

We assessed four different approaches to measuring physical function in patients undergoing cancer treatment.

Only patient-reported physical function detected change and correlated with both step count and patient-perceived physical function change.

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Evaluating Four Approaches to Measuring Physical Function in Cancer: Results of the Integrating 4 Methods to Evaluate Physical Function (In4M) Study

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BACKGROUND

- Physical function (PF) is a core outcome that can inform tolerability in cancer trials and can be assessed by patient report, performance tests and digital sensors.

OBJECTIVES

- In4M aims to evaluate measurement characteristics across PF modalities, including feasibility of assessment and sensitivity to detect PF changes in patients receiving cancer treatment.

METHODS

- In4M** is a prospective study of patients initiating chemotherapy for breast cancer or lymphoma. We serially assessed patient-reported PF (using **PROMIS Short Form v2.0 PF 8c**, **EORTC QLQ-F17 PF Scale**, and **patient-reported ECOG performance status [PS]**), **clinician-reported PS**, **6-minute walk test (6MWT)**, and **wearable data (Fitbit)** from baseline to 9 months. Pearson correlation assessed the relationship between average daily steps and other PF measures. Mean change at 3 months (3M) in each PF measure was assessed using a 2-sided $\alpha=.05$ paired t-test. The **Patient Global Impression of Change (PGI-C)** assessed patient-perceived PF change at 3M. We used Spearman correlation to assess the relation between PGI-C and change in other PF measures. Mean changes in each PF measure between PGI-C groups (worsened versus unchanged/improved) were compared using a 2-sided $\alpha=.05$ Wilcoxon test.

RESULTS

- Of the 208 patients enrolled (65% breast cancer, 35% lymphoma; median age 53), 193 (93%) and 159 (76%) completed surveys, and 121 (58%) and 124 (60%) provided wearable data at baseline and 3M, respectively.
- At both baseline and 3M, patient-reported PF was more strongly correlated with daily steps than clinician-reported PS and 6MWT.
- Significant declines in PF were observed for patient- and clinician-report, but not for other measures.

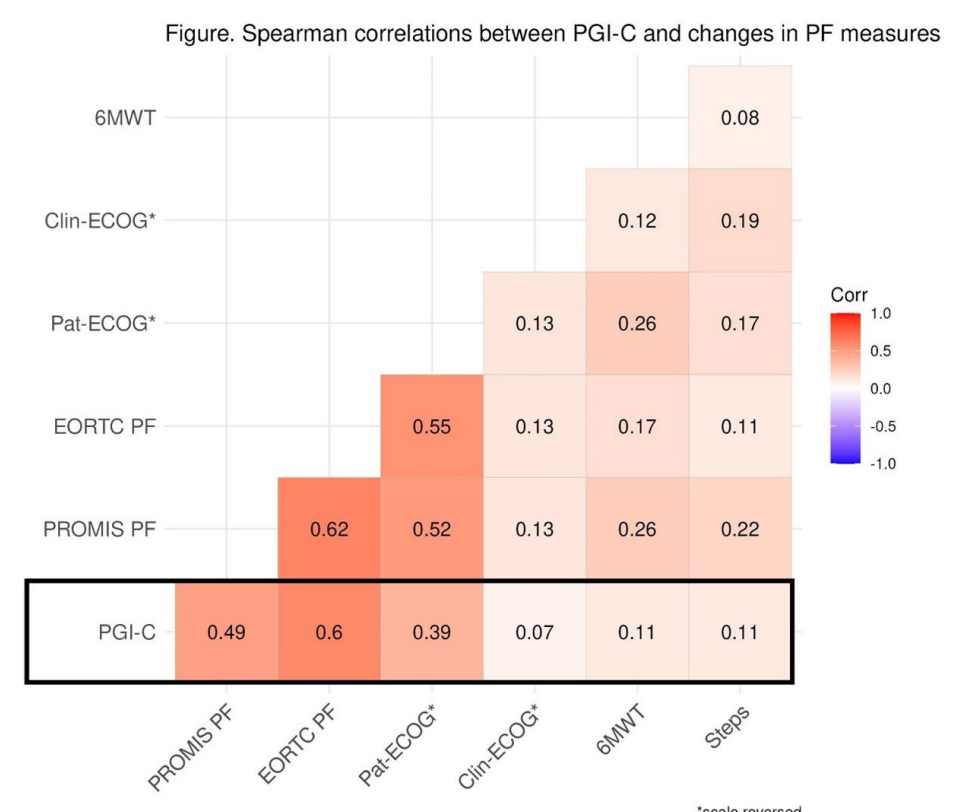
TABLE

Modality	Measure	Scale Range	N	Baseline Mean (SD)	Baseline Corr (P) w/Steps	3M Mean (SD)	3M Corr (P) w/Steps	Change Mean (SD, P)	Standardized Response Mean [^]
Patient-reported physical function	PROMIS Short Form v2.0 PF 8c	T-score (mean 0, SD 50)*	149	53 (9)	0.17 (0.09)	46 (8)	0.34 (<0.001)	-7.1 (8.5, <0.001)	-0.83
	EORTC QLQ-F17 PF Scale	0-100*	148	91 (14)	0.19 (0.05)	76 (20)	0.48 (<0.001)	-15 (16, <0.001)	-0.89
	Pt-reported ECOG Performance Status	0-4**	148	0.57 (0.74)	-0.07 (0.49)	1.24 (0.83)	-0.40 (<0.001)	0.68 (0.83, <0.001)	0.83
Clinician-reported physical function	Clinician-reported ECOG Performance Status	0-5**	145	0.12 (0.32)	0.00 (0.97)	0.28 (0.50)	-0.06 (0.50)	0.17 (0.51, <0.001)	0.33
Performance test	6-Minute Walk Test	Distance in meters*	113	1461 (243)	0.18 (0.08)	1447 (218)	0.20 (0.06)	-17 (147, 0.25)	-0.12
Wearable sensor	Fitbit	Average daily steps*	103	6570 (3441)	--	6013 (3081)	--	-557 (2976, 0.06)	-0.19

*Higher score is better; ** higher score is worse; ^ computed as the mean of the change scores divided by the SD of the change scores

CHART

- At 3M, all changes in patient-reported PF measures significantly correlated with PGI-C, while clinician-reported PS, 6MWT and steps did not.
- Patients reporting worsened PF by PGI-C had a larger mean decline in daily steps than those reporting no change/improvement (-684 [SD 2918] vs -134 [SD 3285]; $p<0.001$).
- Patients reporting worsened PF also had larger mean declines on PROMIS and QLQ-F17 than those reporting no change/improvement (PROMIS: -9.1 [SD 7.7] vs -2.1 [SD 8.2]; QLQ-F17: -19.4 [SD 15.7] vs -3.0 [SD 11.4]; both $p<0.001$).



CONCLUSION

- Multi-modal assessment of PF was feasible.
- Patient-reported PF measures detected change and statistically correlated with both step count and patient-perceived PF change.
- Largest changes based on the standardized response mean were observed for patient- and clinician-report; the smallest changes were observed for 6MWT and wearable sensor data.