Fitbit as an activity monitor in idiopathic inflammatory myopathy: results from a real-world cohort

A. Sharma[1], S. Keret[2], B. Rockette-Wagner[3], R. Lomanto Silva[4], T. Chandra[5], S. Moghadam-Kia[5], C.V. Oddis[5], R. Aggarwal[5]

[1]Internal Medicine, University of Pittsburgh Medical Center Mercy, Pittsburgh, PA, USA; [2]Rheumatology, Bnai-Zion Medical Center, Faculty of Medicine, Technion, Haifa, Israel; [3]Department of Epidemiology, University of Pittsburgh, Pittsburgh, PA, USA; [4]Division of Rheumatology and Clinical Immunology, Massachusetts General Hospital, Boston, MA, USA; [5]Division of Rheumatology and Clinical Immunology, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA.

Abstract

Objective

Idiopathic inflammatory myopathies are systemic autoimmune diseases that can be associated with debilitating muscle weakness and significant limitations in daily activities. Physical activity monitors (PAM) are recognised measures of the frequency and intensity of physical activities. The aim of this study is to investigate the psychometric properties and performance of Fitbit® as a wearable activity tracker in IIM.

Methods

Myositis Patient Centred Tele-Research (MyPACER) is a multi-centre observational prospective study conducted over 6 months recruiting patients with dermatomyositis (DM), necrotising myopathy (NM) and polymyositis (PM). The study had two cohorts, a Tele-Research Cohort (TRC, remote enrolment) and a Centre-Based Cohort (CBC, in person enrolment). Functional and patient-reported outcome measures were completed monthly. Participants were asked to use their wrist-worn Fitbit® for 7 consecutive days per month. Average daily steps per minute and average peak 1-minute cadence were evaluated as PAM measures.

Results

A total of 120 IIM patients (mean age 55.5±13.43; 75% females; 81% White) were enrolled; 82 in the TRC group and 38 in the CBC group. There were 51% DM, 39% PM, and 9% NM. The TRC and CBC cohorts were similar in demographics and disease subtypes. Gender, race/ethnicity, or disease subtypes were not associated with PAM measures. Compliance with Fitbit® wear protocol was very high, with similar results for remote or local recruitment. Average steps/min and average peak 1-minute cadence showed strong test-retest reliability [r=0.89 (p<0.0001 and r=0.86 (p= 0.0001)]. A longitudinal significant positive correlation was found between physical activity metrics and patient-reported and functional measures.

Conclusion

In a large IIM cohort, Fitbit® PAM variables demonstrate favourable compliance and psychometric properties with strong test-retest reliability and validity. PAMs can complement current measurements to remotely track patient performance, quality of life, and disease activity.

Key words

myositis, Fitbit®, validity, reliability, physical activity monitors

Akanksha Sharma, MD
Shiri Keret, MD
Bonny Rockette-Wagner, PhD
Raisa Lomanto Silva, MD
Tanya Chandra, MD
Siamak Moghadam-Kia, MD
Chester V. Oddis, MD
Rohit Aggarwal, MD, MS

Please address correspondence to:
Rohit Aggarwal
Division of Rheumatology and Clinical Immunology,
University of Pittsburgh School of Medicine,
3601 Fifth Ave., Suite 2B,
Pittsburgh, PA 15213, USA.
E-mail: aggarwalr@upmc.edu

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Introduction

Idiopathic inflammatory myopathies (IIM) are a group of rare heterogeneous systemic inflammatory conditions that include polymyositis (PM), dermatomyositis (DM), inclusion-body-myositis (IBM), anti-synthetase syndrome (ASyS), and immune-mediated necrotising myopathy (IMNM) (1). These conditions are clinically characterised by muscle weakness and reduced muscle endurance, limiting daily activities and leading to progressive physical disability (2-4). Despite advancement in our understanding of pathogenesis, there are few approved therapies for IIMs (5). Fortunately, there is increasing interest regarding novel therapeutic approaches in IIM given the approval of IVIG for DM from regulatory agencies (6).

Clinical trials in myositis remain challenging for many reasons, including the lack of reliable objective outcome measures potentially contributing to negative trials in IIMs. The International Myositis Assessment and Clinical Studies (IMACS) group developed and validated core set measures (CSMs) for evaluating disease activity in adult myositis (7), which were incorporated into the 2016 ACR/EULAR myositis response criteria (7). They include (a) physician (MD) global disease activity, (b) patient global disease activity (visual analogue scale [VAS]), (c) manual muscle testing (MMT), (d) Health Assessment Questionnaire (HAQ), (e) muscle enzymes (*e.g.* creatine kinase [CK]), and (e) extra muscular disease activity (*i.e.* organs other than muscle measured through the Myositis Disease Activity Assessment Tool [MDAAT]). Although the introduction of CSMs marked a major advancement in the field, they have limitations, including subjectivity, high inter-examiner variability, and the need for experience and training to administer the CSMs. Moreover, patient's physical activity and function is not well addressed other than the HAQ, which is a patient-reported disability index.

Wearable technology that tracks daily step counts is widely recognised as a valid measure of physical activity. It has also been utilised in several population studies, including the US National Health and Nutrition Examination Survey (8). Practicality, objectivity, continuous longitudinal tracking, and a lack of cognitive input from the patient or the examiner are benefits of physical activity monitoring. Fitbit®, a small wearable device, has high acceptance rates (9) and demonstrates acceptable validity and reliability for tracking daily energy expenditure, steps taken, distance travelled and physical activity. Moreover, Fitbit® accurately measures steps during various activities of daily living, including stair climbing, jogging, walking and running, and has been tested at slower speeds in elderly patients (10). Given that myositis patients have significant lower extremity weakness, with difficulty in activities of daily living, Fitbit® could objectively measure physical activity and function. Moreover, multiple randomised controlled studies have demonstrated the benefits and the safety of exercise in myositis, and Fitbit® may be used to monitor compliance or progress (11-15).

This study aims to test the reliability, validity, and responsiveness of PAM measures, including step count, vector magnitude, and activity patterns, using the low-cost commercial device Fitbit One® as an objective outcome measure in myositis.

Methods

Study design

The 'Myositis Patient Centred Tele-Research' (My PACER) study is a NIAMS/NIH-funded multi-centre, prospective observational study. It is comprised of two independent IIM cohorts: the tele-research cohort (TRC), comprising subjects recruited and enrolled remotely from anywhere in the USA through various online and social media strategies, physician referral, and patient support organisations, and the centre-based cohort (CBC), a traditional cohort recruited and enrolled locally from the University of Pittsburgh Myositis Centre and the Cedars-Sinai rheumatology clinic. Following enrolment, CBC subject were further randomised 1:1 into two sub-cohorts:

i. Local CBC' similar to the conventional myositis cohorts, where subjects

completed all study procedures at the centre with the study coordinator and in person physician evaluations, and data collected on paper or an electronic tablet,

ii. 'Remote CBC', where subjects, similarly to the TRC, completed all study-related tasks from home, and all data were collected remotely via a study specific mobile app or the website.

Study protocol and data collection

All patients had a baseline evaluation, including demographics, myositis assessments and medication ascertainment. Several patient-reported outcomes measures (PROMs) were collected at baseline and monthly for six months. PROMs included the HAQ, patient global disease activity, PROMIS physical function-20 (PF-20), and patient self-performed functional tests (timed up-and-go [TUG] and sit-to-stand [STS]). Physician-reported assessments included the aforementioned CSMS at baseline and the 6-month visit either in person or by telemedicine visit. In addition, assessed MDAAT variables included fatigue, myalgia, myositis, arthralgia, and arthritis. All subjects completed the study procedures and assessments using the study website/mobile app for the TRC group and remote CBC sub-groups. In contrast, in-person clinic evaluation and data collection were done through study coordinators for the local CBC group, ensuring a thorough and accurate data collection. This study was approved by the University of Pittsburgh Institutional Review Board.

Physical activity monitor (Fitbit®)

The Fitbit Charge® physical activity monitor (PAM) assessed daily physical activity levels and participants were instructed to wear the monitor on their wrist for 24-hours/day for seven days each month. The TRC and CBC groups followed the same protocol. The only difference between groups was that the CBC was provided with a pre-activated Fitbit Charge® device and in-person instructions by the study coordinator. In contrast, the TRC was mailed a pre-activated device along with a YouTube demonstration and step-by-step written instructions. Each device was linked to a unique, de-identified account. Subjects downloaded the Fitbit® app on their smartphone allowing for data synchronisation. Raw data (steps, distance, heart rate and physical activity patterns) was extracted remotely from a secure database in 1-minute increments. Minutes were counted as wear time if heart rate and/or step counts were recorded. A valid day required at least 12 hours of wear between 6 AM and midnight, 150 or more steps, and confirmation in the participant's diary (16).

Average steps per minute were calculated by dividing the total number of steps by total wear time (in minutes) across all valid days. Average peak 1-minute cadence was the highest number of steps in any one minute each day, averaged across valid days. A rate of 100 steps per minute was used as a marker for moderate to vigorous activity.

Statistical analysis

All statistical analyses used SAS 9.4 (Carey, NC). Missing data was assumed to be random with no imputation. Baseline characteristics were described using measures of central tendency (mean, median, standard deviation, etc.).

- Compliance

The mean frequency of form completion and compliance between the study groups were compared using the paired t-test and Chi-square test, respectively.

- Reliability

The test-retest reliability of avg. steps/minute and average peak cadence was evaluated by comparing these metrics at baseline (visit 1) with those at the one-month follow-up (visit 2) assessed using Spearman correlation. A subset of patients with physician-determined inactive disease (*i.e.* no treatment escalation), was evaluated by sensitivity analysis.

- Validity

Cross-sectional validity at baseline was assessed between the avg. steps/minute and avg. peak cadence and myositis disease characteristics, patient-reported outcomes, MDAAT variables (categorical variables: myalgia, fatigue, myositis, arthritis; continuous 10 cm VAS score of skin, joint, GI, pulmonary and muscle disease activity) and CSMs using a standard linear regression model. The longitudinal validity analysis used a repeated measures mixed model, adjusting for sex, race, and age at enrolment. Each visit was treated as a repeated measure to account for changes within individuals over time. The β estimates show how much the outcome changes, on average, with a one-unit increase in the variable being studied.

Table I. Demographics and disease subsets in the tele-research cohort (TRC) and the centre-based cohort (CBC).

	Total cohort (n=120)	Centre-based cohort [CBC] (n=38)	Tele-research cohort [TRC] (n=82)	*p*-value
Age (years) at enrolment (Mean± SD)	55.5 ± 13.4	56.9 ± 12.6	54.9 ± 13.8	0.444
Age (years) at diagnosis (Mean ± D)	49.5 ± 14.2	49.3 ± 14.5	49.6 ± 14.2	0.905
Female sex, n (%)	90 (75%)	28 (73.7%)	62 (75.6%)	1.0
White race, n (%)	97 (80.8%)	29 (76.31%)	68 (82.9%)	0.168
Non-Hispanic ethnicity, n (%)	105 (88.2%)	32 (84.2%)	73 (90.1%)	0.371
Myositis disease subtype				
Dermatomyositis	62 (51.7%)	20 (52.6%)	42 (51.2%)	0.509
Polymyositis	47 (39.2%)	14 (36.9%)	33 (40.2%)	
Necrotising myopathy	11 (9.1%)	4 (10.5%)	7 (8.6%)	
Positive MSA (n, %) 63	(33.3%)	21 (33.3%)	42 (51.2%)	0.68
Anti-synthetase antibodies				
(i) Anti-Jo-1		0%	45%	
(ii) Anti-PL-12		0%	2%	
(iii) Anti-PL-7		0%	2%	
(iv) Anti-EJ		0%	2%	
(v) Anti-OJ		33%	0%	
(vi) Anti-KS		0%	0%	
(vii) Anti-Ku		0%	0%	
Positive MAA (n, %)	17 (14.2%)	2 (5.3%)	15 (18.3%)	0.057

Table II. Compliance: comparison among the subgroups for the valid days worn, daily minutes worn and the number of visits) with various myositis outcome measures at baseline.

	Total (n=120)	Local CBC (n=17)	Remote CBC (n=21)	Main TRC (n=82)	*p*-value
Valid days worn					**0.024**
Mean (SD)	6.52 (0.58)	6.39 (0.82)	6.24 (0.70)	6.62 (0.45)	
Mean (CI)	6.52 (6.41, 6.63)	6.39 (5.96, 6.83)	6.24 (5.90, 6.58)	6.62 (6.51, 6.72)	
Median (range)	6.59 (4.00, 8.00)	6.71 (4.00, 7.00)	6.40 (4.50, 7.00)	6.71 (5.00, 8.00)	
Daily minutes worn					**0.049**
Mean (SD)	1307.98 (115.38)	1279.79 (161.86)	1260.96 (175.85)	1326.40 (74.09)	
Mean (CI)	1307.98 (1285.97, 1329.99)	1279.79 (1193.54, 1366.04)	1260.96 (1176.20, 1345.72)	1326.40 (1309.11, 1343.68)	
Median (range)	1339.75 (835.92, 1420.50)	1342.88 (889.56, 1416.14)	1332.20 (835.92, 1416.60)	1341.40 (837.31, 1420.50)	
Number of visits					0.238
Mean (SD)	5.73 (2.42)	4.96 (2.87)	6.00 (2.28)	5.85 (2.32)	
Mean (CI)	5.73 (5.33, 6.13)	4.96 (3.72, 6.20)	6.00 (5.04, 6.96)	5.85 (5.38, 6.33)	
Median (range)	7.00 (1.00, 7.00)	7.00 (1.00, 7.00)	7.00 (1.00, 7.00)	7.00 (1.00, 7.00)	

Results

A total of 120 IIM patients (mean age 55.5±13.43, 75% females, 80.8% White) who completed the baseline visit were enrolled in the study, comprising 82 patients in the TRC group and 38 in the CBC group (Table I). TRC patients were further randomised into TRC (n=21) and the local CBC (n=17). Overall, 62 DM (52%), 47 PM (39%), and 11 NM (9%) patients were enrolled. The TRC and CBC cohorts were similar in terms of demographics and disease subtypes.

Abnormal autoantibodies were noted in 72 (60%) patients, with 62 (53%) having positive myositis-specific antibodies (MSA) and 17 (14.2%) having positive myositis-associated antibodies (MAA), with similar rates among both groups (Table I).

Compliance

Ninety percent of patients wore their Fitbit® devices for at least one valid day each month throughout the study. Compliance with Fitbit® was high, with participants wearing the device on most days of the assigned week (mean of 6.52 days) for the most visits (mean of 5.73 visits out of a maximum of 7 possible visits), with similar results for remote or local recruitment (Table II). However, the main TRC group demonstrated a higher average of 6.62 valid days, compared to 6.39 days in the local CBC group and 6.24 days in the remote CBC group (p=0.02), with the local and remote CBC groups exhibiting comparable outcomes.

Age at diagnosis (CBC: 49.3±14.5 and TRC: 49.6±14.2) was significantly correlated with average steps/minute (p=0.01) but not with average peak 1-minute cadence, showing a decrease in steps with advancing age. Sex, ethnicity, or disease subtypes were not associated with PAM measures.

Reliability

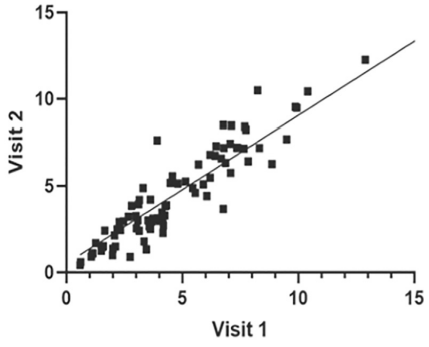
For all the recruited patients, average steps/minute and average peak cadence showed strong test-retest reliability (r=0.89, p<0.0001 and r=0.86, p=0.0001, respectively) and were strongly correlated within-patient (Fig. 1, 2). Among patients with inactive disease, avg. steps/minute and avg. peak cadence also showed strong paired differences (r=0.950, p<0.0001 and r=0.874, p<0.0001).

Validity

- Baseline associations

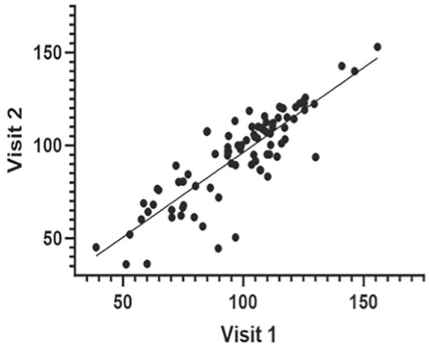
Baseline average steps per minute were significantly associated with some myositis CSMs, including HAQ, extramuscular global disease activity and trend towards MMT-8, as well as demonstrated associations with functional tests, such as STS and TUG (Table III). Baseline average peak 1-minute cadence was correlated with patient-reported symptoms, such as muscle weakness, muscle pain, fatigue and joint pain, and various myositis CSMs, such as physician global, HAQ, patient global and MMT, indicating strong validity. It was also significantly associated with constitutional disease activity and muscle disease activity ascertained by MDAAT, and with functional tests, such as STS and TUG (Tables III and IV).

a. average steps per minute.



r=0.89, p<0.0001
Test re-test reliability at baseline

b. average peak cadence.



r=0.86, p=0.0001
Test re-test reliability at 1-month

Fig. 1. Test-retest reliability at baseline (visit 1) and 1-month (visit 2).

- Longitudinal associations

Average steps per minute. A significant positive association was demonstrated between avg. steps/min and patient-reported outcomes and functional disease measures, including the PROMIS-PF 20 score, patient global disease activity score, HAQ score, pain, STS, and TUG. In addition, avg. steps/min were

Table III. Baseline validity analysis: continuous outcome measures physical activity measures activity measures (avg. steps/minute and avg. peak cadence) with various core set measures (CSMS), pros and functional measures.

	Avg. steps/minute			Avg. peak cadence		
	β	SE	*p*-value	β	SE	*p*-value
Clinician-reported disease measures						
Physician global disease activity (CSM)	-0.06	0.21	0.757	-3.03	1.37	**0.029**
MMT (%) (CSM)	0.04	0.03	0.082	0.46	0.17	**0.008**
Extra-muscular global disease activity (CSM)	0.87	0.29	**0.003**	1.69	2.03	0.407
Constitutional disease activity	0.02	0.28	0.949	-5.18	1.83	**0.006**
Muscle disease activity	-0.19	0.22	0.386	-4.21	1.46	**0.005**
Skin disease activity	0.84	0.35	**0.019**	4.77	2.41	0.051
Joint disease activity	1.01	0.57	**0.079**	-1.23	3.92	0.755
Pulmonary disease activity	0.38	0.47	0.421	-0.87	3.16	0.784
Patient-reported disease measures						
HAQ score (CSM) *	-1.24	0.47	**0.010**	-17.87	2.77	**<0.001**
HAQ pain score *	-0.24	0.42	0.559	-8.36	2.71	**0.003**
Patient global disease activity (CSM) *	-0.16	0.14	0.261	-3.94	0.88	**<0.001**
Sit to stand (mean)	0.27	0.07	**<0.001**	2.61	0.42	**<0.001**
Timed up and go (mean)	-0.09	0.03	**0.010**	-0.73	0.22	**0.002**

* Patient reported yes or no response to these questions.
All disease activity measures are assessed on a 10 cm VAS scale.
CSM: myositis core set measure; HAQ: health assessment questionnaire; MMT: manual muscle testing.

Table IV. Baseline association of physical activity monitors activity measures (avg. steps/minute and avg. peak cadence) with baseline demographics and disease characteristics.

	Avg. steps/minute				Avg. peak cadence			
Parameters	β	SE	*p*-value	R^2	β	SE	*p*-value	R^2
Demographics and diagnosis								
Age at diagnosis	-0.063	0.023	**0.007**	0.073	-0.15	0.16	0.348	0.009
Age at first symptom	-0.069	0.022	**0.003**	0.088	-0.16	0.16	0.322	0.010
Age at enrolment	-0.065	0.025	**0.010**	0.066	-0.22	0.17	0.205	0.017
Male (ref=female)	0.13	0.76	0.861	<0.001	0.73	5.16	0.888	<0.001
Hispanic (ref=non-Hispanic)	-0.34	1.07	0.754	0.001	2.52	7.25	0.729	0.001
Race (ref=White)				0.052				0.071
Other race	0.30	2.38	0.899		6.39	15.63	0.683	
Myositis diagnosis (ref=PM)				0.051				0.038
DM	1.54	0.69	**0.028**		9.07	4.69	0.056	
NM	0.40	1.26	0.750		2.97	8.60	0.730	
Primary myositis doctor (ref=Rheumatologist)				0.025				0.026
Other specialty	-2.61	3.35	0.437		-10.80	22.66	0.635	
Active disease (ref=inactive)	0.22	0.68	0.746	0.001	0.50	4.63	0.914	<0.001
Patient-reported myositis disease characteristics								
Muscle weakness	-0.73	0.72	0.317	0.011	-13.79	4.67	**0.004**	0.088
Muscle pain	0.19	0.73	0.796	0.001	-9.75	4.73	**0.042**	0.045
Fatigue	-0.02	0.89	0.979	<0.001	-16.87	5.66	**0.004**	0.101
Joint pain	-0.26	0.98	0.790	0.001	-13.16	5.67	**0.024**	0.089
Joint swelling	0.56	1.14	0.628	0.004	-4.30	6.93	0.538	0.007
Difficulty breathing	-0.91	1.20	0.452	0.022	-7.60	10.31	0.468	0.020

strongly associated with cutaneous disease activity and extra-muscular global assessment (Table V).

Average peak 1-minute cadence. Average peak cadence was strongly associated with constitutional disease activity, physician global disease activity, muscle disease activity, PROMIS-PF 20 score, patient global disease activity, HAQ score, pain score, STS and TUG (Table V).

Discussion

This prospective study highlights the potential of Fitbit® physical activity monitors in outcomes assessment of physical activity and function in myositis, demonstrating their excellent compliance and strong psychometric properties. The findings emphasise robust test-retest reliability and significant construct validity with both patient- and physician-reported outcomes, positioning Fitbit® as a valuable tool for clinical trials and perhaps clinical practice, particularly in aligning disease status with physician assessments.

Table V. Longitudinal association of PAM activity measures (avg. steps/minute and avg. peak cadence) with various core set measures (CSMS), pros, functional measures and CK.

Parameters	Avg. steps/minute			Avg. peak cadence		
	β	SE	*p*-value	β	SE	*p*-value
Clinician-reported disease measures						
Cutaneous disease activity	0.63	0.28	0.029	3.57	2.33	0.131
Constitutional disease activity	-0.12	0.22	0.594	-6.76	1.74	**<0.001**
Extra-muscular global disease activity (CSM)	0.69	0.22	**0.002**	0.59	1.82	0.747
Physician global disease activity (CSM)	0.03	0.17	0.841	-2.74	1.34	**0.044**
Muscle disease activity	-0.12	0.19	0.523	-4.30	1.52	**0.006**
MMT (CSM)	0.007	0.004	0.078	0.060	0.030	0.053
Pulmonary disease activity	0.43	0.35	0.231	-1.28	2.89	0.659
Skeletal disease activity	0.32	0.49	0.515	-6.29	3.93	0.114
Patient-reported disease measures						
Pain score*	-0.72	0.15	**<0.001**	-10.42	1.19	**<0.001**
HAQ score (CSM)*	-1.51	0.17	**<0.001**	-19.09	1.27	**<0.001**
Patient global disease activity score (CSM)*	-0.26	0.05	**<0.001**	-4.30	0.37	**<0.001**
PROMIS physical function - T score	0.11	0.01	**<0.001**	1.34	0.09	**<0.001**
Functional disease measures						
Sit to stand mean	0.19	0.02	**<0.001**	2.21	0.18	**<0.001**
Timed up and go mean	-0.10	0.02	**<0.001**	-1.13	0.13	**<0.001**
Laboratory measures						
Creatine Kinase (muscle enzyme) (CSM)	0.06	0.57	0.914	-1.84	4.51	0.685

* Patient reported yes or no response to these questions.
All disease activity measures are assessed on a 10 cm VAS scale.
CSM: myositis core set measure; HAQ: health assessment questionnaire; MMT: manual muscle testing.

Notably, the average steps per minute were associated with age at diagnosis (17), indicating fewer steps with increasing age, while average peak cadence correlated with multiple disease activity measures. These insights reveal complex relationships between physical activity and disease activity in myositis patients, suggesting that Fitbit® metrics can serve as valuable indicators of disease burden on patient's activity and functional status.

The study demonstrates high compliance among myositis patients using Fitbit®), with consistent data collection over time especially in TRC, supporting its feasibility for remote patient monitoring. Fitbit® metrics, including average steps per minute and average peak cadence, showed strong test-retest reliability, confirming the device's ability to consistently capture physical activity levels in myositis patients.

This study also reinforces previous findings that Fitbit® metrics correlate well with disease activity and functional status in myositis, validating its use in this population. Additionally, a cross-sectional study comparing Fitbit® with the ActiGraph GT3x+ accelerometer underscores its validity and utility in clinical applications (10).

The validity of Fitbit® in assessing physical activity was further established through significant associations between its metrics and well-known clinical measures of myositis, including both patient- and physician-reported outcomes. The validity and reliability of Fitbit® have been demonstrated in healthy controls and other disease populations, including stroke and cardiac disease patients, with studies showing good concurrent validity and inter-device reliability (8, 18-20).

The CSMs, while widely used to clinically and investigatively monitor disease activity (21-23), are subjective with inter-rater variability, making them less ideal, particularly among less experienced myositis clinicians and researchers. In contrast, Fitbit® and similar PAMs provide continuous, objective data that can complement CSMs by offering additional insights into patient activity levels and functional status. This objectivity is especially valuable in clinical trials and practice, where consistent and reliable outcome measures are essential.

Previous reports of PAM use in IIM patients primarily focused on JDM research, noting a correlation between decreased PAM-measured activity and disease activity (24). One study noted an association between PAM-measured moderate-to-vigorous physical activity and disease duration, glucocorticoid use, and functional tests (23).

A recent review included only eight investigations of PAM use in IIM patients, again focusing mainly on JDM research (25). Of these eight studies, five demonstrated a positive correlation between decreased PAM-measured activity in myositis participants compared with healthy controls and at least one measure of disease activity.

Another cross-sectional study compared 19 JDM and control patients matched by physical activity levels, age, sex, and body mass (24) noting an association between PAM-measured moderate-vigorous physical activity and illness duration (r= -0.509; p=0.026), glucocorticoid use (r= 0.748; p<0.0001), and TUG function test (r= -0.56; p=0.013). A correlation between accelerometer-measured physical activity and direct measures of muscle

strength or function has not yet been established (25).

CK is not a consistently reliable biomarker of disease activity in dermatomyositis or antisynthetase syndrome (26, 27). Furthermore, MMT primarily assesses maximal voluntary strength and does not adequately capture muscular endurance, which may be more accurately reflected by continuous activity metrics derived from wearable devices. Importantly, this study represents a real-world cohort with overall stable disease throughout the observation period. The median total improvement score at six months was approximately 9, indicating only modest clinical change and thereby limiting the magnitude of detectable longitudinal correlations.

Analysis of the results indicates that the extremely elevated CK values observed at visit 1 are largely absent by visit 7 in both groups, with a more pronounced reduction at the upper end of the CK distribution in the CBC group. Additionally, most patients in both groups achieved the maximum MMT score; however, in the CBC group, the distribution at visit 7 is more tightly clustered near the maximum score compared with visit 1, whereas the TRC group shows minimal change over the same period (Supplementary Table S1). Additionally, CK concentrations were comparable between the TRC and CBC cohorts, further suggesting limited discriminatory value of CK in this context (28).

A limitation of our work is the potential difficulty in isolating the specific effects of disease activity on changes in individual activity levels. Factors such as comorbidities, lifestyle habits and environmental conditions can influence daily step counts and activity patterns within an individual, potentially introducing variability. However, since our primary goal is to monitor within-person changes over time, these external influences may be less impactful than they would be in studies emphasising comparisons across individuals.

A weak baseline association was observed between CK levels and clinical measures of disease status, which may reflect the well-recognized limited correlation between CK and active disease in dermatomyositis and antisynthetase syndrome. Additionally, differences in cohort size and antibody distribution between the TRC and CBC groups may further limit the generalisability of these findings.

Also, while PAM monitors provide a valid and reliable method to evaluate physical activity in IIM patients, they may not be as responsive to subtle improvements (10, 29), possibly due to bias from non-disease related factors that affect activity levels, the heterogeneity of the disease, and the low number of patients improving at each level. Developing machine learning algorithms to analyse an individual's activity patterns, including natural fluctuations could potentially mitigate confounding factors and improve the detection of disease-related changes. Additional factors undermining accuracy of the daily step count measurement include the placement of the device, the use of assistive walking aids, ongoing home activities, and variations in body motion during ambulation (30-32). Thus, while physical activity metrics are invaluable for assessing functionality and disease severity, a comprehensive approach integrating multiple factors is essential to capture the full patient experience.

This study has several strengths. When using physical activity monitors in observational studies or clinical trials to track individuals over time, the impact of non-disease factors and inter-individual variability becomes less significant, as the focus shifts to within-person changes. Also, commercial PAMs, including Fitbit® offers several advantages, including accessibility and ease of use, making it a practical tool for both patients and healthcare providers. Not only did we utilise a commercial PAM, but we built on previous work that used a less practical waist-worn instrument which was feasible and valid in IIM patients (29, 33). Our results show that wrist worn devices, which are more widely used in real-world settings, are also reliable, valid and useful for remote monitoring. Additionally, it should be noted that integrating PAMs into routine care could enhance patient engagement and encourage healthy behaviours, potentially leading to better health outcomes. Recent partnerships between PAM manufacturers and health insurers, offering discounts on these devices, could further promote their adoption and utility in clinical practice.

At present, the integration of Fitbit technology into clinical practice should be viewed as a complementary tool for the remote monitoring of patients with idiopathic inflammatory myopathies, rather than as a substitute for established and validated clinimetric assessments conducted during in-person visits.

In summary, Fitbit® physical activity monitors exhibit compliance, robust reliability, and good validity in evaluating physical performance among myositis patients. These devices are valuable options for remote monitoring, particularly with increased compliance observed in patients receiving care remotely. Thus, the potential for engaging larger cohorts with enhanced monitoring options is obvious. Consequently, Fitbit® offers a robust and accessible technology for tracking both patient activity and disease progression remotely. These findings support the incorporation of physical activity monitors into clinical trials and everyday practice, serving as complementary tools alongside traditional outcome measures.

Take home messages

- Physical activity monitors are reliable, valid tools with strong responsiveness to changes in myositis.
- Physical activity monitors should complement traditional outcome measures in clinical trials and routine practice.
- Activity monitors provide continuous, objective data, offering deeper insights into patient activity levels and function.

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