjective quantity that is usually assessed through a patient-reported outcome (PRO) such as a questionnaire.

Pain PROs often require paper or electronic diaries that the subject has to fill out at certain times of the day. This requirement for subject participation tends to decrease subject adherence to the protocol as a result of their forgetting to fill in the diary or the inconvenience of finding it and completing it at the prescribed times[5]. To facilitate the collection of these important subjective pain endpoints, Philips Respironics has developed the Actiwatch Spectrum PRO which records day and nighttime activity (sleep and activity) and allows subjects to enter subjective Likert scores related to two different aspects of their pain (e.g. pain and fatigue levels on a scale of 0-10).

The simultaneous collection of activity, sleep, and pain data in one wrist-worn device could improve the collection of this data. It needs to be demonstrated, however, that patients in pain would be able and willing to follow the directions regarding the entry of data into the device at specific times.

The Actiwatch Spectrum PRO provides auditory and/or vibration reminders when the subjects are to enter their assessments of pain and fatigue. If they do not enter the data within five minutes of the reminder, a second alarm/vibration occurs. This study was designed to assess the subject's perception of the usability of the Actiwatch Spectrum PRO and determine the level of adherence with the instructions compared to a paper diary.

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Methods

This was a prospective study using a pre-production prototype of the Actiwatch Spectrum PRO. A convenience sample of 20 participants was recruited from an established pain clinic (Alabama Pain Management Clinic, Birmingham, AL). The released version of the Actiwatch Spectrum PRO does not differ in any significant way from the version used in the study. Eligibility criteria are listed in Table 1. Participants were referred to the Sleep Disorders Center of Alabama, Birmingham, AL sleep center for instructions and to receive the Actiwatch Spectrum PRO and paper diaries.

Inclusion criteria

- Adults (ages 30-85), either gender
- Prescribed medications for chronic pain
- Speaks English as primary language
- Able to follow instructions
- Expressing willingness to complete study procedures

Exclusion criteria

- Participants declared legally blind
- Participants with significant hearing impairment
- Participants known or suspected to be drug abusers
- Participants currently enrolled in another interventional pain trial
- Participants that are shift workers
- Wrist circumference that is not compatible with the wristband of the device (wrist is either too large or too small to wear the device)
- Participants who, in the opinion of the investigator, would not be willing or able to adhere to and complete the requirements of the trial
- Participants with physical limitations preventing them from pushing the buttons on the Actiwatch Spectrum PRO device (e.g. severe arthritis of the fingers)

The study was approved by an independent institutional review board. After verifying eligibility and obtaining informed consent, participants underwent a brief medical and pain history. Pharmacy records were obtained to record all medications each participant was prescribed.

Participants were given an Actiwatch Spectrum PRO and received verbal instructions on the protocol and the use of the device. After the introductory information was provided, participants were asked to complete questionnaires about the Actiwatch Spectrum PRO display, icons, and the visual and auditory reminders. While at the sleep center, the participants were asked to evaluate the features and operation of the Actiwatch Spectrum PRO.

Participants were instructed to enter their responses for two questions; one concerned with pain and the other fatigue. For pain, they were asked to indicate the number on a scale of 0-10 that indicated their pain level with 0 being no pain, and 10 being the worst pain imaginable. For fatigue, they were asked to indicate the number on a scale of 0-10 that indicated their level of fatigue with 0 being no fatigue, and 10 being the worst fatigue possible. They were asked to enter the same values for each question on the paper and Actiwatch Spectrum PRO whenever the Actiwatch Spectrum PRO generated a notification. The Likert scales were provided in a single binder with copies for each day of the five-day trial.

Each Actiwatch Spectrum PRO device was programmed to notify participants to enter responses to pain and fatigue ratings at 8 a.m. and 12 p.m., 4 p.m., and 8 p.m. In addition to the programmed notifications, participants were asked to manually enter pain and fatigue ratings once in the morning and once in the afternoon or evening without being reminded by the Actiwatch Spectrum PRO device. Participants returned the binders and Actiwatch Spectrum PRO devices after the fifth day. Participants were encouraged to undertake normal daily activities for the duration of the trial.

Participants evaluated functional, mechanical, visual, audible, and other factors of the Actiwatch Spectrum PRO again at the conclusion of the trial.

Results

Twenty participants (12 females and 8 males) with an average age of 53.8 ± 7.3 years, an average BMI of 34.9 ± 12.0, and an average wrist circumference of 6.9 ± 0.7 inches were given Actiwatch Spectrum PROs and the results from all 20 participants were included in the analysis. In addition to chronic and stable pain medications, participants were taking medications for the treatment of anxiety, depression, insomnia, hypertension, and allergies.

At the initial study visit, all participants demonstrated that they could correctly operate or interpret the following features:

- Battery and charge status icon
- Audible notification
- Tactile notification
- Enter a low value for one patient-reported outcome
- Enter a high value for one patient-reported outcome
- Menu navigation
- Legibility of the LCD display in ambient light and in dark conditions

Participants evaluated usability factors of the Actiwatch Spectrum PRO. The majority of participants were able to recognize, identify, or interpret each of the following features and perform each of the operations listed below (Table 2).

Table 2: Usability Factors

Questions:	% Yes (N=20)
I was able to read the time of day display and icons (AM/PM, audible, battery) in ambient conditions	95% (N=19)
I was able to identify the AM/PM status	95% (N=19)
I can identify when the audible reminder is turned off	90% (N=18)
I feel the icons on the Actiwatch Spectrum PRO device are easy to recognize	90% (N=18)
I was able to feel/recognize the vibration (tactile) reminder	90% (N=18)
I did not have any discomfort from the vibratory reminders on my wrist	90% (N=18)
I was able to hear the audible reminder	80% (N=16)*
I could read the A ---- and b ---- icons display in ambient light conditions	95% (N=19)
I could read the A ---- and b ---- icons display in dark conditions	80% (N=16)
I was able to read the time of day display and icons (AM/PM, audible, battery) in dark conditions	80% (N=16)

*Three of the participants had hearing impairment but were able to detect the tactile reminder. The response rate was high even with these individuals.

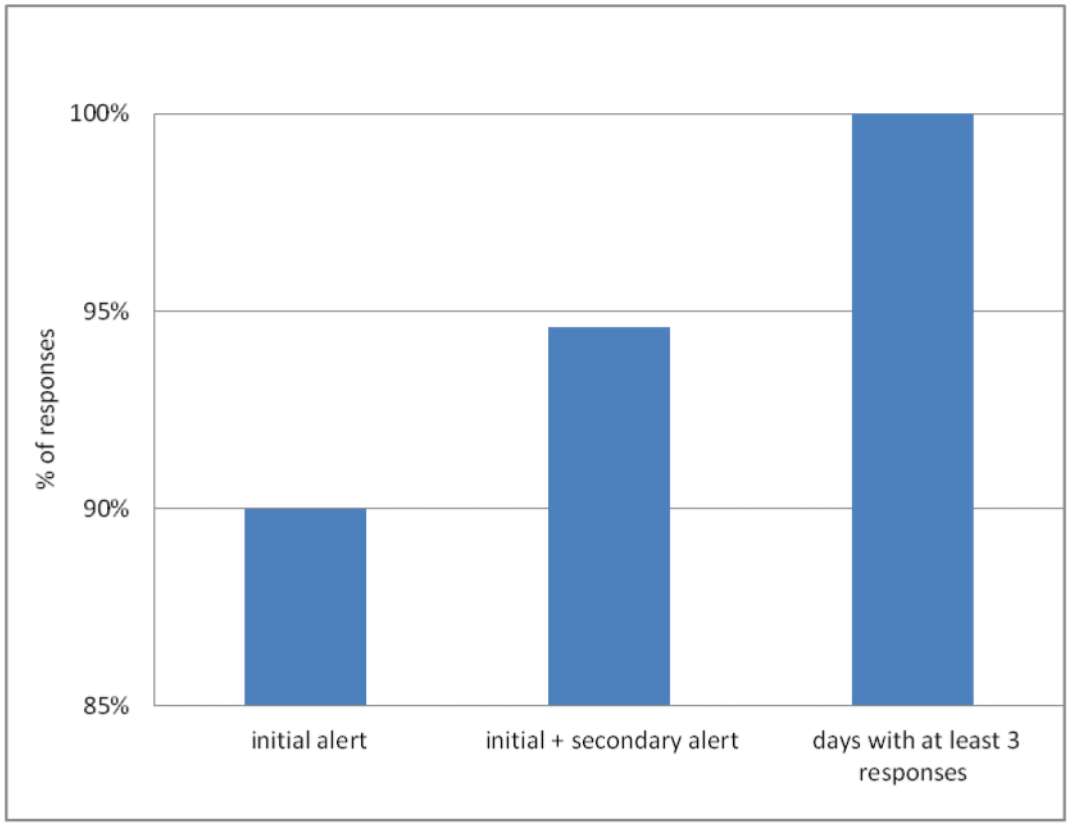

Figure 1. Participant response rates to Actiwatch Spectrum PRO alerts.

Response rates are shown in Figure 1. Participants responded to the initial notifications and entered values for pain and fatigue using the Actiwatch Spectrum PRO device 90% of the times they were initially prompted to do so. Inclusion of the responses that occurred after the five- minute reminder increased the overall adherence rate to 94.6%. Daily data was available for at least three of the four time points in 100% of the subjects.

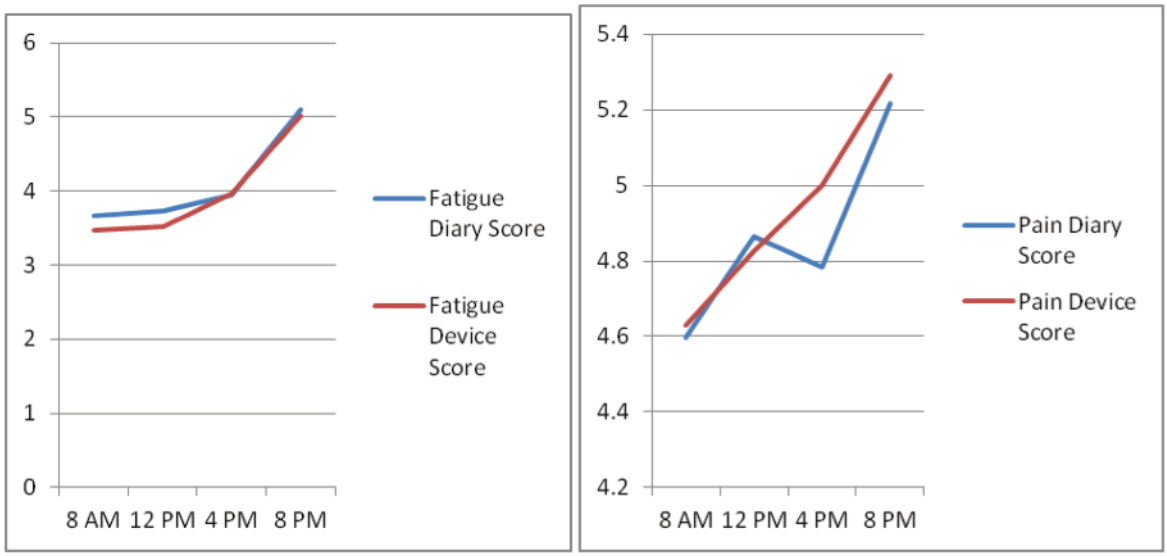

Figure 2. Pain and fatigue score trends

Figure 2 shows the average responses between 8 a.m. and 8 p.m. for all days and all participants. The recognized trend of increasing scores during the course of the data was apparent with both the Actiwatch Spectrum PRO and the diary data6. Even though the subjects were instructed to enter the same scores in both the Actiwatch Spectrum PRO and the paper diaries, and the mean values were not significantly different from each other, these scores agreed only 82% of the time. The cause of this difference is not known, but one possibility is that the diaries were filled in some time after the prescribed time and the subjects did not remember the scores they had entered in the Actiwatch Spectrum PRO.

Manual entries (non-programmed notifications) for fatigue and pain were to be completed at least once in the morning and once in the afternoon or evening. On average, participants entered a manual score into the Actiwatch Spectrum PRO 3.5 ± 1.3 times a day.

Discussion

This study demonstrates that the Actiwatch Spectrum PRO is a reliable tool to assess pain and fatigue in a non-malignant, chronic pain population. The device generates a high rate of schedule adherence and is easy and convenient to use. In this group of patients undergoing treatment for chronic, non-malignant pain, the Philips Respironics Actiwatch Spectrum PRO device provided an unobtrusive and convenient tool to collect subjective PRO data.

The device can help keep patients adherent to protocol requirements and may help in the assessment of pain treatment and other interventions. The combination of actigraphy and patient-reported outcome data collected with the Actiwatch Spectrum PRO provides a contemporaneous and comprehensive assessment of the subjects' pain and its relation to their sleep and activity.

In this study, we objectively demonstrated a high rate of adherence to the scheduled response times attributable to the audible and tactile reminders. Stone et al., identified issues with adherence in completing paper diaries[5]. Participants in their study reported completing paper diaries within 15 minutes of the scheduled time 90% of the time, but in reality only 11% completed them within that window. Additionally, the diaries were not even opened 32% of the days.

The Actiwatch Spectrum PRO is readily available to the user and allows outcomes to be reported in a timely manner. This method of data collection is more reliable because it is always available to the subjects and the reminder feature helps increase adherence with protocol instructions.

The Actiwatch Spectrum PRO is easy to use. Participants received a single review of instructions for use yet were able to use the Actiwatch Spectrum PRO properly and consistently. The process of navigating the menus and entering scores is simple and was not a barrier to participant data entry.

Collecting patient-reported outcomes using paper questionnaires is inconvenient and prone to errors. One participant stated that they "did not like having to carry extra items to work, church, etc., and if paperwork isn't right at hand when time to do scores, may forget." Despite the relatively small size of the Actiwatch Spectrum PRO, study participants were able to operate features and interpret icons and displays. One participant noted they were using the Actiwatch Spectrum PRO without wearing their glasses.

References

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