Video Article

Multi-Modal Home Sleep Monitoring in Older Adults

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Abstract

The gold standard for sleep monitoring is attended in-lab polysomnography; however, this method may be cost-prohibitive and inconvenient for patients and research participants. Home sleep testing has gained momentum in the field of sleep medicine due to its convenience and lower cost, as well as being more naturalistic. The accuracy and quality of home sleep testing, however, may be variable because studies are not monitored by sleep technologists. There has been some success in improving the accuracy of home sleep studies by having trained sleep technicians assist participants inside their homes with putting on the devices, but this can be intrusive and time-consuming for those involved. In this protocol, participants undergo at-home sleep monitoring with multiple devices: 1) a single-channel EEG device; 2) a home sleep test for sleep-disordered breathing and periodic limb movements; 3) actigraphy; and 4) sleep logs. A major challenge of this study is obtaining high-quality sleep monitoring data on the first attempt in order to minimize participant burden. This protocol describes the implementation of educational manuals with step-by-step instructions and photos. The goal is to improve the quality of home sleep testing.

Introduction

The relationship between sleep and Alzheimer's disease (AD) is a growing area of research with sleep disturbances hypothesized to have a role in both AD pathogenesis and as a biomarker for AD pathology[1,2]. In order to study the relationship between sleep and AD biomarkers, cognitively normal or very mildly impaired participants aged ≥65 years old are recruited from a longitudinal study of aging at the Knight Alzheimer's Disease Research Center (ADRC) at Washington University School of Medicine. Although this study was focused on AD research, the methods presented here have broad applicability to home sleep testing in older adults. Attended in-lab polysomnography is the gold standard for sleep monitoring[3], but such monitoring can be cost-prohibitive and inconvenient for participants. An alternative is home sleep testing. The accuracy of home sleep studies may be improved by having trained sleep technicians assist participants inside their homes with device placement, but this can also be intrusive and time-consuming[4]. Therefore, this protocol was developed to instruct the participants how to set up sleep monitoring devices at home and still collect reliable data.

Participants were asked to wear a home sleep test (HST) for measuring sleep-disordered breathing (e.g., obstructive sleep apnea) and periodic leg movements. Following HST recording, participants wore a single-channel EEG device for 6 nights to monitor brain waves for EEG-based sleep staging. Previous findings indicate that the single-channel EEG device has a high level of agreement with polysomnography for multiple sleep parameters[5]. Throughout the single-channel EEG and HST monitoring period, participants completed a sleep log and were asked to wear actigraphy on their nondominant wrist for the entire duration of the sleep study to track activity. Studies were defined as acceptable if there were at least 2 nights recorded by the single-channel EEG device with <10% artifact and at least 1 night recorded on the HST with ≥4 hours of scorable data. Initially, the failure rate due to poor data quality was ~40−50%. Repeat monitoring for participants with poor data quality was deemed too burdensome, therefore, this protocol was developed.

Previous work found that many elderly persons have difficulty adjusting to technological interventions[6,7,8,9]. This impacts numerous fields from geriatrics to education and is particularly relevant to medical studies in which older adults must use or interact with unfamiliar technologies. In order to reduce in-home study failure rates, education manuals were created that provided pictures and step-by-step directions to set up the HST and single-channel EEG devices. The education manuals were derived from the device user manuals[10,11]. Additionally, a 24-hour helpline was provided to participants, so they could reach a member of the study team at any time with any questions or concerns.

To analyze the impact of this protocol, a retrospective review was conducted on the success and failure rates for acceptable data quality from the at-home sleep monitoring before and after implementation of the education manuals. The data sources were successful recordings and participant calls to research study staff with questions. Participants were asked to come into the sleep center to learn about the sleep monitoring equipment. During the 2-hour visit, a study team member educated each participant about the equipment using the manuals, which provided step-by-step instructions for device usage. After reviewing the manuals in the office and being guided through the application and use of the devices, participants were given the opportunity to independently practice applying the home sleep monitoring devices using the manuals as a guide. Feedback was provided to participants during the visit and they were given the opportunity to ask questions in addition to reapplying the

equipment as needed. Participants then took the equipment home, put the ambulatory equipment on themselves at night, and were encouraged to call a study team member at any time, day or night, for assistance troubleshooting any questions or problems.

All single-channel EEG studies were scored manually by registered sleep technologists who were validated, gold-standard scorers using modified American Academy of Sleep Medicine (AASM) scoring criteria[5]. HST recordings included airflow measured by nasal pressure transducer and thermistor, respiratory effort measured by thoracic and abdominal respiratory inductance plethysmograph belts, body position, pulse oximetry, and leg electromyogram (EMG) using the optional electrocardiogram (ECG) yoke. Lights off and lights on were determined by the time that each participant pressed the event button on the HST device and/or entry in a sleep log. A registered sleep technologist manually scored the HST studies and then a board-certified sleep physician performed an epoch-by-epoch review of each study.

Following the introduction of this protocol, the failure rate was reduced to 19% and reliable data was obtained. The protocol represents a novel, low-cost, and effective way to increase the success rate of at-home sleep studies. While the HST device has been used in some studies, it is primarily used as a diagnostic tool and not for scientific studies[12,13]. This protocol also provides a method that allows participants to easily use a Positive Airway Pressure (PAP) machine while they are wearing either the HST or single-channel EEG device. The use of the HST and single-channel EEG devices with education manuals is a particularly useful research tool that could be more widely utilized using the method shown in this protocol.

Protocol

This protocol was approved by the Washington University Human Research Protection Office.

Instructions were written specific to commercially available devices and their related software for data collection (see Table of Materials).

1. Set up of the sleep monitoring devices prior to the participant visit

1. Connect a fully charged actigraphy device to the docking station and open the actigraphy software. Initialize actigraphy device to record for the desired timeframe[14]. Use the following parameters.
    1. Select the 30 second epoch length from the drop-down menu for epoch duration. This allows for comparison to 30 second epochs on the single-channel EEG and HST recordings.
    2. Select activity and light logging mode from the drop-down menu for logging mode. The light logging mode allows measurement of light exposure at night.
    3. Collect actigraphy data for the duration of HST and single-channel EEG device recordings. Measure actigraphy for approximately one week for this protocol.

2. Connect a charged, single-channel EEG device to computer. Open device software and select data management and edit patient data prior to the start of the recording[15].
3. For home sleep testing, insert batteries and data card into the HST device. Connect HST device to computer and power the device on.
    1. Open device software and select **Device Configuration** from the menu. Choose the appropriate study montage[10].
    2. Select **Auto Start**. Enter times for auto start and stop beginning 2 hours prior to and ending 2 hours after the participant's habitual bedtime to ensure the entire sleep period is recorded.
    3. Choose the option to automatically record for 2 consecutive nights. Click on the good study indicator tab and choose 6 hours.
    4. Use a Positive Airway Pressure (PAP) adapter kit in place of the thermistor and pressure transducer to monitor airflow if the participant wears PAP.

2. Participant visit for instruction on wearing the sleep monitoring devices

1. Instruct participant to wear the actigraphy device on the non-dominant wrist for the duration of the study with the exception of bathing or swimming.
    1. Ask the participant to press the event button at the bedtime and wake time to set a lights-out and lights-on marker on the actogram.
    2. Complete the sleep log every morning upon awakening. Instruct the participant to document the following:
    Bedtime and wake-up time;
    How long it took to fall asleep;
    Number of nighttime awakenings;
    Occurrence of unusual events that may impact sleep.
    3. Place the device on the participant's wrist during the visit and provide detailed written instructions to the participant.

2. Instruct the participant regarding the Home Sleep Test Device (HST) and review the education manual.
NOTE: Following the educational session, participants were given the opportunity to independently apply the device using the manual and then receive verbal feedback from a study team member.
    1. Position the blue belt with the holster around the chest directly under armpits with the buckle almost centered.
        1. Center holster on the chest and tighten the belt until it is snug enough so that the holster will stay in the center of chest when moving during the night. Point the arrow on the belt buckle facing down.
        2. Place the black lanyard strap around the neck and tighten until it is comfortably snug. Place the other blue belt around the waist and tighten the belt until it is snug enough that it does not slide when moving during the night. Point the arrow on the belt buckle facing down.
        3. Snap the white box into the holster on the chest belt. Ensure that there are 2 clicks as the box goes into the holster. Orient the label of the HST device outward.

2. Open the device by sliding the button at the top of the device. Refrain from pressing the power button since the device is set to auto start and stop. Look at the device window.
   NOTE: All the sensors will stop flashing when they are either plugged into the device or placed on the body.
3. Instruct participant that the line connected to the mouth (purple rectangle) will flash the entire time if used with PAP.
4. Plug the chest (thoracic) wires into the ports on the bottom of the chest belt buckle. Repeat this step and plug abdominal wires into the ports on the bottom of the abdominal belt buckle.
5. If PAP is worn, skip steps the following sub-steps.
   1. Place the prongs of the white wire (thermistor) in the nose and wrap the wire around ears. Pull the plastic piece up toward the neck to secure.
   2. Position the second set of prongs (clear nasal cannula) in nostrils and wrap tubing around ears. Ensure that the two prongs from the cannula fit just inside the nose and position the longer prong in front of the mouth, trim to fit area by mouth opening.
   3. Slide up the plastic piece toward the neck to secure. Use a small piece of tape to affix both sets of tubing to each cheek.
6. Run the long red and white leg wires through each pant leg along the side to avoid them getting tangled during the night. Use sticky patches to attach a red and white wire to each leg.
7. Place a hand on the shin and flex one foot up and down to locate the anterior tibialis muscle on the outside (lateral front) of the lower leg and place patches directly on the muscle at least 2 finger widths apart from one another.
8. Apply tape over each sticky patch sufficient to cover patch, wire, and skin to secure. With knee bent (to give plenty of slack in the wires), tape the wire above each knee to prevent the wires from getting tangled.
9. Use an oximeter to measure oxygen levels throughout the night.
   1. Pinch the top of the oximeter to open the clip. Match up the picture of a fingernail on the outside of the clip to the fingernail of middle or index finger and place the oximeter on index or middle finger.
   2. Wrap tape around the outside of the oximeter clip to secure. Place a piece of tape over the oximeter wire to attach it to hand just above the wrist. Tuck the extra oximeter cable in the chest belt to avoid getting tangled in the wire.
10. Look at the man on the display screen and confirm that no signals are flashing. Once all sensors are on properly and lines are solid (unless using PAP), close the device.
11. Instruct the participant that if the yellow light on the outside of the device starts flashing during the night, the device has lost a signal. If this happens, open up the device to check the display window to determine which signal has been lost. Once identified, reattach the sensor(s) that has come off.
12. Press the circular event button on the outside of the device at lights out and again at lights on. Open the device and check the good study indicator circle.
    NOTE: Participants are asked to call the study team in the morning if the good study indicator does not display a complete study. The device is set to record a second night for this reason. If the participant is willing to wear the device a second night, then discuss troubleshooting measures over the phone and encourage the participant to call again at night with any questions or concerns.
13. After waking up in the morning for the last time, make an entry in the sleep log.

3. If participant wears PAP, attach a PAP titration kit to the device to measure PAP flow. Do this by twisting it into the connector designated for the nasal cannula. Ask the participant to attach the PAP mask to one side of the titration kit adaptor and the hose to the other side of the adapter. Provide a picture to the participant and demonstrate this during the office visit. Inform the participant that all masks and hoses are universal and will fit the provided kit.
   NOTE: If the hose does not fit in the adapter, ask participants to feel the end of the hose for a hard-plastic piece. If the mask adapter is still in the hose, the PAP kit adapter will not fit until it is removed.
4. Instruct participant regarding single-channel EEG device[11] and review the education manual.
   1. Place the device over the participant's head to demonstrate proper placement. Instruct the participant on how to adjust the headgear for proper fit and where to affix the electrodes on the forehead for accurate placement.
   2. Provide charging instructions and a demonstration in the office.
   3. Provide extra electrodes to participant in case they are needed.
   4. Ask participant wearing PAP to bring his current mask to the visit as a mask fitting may be required.
      1. Check PAP masks for a forehead component. If present, provide a loaner mask for the duration of the study to ensure proper fit of the single-channel EEG device.
      2. Educate the participant about the application of the mask and headgear. Allow participant to apply the mask and adjust the headgear as needed. Instruct participant to apply the device before the mask at night. This will allow removal of mask without dislodging the device.
         NOTE: Hard-of-hearing participants are encouraged to call the helpline when attaching the single-channel EEG so that the research coordinator can confirm the single-channel EEG is properly initialized.

3. Data Download and Processing

1. Place the actigraphy device on the docking station to connect to computer for download.
   1. Open software and retrieve data[14]. End the recording and put watch to sleep until next use.
   2. Launch actogram to view recording. Use a previously described protocol for reviewing and scoring actigraphy device and sleep log data[16].
      1. Remove all automatically scored intervals and manually score sleep interval using sleep log bedtime and wake time[17].
      2. If the reported times are misaligned with actigraphy by more than 30 min and the event marker button was pressed within 30 min of activity changes, score the sleep interval using the event markers.
   3. Set the following data processing parameters prior to generating reports.

1. Set **Wake Threshold** to low with a value of 20.
2. Set **Immobile Minutes** for sleep onset and sleep end to 10.
3. Generate a clinician's report and convert data to analysis software (e.g., Excel) for further analysis.

2. Connect the single-channel EEG device to computer, open portal and select data management to upload study[15].
   1. Convert the study to a European Data Format (EDF) files in the portal. Select **Record**, click on **Actions and Reports** and choose **Export EDF File**. Download EDF file to computer. If needed, use a split EDF tool to timestamp and split multiple studies on a saved file.
   2. Set sleep tags using the sleep log bedtimes and wake times.
   3. Score EDF study using AASM scoring criteria[5] and generate a report using any sleep system software.

3. Connect the HST device to computer, open software, click on **File** and **Import** to upload study to database.
   1. Visually inspect the data after download to ensure that there are at least 4 hours of scorable data.
   2. Score study in the HST database using AASM scoring criteria[18]. To generate a report, click on **Report** and choose **Generate PSG Report**.

4. Quality assurance procedures

NOTE: All recordings are reviewed by a registered sleep technologist and a board-certified sleep physician. Specific markers of quality assurance are reviewed as follows:

1. Review the actograms to ensure the lights out and lights on times are set accurately to the sleep log times or the event markers per protocol.
2. Review the single-channel EEG recording while referencing the sleep log and actigraphy. Recordings are rejected for the following reasons: there is >10% artifact present in the single-channel EEG recording and movement on actogram does not align with artifact; or the EEG recording started 30 minutes late or ended 30 minutes early in comparison to the actogram.
3. Reject HST recordings if there is <4 hours of scorable data. A board-certified sleep physician reviews each study epoch by epoch to ensure accuracy of scoring.

Representative Results

Single-channel EEG
At the start of the study, an acceptable overnight recording with the single-channel EEG device was defined as 1) aligning with the sleep period defined by sleep log and/or actigraphy device, and 2) <10% of the recording unscorable due to movement, myogenic, electrode, or other artifacts. Each participant needed at least 2 nights meeting these criteria. Prior to the implementation of the single-channel EEG manual, 14 participants wore the single-channel EEG device. Of those 14 participants, 42% (6) needed to repeat testing due to inadequate collection of acceptable data as defined above. After implementing the protocol with the instruction manual, only 2 of 15 (13%) participants needed to repeat monitoring with the single-channel EEG device due to poor data quality (**Table 1**). Example hypnograms of an acceptable good and unacceptable poor single-channel EEG recording are shown (**Figure 1**).

Home Sleep Test
For the HST, an acceptable recording was defined as 4 or more hours of data scorable for respiratory events and periodic leg movements. Poor data quality is usually due to one or more of the sensors failing to record, such as from artifacts or losing contact. In this study, one common indication of unscorable data was breaks in the SpO_2 channel. Prior to using the HST instruction manual, 3 of 7 (42%) participants failed to meet this standard for one HST recording. 16 participants wore the HST over 2 months after implementing the instruction manual with only 3 (19%) participants failing to meet the acceptable "good" recording standard (**Table 1**). Example hypnograms of an acceptable good and unacceptable poor HST recordings are shown and the SpO_2 channel is highlighted (**Figure 2**).

	Single-Channel EEG		Home Sleep Test	
	Acceptable	Unacceptable	Acceptable	Unacceptable
Pre-protocol	8	6	4	3
Post-protocol	13	2	13	3

Single-channel EEG: Fisher's exact test, p=0.11
Home sleep test: Fisher's exact test, p=0.32

Table 1. Participants with Acceptable Sleep Studies Pre- and Post-Protocol Implementation. Before implementing this study protocol, fourteen participants wore the single-channel EEG device and seven participants wore the home sleep test (HST). For the single-channel EEG and the HST, 43% of participants had an unacceptable study. After implementation of the protocol, this was reduced to 13% of participants with unacceptable single-channel EEG studies and 19% of participants with unacceptable HSTs. Neither of these differences were significant.

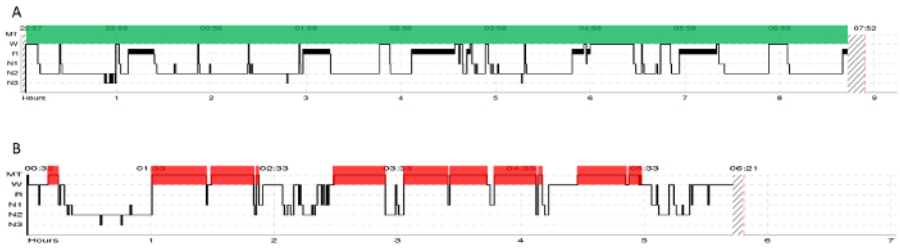


Figure 1. Acceptable and unacceptable hypnograms from 1-night recording on the single-channel EEG device. (**A**) A single-channel EEG hypnogram showing artifact-free data collection. This figure shows data for one night of single-channel EEG recording on an hour-by-hour basis. The x-axis indicates the number of hours starting from the beginning (lights-off) to the ending (lights-on) of the recording. The y-axis indicates sleep stages. Movement (MT) indicates artifact during the recording from movement, muscle, electrodes, or other sources. Artifact-free data was recorded throughout the study (shown in green) and were scored for different sleep stages. (**B**) A single-channel EEG hypnogram showing unscorable data due to artifact. This figure shows data for one night of single-channel EEG recording on an hour-by-hour basis with the same x-axis and y-axis as in (**A**). This data represents a hypnogram in during which the single-channel EEG recorded artifact indicated by MT (shown in red). The sensors on the single-channel EEG were unable to record brain wave activity that were scored for during different sleep stages during these time periods. W: wake; R: rapid eye movement sleep; N1: non-rapid eye movement (NREM) stage 1; N2: NREM stage 2; N3: NREM stage 3. Please click here to view a larger version of this figure.

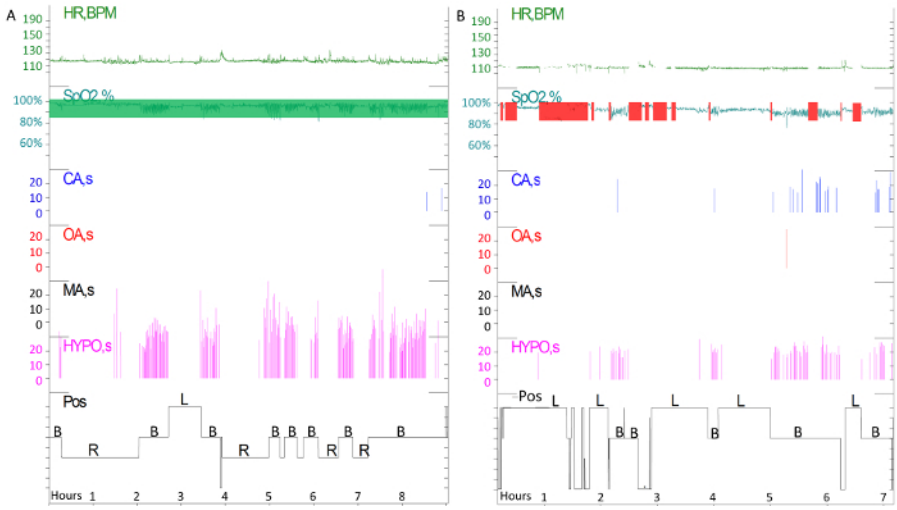
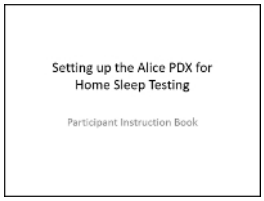


Figure 2. Acceptable and unacceptable hypnograms from 1-night recording on the home sleep test. (**A**) A home sleep test (HST) hypnogram showing artifact-free data collection over one night. The x-axis indicates the time in hours that the recording was taken, and the y-axis indicates heart rate, oxygen saturation, sleep-disordered breathing, and body position. Note, there are no breaks in the SpO_2 channel (shown in green) indicative of data loss, artifact, or otherwise unscorable data. (**B**) **A** HST hypnogram showing an unacceptable "poor" recording over one night with a large proportion of artifact during the study. The x-axis and y-axis are the same as in (A). There are breaks or missing data in the SpO_2 channel (shown in red) indicative of unscorable data from artifact or other data loss. HR: heart rate; BPM: beats per minute; SpO2: percent oxygen saturation; CA: central apnea; OA: obstructive apnea; MA: mixed apnea; HYPO: hypopnea; S: seconds; Pos: position; B: back; R: right; L: left. Please click here to view a larger version of this figure.



Supplemental File. Selected pages from the Home Sleep Test education manual showing the step-by-step set-up instructions are provided as an example. Please click here to download this file.

Discussion

This protocol is the novel application of instructional manuals in conjunction with participant education for in-home ambulatory sleep monitoring. Based on the results, the implementation of the protocol with instruction manuals improves the feasibility of in-home sleep testing in older adults. In-lab polysomnography remains the gold standard for sleep monitoring but may be limited by cost as well as disrupted sleep due to the new environment (i.e., the "first night" effect[19]). This protocol has shown that it is feasible to obtain high quality sleep monitoring at home in an elderly population with a single-channel EEG device for sleep staging and a HST to screen for sleep disorders such as obstructive sleep apnea.

Additionally, this protocol provides a method that enables participants to use a PAP machine in conjunction with both the single-channel EEG and HST system.

Participants were educated on the use of all the sleep monitoring devices during an in-person visit with a study team member. Additionally, written instructions were provided for the actigraphy device and sleep log and step-by-step instructional manuals are provided for the single-channel EEG and HST devices. The detailed instructions were tailored to the devices selected (see Table of Materials) and may vary with alternative equipment. The HST instructions were broken down in step-by-step instructions and pictures were inserted to provide a reference for proper sensor placement (**Supplemental File**).

During the study visit, participants were given the opportunity to apply all study equipment to get feedback on sensor placement and ensure all questions were answered prior to departure. Participants were provided a 24-hour helpline to call with any questions or concerns should they arise during testing. Study team members noted that utilization of the helpline appeared to vary by age, cognitive ability, and participant support system (e.g., if a spouse or partner attended the visit and was available to assist with the devices). Finally, participants were asked to apply the devices at home without a study team member being present.

A strength of the protocol are the novel solutions developed to solve specific problems with home sleep monitoring in older adults. One example is that the HST device has multiple sensors that need to be applied by the participant and this can seem overwhelming initially. Breaking the instructions down into step-by-step directions with pictures and eliminating steps when possible helps to simplify the procedure. For instance, sending participants home with the holster attached to the chest belt eliminates the risk that the participant may open the battery compartment and dislodge the memory card. The protocol is designed to educate the participant about the HST at the office visit by following the steps of the manual while placing the equipment on the participant's body. Afterwards, the HST is removed and participants are given the opportunity to put on the HST unassisted while using the manual. The practice session helps to clarify any steps that the participant does not understand. In addition, the study team member provides feedback about the participant's HST self-hook up afterwards.

All participants were provided a 24-hour contact number to call with any questions. They were encouraged to call as soon as an issue was identified to avoid frustration with the equipment. Participants called for a variety of reasons, but it was common for participants to call for assistance troubleshooting the equipment prior to bedtime. Some participants needed extra guidance with sensor application and others called when a light remained flashing on the HST device after all of the sensors were on the body. The study team member on call would ask questions and walk the participant through any steps needed to resolve the issue. At times, the answers were in the manual and at other times additional information was needed to troubleshoot the problem. If participants had difficulty applying sensors at the office visit, the study team offered to talk through the entire hookup process over the phone at night. The participant was asked to call when ready to apply the sensors and the study team member would talk through each step of the manual as the participant placed each wire on the body.

Participants were asked to call in the morning if the HST device did not display a complete study. Any issues that arose during the night were discussed and participants were asked if they were willing to wear the device a second night. Troubleshooting measures were reviewed as needed and the participants were encouraged to call with any questions during the hookup process or during the night. It was also common for participants to call in the morning with questions about the button on the actigraphy device. The button does not make a noise when pressed and participants had concerns about inadvertently powering the device off. Participants were reassured that the equipment was recording, and they were following the study protocol.

Another novel aspect is the success in having participants who use PAP to treat obstructive sleep apnea wear both the HST and the single-channel EEG device. This requires an adapter to measure air flow on the HST. For participants using a PAP mask with a forehead attachment, a loaner mask was provided if the participant agreed. Using this protocol allowed for assessment of participants using PAP under their normal sleep conditions both in terms of sleep staging with the single-channel EEG and obstructive sleep apnea severity with the HST.

A major limitation of the protocol is application in the clinical setting. Participant visits to review the equipment, instruction manuals, and practice runs setting up the devices take ~2 hours. In addition, participants are able to call a sleep technologist at night to troubleshoot problems they may experience. It would be challenging to implement this protocol in a clinical setting due to these constraints.

This protocol provides a method to successful use multiple in-home sleep monitoring devices, including a single-channel EEG and HST in older adults. To date, >300 research participants have completed this protocol. While these devices are validated, cost-effective tools, they are not a replacement for attended polysomnography. This protocol does demonstrate that a simple and low-tech introduction of instruction manuals and education can improve the success of in-home sleep studies. This same protocol can be adapted for use with other types of technology and demonstrates the importance of communication and availability for encouraging use of technological research tools in studies, particularly those involving the elderly. This also answers the increasing need for diagnostic tools to address sleep disorders and improve sleep in the general population[20]. However, this study only considered elderly individuals and was limited to three types of sleep monitoring devices. Further protocol revisions may be needed with different in-home ambulatory equipment are needed.

Disclosures

CDT, JSM, CMS, IRB, JB, and BPL: Authors have nothing to disclose.

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