Application of Managing Cancer and Living Meaningfully (CALM)

in advanced cancer patients. An Italian pilot study.

Rosangela Caruso, MD, PhD[1,2], Silvana Sabato, MSPsy, PsyD, [1] Maria Giulia Nanni, MD[1,2], Sara Hales, MD[3,4], Gary Rodin, MD[3,4], Carmine Malfitano, PhD[3,4] Elisa Tiberto,[1,5] MSPsy, Silvia De Padova, MSPsy [6] Tatiana Bertelli, MSPsy [6] Luigi Grassi, MD, MPhil[1,2]

[1] Institute of Psychiatry, Department of Biomedical and Specialty Surgical Sciences, University of Ferrara, Ferrara, Italy
[2] University Hospital Psychiatry Unit, Integrated Department of Mental Health and Addictive Disorders, Health Trust and University S. Anna Hospital, Ferrara, Italy
[3] Department of Supportive Care, Princess Margaret Cancer Centre, Toronto, Canada.
[4] Department of Psychiatry, University of Toronto, Toronto, Canada
[5] Department of Philosophy, Sociology, Education and Applied Psychology, University of Padua, Italy
[6] Psycho-Oncology Unit, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS, Meldola, Italy

Corresponding Author

Luigi Grassi
Institute of Psychiatry
University of Ferrara
Via Fossato di Mortara 64/a, 44121
Ferrara, Italy
e-mail address: luigi.grassi@unife.it

Depression and anxiety occur in 25-30% of advanced cancer patients, as conditions arising from a final pathway of distress determined by the interaction of multiple factors.[1,] Within the psychotherapeutic intervention developed to address these conditions, Managing Cancer and Living Meaningfully (CALM),[2] is an individual meaning and supportive-expressive intervention for patients with advanced cancer. In preliminary pilot studies, CALM was found to decrease depression and anxiety, and improve spirituality and attachment,[3,4] while in a randomized clinical trial, CALM reduced depression and improved end-of-life preparation.[5]

We conducted a pilot study of CALM using a mixed method approach, in order to: (i) understand the possible application of CALM in a different cultural context (i.e. Italy) and examine patients' subjective impact of CALM; (ii) preliminarily explore, as already done in other countries (i.e. Germany),[6] the possible effects of CALM on psychosocial outcomes.

The study was carried out on advanced cancer patients referred to the Program of Psycho-Oncology Psychiatry in Palliative Care, University of Ferrara, Ferrara, Italy. Inclusion criteria were: age ≥18 years; a diagnosis of advanced cancer (expected survival of 12-18 months); no cognitive impairment; a score ≥10 at the Patient Health Questionnaire-9 (PHQ-9) or ≥20 at the Death and Dying Distress Scale (DADDS). The study was approved by the Ethical Committee of the institution (please refer to the supplementary file for details).

According to the CALM protocol, each patient was assessed at baseline, (T0) three (T1) and six months later (T2) by using a battery of psychometric instruments, including: the PHQ-9 for depression, the DADDS for death anxiety, the Generalized Anxiety Disorders-7 (GAD-7) to screen on anxiety symptoms; the Posttraumatic Growth Inventory (PTGI); the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale (FACIT-Sp) for spirituality and meaning; the Experiences in Close Relationships Inventory Modified Short Form Version (ECR-M-16); the Quality of Life at the End of Life-Cancer Scale (QUAL-EC). A 7-item tool, the Clinical Evaluation Questionnaire (CEQ) was used at three and six months (T1 and T2) to assess the subjective perception of both treatments and the insight patients have gained).

Each patient, after random allocation to CALM intervention or usual care (UC) received 12 individual sessions (45-60 minutes each), delivered over 6 months on a 15-day basis. CALM therapist, as in the original manual,[7] explored meaning, preparation for death, symptom management and interpersonal relationships domains. Participants in the UC received, by a different psychotherapist, unstructured psychological support. Also, in spite of the pilot nature of the study, preliminary statistical analysis on the quantitative data were carried out.

Of 50 eligible referred patients, complete data were available for 25 (mean age 60 ±11.8 years; education 13.2±2.8 years; breast, 36%; gastrointestinal, 28%, and lung, 12%). Twenty-seven patients were allocated in CALM and 23 in UC. Thirteen subjects completed T1 and T2 in CALM and 12 in UC. A greater satisfaction with care was found in CALM vs. UC (supplementary Table 1). A series of themes, attributing value and meaning to the CALM experience (supplementary document 1) emerged and were explored in terms of their content.

A statistically significant improvement on PHQ-9, DADDS, GAD-7 and PTGI was found in CALM vs. UC at T1 and T2, as well as, on the same dimensions across time (T1-T2) in CALM, but not in the UC group.

This is the first CALM study in Italian cancer patients. In line with other CALM qualitative studies,[8,9,10] CALM was also positively accepted by the patients, as indicated by their general satisfaction and their comments, indicating the construction of a shared reflective space in which the therapist facilitated the patients in the discussion about death and dying, loss, spirituality, and aftermath concerns. In spite of the small number of participants, CALM showed to be effective, both across time and with respect to UC, to reduce the levels of depression, death and general anxiety, and to increase the levels of post-traumatic growth at both T1 and T2. These results are in line with other CALM studies both in Canada and Germany and seem to confirm the role of this semi-structured intervention acting on meaning in ameliorating psychosocial parameters in advanced cancer patients. In contrast with the original Canadian study, CALM had no effect on attachment issues and quality of life issues.

The relevance of this pilot study is mainly linked to the possibility to further application of CALM, and other forms of meaning psychotherapy, in Southern-European cultural context, such as Italy. As limitations, the small number of patients indicates the need to expand the sample size. Also, since we compared CALM with UC, we cannot conclude that CALM is superior to or similar to other meaning-centered psychotherapy. A larger RCT multicenter study, in agreement with what in progress in other countries (e.g. Germany), is in a developing phase and the full study will address some of the limitations here underlined.

Disclosure and Acknowledgments: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The study has been funded by the University of Ferrara (UniFE - FAR funding). The authors are grateful to all the patients participating to the study and the health care professionals who contributed in facilitating the phase of data collection.

References

1 Caruso R, Nanni MG, Riba MB, et al.: The burden of psychosocial morbidity related to cancer: patient and family issues. Int Rev Psychiatry. 2017;29(5):389-40

2 Hales S., Lo C., Rodin G.: Managing Cancer and Living Meaningfully (CALM) Therapy. In Edited by Jimmie C. Holland, William S. Breitbart, Paul B. Jacobsen, Matthew J. Loscalzo, Ruth McCorkle, Phyllis N. Butow (Ed.s). Psycho-Oncology, Oxford University Press, New York, 2015 pp. 487-491

3 Lo C., Hales S., Jung J., et al.: Managing Cancer And Living Meaningfully (CaLM): phase 2 trial of a brief individual psychotherapy for patients with advanced cancer. Palliat Med., 2014;28(3):234-42.

4 Lo C, Hales S, Chiu A, Panday T, Malfitano C, Jung J, Rydall A, Li M, Nissim R, Zimmermann C, Rodin G.: Managing Cancer And Living Meaningfully (CALM): randomised feasibility trial in patients with advanced cancer BMJ Support Palliat Care. 2016 Jan 19. pii: bmjspcare-2015-000866.

5 Rodin G, Lo C, Rydall A, et al.: Managing Cancer and Living Meaningfully (CALM): A Randomized Controlled Trial of a Psychological Intervention for Patients With Advanced Cancer. J Clin Oncol. 2018 ;36(23):2422-2432.

6 Scheffold K, Phillipp R, Engelmann D, et al.: Efficacy of a brief manualized intervention Managing Cancer and Living Meaningfully (CALM) adapted to German cancer care settings: study protocol for a randomized controlled trial. BMC Cancer, 2015; 15:592

7 Hales S, Lo C, Rodin G.: Managing Cancer And Living Meaningfully (CALM) Treatment Manual: An Individual Psychotherapy for Patients with Advanced Cancer. Toronto, Ontario, Canada, Princess Margaret Cancer Centre, University Health Network, 2015

8 Nissim R, Freeman E, Lo C, Zimmermann C, Gagliese L, Rydall A, Hales S, Rodin G. Managing Cancer and Living Meaningfully (CALM): a qualitative study of a brief individual psychotherapy for individuals with advanced cancer. Palliat Med. 2012;26(5):713-21

9 Shaw C, Chrysikou V, Lanceley A, Lo C, Hales S, Rodin G. Mentalization in CALM psychotherapy sessions: Helping patients engage with alternative perspectives at the end of life. Patient Educ Couns. 2019;102(2):188-197

10 Shaw C, Chrysikou V, Davis S, Gessler S, RodinG, Lanceley A. Inviting end-of-life talk in initial CALM therapy sessions: A conversation analytic study. Patient Educ Couns. 2017;100(2):259-266.