

Brief report

Cognitive Function, Consent for Participation, and Compliance With Wearable Device Protocols in Older Adults

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Abstract

Background: Population-based studies of older adults increasingly use wearable devices to measure activity and sleep. Whether cognitive impairment reduces consent and compliance has not been assessed.

Methods: In the context of a nationally representative cohort of community-dwelling adults aged 62–90, individuals were invited to participate in a sleep and activity substudy that required wearing a wrist actigraph for 72 consecutive hours. Cognitive function in the parent study was assessed with the survey adaptation of the Montreal Cognitive Assessment, and individuals were categorized as normal, mild cognitive impairment, or dementia. Participants were asked to press an event marker on the actigraph when they started trying to fall asleep and when they awoke each day. Logistic and negative binomial regressions were used to link cognitive status to nonconsent, returning usable data, wearing the actigraph three full days, ever taking the device off-wrist during the 3-day study period, and pushing the event markers, controlling for demographics.

Results: Cognitive status was not associated with nonconsent, returning usable data, off-wrist, or missing days. However, individuals classified with dementia were more likely to miss bedtime and wake-up event markers. Individuals classified as mild cognitive impairment were more likely to miss wake-up event markers.

Conclusions: Impaired cognition does not seem to be a barrier to compliance with simply wearing a device but may affect compliance with additional action such as pressing event markers.

Keywords: Cognition, Epidemiology, Psychosocial, Survey compliance

A significant challenge to a more complete understanding of how physical activity and sleep change with, and relate to, aging and illness is the difficulty of obtaining accurate information from surveys about both behaviors (1,2). An increasing number of population-based studies in gerontology have sought to overcome the inaccuracy and potential biases in self-reported behavior by incorporating wearable devices that estimate activity or sleep with motion tracking devices (eg, 3–5). Motion data are captured over several days, stored and downloaded, and used to estimate sleep characteristics, physical activity, or both. Improved measures of activity and sleep from population-based and clinical studies could lead to a more accurate understanding of aging, physical activity, and sleep and the extent

to which interventions around these two key restorative behaviors would influence health and well-being (6–9).

Motion tracking devices can be worn on different parts of the body; the usual sites are the wrist or the hip (10–13). Although hip placement may be more accurate for monitoring daytime activity, it is not generally considered feasible for measuring sleep, for which wrist devices are the norm. A typical research protocol seeks to measure either sleep or both sleep and physical activity with a wrist actigraph worn continuously over several 24-hour periods, without taking it off, except in some cases to bath, because not all devices are waterproof. There are many different device manufacturers. Several popular models have “event markers,” which are buttons on the

device that place a time stamp but do not start or stop recording. To more accurately set the software to assess sleep, protocols ask participants to press the event marker to indicate the beginning and end of their main nighttime rest interval (14,15). Without event markers, sleep intervals are often set just based on activity patterns; this may overscore quiet wakefulness outside the rest interval as sleep (16) and thus produce biased sleep parameters. Hence, respondents' compliance with an event marker protocol improves the accuracy of both daytime activity and sleep measures from actigraphy (17).

However, little research has considered compliance issues for wearable devices such as wrist actigraphs among older adults, which typically require respondents to remember and independently carry out instructions, with respect to the number of days the device is to be worn, keeping it on continuously or, if not, putting it back on if removed, and pressing event markers. One specific factor that may affect compliance with such protocols is cognitive function. Cognitive function declines with age (18). Although minor to moderate cognitive impairment usually does not affect older adults' competence for independent living, it is associated with memory loss and decreased problem-solving ability (18), all of which suggests the possibility that moderate cognitive impairment or dementia may decrease ability to comply with instructions. Ample evidence indicates that impaired cognitive function is an independent predictor of medication nonadherence (19,20). However, using an objective measure would be particularly valuable for older adults with cognitive impairment because they may not have the memory or the understanding to provide consistent responses to difficult survey questions (21). A number of clinical studies among cognitively impaired patients have used wearable devices to measure sleep or physical activity (eg, 22–27).

A systematic review of clinical studies among Alzheimer's disease patients using actigraphy to measure sleep found that several studies reported problems with patient compliance, either removing the actigraphs at night or removing them repeatedly (22). Without adequate actigraphy data, some participants were omitted from analyses. To our knowledge, no study has investigated compliance with a wrist actigraphy protocol among a population that included a broad range of cognitive function and impairment, to determine whether more impaired individuals are less likely to provide usable or adequate data.

The ability to investigate the complex relationships between cognition, sleep, and activity would be enhanced by consistent objective measures. Extant evidence shows that poor sleep predicts cognitive impairment (28) and that increased cognitive impairment is associated with increased sleep disturbance (29). If cognitive impairment is related to lower level of compliance either wearing the actigraph or pressing an event marker that allows more accurate scoring, then studies may inaccurately assess the relationship between cognitive impairment and sleep.

In this study, we use a nationally representative community-based study of older adults to compare consent for participation and compliance with an actigraphy protocol by cognitive status. If participants at risk of mild cognitive impairment (MCI) and dementia have lower participation and higher noncompliance, future clinical and community-based studies need to determine ways to enhance participation and facilitate compliance.

Methods

Data

The National Social Life, Health and Aging Project (NSHAP) is a nationally representative, population-based, longitudinal study of

approximately 3,000 community-dwelling older Americans that began in 2005 and includes in-person interviews in respondents' homes (30). At the second wave of data collection in 2010, a one-third random sample ($n = 1,117$) of respondents was invited to participate in an ancillary "Activity and Sleep Study," which included wearing a wrist actigraph for 72 hours straight (three full days) (1). About 80% of those invited agreed to participate ($n = 897$). The sleep substudy was not completely integrated into the core data collection, and consenting individuals needed to be recontacted to arrange to send them an actigraph. Not all who had consented were successfully reached in the time window for the substudy, and the final sample size of those returning actigraphs with usable data was 780. The instructions asked participants not to remove the device (and if removed, to put it back on as soon as possible) during the 3 days. In addition, individuals were asked to press an event marker button on the device when they started trying to fall asleep each night and when they woke up each morning. Event markers do not start or stop data collection but just place a timestamp on the activity data. Finally, along with the device, individuals were sent a prepaid mailer to return the device.

Measures of Nonconsent and Noncompliance

This study focused on six nonconsent and noncompliance measures. The first was declining to participate in the substudy. The second was returning the actigraph without usable data. The third was failing to wear the actigraph for the three full days. The fourth was taking the device off-wrist during the 3-day study period. The fifth and sixth measures of noncompliance were the number of bedtime event markers missed and the number of wake-up time event markers missed. We adjusted the number of missing event markers to the number of days of actigraphy completed.

Cognitive Status

Cognitive function was assessed by an 18-item survey adaptation of the Montreal Cognitive Assessment (MoCA-SA) (31). The original MoCA was designed to assess variation in milder levels of cognitive impairment than dementia screeners, and it was designed to be used in the clinical context. The MoCA-SA was developed to be suitable for large population-based surveys administered by trained lay personnel (28). The MoCA-SA assesses six domains: (i) orientation, (ii) executive function, (iii) visuospatial skills, (iv) memory, (v) attention, and (vi) language. The MoCa-SA score can be converted to a full MoCA score (31).

The reason to convert to a full MoCA score is to make use of validated cut points for cognitive status; many studies have demonstrated the usefulness of MoCA as a screening tool for dementia and MCI (32,33).

We used procedures developed by Kotwal and colleagues (34,35) to convert MoCA-SA score to the full MoCA score. Then, we group individuals into three cognitive status categories: normal (>22 points), MCI (18–22 points), and dementia (<18 points) (31).

Statistical Analysis

For each measure of noncompliance, we first used chi-square tests to assess whether adherence and cognitive status were independent. Then, to adjust for potential confounders, we employed logistic or negative binomial regression to link cognitive status categories. All regressions controlled for age, gender, race and ethnicity, education, household income, and marital status. Because the purpose of the analysis was to examine cognitive function and survey compliance, we present results from unweighted regressions. Sensitivity analyses

were conducted to include weights that accounted for the complex survey design of NSHAP. The results were very similar. Multiple imputation was used to allow the inclusion of individuals with missing data on covariates, such as education (36).

Results

Table 1 shows prevalence of compliance by cognitive status. The first four compliance measures did not differ significantly by cognitive status. There were significant differences in event marker use by cognitive status. Missing one bedtime or wake-up event marker was the most common category, and relatively few participants missed two or more event markers. For individuals at high risk of dementia, however, 37% missed two or three bedtime event markers and 32% missed two or three wake-up event markers. Comparable percentages were 16 and 11 for the normal cognitive group.

Table 1. Percentage of Actigraphy Noncompliance by Cognitive Function Status

	Normal	MCI	Dementia	Chi-Square Test
1. No consent	20%	18%	22%	$p = .263$
Sample size	614	336	167	
2. No usable data returned	12%	14%	14%	$p = .818$
Sample size	492	277	128	
3. Three-day actigraphy				$p = .712$
One day missed	1%	2%	1%	
Two days missed	6%	5%	6%	
Sample size	428	242	110	
4. Ever taken device off-wrist	1%	1%	4%	$p = .152$
Sample size	428	242	110	
5. Bedtime event markers				$p = .000$
One missed	26%	27%	22%	
Two missed	8%	9%	12%	
Three missed	8%	11%	25%	
Sample size	428	242	110	
6. Wake-up event markers				$p = .000$
One missed	21%	19%	25%	
Two missed	6%	9%	11%	
Three missed	5%	12%	21%	
Sample size	428	242	110	

Note: MCI = mild cognitive impairment. Total sample sizes varied by non-compliance measures.

Table 2 presents results from logistic and negative binomial regression models that link cognitive status to measures of nonconsent and noncompliance, accounting for demographic characteristics. Results showed that cognition was not associated with consent, return of usable data, off-wrist, or with the number of days completed. Older adults categorized as MCI and dementia were similarly likely to complete 3 days of actigraphy compared with older adults who were without MCI or dementia. However, cognitive status was significantly associated with pushing the event markers. Individuals with dementia had a higher proportion of missing bedtime event markers and wake-up event markers. Individuals categorized as MCI had a higher proportion of missing wake-up event markers.

We carried out additional analyses with the separate cognitive domains (Table 3). Results suggested that orientation was the domain associated with returning devices with usable data. Memory and attention were the domains associated with higher chances of missing wake-up event markers.

Discussion

Many studies have assessed the validity of actigraphy for estimating sleep and physical activity characteristics, but few have assessed adherence to actigraphy protocols, and none to our knowledge has examined whether cognitive status is a barrier to collecting data with actigraphs. In the context of a nationally representative cohort of older adults, we found that cognitive status, as defined by a multidomain survey assessment, the MOCA-SA, was not associated with consent for participation and compliance with key aspects of wrist actigraphy protocol: wearing the device the requested number of days without taking it off and returning the device with usable data. However, individuals with impaired cognitive status and dementia were more likely to fail to push event markers, which they had been instructed to do when they started trying to fall asleep each night and when they woke up each morning. Taken together, these findings suggest that cognitive status is not a barrier to incorporating wearable devices into study protocols. However, our results also suggest that more complicated instructions may be a bigger problem for those with MCI or dementia compared with those with normal cognitive status.

These findings have implications for epidemiologic studies of older adults that use wearable devices to measure sleep or activity. Dementia often accompanies changes in gait and in sleep patterns

Table 2. Predictors of Actigraphy Compliance in the National Social Life, Health, and Aging Project, Results From Logistic and Negative Binomial Regressions (Unweighted)

	No Consent	No Usable Data Returned	Number of Days Missed	Ever Off-wrist	Number of Bedtime Markers Missed	Number of Wake-up Markers Missed
	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Incident Rate Ratio (95% CI)	Odds Ratio (95% CI)	Incident Rate Ratio (95% CI)	Incident Rate Ratio (95% CI)
Cognitive status (ref. = normal)						
MCI	0.77 (0.53, 1.13)	0.86 (0.53, 1.39)	0.94 (0.44, 1.00)	0.67 (0.13, 3.40)	1.33 (0.95, 1.86)	1.57 (1.07, 2.28)*
Dementia	0.98 (0.63, 1.54)	0.85 (0.45, 1.59)	1.17 (0.41, 3.31)	2.07 (0.46, 9.36)	1.51 (1.03, 2.21)*	1.89 (1.27, 2.80)**
Sample size	1,117	897	780	780	780	780

Note: CI = confidence interval; MCI= mild cognitive impairment. Results for “no consent”, “no usable data returned”, and “ever off-wrist” were based on logistic regressions and results for the remaining noncompliance measures were based on negative binomial regressions. All regressions controlled for age, gender, race/ethnicity, education, household income, and marital status.

* $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3. Results From Logistic and Negative Binomial Regressions Linking Actigraphy Compliance on Each Domain of Cognitive Function (Unweighted)

	No Consent	No Usable Data Returned	Number of Days Missed	Ever Off-wrist	Number of Bedtime Markers Missed	Number of Wake-up Markers Missed
	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Incident Rate Ratio (95% CI)	Odds Ratio (95% CI)	Incident Rate Ratio (95% CI)	Incident Rate Ratio (95% CI)
Orientation	1.15 (0.67, 1.98)	0.51 (0.28, 0.96)*	0.37 (0.12, 1.13)	0.71 (0.08, 6.00)	0.73 (0.54, 0.99)*	1.05 (0.68, 1.60)
Executive function	0.96 (0.75, 1.22)	0.84 (0.61, 1.14)	1.53 (0.98, 2.39)	1.64 (0.67, 4.09)	1.01 (0.86, 1.18)	0.91 (0.71, 1.17)
Visuospatial skills	0.98 (0.78, 1.23)	0.92 (0.69, 1.24)	0.82 (0.45, 1.49)	0.75 (0.33, 1.72)	0.84 (0.73, 0.98)*	0.91 (0.73, 1.13)
Memory	0.95 (0.85, 1.05)	0.94 (0.82, 1.09)	0.95 (0.78, 1.17)	1.12 (0.75, 1.69)	0.96 (0.89, 1.02)	0.91 (0.85, 0.97)**
Attention	1.04 (0.93, 1.16)	1.06 (0.92, 1.68)	0.90 (0.72, 1.13)	1.01 (0.67, 1.52)	0.98 (0.89, 1.04)	0.91 (0.84, 0.98)*
Language	0.88 (0.71, 1.10)	1.25 (0.93, 1.68)	0.95 (0.62, 1.44)	0.87 (0.39, 1.97)	1.01 (0.88, 1.15)	0.94 (0.80, 1.10)
Sample size	1,117	897	780	780	780	780

Note: CI = confidence interval. All regression controlled for age, gender, race/ethnicity, education, household income, and marital status.

* $p < .05$. ** $p < .01$. *** $p < .001$.

(29,37,38). Wearable device potentially provides more accurate measures of activity and sleep and would provide better data about these associations. The role of activity and sleep as potential risk factors for chronic diseases has been a topic of great interest in the clinical and epidemiologic literatures (39–42). Results from our analyses suggest that actigraphy is equally acceptable and useful among older adults with dementia or MCI, compared with those with normal cognitive status. However, developing simple protocols for wearable devices would avoid a potential bias with impaired cognitive function being linked to less accurate data.

This study has some limitations, however. First, results were associational instead of causal due to the cross-sectional nature of the data. Second, the sleep protocol was only 3 days in NSHAP, whereas many studies with wrist actigraphy have longer protocols of 4–10 consecutive days. Other differences in compliance with cognitive status might emerge in longer protocols, such as wearing the device the requested number of days.

In the past decade, new technologies have created opportunities for collecting objective data on the health and functioning of older adults, as well as other populations. Our results suggest that variation in cognitive status among older adults is not a barrier to using wearable devices in studies with older adults with cognitive impairment; however, protocols that do not call on participants to do more than just wear the device should yield more complete and consistent data in this population.

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Conflict of Interest

None reported.

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