

Integrating psychosocial care into routine cancer care: A phase III, cluster randomized clinical trial (RCT) to evaluate effectiveness of the HuCare Quality Improvement Strategy (HQIS) on health-related quality of life (HRQoL).

Rodolfo Passalacqua, Elisa Iezzi, Maria Antonietta Annunziata, Claudio Verusio, Carmine Pinto, Mario Airoidi, Marcello Aragona, Francesca Caputo, Saverio Cinieri, Paolo Giordani, Stefania Gori, Rodolfo Mattioli, Silvia Novello, Antonio Pazzola, Giuseppe Procopio, Antonio Russo, Cosimo Sacco, Giuseppina Sarobba, Filippo Zerilli, Caterina Caminiti.

Background: Cancer patients (pts) often do not receive evidence-based psychosocial care. We evaluate the effects of an implementation strategy we previously demonstrated feasible, which includes communication skill training for all physicians and nurses; four support visits at the centers by an improvement team to assist staff in identifying obstacles, finding solutions, and strengthening motivation; screening for distress and social needs; individualized pts' education with a referring nurse; use of a question prompt list.

Methods: Multicenter incomplete SWD-RCT with 3 clusters of 5 centers each. Consecutive outpatients requiring medical treatment and diagnosed in the previous 2 months were eligible. Primary endpoint: difference of at least one of the 2 domains of HRQoL emotional or social functions, at 3 months from baseline, in pts of the centers that implemented the HQIS vs standard of care (SoC). Secondary endpoints include: patient mood, long-term effect, overall HRQoL. Analyses were performed using a beta-binomial regression model.

Results: 762 pts were enrolled. At baseline, 41% showed high anxiety (HADS-A>7), and 88% had at least one psychosocial need. 299 health professionals attended 3-day courses (84% of all clinical staff). 647 pts (85%) were available for analysis. The 315 pts who received HQIS exhibited better quality of life for the emotional domain than those assigned to SOC (OR=1.115, p=0.016). Pts who showed the greatest improvement were the older (OR=1.003, p=0.035), had lower anxiety basal levels (OR=0.853, p<0.001), and social needs were met (OR=1.182, p<0.001). The difference was not significant for the social domain (OR=0.955, p=0.353). The HQIS's long-term effect was confirmed for the emotional domain at 12 months. No effect on mood (HADS-D) and overall HRQoL was observed.

Conclusions: To our knowledge this is the first RCT demonstrating the effectiveness of a psychosocial care implementation strategy on cancer patients' emotional well-being.