

ANGELS Randomized Controlled Trial: The role of pAtient NaviGators in Enhancing oncoLogic care outcomeS.

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INTRODUCTION: Cancer patients are in need of a much complex assistance compared to other patients from our healthcare systems. Patient Navigator (PN) programs aim to help patients by giving them personalized assistance throughout the entire cancer process. This includes appointment management, enhancing physician-patient communication and providing support during medical appointments. The aim of this study is to evaluate the impact of a PN program in the satisfaction and quality of care of lung cancer patients from a university hospital in Madrid, Spain.

METHODS: This is a randomized prospective open-label study including patients with lung cancer treated by the Medical Oncology department of University Hospital Puerta de Hierro. Patients were randomized 1:1 to a PN program or a usual care practice group and were asked to complete standardized questionnaires (Patient Satisfaction with Logistical Aspects of Navigation Scale - PSN-L) at baseline and after 6 months. In addition, patients in the PN group were asked to complete an additional survey (Patient Satisfaction with Interpersonal Relationship with Navigator - PSN-I-SP) to evaluate the figure of PN. The primary endpoint was the mean change in PSN-L after 6 months in the two groups. Secondary endpoints included mean score and frequency of responses on PSN-I-SP in the PN group.

RESULTS: The characteristics of patients are described in Tab 1. 53% were included in the usual care practice group and 47% in the PN group. 39 and 29 patients respectively completed the 6-month questionnaires and were analyzed. PSN-L (25-item; range 0–75, higher score indicating greater satisfaction) was assessed at baseline and at 6 months in both groups. Among patients in the usual care practice group, median score increased from 38 (IQR 28–59) to 50 (IQR 42–61) at 6 months vs 55 (IQR 43–66) to 57 (IQR 48–67) in the experimental arm. Although scores increased in both groups over time (median change 9 vs 3), no significant differences were observed between groups (Wilcoxon signed-rank test, $p=0.15$; Fig 1). PSN-I-SP (9-item; range 9–45, higher score indicating greater satisfaction) was assessed after 3 and 6 months in the PN group, with a total of 26 patients answering both. No significant differences were observed in median scores over time [3 months: 45 (IQR 41–45) ; 6 months: 45 (IQR 45–45)], (Wilcoxon signed-rank test, $p = 0.466$; Fig 1).

	n (%)
Age - mean (range)	68 years (51-87)
Sex	
Male	60 (58%)
Female	43 (42%)
Marital status	
Single	12 (12%)
Married	64 (62%)
Divorced	18 (17%)
Widowed	6 (6%)
Other	3 (3%)
Educational status	
No formal studies	7 (7%)
Primary education	21 (20%)
Secondary school	31 (30%)
Tertiary education	44 (43%)
Employment status	
Employed	20 (19%)
On sick leave	19 (18%)
Retired	60 (58%)
Other	4 (4%)
Tumor histology	
Adenocarcinoma	60 (58%)
Squamous cell carcinoma	22 (21%)
Small cell carcinoma	16 (16%)
Other	5 (5%)
Tumor stage	
II	4 (3%)
III	15 (15%)
IV	84 (82%)
Type of treatment	
Chemioimmunotherapy	63 (61%)
Tyrosin kinase inhibitors	16 (15%)
Immunotherapy	11 (11%)
Chemotherapy +/- radiotherapy	10 (10%)
Treatment intention	
Curative	20 (19%)
Palliative	80 (78%)

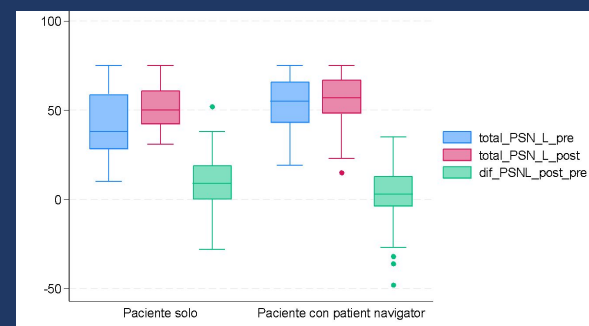


Fig 1. PSN-L in each group at baseline and 6 month

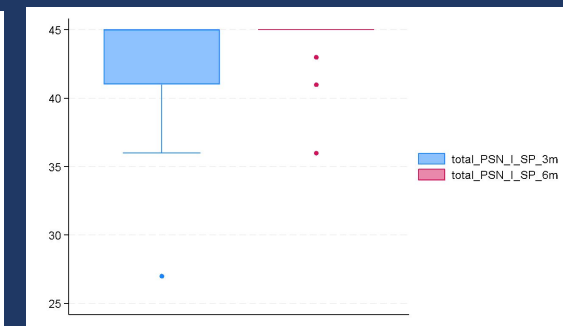


Fig 2. PSN-I-SP at 3 and 6 month

CONCLUSION: No differences were observed between the usual care practice and the PN group in the PSN-L score, probably due to different baseline scores. Among patients in the PN group, no significant changes in satisfaction were observed, likely due to scores remaining at their highest levels over time.