

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Major Diagnostic Category*:** Oncologia**Project Classification IRG:** Surgical Sciences, Biomedical Imaging, and Bioengineering**Project Classification SS:** Surgery, Anesthesiology, and Trauma - SAT**Project Keyword 1:** Tissue, organ and systemic injury responses to surgery, trauma, burn, sepsis, hemorrhage, ischemia-reperfusion, or resuscitation, including integrating pathways and signals.**Project Keyword 2:** Prehabilitation**Project Keyword 3:** Physical function and postoperative complications**Project duration (months):** 36**Project Request:** Animals: Humans: Clinical trial: **The object/s of this application is/are under patent copyright Y/N:** **Operative Units / WP**

	INSTITUTION	Department/Division/Laboratory	Role in the project
1	Emilia-Romagna	Department of Surgery/U.O. Chirurgia Generale Provinciale - Azienda USL di Ferrara	Conception of the study and research hypothesis, enroll and operate on patients, evaluate and treat mood and psychological disorders of the patients, coordination of the study
2	Azienda Usl di Ferrara - Emilia-Romagna	Department of Sports Medicine/Division of Exercise and Sports Medicine - Azienda USL di Ferrara	Prehabilitation of surgical patients
3	Azienda Ospedaliero-Universitaria di Ferrara - Emilia-Romagna	Department of Medicine/Division of Internal Medicine/Center for Clinical Epidemiology - Azienda Ospedaliero- Universitaria di Ferrara	Design and implementation of the study and statistical analysis

Investigators, Institution and Role in the Project

	Co-PI	Under40	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1	X		Graffi Giovanni	Azienda Usl di Ferrara - Emilia-Romagna	Prehabilitation and rehabilitation of surgical patients	08/11/1957
2			VOLPATO STEFANO	Azienda Ospedaliero-Universitaria di Ferrara - Emilia-Romagna	Design and implementation of the study and statistical analysis	05/11/1966
3		X	DE TROIA ALESSANDRO	Azienda Ospedaliero-Universitaria di Ferrara - Emilia-Romagna	Screening and enrollment of eligible patients	03/11/1983
4			CARUSO ROSANGELA	Emilia-Romagna	Evaluate and treat mood and psychological disorders of the patients	18/02/1974

Overall Summary

Postoperative complications occur in up to 50% of patients and are associated with higher mortality, cancer recurrence rate



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and hospital costs. The number and severity of complications are closely related to preoperative functional capacity and nutritional status. This study aims to determine the effect of prehabilitation on patients' functional capacity and postoperative complications. It is a randomized trial including 112 patients undergoing colorectal surgery for cancer. Patients will be allocated to intervention group receiving 4 weeks trimodal prehabilitation (N=56) or control group receiving no prehabilitation (N=56). After surgery, both groups will follow 8 weeks rehabilitation based on Enhanced Recovery After Surgery (ERAS) guidelines. The primary endpoint is functional capacity, secondary outcomes include postoperative complications and a cost-effectiveness analysis. Multimodal prehabilitation is expected to increase functional capacity and lower postoperative complications.

Background / State of Art

Postoperative complications occur in up to 50% of patients undergoing cancer colorectal resection and are associated with poor prognosis, increased costs, and lower health-related quality of life (HRQoL).¹⁻³ Even with no complications, major surgery is associated with 20 to 40% reduction in physiological and functional capacity and higher level of fatigue 6 to 8 weeks after surgery.⁴ Functional performance reduction is correlated with preoperative health status and degree of surgical trauma as well as intensity of metabolic response. Patients may also need postoperative chemo- and radiation therapy, more physically challenging if surgery has lowered functional capacity. Many negative effects of major surgery can be reduced attenuating the surgical stress response by Enhanced Recovery After Surgery (ERAS) programs, to facilitate return of functional activities and accelerate convalescence.⁵ However, the postoperative period may not be the best time to ask surgical patients to change their nutrition and exercise habits, as they may be tired, anxious, and depressed awaiting for additional treatments. Also, poor baseline physical performance capacity, particularly in the elderly and frail patients, increases the risk of complications and prolongs recovery after major surgery. Thus, patients' prehabilitation, the process of enhancing functional capacity to withstand an incoming stressor between the time of cancer diagnosis and surgical treatment, may represent a better time frame to intervene in factors contributing to the recovery process enhancing recuperation of postoperative functional capacity.^{6,7} A recent systematic review including 20 studies evaluating the prehabilitation program in gastrointestinal cancer surgery, strongly supported multimodal rather than unimodal interventions, but highlighted the need for further prospective studies, also evaluating health economic outcomes, before the definitive value of prehabilitation programs can be clarified.⁸

It's available a Systematic Review on this topic? Si

It's available as publication please report bibliographic data? Si

Bibliographic data (DOI): 10.1097/DCR.0000000000000987

Hypothesis and Specific AIMS

Hypothesis and Significance:

Recent level I evidence from North America suggests that optimizing functional exercise capacity alone before colorectal surgery can result in better physical performance, but not significant fewer postoperative complications and shorter hospital length of stay (LOS).^{9,10}

In this study, we hypothesise that the implementation of a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation will determine: 1) better physical performance at 8 weeks after surgery, 2) decrease in postoperative

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complications and LOS, and 3) reduced direct and indirect costs.

To date, there is no evidence of the implementation of such a trimodal prehabilitation program in Italy and the only published RCT was conducted in Canada, a very different social, economic and environmental context. Furthermore, in this study the mean age of patients who underwent prehabilitation was 65.7 years and 74% were ASA I-II.

Preliminary Data:

Since 2013, at the University Hospital of Ferrara a multidisciplinary team including surgeons, anaesthesiologists, and nurses has implemented an integrated ERAS perioperative care protocol in colorectal surgery, founded on elements selected based on high-grade evidence of clinical efficacy.⁵ Recently, also two dietitians, a geriatrician with consolidated experience in sarcopenia and performance-based functional assessment of older patients, two sports medicine physicians, and two psycho-oncologists have joined the team to integrate the ERAS methodology with a prehabilitation colorectal program.

Recently, the prehabilitation protocol has been applied by the team to a small number (N=10) of patients who underwent ERAS colonic resection for cancer. According to the protocol, patients were evaluated at baseline and after a 4-week prehabilitation program with the 6-minute walking test (6MWT). Mean baseline walking capacity was 571.5 ± 64.1 m, while following the 4-week prehabilitation program increased to 618.8 ± 57.5 m. At present, we are still collecting the postoperative data on walking capacity.

Picture to support preliminary data:

Boxplot preliminary data.jpg

Specific Aim 1:

To compare the postoperative functional capacity in two groups of colorectal cancer patients undergoing colorectal resection following an ERAS program, one treated with trimodal prehabilitation before surgery followed by standard rehabilitation (experimental group) and the other undergoing standard rehabilitation alone after surgery (control group).

Specific Aim 2:

To compare the postoperative complications in the experimental group versus the control group.

Specific Aim 3:

To compare both direct (hospital) and indirect (social and non-hospital health care) costs in the experimental group versus the control group.

Experimental Design Aim 1:

Single centre, single-blind, RCT with 2 groups. Written informed consent will be obtained. Ethical approval was obtained by the local Ethics Committee.

Patients of age >17 years undergoing elective colorectal resection for cancer are eligible. Exclusion criteria are metastatic disease, severe walking impairments, renal failure stage >2, ASA score >3, preoperative chemo-radiation therapy.

Patients will be randomized either to prehabilitation intervention group, receiving 4-week prehabilitation, or to control receiving no prehabilitation. Both groups will receive rehabilitation following current international ERAS guidelines.

The primary outcome for functional capacity is measured by the 6MWT, chosen because it is a validated, objective measure of colorectal surgery recovery integrating all components of physical activity.¹⁰

Secondary outcomes for aim 1 are: a) cardiopulmonary exercise testing (CPET), b) handgrip strength, c) sit-to-stand, d)



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body composition and nutritional status, e) depression/anxiety, f) HRQoL.

All measures will be recorded in both study groups at baseline (beginning of prehabilitation period) and prior to surgery (end of prehabilitation period) to measure the effect of intervention, and at 4 and 8 weeks after surgery to assess the impact of the intervention throughout the perioperative period. The person performing the 6MWT and helping the subjects with questionnaires and forms will not be aware of the study hypothesis and will not have access to data.

ELEMENTS OF TRIMODAL PREHABILITATION:

1) EXERCISE PROGRAM. A sports physician will assess patients mobility and capacity to exercise. All participants will undergo CPET and the exercise intensity will be defined and personalized. Based on the evaluation, the sports physician will prepare, explain and coordinate a personalized program.¹¹

Patients will receive 3 supervised trainings/week including interval and resistance training. They will be instructed on how to conduct aerobic exercises at home (walking or cycling), initially at 50% of the calculated heart rate reserve aiming at 60 min 4 times/week as tolerated by the patient. Accurate measurement of compliance is critical to determine the true effect of prehabilitation; therefore, patients will always wear an accelerometer during the 4 weeks of intervention.

2) NUTRITIONAL SUPPLEMENTS. The goal is to attain an anabolic preoperative state in all patients, improving in cachectic patients the lean body mass amount. At baseline, dietician will assess patients nutritional status (body composition, caloric balance and dietary intake). Nutritional supplements will be tailored to patient food intake. If there is weight loss/cachexia and indication for extra feeding and no medical limitation increased protein intake is aimed at 1.5 g/kg/day. Extra supplements as multivitamins and 2 weeks of omega-3 fatty acids from fish oil will be added.

3) PSYCHOLOGICAL COPING. Patients undergoing surgery for cancer may be anxious with depression symptoms which may influence social and functional activities. Thus, patients will be evaluated by a trained psycho-oncologist using validated questionnaires (GAD-7, PHQ-9).^{12,13} The goal is to reduce anxiety and avoid depression by putting the patients in a well-informed active coping role in dealing with the disease. If indicated, patients will receive 90 min of psychological intervention in the first session and more sessions during the 4 weeks of prehabilitation. In the first preoperative session, the 1st hour will address the patients anxieties, coping strategies, and post-operative expectations. The last 30 min will be devoted to teaching relaxation techniques and breathing exercises and to give written instructions for home practice.

CONTROL GROUP

Patients will be encouraged to walk daily for at least 30 min, to perform breathing exercises for 5 min per day and 5-10 min of aerobic exercises.

Experimental Design Aim 2:

The Clavien-Dindo classification and the Comprehensive Complication Index (CCI) as a combined outcome measure of morbidity and mortality will be used to assess complications.^{14,15} CCI is calculated as the sum of all complications that are weighted for their severity (multiplication of the median reference values from patients and physicians). The final formula yields a continuous scale to rank the severity of any combination of complications from 0-100 in a single patient. The CCI showed high sensitivity detecting treatment effect differences, inverse correlation with postoperative health status, and high correlation with the results of patient-rated single and multiple complications on conjoint analysis ($r=0.94$, $P<0.001$). The CCI summarizes all postoperative complications and is more sensitive than existing morbidity endpoints.¹⁵ Both indexes will be assessed 4 weeks after surgery.

Experimental Design Aim 3:

The analysis of social costs for patients in the prehabilitation and control groups will be assessed by cost-effectiveness analysis, evaluating both direct and indirect costs, including the value of time spent by unpaid caregivers (formal and informal) in assisting the patients. Costs and benefits will be evaluated from the societal point of view. Costs (both public



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and private as well as direct and indirect) and outcomes (health status and quality of life of both patients and caregivers) will be compared. Indicators of socio-economic characteristics, perceived quality of life (Short Form-36, EORTC 29, 30), and patients use of social and health care resources will be collected. Relevant caregivers' information will be acquired by ad hoc questionnaire. Direct costs (e.g., enhancement of costs and nursing care workload related to prehabilitation protocol) will be measured through the information collected by questionnaires. Indirect costs will be evaluated through two alternative approaches: 1) replacement cost (revealed preferences or proxy good); 2) contingency evaluation based on data collected by caregivers questionnaire. An analysis of the incremental cost-effectiveness ratio will be carried out over a 2-year period.

Metodologies and statistical analyses:

We will conduct a single centre single blind randomized clinical trial. Patients will be randomized with a 1:1 allocation by means of randomization software. We plan to enrol 112 patients, 56 per group. The sample size calculation was based on the primary aim, the 6MWT. We used preliminary data from a sample (N=10) who underwent ERAS colonic resection for cancer, evaluated at baseline and after a 4-week prehabilitation program with 6MWT. Mean baseline walking capacity was 571.5 ± 64.1 meters, while following the 4-week prehabilitation program increased to 618.8 ± 57.5 m with a mean change of $+47.2 \pm 57.5$ m. We hypothesized that 8 weeks after surgery the difference in the 6MWT between the prehabilitation and the control group would be about 45 m. Assuming a similar baseline walking capacity between the two study groups and an 8 weeks difference of about 45 ± 57 meters, with an alpha level of 0.05 a power of 80%, the required sample size is 51 patients per group. Assuming a 10% attrition we planned to enrol 112 patients. Univariate analyses will be conducted to determine differences between groups on one time point with independent t-tests for continuous variables and chi-square analyses for categorical variables. Generalized mixed models for repeated measure will be used to analyse the effect of the prehabilitation program on several outcomes. Linear models will be used for continuous outcomes (primary research question) and logistic models for dichotomous outcomes. Socio-demographic and clinical characteristics will be analysed as time-invariant predictors.

Expected outcomes:

AIM 1. Better functional capacity (6MWT) in the experimental group (prehabilitation) at 8 weeks after surgery.

AIM 2. Decrease in postoperative complications due to the trimodal prehabilitation program.

AIM 3. Higher net social benefits for patients on prehabilitation compared to controls. We expect lower tangible costs and higher effectiveness and better quality of life for patients and caregivers.

Risk analysis, possible problems and solutions:

- PATIENTS REFUSAL. Based on preliminary data, about 20% of patients may decline participation due to work commitments or unwilling to exercise. Thus, we will enrol patients over a 30-month period. In a recent study on implementation of an ERAS program for patients <81 years old undergoing bowel resection for colonic cancer at our institution we enrolled about 40 patients/year. Thus, considering the wider age range and the inclusion of rectal cancer with no preoperative treatment we are confident to reach the required sample. Some patients may fear to delay surgery, but the usual wait at our institution for elective cancer surgery is about 5 weeks.

- LACK OF PATIENTS BLINDNESS. As patients in the study cannot be masked to the intervention, controls may increase their physical activity awaiting for surgery due to the hypothesised potential benefit of prehabilitation. Thus, in order to monitor this potential bias, we planned to objectively assess in both groups the amount of preoperative physical activity using an accelerometer. These data may be helpful for the interpretation of the results.



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- RISK OF OBSERVER BIAS. The assessors will be masked regarding the study group of the patients (single-blind study design).

Significance and Innovation

Routine standard perioperative care currently does not include special nutrition, exercise and psychological anxiety support before surgery. In colorectal patients undergoing surgery morbidity and mortality remains high with reduced physiological and functional capacity. Patient lifestyle is a risk factor for cancer which may impair the nutritional status that in turn aggravates deconditioning and muscle wasting, suggesting that improvement in both nutrition and functional exercise capacity may be of benefit. Traditional approaches targeted the postoperative period for rehabilitation and lifestyle changes, but postoperative complications are closely related to preoperative functional, nutritional and psychological status and the preoperative period may be a better timeframe to intervene. Implementing a trimodal program targeting those problems would represent a very innovative approach that, if beneficial, will promote a radical innovation in patients' preparation for surgery.

Description of the complementary and sinergy research team

The integrated activity of several distinct professionals with different and complementary scientific backgrounds is required. A multidisciplinary prehabilitation team was constituted in 2016 integrating the ERAS group, including surgeons, anaesthesiologists, and nurses with dietitians, a geriatrician experienced in sarcopenia and functional assessment, sports medicine physicians and psycho-oncologists.

Formal meetings of the multidisciplinary prehabilitation group will be held on a monthly basis to revise and discuss the care pathway of enrolled patients, analyse and solve potential problems.

Patients will be seen in the office by the surgeon following colorectal cancer diagnosis and screened for eligibility; preoperative staging imaging will be prescribed and surgery will be scheduled approximately 4 weeks after the end of the diagnostic work-up. Patients who provide informed consent for the study, will be randomized to either prehabilitation or control group and will be sent to sports physician, for baseline evaluation. Patients allocated to prehabilitation will be also evaluated by psycho-oncologist and dietitian and will start the trimodal prehabilitation program. Patients in both study groups will be reassessed the week before operation and at 4 and 8 weeks after surgery by the sports physician.

A specifically trained and dedicated research case manager will coordinate the research care protocol, including assessments.

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Training and tutorial activities

The ERAS group visited in December 2014 the McGill University Health Centre in Montreal (CAN) where a perioperative program including prehabilitation was investigated (<https://www.mcgill.ca/peri-op-program/>). A conference on Surgical Prehabilitation was also attended at McGill University in June 2017. At that time, meetings with the local multidisciplinary team (anesthesiologists, surgeons, nurses, kinesiologists, nutritionists) were held, and the organization as well as pattern of prehabilitation was seen and discussed.

We then defined a prehabilitaion care protocol founded on the elements selected on available evidence of clinical efficacy. Members of our prehabilitation team will formally visit the team at McGill University to further specialize on trimodal prehabilitation, and will then share the training received with the other staff members.

The McGill team will provide support to the project also by discussing and analysing the data and difficulties throughout the process.

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Timeline / Deliverables / Payable Milestones

0-1 MONTH

Setting up:



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- Screening form for patients' selection and enrolment

- Form for baseline data collection

- Form for follow-up data collection

- Investigator's manual

2-3 MONTHS

- Kick-off investigators' meeting

- Assessors recruitment and formal training

- Setting up electronic database

4-33 MONTHS

- Patients enrolment and delivery of interventions and assessments

- Electronic data entry

21-22 MONTHS

- Interim analysis

34-36 MONTHS

- Statistical analysis and manuscript drafting

Milestones 18 month

1) Development of the dedicated web-based electronic database;

2) Enrolment of 40% (N=45) of scheduled patients for both study groups;

3) Complete follow-up and data entry for 25-30% of the patients enrolled.

Milestones 36 month

1) Enrolment of 100% of scheduled patients (115 patients);

2) Complete follow-up assessment and electronic data entry for all the patients enrolled;

3) Complete statistical and cost-effectiveness data analysis;

4) First manuscript drafting.

Gantt chart

Gantt_RF-2018.pdf



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Equipment and resources available

1. Facilities Available

- SURGERY. Patients are usually seen before surgery in the preoperative clinic to determine if they are fit for surgery and to adjust their medication. Routine standard perioperative clinical care at our institution currently do not include special nutrition, exercise, and psychological support to cope with anxiety before surgery, but does include preoperative smoking cessation and hematologic optimization (target hemoglobin level 11 g/dl). After surgery, they are not offered an in-hospital exercise program, but are given generic instructions by the surgeons about mobilization and return to normal activities. Some patients may be referred to a physiotherapist by their treating doctor. The introduction of interventional measures of nutrition, exercise and coping strategies is solely for research purposes. A laparoscopic approach is elected for colorectal cancer resection. Perioperative care is guided by a standardized multi-element evidence-based comprehensive ERAS pathway following the consensus review on best care for patients undergoing colorectal surgery (Fearon KC, et al. Clin Nutr 2005;24:466-77).

- CENTRE FOR BIOCHEMICAL STUDIES APPLIED TO SPORTS MEDICINE UNIVERSITY OF FERRARA - AZIENDA USL FERRARA. Experienced centre for development, validation and implementation of comprehensive personalized protocols of physical activity for patients with several diseases including cardiovascular, metabolic and neurological diseases. The facility is equipped with all the instruments required for the evaluation of functional exercise capacity, including CPET.

- CENTRE FOR CLINICAL EPIDEMIOLOGY UNIVERSITY OF FERRARA. Experienced centre for the design and conduction of clinical studies including RCTs and for biostatistical analysis with quality data control. The centre includes a methodologist for clinical study (MPH degree) and a biostatistician with a postgraduate degree in biostatistics.

2. Subcontract

- RESEARCH CENTRE ON HEALTH MANAGEMENT UNIVERSITY OF FERRARA. An economist expert in health management is included in the research team in order to plan and conduct the cost-effectiveness and efficacy analysis.

- DIETITIAN. As part of the trimodal prehabilitaiton intervention, patients will be evaluated perioperatively (at baseline, immediately before surgery and at 4 and 8 weeks after surgery) by a dietitian for nutritional status assessment and nutritional supplementation if needed.



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Translational relevance and impact for the National Health System (SSN)

Trimodal prehabilitation can greatly affect the quality of care within the SSN affecting three dimensions:

- 1) THE STRUCTURE (where health care is delivered). Better postoperative physical function, reduced morbidity and length of hospital stay should decrease both hospital and social costs as well as support from other health-care institutions (nursing homes, family doctors). In addition, waiting lists in public hospitals might be shortened as rapid turnover yields increasing bed availability. Optimized performance and use of resources may provide financial benefits to the hospital, stimulating a wider application of such methodology within the SSN;
- 2) THE PROCESS (care received). Better physical function, reduced morbidity, accelerated recovery may all improve the quality of care;
- 3) THE OUTCOMES (mortality, morbidity, length of stay). Trimodal prehabilitation may improve the outcome of patients by decreasing postoperative morbidity, promoting safety and improving quality of life.

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type:** Ordinary/Progetti ordinari di Ricerca Finalizzata**PRINCIPAL INVESTIGATOR PROFILE**

Name FEO CARLO	Institution Emilia-Romagna
	Department/Unit Department of Surgery/U.O. Chirurgia Generale Provinciale
	Position Title Chief, U.O. Chirurgia Generale Provinciale; Associate professor

Personal Statement

- To implement a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation, expecting better physical performance at 8 weeks after surgery, decreased postoperative complications, and reduced direct and indirect costs compared to controls (patients undergoing ERAS colorectal resection for cancer with standard rehabilitation and NO prehabilitation).
- Conception of the study and research hypothesis, enroll and operate on patients, coordination of the study.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
School of Medicine, University of Sassari, Sassari (Italy)	Medical Doctor (M.D.)	1991	Medicine and Surgery
University of Ferrara and Department of Surgery Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy	Residency in General Surgery, Board certified in General Surgery	1996	General Surgery
Department of Surgery, University of California San Francisco (UCSF), San Francisco (USA)	Research fellowship	1996	Pathophysiology and surgical treatment of gastro-oesophageal reflux disease and primary motility disorders of the oesophagus.
Department of Surgery, University of California San Francisco (UCSF), San Francisco (USA)	Clinical fellowship	1998	Advanced laparoscopic surgery
University of Bologna, Bologna (Italy)	Master degree	2015	Health policy

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Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Positions**

Institution	Division / Research group	Location	Position	From year	To year
Azienda Ospedaliero-Universitaria di Ferrara	UO Clinica Chirurgica	Ferrara, Italy	Assistant surgeon	1999	1999
Azienda Ospedaliero-Universitaria di Ferrara	UO Clinica Chirurgica	Ferrara Italy	Consultant	1999	2002
University of Ferrara	UO Clinica Chirurgica	Ferrara, Italy	Assistant professor	2002	2011
Azienda Ospedaliero-Universitaria di Ferrara	UO Clinica Chirurgica	Ferrara, Italy	Attending	2002	2017
University of Ferrara	UO Clinica Chirurgica	Ferrara, Italy	Associate professor	2011	2018
Azienda USL di Ferrara	U.O. Chirurgia Generale Provinciale	Ferrara, Italy	Chief	2017	2022

Official H index: 20.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 7006128539**ORCID ID:** 0000-0003-0699-568**RESEARCH ID:** K-5134-2016**Awards and Honors:**

1999: Research scholarship Azienda Ospedaliera di Ferrara

2010-Present: Fellow American College of Surgeons

2011-13, 2018-20: Vice-President Società Medico Chirurgica di Ferrara

2012-17: Member Board of Research Azienda Ospedaliero-Universitaria di Ferrara

2015: Best session poster at Euroanesthesia 2015, Berlin (D)

2016-18: Educational Dean School of Nursing University of Ferrara

REVIEWER of journals (eg, Lancet, Ann Surg) and EDITORIAL BOARD of World J Gastrointest Surg, J Lap Adv Surg Tech

Other CV Informations:

1991: Medical Doctor degree cum laude

1996: Educational Commission Foreign Medical Graduate (ECFMG) Standard Certificate valid indefinitely

1996: Research fellow, Department of Surgery University of California San Francisco (UCSF), USA

1996-1998: Clinical fellow, Department of Surgery UCSF

2006-Present: Instructor Advanced Trauma Life Support

1997-2005: Member Society American Gastrointestinal Endoscopic Surgeons (SAGES)

1997-2010: Member Society Surgery Alimentary Tract (SSAT)

2006-Present: Member European Association Endoscopic Surgeons (EAES)

2013-2014, 2015-2016: Director Postgraduate course in OR Surgical Nursing, University of Ferrara

2013, 2018: National Academic Qualification as Full Professor of Surgery

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Selected peer-reviewed publications of the PI**

Valid for PI minimum expertise level				
Title	DOI	PMID	Cit. **	P.*
Laparoscopic approach for esophageal achalasia with epiphrenic diverticulum. Surgical Laparoscopy, Endoscopy and Percutaneous Techniques 2001;11:112-115	10.1097/00019509-200104000-00009	11330375	7	F
The ideal lenght of hospital stay in the surgical treatment of colo-rectal cancer. Annali Italiani di Chirurgia 2002;73:13-16		12148416	4	F
Early oral feeding after colorectal resection: a randomized controlled study. ANZ J Surg. 2004;74:298-301		15144242	67	F
Preoperative dexamethasone improves postoperative nausea and vomiting following laparoscopic cholecystectomy: A randomised controlled trial. Br J Surg 2006;95:295-299	10.1097/CEJ.0b013e3283429ea3	16400707	57	F
Fast track postoperative management for patients undergoing elective colorectal resections: A controlled trial Am Surgeon 2009;75:1247-1251		19999921	14	F
The first 2 years of colorectal cancer screening in Ferrara, Italy. Eur J Cancer Prev 2011;20:166-168	10.1097/CEJ.0b013e3283429ea3	21445018	3	C
Minimally invasive myotomy for the treatment of esophageal achalasia: The evolution of the surgical procedure and of therapeutic algorithm. Surg Laparosc Endosc Percutan Tech 2012;22:83-87	10.1097/SLE.0b013e318243368f	22487617	5	L
Esophageal achalasia with recurrent aspiration pneumoniae treated by laparoscopic Heller myotomy. Am Surgeon 2012;78:168-170		22524750	0	F
Radio-guided selective compartment neck dissection improves staging in papillary thyroid carcinoma: a prospective study on 345 patients with a 3-year follow-up. Surgery 2014;156:147-157 PMID:	10.1016/j.surg.2014.03.045	24929764	6	L
Preoperative endoscopic tattooing to mark the tumour site does not improve lymph node retrieval in colorectal cancer: a retrospective cohort study. J Negat Results Biomed 2015;14:9	10.1186/s12952-015-0027-7	25947298	2	F
Applicability of laparoscopic approach to the resection of large adrenal tumours: A retrospective cohort study on 200 patients. Surg Endosc 2016;30:3532-3540.	10.1007/s00464-015-4643-6	26541739	1	F
The impact of an Enhanced Recovery Program in elective retroperitoneal abdominal aortic aneurism repair: A retrospective cohort study on 221 patients. J Vasc Surg 2016;63:888-894	10.1016/j.jvs.2015.09.060	26806521	4	F
Laparoscopic versus open incisional hernia repair: A retrospective cohort study with costs analysis on 269 patients. Hernia 2017;21:609-618	10.1007/s10029-017-1601-3	28396956	1	L
Impact of a colorectal enhanced recovery program implementation on clinical outcomes and institutional costs: a prospective cohort study with retrospective control. Int J Surg 2018;203: 206-213	10.1016/j.ijsu.2018.03.005	29548700	0	L

* Position: F=First L=Last C=Corrispondent

** Autocertificated

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****For evaluation CV**

Title	DOI	PMID	Cit. *
Importance of pre- and postoperative pH monitoring in patients with esophageal achalasia. J Gastrointest Surg 1997;1:505-510		9834385	66
Comparison of laparoscopic and thoracoscopic Heller myotomy for achalasia. J Gastrointest Surg 1998;2:561-566		10457314	71
Laparoscopic repair of paraesophageal hiatal hernias. J Am Coll Surg 1998;186:428-432		9544957	83
An analysis of operation for GERD: Identifying the important technical elements. Arch Surg 1998;113:600-607		9637457	75
Laparoscopic Heller myotomy relieves dysphagia in achalasia when the esophagus is dilated. Surg Endosc 1999;13:843-847		10449836	72
The effects of previous treatment on the results of laparoscopic Heller myotomy for achalasia. Dig Dis Sci 1999;44:2270-2276		10573373	116
Effect of laparoscopic fundoplication on gastroesophageal reflux disease-induced respiratory symptoms. J Gastrointest Surg 2000;4:143-149		10675237	82
Preoperative dexamethasone improves postoperative nausea and vomiting following laparoscopic cholecystectomy: A randomised controlled trial. Br J Surg 2006;93:295-299	10.1002/bjs.5252	16400707	57
Intrathoracoscopic localization techniques. Review of literature. Surg Endosc 2006;20:1341- 1347	10.1007/s00464-005-0407-z	16703435	26
Clinical and therapeutic importance of sentinel node biopsy of the internal mammary chain in patients with breast cancer: a single-center study with long-term follow-up. Ann Surg Oncol 2006;13:1338-1343	10.1245/s10434-006-9062-4	16952022	38

* Autocertified

Grant

Funded Institution / Country	Year	Title	Position in Projects
Ministry of Health	2012-2016	The implementation of an enhanced recovery program (fast track) after colorectal resection for colonic cancer Coordinator.	Coordinator

Employment contract extension:

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Biographical Sketch Contributors 1**

Name:	Institution	Azienda Usl di Ferrara - Emilia-Romagna
Graffi Giovanni	Department/Unit	Department of Sport Medicine/Division of Exercise and Sports Medicine - Azienda USL di Ferrara
	Position Title	Attending, Program coordinator

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Ferrara	Medical Doctor (M.D.)	1983	Medicine and Surgery
University of Chieti	Residency in sports medicine, Board certified in sports medicine	1986	Sports Medicine

Personal Statement:

- To implement a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation, expecting better physical performance at 8 weeks after surgery, decreased postoperative complications, and reduced direct and indirect costs compared to controls (patients undergoing ERAS colorectal resection for cancer with standard rehabilitation and NO prehabilitation).
- Prehabilitation of patients.

Institution	Division / Research group	Location	Position	From year	To year
Italian Olympic Committee	Centre for Biochemical studies applied to Sports Medicine, University of Ferrara - Azienda USL of Ferrara	Ferrara, Italy	Research fellow	1984	1990
Italian National Health Care System	USL n. 32 (Emilia-Romagna) e ULSS 21 (Veneto)	Ferrara and Legnago, Italy	Sports Medicine physician	1992	2003
Azienda Ospedaliero-Universitaria di Ferrara	Cardiac rehabilitation program	Ferrara, Italy	Sports Medicine Physician	1997	2001
University of Ferrara	Department of Biomedical and Surgical Specialization Sciences	Ferrara, Italy	Assistant Professor of Sports Medicine	2004	2018



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Project Title:

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272

Principal Investigator: FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna

Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata

Awards and Honors

Official H index: 9.0 (autocertificated)

Source: Scopus

Scopus Author Id: 6505775983

ORCID ID: 0000-0001-9649-8875

RESEARCH ID: K-5391-2016

Awards and Honors:

- 2012, 2014: Award as best scientific presentation at National meeting of Italian Group of Cardiac Rehabilitation
- 2005: National patent

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Biographical Sketch Contributors 2**

Name: VOLPATO STEFANO	Institution Azienda Ospedaliero-Universitaria di Ferrara - Emilia-Romagna
	Department/Unit Department of Medicine/Division of Internal Medicine/Center for Clinical Epidemiology - Azienda Ospedaliero-Universitaria di Ferrara
	Position Title Attending physician, Associate Professor

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Ferrara, Ferrara, Italy	Medical Doctor (MD)	1991	Medicine and Surgery
University of Ferrara, School of Medicine, Ferrara, Italy	Residency in Endocrinology and Metabolic disease Board in Endocrinology and Metabolic disease	1997	Endocrinology and Metabolism
Johns Hopkins University, School of Hygiene and Public Health, Bethesda, Maryland	Master in Public Health	1999	Epidemiology, Biostatistics, Clinical studies, including clinical trials
University of Padova, School of Medicine, Padua, Italy	Residency in Geriatrics, Board certified in Geriatrics	2006	Geriatrics and Gerontology

Personal Statement:

- To implement a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation, expecting better physical performance at 8 weeks after surgery, decreased postoperative complications, and reduced direct and indirect costs compared to controls (patients undergoing ERAS colorectal resection for cancer with standard rehabilitation and NO prehabilitation).
- Design and implementation of the study and statistical analysis.

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata**

Institution	Division / Research group	Location	Position	From year	To year
University of Ferrara, Azienda Ospedaliero- Universitaria di Ferrara	Department of Medicine	Ferrara	Clinical Staff Fellow	1997	1998
National Institute on Aging, National Institutes of Health	Epidemiology, Demography, and Biometry Program	Bethesda, Maryland, USA	Research Fellow	1999	2001
University of Ferrara, Azienda Ospedaliero- Universitaria di Ferrara	Department of medical Sciences	Ferrara, Italy	Assistant professor	2001	2014
University of Ferrara, Azienda Ospedaliero- Universitaria di Ferrara	Department of medical Sciences	Ferrara, Italy	Associate Professor	2014	2018

Awards and Honors**Official H index:** 47.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 35330577100**ORCID ID:** 0000-0003-4335-6034**RESEARCH ID:** H-2977-2014**Awards and Honors:**

1991: Graduated Magna Cum Laude, University of Ferrara

1997: Scholarship by Arlotti Foundation, Italy, for the research project: "Epidemiological study of disability and correlated metabolic diseases in the elderly"

2005: Award as young researcher for the best scientific article in the 2003-2005 period. Italian Foundation for Aging Research (F.I.R.I) in the 2003-2005 period.

2009: Fellow of the Gerontological Society of America

2014: Highly Cited Researcher (Thompson Reuters-Social Sciences)

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Biographical Sketch Contributors 3**

Name: DE TROIA ALESSANDRO	Institution Azienda Ospedaliero-Universitaria di Ferrara - Emilia-Romagna
	Department/Unit Department of Surgery/U.O. Chirurgia 2 - Azienda Ospedaliero-Universitaria di Ferrara
	Position Title Attending

Education/Training - Institution and Location	Degree	Year(s)	Field of study
School of Medicine, University of Ferrara, Ferrara, Italy	Medica Doctor (M.D.)	2008	Medicine and Surgery
University of Ferrara and Department of Surgery Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy	Residency in General surgery Board certified in General Surgery	2015	General Surgery
University of Ferrara and Department of Surgery Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy	Research Fellowship	2016	Intraoperative radiotherapy in breast cancer surgery

Personal Statement:

- To implement a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation, expecting better physical performance at 8 weeks after surgery, decreased postoperative complications, and reduced direct and indirect costs compared to controls (patients undergoing ERAS colorectal resection for cancer with standard rehabilitation and NO prehabilitation).
- Screening and enrollment of eligible patients.

Institution	Division / Research group	Location	Position	From year	To year
University of Ferrara	U.O. Clinica Chirurgica - Azienda Ospedaliero-Universitaria di Ferrara	Ferrara, Italy	Research and Clinical Fellow	2015	2016

Awards and Honors**Official H index:** 1.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 57200918030**ORCID ID:** 0000-0002-0078-3303**RESEARCH ID:** K-7691-2016**Awards and Honors:**

- 2008: Degree in Medicine and Surgery University of Ferrara Italy 110/110 cum laude
- 2010: Winner of the "Premio di Studio di ricerca in oncologia E.Zanetti" - Graduate Thesis in Oncology
- 2016: Research Collaborator (Enrollment - Methodologist) in RF -2013-02358165 "Axillary Reverse Mapping (ARM). Try to identify and spare lymphatic pathways in breast cancer surgery to prevent breast cancer related lymphedema (BCRL)" P.



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Project Title:

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272

Principal Investigator: FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna

Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata

I. Prof. P. Carcoforo, founded by Italian Ministry of Health

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Biographical Sketch Contributors 4**

Name: CARUSO ROSANGELA	Institution Emilia-Romagna
	Department/Unit Department of Mental Health/Division of Psychiatry - Azienda USL di Ferrara
	Position Title Evaluate and treat mood and psychological disorders of the patients

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Ferrara, Ferrara, Italy	Medical Doctor (M.D.)	2004	Medicine and Surgery
University of Ferrara	Residency in Psychiatry, Board certified in Psychiatry	2008	Psychiatry

Personal Statement:

- To implement a trimodal prehabilitation program (physical exercise, psychological support and nutritional optimization) in patients undergoing ERAS colorectal resection for cancer with standard rehabilitation, expecting better physical performance at 8 weeks after surgery, decreased postoperative complications, and reduced direct and indirect costs compared to controls (patients undergoing ERAS colorectal resection for cancer with standard rehabilitation and NO prehabilitation).

- Evaluate and treat mood and psychological disorders of the enrolled patients with colorectal cancer.

Institution	Division / Research group	Location	Position	From year	To year
University of Ferrara	Department of Biomedical Sciences and Surgical Specialties	Ferrara	Resident in Psychiatry	2007	2012
University of Ferrara	Department of Biomedical Sciences and Surgical Specialties	Ferrara	PhD Candidate	2012	2014
University of Ferrara - Azienda USL di Ferrara	Department of Biomedical Sciences and Surgical Specialties/ Department of Mental Health	Ferrara	Assistant Professor/Psychiatrist	2015	2018



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Project Title:

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272

Principal Investigator: FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna

Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata

Awards and Honors

Official H index: 9.0 (autocertificated)

Source: Scopus

Scopus Author Id: 36623259500

ORCID ID: 0000-0002-6662-2270

RESEARCH ID: L-4254-2016

Awards and Honors:

- Member of the Psycho-Oncology Italian Association (SIPO)
- Member of the Italian Consultation Psychiatry Society (SIPC)
- Founding member of the Italian Cognitive-Analytic Therapy Association (ITACAT)

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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Expertise Research Collaborators**

Selected peer-reviewed publications of the Research Group / Collaborators				
Collaborator	Title	DOI	PMID	Cit. *
Grazzi Giovanni	Home-centred physical fitness programme in morbidly obese individuals: a randomized controlled trial. Clin Rehabil 2008; 22:940-950	10.1177/0269215508092788	18955426	10
VOLPATO STEFANO	Predictive value of the Short Physical Performance Battery following hospitalization in older patients. J Gerontol A Biol Sci Med Sci. 2011;66:89-96	10.1093/gerona/glr167	20861145	116
CARUSO ROSANGELA	Educational Intervention in cancer outpatients clinics on routine screening for emotional distress: an observational study. Psychooncology 2011;20:669-674	10.1002/pon.1944	21370316	31
VOLPATO STEFANO	Role of muscle mass and muscle quality in the association between diabetes and gait speed. Diabetes Care 2012;35:1672-1679	10.2337/dc11-2202	22596176	82
VOLPATO STEFANO	Handgrip strength predicts persistent walking recovery after hip fracture surgery. Am J Med 2013;126:1068-1075	10.1016/j.amjmed.2013.04.017	24054175	23
Grazzi Giovanni	Association between VO ₂ peak estimated by a 1-km treadmill walk and mortality. Int J Cardiol 2014;173:248-252	10.1016/j.ijcard.2014.02.03	24630380	10
VOLPATO STEFANO	Volpato S, Guralnik JM. Hip fractures: comprehensive geriatric care and recovery. Lancet. 2015;385:1594-1595	10.1016/S0140-6736(14)61592-0	25662417	4
CARUSO ROSANGELA	Role of Psychosocial Variables on chemotherapy-induced nausea and vomiting and health-related quality of life among cancer patients. A European Study. Psychother Psychosom 2015;84:339-347	10.1159/000431256	26402426	16
Grazzi Giovanni	Improved walking speed is associated with lower hospitalisation rates in patients in an exercise-based secondary prevention programme. HEART 2016;102:1902-1908	10.1136/heartjnl-2015-309126	27390367	8
VOLPATO STEFANO	Prevalence and Clinical Correlates of Sarcopenia, Identified According to the EWGSOP Definition and Diagnostic Algorithm, in Hospitalized Older People: The GLISTEN Study J Gerontol A Biol Sci Med Sci,2017;72:1575-1581	10.1093/gerona/glw343	28329345	5

* Autocertificated

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Grant**

Funded Institution / Country	Year	Title	Position in Projects	Collaborator
Istituto Oncologico Romagnolo, Forlì Italy	2010-2012	Relational and psychosocial variables connected with adherence to therapies antiemetic during chemotherapy - FUND GRANT: €10.000	Collaborator	VOLPATO STEFANO
Programma di Ricerca Regione- Università 2010-2012: Area 1 Ricerca Innovativa Programma Strategico area 1	2013	Role of Rehabilitation after cerebral and myocardial damage - FUND GRANT: €27000	Collaborator	VOLPATO STEFANO
Programma CCM (CENTRO NAZIONALE PER LA PREVENZIONE E IL CONTROLLO DELLE MALATTIE)	2013	Implementazione di un modello organizzativo integrato per la gestione del paziente con demenza: dalla prevenzione alla cura con presa in carico - POSITION IN PROJECT: Local PI - FUND GRANT: €49.000	Coordinator	VOLPATO STEFANO
Regione Emilia Romagna - Programma di Ricerca Regione-Università 2014 - Area 3 FORMAZIONE ALLA RICERCA E CREAZIONE DI RESEARCH NETWORK	2014	Formazione di una rete statistica aziendale per il supporto alla ricerca biomedica - FUND GRANT: €83.000	Coordinator	VOLPATO STEFANO
Italian Ministry of Health	2016	RF -2013-02358165: Axillary Reverse Mapping (ARM). Try to identify and spare lymphatic pathways in breast cancer surgery to prevent breast cancer related lymphedema (BCRL)	Collaborator	DE TROIA ALESSANDRO
H2020-HEALTH	2017	EUROlinkCAT: Establishing a linked European Cohort of Children with Congenital Anomalies - POSITION IN PROJECT: Local PI - FUND GRANT: €343.217	Coordinator	VOLPATO STEFANO

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
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Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Total proposed budget (Euro)**

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	270.000,00			0,00
1b Researchers' Contracts	174.000,00	0,00	174.000,00	48,33
2 Equipment (Leasing - Rent)	130.000,00	90.000,00	40.000,00	11,11
3a Supplies	30.900,00	0,00	30.900,00	8,58
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	30.100,00	0,00	30.100,00	8,36
3d Patient Costs	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	10.000,00	0,00	10.000,00	2,78
5 Publication Costs	6.000,00	0,00	6.000,00	1,67
6 Convegni	3.000,00	0,00	3.000,00	0,83
7 Travels	6.000,00	0,00	6.000,00	1,67
8 Overheads	30.000,00	0,00	30.000,00	8,33
9 Coordination Costs	30.000,00	0,00	30.000,00	8,33
Total	720.000,00	360.000,00	360.000,00	100,00

Report the Co-Funding Contributor:

Staff salary: PI, CO-PI and all collaborators

Equipment: depreciation of the equipment value

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Budget Justification**

1a Staff Salary	salary Pi, Co-PI, RUO and other collaborators
1b Researchers' Contracts	contracts for the management of the whole study workup
2 Equipment (Leasing - Rent)	depreciation of equipment value - specific equipment for the study: Accelerometer x 10, Bioelectrical impedance analyser x 2 for body composition analysis, Manual idraulic dynamometer x 2 for grip strength evaluatation, laptops for real time data entry
3a Supplies	consumables and devices useful for the successful completion of the project
3b Model Costs	none
3c Subcontracts	this budget will cover expences for economical analysis and nutritional evaluation of patients on prehabilitation
3d Patient Costs	none
4 IT Services and Data Bases	software related to the development of the project
5 Publication Costs	abstract submission for interim results and full papers for final results
6 Convegni	partecipation in workshop to disseminate results
7 Travels	travels will be needed to attend pertinent meeting of specific interest to the project
8 Overheads	general costs generated to project management
9 Coordination Costs	logistic costs relating to data presentation at meeting and congresses

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata**

Proposed total budget UO1 Institution: Emilia-Romagna (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	90.000,00			0,00
1b Researchers' Contracts	84.000,00	0,00	84.000,00	35,99
2 Equipment (Leasing - Rent)	130.000,00	90.000,00	40.000,00	17,14
3a Supplies	16.400,00	0,00	16.400,00	7,03
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	18.000,00	0,00	18.000,00	7,71
3d Patient Costs	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	10.000,00	0,00	10.000,00	4,28
5 Publication Costs	6.000,00	0,00	6.000,00	2,57
6 Convegni	3.000,00	0,00	3.000,00	1,29
7 Travels	6.000,00	0,00	6.000,00	2,57
8 Overheads	20.000,00	0,00	20.000,00	8,57
9 Coordination Costs	30.000,00	0,00	30.000,00	12,85
Total	413.400,00	180.000,00	233.400,00	100,00

Report the Co-Funding Contributor:

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Budget Justification**

1a Staff Salary	salary PI, and other collaborators
1b Researchers' Contracts	contracts for the management of the whole study workup
2 Equipment (Leasing - Rent)	depreciation of equipment value specific equipment for the study: Accelerometer x 10, Bioelectrical impedance analyser x 2 for body composition analysis, Manual idraulic dynamometer x 2 for grip strength evaluation, laptops for real time data entry
3a Supplies	consumables and devices useful for the successful completion of the project
3b Model Costs	none
3c Subcontracts	this budget will cover expences for economical analysis and nutritional evaluation of patients on prehabilitation
3d Patient Costs	none
4 IT Services and Data Bases	software related to the development of the project
5 Publication Costs	abstract submission for interim results and full papers for final results
6 Convegni	partecipation in workshop to disseminate results
7 Travels	travels will be needed to attend pertinent meeting of specific interest to the project
8 Overheads	general costs generated to project management
9 Coordination Costs	logistic costs relating to data presentation at meeting and congresses

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata**

Proposed total budget UO2 Institution: Azienda Usl di Ferrara - Emilia-Romagna (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	90.000,00			0,00
1b Researchers' Contracts	60.000,00	0,00	60.000,00	66,67
2 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a Supplies	14.500,00	0,00	14.500,00	16,11
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	8.500,00	0,00	8.500,00	9,44
3d Patient Costs	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	0,00	0,00	0,00	0,00
5 Publication Costs	0,00	0,00	0,00	0,00
6 Convegni	0,00	0,00	0,00	0,00
7 Travels	0,00	0,00	0,00	0,00
8 Overheads	7.000,00	0,00	7.000,00	7,78
9 Coordination Costs				0,00
Total	180.000,00	90.000,00	90.000,00	100,00

Report the Co-Funding Contributor:



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Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli Enti

BANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017

Project Title:

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272

Principal Investigator: FEO CARLO

Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4

Applicant Institution: Emilia-Romagna

Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata

Budget Justification

1a Staff Salary	salary co-PI
1b Researchers' Contracts	contracts for the management of the whole study workup
2 Equipment (Leasing - Rent)	none
3a Supplies	consumables and devices useful for the successful completion of the project
3b Model Costs	none
3c Subcontracts	this budget will cover expences for economical analysis and nutritional evaluation of patients on prehabilitation
3d Patient Costs	none
4 IT Services and Data Bases	none
5 Publication Costs	none
6 Convegni	none
7 Travels	none
8 Overheads	general costs generated to project management
9 Coordination Costs	none

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
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esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata**

Proposed total budget UO3 Institution: Azienda Ospedaliero-Universitaria di Ferrara -
Emilia-Romagna (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	90.000,00			0,00
1b Researchers' Contracts	30.000,00	0,00	30.000,00	81,97
2 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a Supplies	0,00	0,00	0,00	0,00
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	3.600,00	0,00	3.600,00	9,84
3d Patient Costs	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	0,00	0,00	0,00	0,00
5 Publication Costs	0,00	0,00	0,00	0,00
6 Convegni	0,00	0,00	0,00	0,00
7 Travels	0,00	0,00	0,00	0,00
8 Overheads	3.000,00	0,00	3.000,00	8,20
9 Coordination Costs				0,00
Total	126.600,00	90.000,00	36.600,00	100,00

Report the Co-Funding Contributor:

*Ministero della Salute*Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli EntiBANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017**Project Title:**

Multimodal prehabilitation in colorectal cancer patients to improve functional capacity and lower postoperative complications: A randomized clinical trial.

Project Code: RF-2018-12367272**Principal Investigator:** FEO CARLO**Research Type:** b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecniche/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4**Applicant Institution:** Emilia-Romagna**Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata****Budget Justification**

1a Staff Salary	salary UO collaborators
1b Researchers' Contracts	contracts for the management of the whole study workup
2 Equipment (Leasing - Rent)	none
3a Supplies	none
3b Model Costs	none
3c Subcontracts	this budget will cover expences for economical analysis and nutritional evaluation of patients on prehabilitation
3d Patient Costs	none
4 IT Services and Data Bases	none
5 Publication Costs	none
6 Convegni	none
7 Travels	none
8 Overheads	general costs generated to project management
9 Coordination Costs	none



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BANDO RICERCA FINALIZZATA 2018
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Applicant Institution: Emilia-Romagna

Project Type: Ordinary/Progetti ordinari di Ricerca Finalizzata

Principal Investigator Data

Cognome: FEO

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Qualifica: DIRETTORE STRUTTURA COMPLESSA - UO CHIRURGICA GENERALE PROVINCIALE

Struttura: U.O. CHIRURGIA GENERALE PROVINCIALE -DIPARTIMENTO CHIRURGICO - AUSL Ferrara

Istituzione: REGIONE EMILIA-ROMAGNA - AZIENDA USL