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# A continuity care program in chronic, complex and frail patients: the PRO-CCF study protocol

Sarah Damanti[1], Giuseppe Alvise Ramirez[2], Enrica Paola Bozzolo[3], Carla Desa Pedroso[3], Gaia Deonette[3], Gianmaria Brambilla[4], Barbara Rizzi[4], Giada Lonati[4], Moreno Tresoldi[3]

[1] Vita Salute University, Milan; [2] Unit of Immunology, Rheumatology, Allergy and Rare Diseases, IRCCS Ospedale San Raffaele, Milan, Italy; [3] Unit of General Medicine and Advanced Care, IRCCS Ospedale San Raffaele, Milan, Italy; [4] VIDAS Foundation, Milan, Italy

**Background and aims**. The aging of the world population has inevitably led to an increase in the number of multi-morbid patients seeking healthcare assistance. The transition from hospital to territory is a particularly delicate moment. New treatment paradigms are required to optimize the continuity of care and to satisfy patients and caregivers' needs. The San Raffaele hospital signed an agreement with the VIDAS association for providing an integrated home care for chronic, complex and frail (CCF) patients, after hospital discharge. We aim at evaluating the effectiveness and satisfaction of an experimental transitional care program between hospital and territory, CCF patients.

**Methods**. CCF patients discharged from an Internal Medicine Ward, and based on the geographical area of residence (covered or not by VIDAS assistance) will be divided into two groups: 1) receiving standard care 2) involved in the transition care program.

The administration of PACIC questionnaire, to assess the eventual organizational improvement in the study group, will be performed at hospital discharge and at 6- and 12-month follow-ups.

**Conclusions**. If this innovative intervention proves to be effective, it will be able to improve the management of chronic, complex and frail patients, reducing the risk of negative health outcomes and diminishing the related healthcare expenditure.

**Key words**: chronic patients, frailty, continuity of care programs, hospital discharge, multi-morbidity, transition of care

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**Correspondence**
Sarah Damanti
E-mail: damanti.sarah@hsr.it

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## INTRODUCTION

The progressive aging of the world population has led to an increased prevalence of chronic morbidity, along with higher demands for palliative care in the general population. Consequently, growing pressure has been put on healthcare systems, especially in settings where these trends have been more evident, such as Italy. In fact, Italy is the eldest country in Europe, the second in the World despite ranking the twelfth and below the European Union average, for healthcare expenditures, in terms of fraction of the gross domestic product (source: Eurostat). The clinical and organisational long-term management of patients with high burdens of chronic morbidity but not eligible to palliative care is still ill-defined, and

lacks a holistic assessment [1]. Chronic complex and frail (CCF) subjects, characterised by multi-organ damages, autonomy loss and enhanced susceptibility to complications after acute events, require dedicated assistance programmes, taking into account not only the degree of consumption of their physiological reserves, but also socio-economic, cultural and environmental factors, which may affect their medium and long-term prognosis [2].

The transition from hospital to territory after an acute event is a particularly delicate moment, which could affect future readmissions, adverse events and mortality [3]. Previous transition of care programs demonstrated the efficacy of interventions in reducing emergency department and hospital readmissions, and in improving the life quality of the assisted patients.

The Transitional Care Model (TCM) developed by Mary Naylor [4,5] is a nurse-led, multidisciplinary transition of care model, which includes a hospital planning and home follow-up with an important collaboration with the patient family. Moreover, the nurse in charge of the program accompanies the patient to follow up visits. This model proved to reduce both emergency departments and hospital readmissions [6-8].

The Care Transitions (CTI) Program developed by Eric A. Coleman [9] is a transition of care model ,characterized by a comprehensive care plan, organized by trained practitioners who know their patients' goals, preferences, and clinical status. The program is characterised by a hospital visit before discharge, a home visit, and three follow-up calls, made by the Transition Coach. In this program, the role of the transition coach is assumed by either nurses or social workers. The coach stimulates new behaviours to face common problems that might arise during transitions. Moreover, this program favours the acquirement of self-management skills.

This model of care has proved to reduce hospital readmissions and health care costs, and increased the achievement of symptom management, and functional recovery [10].

The Chronic Care Model (CCM), developed by Edward Wagner (1998), is a transition of care program, designed by a physician, with the aim of providing safe and effective care to older adults, affected by chronic diseases [11]. The model is characterised by care coordination and case management, and has been more frequently applied in the outpatient setting so far [12], providing benefit in the care of people with chronic conditions [13-16]. However, the previous programs did not specifically targeted frail patients, a population particularly at risk of developing negative outcomes. In addition, these programs did not involve any association which could include various characters (physicians, nurses, social workers), all with validated skills in assisting chronic and terminally ill patients. Finally, these interventions were not specifically tailored for the emerging type of complex and frail but not yet terminal patients, who are typically hospitalised in the Italian Medicine and Geriatric Wards.

In order to tackle the existing need for a rational model which can identify and fast-track CCF patients to a dedicated home-care programme, IRCCS San Raffaele Hospital (Milan, Italy) and the private charity VIDAS ("Volontari Italiani Domiciliari per l'Assistenza ai Sofferenti") agreed on a pilot project, aimed at improving the transition of CCF patients from hospital acute care to territorial assistance. In this project social workers play a strategic role, since they are involved in the moment of taking charge the enrolled patients. Social workers contact the patients' family, understand their social needs and remain at disposal during the follow-up, as a back-up for the patient care.

## DESIGN OF THE STUDY

This is a prospective, monocentric observational cohort study with an additional procedure (administration of questionnaires) to collect data on the efficacy, and user appreciation of the transition programme for CCF patients. The study was approved by the local review board (13th October 2021).

### Inclusion criteria

Patients of both sexes, aged ≥ 18 year, admitted to the General Medicine and Advanced Care Department of the San Raffaele Hospital from 30.10.2021 to 30.10.2023 and classified as CCF subjects, according to fulfilment of all the following criteria:

- Cumulative illness rating scale (CIRS)-C Comorbidity Index ≥ 3 [17];
- Blaylock Risk Assessment Screening Score (BRASS) ≥ 11 [18];
- 4 ≤ Clinical Frailty Scale ≤ 7 [19];
- Negative response to Surprise Question: would you be surprised if this patient died in the next 24 months? [20];
- Written informed consent to participate to the study.

We are going to include all adults and not only older people, because frailty is not just an age-related phenomenon and also adult people can be frail.

### *Intervention group*

The patients who met the inclusion criteria, and who reside in a geographical area where it is possible to receive assistance from VIDAS, and those who accept the care by VIDAS w wincluded in the intervention group.

The social worker in the palliative care context will

intervene to satisfy a series of social needs, with the aim of supporting the living conditions of the person in difficulty, and of his/her family. Social workers will perform a careful assessment of the social conditions, to implement individualized assistance plans, adapted to the patients' needs. Moreover, social workers will collaborate daily with the other internal members of the palliative team (psychologists, social operators, doctors, and nurses) to constantly offer the best treatment solution. In this context of Palliative Home Care, social workers I have a role of promotion and enhancement of family resources. Moreover, they can identify one or more reference figures – caregivers – and I stimulate them and the family, to take an active role in the management of the patient, to implement the instructions of the treating team, and to detect any other patient's needs. Social workers will ascertain the level of the assistance capacity that the family network can guarantee, and I calibrate the activity of the palliative team according to this. Finally, thanks to their skills and experience, they can offer support in the knowledge of the rights and related benefits, that national and regional regulations offer to those who are in a terminal condition or to their caregivers.

### *Control group*

The patients who meet the inclusion criteria but who are not treated by VIDAS because:

- they refuse consent to home care but accept study participation;
- they reside in a geographical area not covered by VIDAS assistance.

No socio-demographic difference exists between the areas covered and not covered by the private charity VIDAS. The patients in the control group are clinically entrusted to the care of their general practitioner (GP), as per the current "standard of care".

Randomization in the two groups was not performed because this is a pilot study and we aim at assessing whether the intervention is feasible and efficient.

#### Exclusion criteria

- Patients unable to answer study questionnaires;
- Patients who do not provided a written informed consent to participate in the clinical study;
- Terminally ill patients (with prognosis < 1 year);
- Dependent patients without a stable caregiver.

## POPULATION AND SAMPLE SIZE

We are going to enrol 200 subjects (100 per group). For the calculation of the sample size, we considered a study which used the 20-element Patient Assessment of Chronic Illness Care (PACIC) score, to quantify patient perceptions about the quality of assistance [8,9,11,20]. This was a multicentre study aimed at defining the effectiveness of a territorial management of the needs of chronic patients, in improving their quality of life. The study used the 20-item PACIC score to quantify patients' perceptions of the quality of the service received. The PACIC score consists of five domains (definition of objectives, coordination of care, decision support, problem solving, patient activation) which can be judged as more or less satisfying, in terms of consistency of care, on a scale from 1 to 5. An additional domain, calculated as the average of the previous ones, represents an "aggregate" evaluation of the quality of care. The authors of the study, further simplified the calculation of the original score, by introducing a dichotomous classification (score greater than vs less than 4 points) or tripartite (score < 3, between 3 and 4, greater than 4). The questionnaire relating to the PACIC score was administered at several intervals and in particular at 6 and 18 months, after hospital discharge. At 18 months, the authors recorded a significantly higher percentage of aggregate scores, > 4 points (dichotomous class indicative of "high" quality) in the subjects treated with the new care model (20%), compared to those followed with the standard of care (11%). The authors report an unadjusted odds ratio of 2.03 with respect to the propensity of patients to declare a "high" quality of care with the new model, compared to the old one. Based on this parameter, using Chinn's formula to derive the effect size from the odds-ratio (effect size = 0.39118), it is deduced that a sample of at least 52-85 patients is necessary, to obtain a statistical power of 80-95%, setting the alpha probability of error at 5%.

## STUDY PROCEDURES

The study consists in the administration of questionnaires, aimed at assessing the quality of post-hospital care and the patient quality of life. Caregivers will also be involved anonymously. These data will be integrated with clinical variables, related to hospital admission and subsequent 12-month follow-up.

The primary endpoint of the study is the percentage of patients who report a "high" quality of care, after six and 12 months after hospital discharge, by comparing VIDAS versus standard assistance. Quality of care is being assessed through the PACIC score [21]. The PACIC score consists of five domains (definition of objectives, coordination of care, decision support, problem solving, patient activation) which can be judged as more or less satisfied, in terms of consistency of care on a scale from 1 to 5. An additional domain, calculated as

the average of the above, represents an "aggregate" assessment of the quality of care.
The secondary endpoints are:

- change over time in the patient quality of life as measured by the EuroQol 5D-5L scale [12], at hospital discharge, and at six and 12 months of follow-up. Both Inter- and intra-group comparisons will be performed;
- change in the patient performance status as measured by the Karnofsky scale [22] at hospital discharge, and at six and 12 months of follow-up. Both Inter- and intra-group comparisons will be performed;
- number of accesses to the emergency department between the two groups, in the 12 months after hospital discharge;
- number of hospitalizations in the two groups in the 12 months after hospital discharge;
- survival in the two groups at six and 12 months after hospital discharge;
- institutionalizations in the two groups in the 12 months after hospital discharge;
- change over time in the Modified Caregiver Strain Index (MCSI) score [23] at discharge, and at six and 12 months of follow-up. Comparison of MCSI scores at discharge, and at six and 12 months in the two groups. The MCSI is an easy-to-use tool for the strain screen of long-term caregivers. The tool is composed by 13 questions that measure strain, related to care provision. The main domains are: financial, physical, psychological, social, and personal ones. Each question receives a score of 2 points if the answer is 'yes', 1 point if the answer is 'sometimes', and 0 if the answer is 'no'. The score ranges from 26 to 0, with higher scores indicating a higher level of caregiver strain;
- comparison of the number and timing of transition to palliative care in the two groups, in the 12 months after hospital discharge;
- comparison of the number of interventions by social workers, and request for an interview by relatives in the two groups, in the 12 months after hospital discharge;
- evaluation of the therapy [16,24] at discharge, at six and 12 months and comparison between the two groups at discharge, at six and 12 months;
- change in the Mini Nutritional Assessment (MNA) short form [17] and SARC-F [18] score at discharge and at six and 12 months of follow-up. Comparison of MNA and SARC-F scores at discharge, and at six and 12 months in the two groups;
- change in the Clinical Frailty Scale score [19] at discharge, at six and 12 months of follow-up, and comparison of Clinical Frailty Scale scores in the two groups at discharge, and at six and 12 months of follow-up;
- change in the simplified ACIC-S score [19] before and after hospitalization, and at six and 12 months after discharge. Both Inter- and intra-group comparisons will be performed.

## STATISTICAL CONSIDERATIONS

Descriptive statistics will be used to describe the study variables. The characteristics of the two groups of patients will be compared with the Student's t-test or the Mann-Whitney test for continuous variables, and with the Pearson's Chi-square test for categorical variables. The variation of the questionnaire scores and scales from hospital discharge till the sixth and twelfth month of follow-up, will be evaluated with repeated measure ANOVA test or the Friedman Test.
Differences in the interventions of social workers, number of interviews requested by relatives, number of adverse drug reactions, and number of inappropriate drugs between the two groups will be evaluated with the Student's t-test or Mann-Whitney test. Hospital admissions, accesses to the emergency department, institutionalization, transitions to palliative care in the months following discharge, will be compared between the two groups of patients, using the Time-To-Event Analysis, Cox regressions or proportional hazard model Hazard Ratios (HRs) will be reported with 95% confidence intervals. Survival analysis will be performed according to the Kaplan-Meier method, and survival times will be reported as a mean with a 95% confidence interval.
All data processing will be carried out using Microsoft Excel v. 2019 or later, JMP Pro v. 14.1.0 (SAS, Cary, NC, USA), Statacorp STATA v. 15.0 or later or IBM SPSS v. 21 or later.

## MAIN OBSTACLES IN THE IMPLEMENTATION OF THE PROGRAM

We expect that the main obstacles in the implementation of the program will be: the recruitment of controls and the follow-up of the patients. Physicians could be more concentrated in the assessment of the patients to be included in the study group, but could pay less attention to the people who meet the inclusion criteria but will not be followed up by VIDAS. An asymmetry in the recruitment could compromise the comparison of the two groups and the demonstration of the efficacy of the intervention.
During the one year follow-up, the patients who experience adverse events and deteriorate, may refuse to perform the questionnaires necessary to the evaluations

described in this protocol. This could have a negative impact on the results of the study and can be a common complication when dealing with frail older adults.

## CONCLUSIONS

This study has the merit of including a highly vulnerable population, often hospitalised in acute units but seldom involved in research. Hospital transition to the territory is a particularly critical moment for chronic and frail older people, because of the inadequacy of the present territorial assistance models for such complex patients. In the project promoted by San Raffaele and VIDAS, to improve the transition of CCF patients from hospital acute care to territorial assistance, the social worker practice with terminally ill patients, configures as part of a multicomponent palliative care intervention.

We expect that this experimental intervention, aimed at modifying traditional models of care in acute units, will improve the quality of perceived care and the patient quality of life. Moreover, this innovative intervention could reduce the risk of negative health outcomes, such as inappropriate hospital admissions, and might contribute to contain healthcare expenditures. However, the study sample size was calculated to ensure enough statistical power for the primary outcome but not for the secondary outcomes. Thus, further studies may be necessary to validate the efficacy of the intervention for the secondary outcomes.

If this model of care will prove sustainable, by improving physician workload and filling the gap between hospital and territory, it could be proposed for application in other hospital settings.

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### Conflict of interest statement

The authors declare no conflict of interest.

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### Author contributions

SD: GAR, EPB, MT, GB, BR, GL: study conception and design; EPB, CDP, MT, GB: data collection; SD, GAR, MT, EPB, CDP: analysis and interpretation of results; all authors: draft manuscript preparation. All authors reviewed the results and approved the final version of the manuscript.

### Ethical consideration

This study was approved at the Local Review Board of the San Raffaele Hospital CE: (prot. number: 158/INT/2021).

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

Written informed consent was obtained from each participant/patient for study participation and data publication.

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