

MULTICENTER OSTEOARTHRITIS STUDY READING CENTER DATASET DESCRIPTION V35STEPWATCH

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1. Introduction

The Multicenter Osteoarthritis Study (MOST) is a longitudinal, prospective, observational study of knee osteoarthritis (OA) in older Americans with knee OA disease or at increased risk of developing it.

Accurate and reliable assessment of physical activity remains an important measurement for epidemiologists, exercise scientists, clinicians, and behavioral researchers. Recent advances in accelerometers, which quantify body movements by measuring acceleration in multiple planes, offer a cost-effective way to objectively record gait and physical activity. Accelerometry is considered to be the "gold standard" for measuring habitual physical activity.

The StepWatch Activity Monitor (SAM) used was a research-grade instrument (StepWatch 3TM activity monitor) for long-term assessment of ambulatory activity during day-to-day life. It is a small, waterproof, self-contained device that was worn comfortably on the ankle and records the number of strides taken every minute for extended periods of time. Participants in the MOST study wore the monitor for 7 days. All participants started wearing the device at the end of their clinic visit and were given a self-addressed postage-paid envelope to mail the device back to the clinic at the end of the seven days.

Examiners responsible for conducting assessments using the StepWatch monitor have undergone on-site training by an experienced investigator. Certification required that examiners complete all training requirements including demonstrating that they understood the correct set up and return procedures. Examiners also conducted the exam on two volunteers. Examiners were also recertified midway through the examination cycle. Processing of the accelerometer data in order to extract the parameters of interest was performed by the Accelerometry Reading Center, supervised by Dr. Dan White in his laboratory at Delaware University (see Reading Protocol below - section 6)

2. Data Management

<u>Transfer of digital exam data to the UCSF Coordinating Center (CC)</u>. Digital examination data were transferred regularly from the clinics to the UCSF CC over the internet using a secure data transfer method and following data transfer SOPs detailing responsibilities of the sender and recipient.

Receipt of data at UCSF CC.

Basic quality control checks done by UCSF CC before transfer to reading center

- Study identifiers on form match electronic file identifiers
- Study ID and Acrostic (second identifier) and date of exam (date of recording) must always match gold standard in master data system
- Confirm length of data is sufficient (determine using the file size)

<u>Transfer of data to the reading center</u>. At the CC, receipt and completeness of data collection was evaluated against measurement acquisition tracking data recorded by the clinics in the study database (see above). The CC notified the reading center when data passed quality assurance checks and was ready for the reading center to download from the secure FTP site or other prearranged method.

<u>Transfer of data from the reading center to the CC</u>. Reading center uploaded results of their analyses via Box for integration into the study database.

3. Dataset description and Analyst Notes

Dataset: MOSTV35STEPWATCH.sas7bdat Observations: 1895 records (1895 participants; 1 record per participant) Documentation:

- VariableGuide V35STEPWATCH.pdf
- Distributions_V35STEPWATCH.pdf
- Operation manual chapter: 3K_Accelerometry_v1.0pSept2021.pdf

V35STEPWATCH dataset contains 1895 records; one record per participant. V35STEPWATCH Accelerometry data collected during 60m clinic visit (V3) for all participants who agreed to participate (no exam exclusion criteria) and at the 84m clinic visit (V5) (all participants who participated in 60m data collection were eligible for device distribution at 84m clinic visit). In addition, if step watch data file was lost, unreadable, contained unreliable information (mismatch ID/Acrostic or dates in tracking form and data file), record was not included in the final Reading Center dataset.

At 60-months, all participants were eligible for accelerometry exam during clinic visit (see Accelerometry Operations Manual). At 84-month, participants without 60-month processed accelerometry data were excluded from the accelerometry exam with some exceptions. The StepWatch reading summary reports are provided in Appendix.

Dataset structure:

- Variables #1 to #3 included ID (for linkage with clinical data) and sex (for tabulation).
- Variables #4 to #13 prefix V3 number of days, summary reading parameters and derived variables from 60m data files provided by reading center
- Variables #14 to #23 prefix V5 number of days, summary reading parameters and derived variables from 84m data files provided by reading center

VxDAYS	Num days worn
Vx_STEPS_DAY	Mean Steps per Day
Vx_STEPS_SD	SD of Mean Steps per Day
Vx_MIN_WORN	Mean Minutes Worn per Day
Vx_MIN_WORN_SD	SD of Mean Minutes Worn per Day
Vx_MIN_WORN100	Mean Minutes Above 100 steps per Day
Vx_MIN_WORN100_SD	SD of Mean Minutes Above 100 steps per Day
Vx_MEAN_SUSTAIN_WB	Mean Minutes Sustained Above 100 steps for 10 min, with breaks of at most 2 min
Vx_MEAN_SUSTAIN_WB_SD	SD of Mean Min Sustained Above 100 for 10 min, with breaks of at most 2 min
Vx_MEAN_5PEAK	Mean of top 5 steps in each day

NOTE:

- Reading center recommends using summary parameters provided in conjunction with variable VxDAYS. The recommended number of days to use is 3 or more days worn. If data from 1-2 days is used in an analysis, a sensitivity analysis is required. Analyst and PI should discuss and strategize the approach.
- There are significant clinic differences between who wore the StepWatch device and whether device returned with or without data. The CC recommends controlling for clinic in all analyses.

4. FLOW CHART – Step Watch (Accelerometry) exam completion and reading status

Enrolled in MOST Cycle 2	2768
Completed CV	60M 84M 2330 ppts 2146 ppts
Step Watch distributed	1942 1509
Step Watch data received	1852 1446
Step Watch data processed (1+ day)	1760 1392

5. References

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6. Reading protocol - STEPWATCH PROCESSING (BY D WHITE)

We first determine if subjects wore the monitor long enough to be counted as a full day. We adopted a published method for processing accelerometry data.² In particular we defined ten hours of monitoring as the minimum amount of time needed to define a full day. The ten hour threshold represents more than 66% of waking hours and has been utilized as a threshold in studies of physical activity in the general adult population³ and people with knee OA.²

Time in use was counted from the first step recorded in the morning to the last step recorded in the evening. To exclude times subjects may have taken off the StepWatch during the day, we omitted times where the monitor registered no steps for 180 consecutive minutes during the day.

Previous literature to distinguish periods of inactivity from non-wear have employed monitors designed to measure all types of physical activity (Actigraph). These studies have employed thresholds of 60 minutes to 90 minutes of no activity to represent non-wear. However, it is not known if these same thresholds can be generalized to a monitor only measuring step counts, as periods of physical inactivity likely differ from periods of not walking worn by people with or at high risk of knee OA. One previous study of adult bariatric surgical candidates found a threshold of 120 minutes of no steps was suggested as non-wear time.⁴ We examined how increases in threshold values of non-wear time changed reporting of the daily average wear time, steps, and time walking at a moderate intensity.



As threshold values of non-wear time increased, the monitor was counted as being worn for a greater duration of time. Subsequently, the average number of steps/day decreased. However, changes in steps/day did not change appreciably using threshold values of non-wear greater than 180 minutes. As a result, we employed a 180 minute threshold of no steps to distinguish periods of inactivity from not wearing the monitor.

We quantified walking as the total number of steps taken per day on average as a continuous outcome. We calculated steps/day by totaling the number of steps taken each valid day of monitoring divided by the number of valid days. We did this by imputing the excel files (.xls) from stepwatch into a Python program we customized to process the data.

7. Appendix. Data summary report by visit

60m-visit: 2330 ppts completed CV

Table 1. Status of accelerometry exam completeness status by clinic.

60m Accelerometry	Total		Clinic=1		Clinic=2	
	Ν	col%	Ν	col%	Ν	col%
Acc not done - refused	306	13	293	26	13	1
0=Acc not done	82	3.5	67	6	15	1
1=Acc data lost	90	4	56	5	34	3
2=Acc data unreliable	92	4	47	4	45	4
4=Data available	1760	75.5	670	59	1090	91
Total	2330	100	1133	100	1197	100

Table 2. Number of days for the StepWatch reading completed

60m valid days		tal	Clir	nic=1	Clinic=2	
	Ν	col%	Ν	col%	Ν	col%
1-2 days	71	4	34	5	37	3
3-5 days	222	13	131	20	91	8
6 plus days	1467	83	505	75	962	88
Total	1760	100	670	100	1090	100

84m-visit: 2146 ppts completed CV

Table 3. Status of accelerometry exam completeness status by clinic.

84m Accelerometry	erometry Total Cl		Clir	nic=1	Clin	ic=2
	Ν	col%	Ν	col%	Ν	col%
Acc not done - not eligible (no data at 60m)	397	19	361	37	36	3
Acc not done - refused	217	10	183	19	34	3
0=Acc not done	23	1	18	2	5	0
1=Acc data lost	63	3	30	3	33	3
2=Acc data unreliable	54	3	25	3	29	2
4=Data available	1392	65	366	37	1026	88
Total	2146	100	983	100	1163	100

Table 4. Number of days for the StepWatch reading completed

84m valid days		tal	Clir	nic=1	Clinic=2	
	Ν	col%	Ν	col%	Ν	col%
1-2 days	27	2	19	5	8	<1
3-5 days	190	14	112	31	78	8
6 plus days	1175	84	235	64	940	92
Total	1392	100	366	100	1026	100

Data Available for Longitudinal analysis 60m to 84m

All	Total 84m CV done		NOT eligible (no 60m data)		0=Acc not done or refused		1=Acc data lost		2=Acc data unreliable		4=Data available	
	Ν	col%	Ν	col%	Ν	col%	Ν	col%	Ν	col%	Ν	col%
60m CV not done	116	5	70	18			2	3	2	4	42	3
0=Acc not done	293	14	286	72	1	0.4					6	0.4
or refused												
1=Acc data lost	73	3	41	10	5	2	1	2			26	2
2=Acc data	80	4			12	5	3	5	4	7	61	4
unreliable												
4=Data available	1584	74			222	93	57	91	48	89	1257	90
Total	2146	100	397	100	240	100	63	100	54	100	1392	100

Table 5. 60m Accelerometry reading status vs 84m accelerometry reading status (among 2446 84m CV done)

Table 6. Available for longitudinal analysis and includes only those with 60m and 84m processed data.

All	То	tal	84m valid days								
60m valid			1-2	days	3-5	days	6 plus days				
days	Ν	col%	Ν	col%	Ν	col%	N	col%			
1-2 days	38	3	0	0	12	7	26	2			
3-5 days	129	10	7	28	36	22	86	8			
6 plus days	1090	87	18	72	117	71	955	90			
Total	1257	100	25	100	165	100	1067	100			