Il modello FORCE: L’approccio Integrato al Paziente Oncologico

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What’s New???
Treatment-related Decision-making process in cancer
Treatment Goals in Advanced Disease

When patients are **still fit** for active treatment:

- Symptom control
- Disease control
- Prolonged survival

When patients are **no longer fit** for active treatment:

- Best supportive and palliative care
- Treatment goals ➔ Goals of care

**OVERALL GOAL**

Best possible Quality of Life
An integrated approach

ASCO statement (2009) and provisional opinion (2012)

“(…) combined standard oncology care and palliative care should be considered early in the course of illness for any patient with metastatic cancer and/or high symptom burden.”
Benefit of early palliative care is REAL!

Primary endpoint: QoL
Secondary endpoint: overall survival, mood, use of healthcare services, aggressiveness in the EoL
Benefit of early palliative care is REAL!

Study results:

Improved QoL in the intervention group for the total FACT-L scale, the LCS, and the Trial Outcome Index

Lower depression scores in the intervention group measured by HADS and PHQ-9

More aggressive end-of-life care in the control group (54% vs. 33%, p = 0.05)

Less advanced care planning documentation in the control group (28% vs. 53%, p = 0.05)

Temel JS, NEJM 2010
Palliative Care: values & principles

- Promoting dignity and autonomy
- Multidimensional assessment and management of patient and caregivers
- Relief of suffering across the trajectory of disease, continuous coordination of services including end-of-life & bereavement care
- Optimise quality of life
- Supporting decision-processes, advanced care planning and preparing transitions
- Multi-professional approaches

Focus On Research and CarE (FORCE)

Approccio di Presa in Carico Globale Integrata
Evidence-based nel Paziente Oncologico

Oncologia Medica, Dipartimento di
Medicina, Università di Verona,
Azienda Ospedaliera Universitaria Integrata,
Verona
Filling the gap ... with our patients

I think you'll find I'm one of the most empathetic doctors around.
Filling the gap ... with our colleagues
A Team taking care of the Person

Oncologist
(dr. Sara Pilotto)
- Coordinator

Psycho-oncologist
(dr. Daniela Tregnago)
- Psychological individual support

Kinesiologist
(dr. Alice Avancini)
- Adapted physical activity

Dietitian
(dr. Ilaria Trestini)
- Screening e nutritional assessment
- Nutritional Counseling
... with a Personalized Approach
... with a Scientific Evidence-Based Approach

Create a model to be universally implemented into the oncological setting, but also for other chronic complex disease

Provide new reliable scientific evidences to increase the currently available knowledge

Give to our Patients the best therapeutical approach
A lot of hard work ..
Prognostic impact of early nutritional support in patients affected by locally advanced and metastatic pancreatic ductal adenocarcinoma undergoing chemotherapy.

Trestini I, Carbognin L, Sperduti I, Bonaiuto C, Auriemma A, Melisi D, Salvatore L, Bria E, Tortora G.

The time between the diagnosis of PDAC and the nutritional support was an independent predictor of OS.
Clinical implication of changes in body composition and weight in patients with early-stage and metastatic breast cancer.

Evidence-based nutrition educational intervention improves adherence to a dietary guidelines (ADG) and weight management among early-stage breast cancer (EBC) patients (pts): a prospective trial.

<table>
<thead>
<tr>
<th>Variables</th>
<th>At baseline</th>
<th>After 12-months intervention</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>underweight, N (%)</td>
<td>5 (3.3)</td>
<td>0 (0)</td>
<td>p=0.003</td>
</tr>
<tr>
<td>normal weight, N (%)</td>
<td>73 (48.0)</td>
<td>126 (82.9)</td>
<td></td>
</tr>
<tr>
<td>overweight, N (%)</td>
<td>60 (39.5)</td>
<td>21 (13.8)</td>
<td></td>
</tr>
<tr>
<td>obesity, N (%)</td>
<td>14 (9.2)</td>
<td>5 (3.3)</td>
<td></td>
</tr>
<tr>
<td>WC (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>central obesity</td>
<td>58 (38.2)</td>
<td>11 (7.2)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>not central obesity</td>
<td>94 (61.8)</td>
<td>141 (92.8)</td>
<td></td>
</tr>
</tbody>
</table>
Tailored nutritional intervention in patients affected by Head and Neck Cancer undergoing chemotherapy and/or radiotherapy: a ‘Real-World’ study.


The nutritional intervention was an independent predictor for better OS.
Muscle derangement and alteration of the nutritional machinery in NSCLC.

IMPACT OF NUTRITIONAL DERANGEMENT ON TREATMENT OUTCOME IN ADVANCED NON-SMALL-CELL LUNG CANCER (A-NSCLC) PATIENTS (PTS).


PFS in relazione all’NRS-2002

OS in relazione all’NRS-2002

I pazienti con NRS-2002 ≤ 3 beneficiano anche di una migliore ORR (66.7% vs 21.4%, \( p=0.016 \)) rispetto a coloro con NRS-2002 > 3

L’indice di massa corporea (IMC) non influenza PFS e OS
Risultati – Deplezione muscolare e immunoterapia

Nei pazienti trattati con **immunoterapia** (n=16, 42.1%) la riduzione della massa magra correla con un peggior *outcome* (PFS, OS e ORR).
Malnutrition significantly improved after nutritional intervention

- Baseline: 35.3%
- After 3-months of intervention: 88.2%

$p = 0.004$
Impact of Cognitive-Behavioral-Therapy (CBT) on levels of anxiety, depression and distress in cancer patients (pts)

Physical Activity and Exercise in Lung Cancer Care: Will Promises Be Fulfilled?

Alice Avancini, Giulia Sartori, Anastasios Gkountakos, Miriam Casali, Ilaria Trestini, Daniela Tregnago, Emilio Bria, Lee W. Jones, Michele Miele, Massimo Lanza, Sara Pilotto

Avancini A., et al. The Oncologist 2019
**C.H.O.i.C.E. (Choose Health: Oncological patients Centered Exercise)**

- Trial randomizzato multicentrico, che valuti l’efficacia preliminare, di un programma di esercizio fisico, basato sulle attuali linee guida, ma tenga in considerazione le preferenze delle persone.

**M.O.T.O (Motives, Obstacles Towards run in Oncology)**

- Analisi qualitativa delle motivazioni e delle barriere nell’attività podistica, nel contesto dell’iniziativa «Run for Science».

**E.D.u.C.A. (Educational materials Development for physical activity in CAnce patients)**

- Validazione di una guida informativa e pratica sull’attività fisica nei pazienti con diagnosi oncologica.


- Identificare l’opinione degli operatori sanitari verso la raccomandazione della pratica di esercizio fisico nel contesto oncologico;
- Identificare le conoscenze, le barriere e le motivazioni riguardo la promozione dell’esercizio fisico.
S.P.R.I.N.T. (Short Preoperative tRaining In Lung patientTs)

• Trial randomizzato, che valuta l’efficacia, di un programma di esercizio fisico in fase preoperatoria, sulle complicanze postoperatorie;

P.E.P.SY (Preoperative Exercise in Pancreatic SurgerY)

• Studio prospettico osservazionale per valutare il ruolo della fitness fisica nell’outcome chirurgico (complicanze e mortalità).

..e molti altri in arrivo..
Team Work makes Dream Work!
FASE 1
• Obiettivo: esplorare le attitudini, le conoscenze, le barriere e le motivazioni verso la pratica dell’attività fisica
• Metodologia: indagine qualitativa (focus group)

FASE 2
• Obiettivo: validazione dell’adeguatezza della guida informativa e pratica sull’attività fisica dopo una diagnosi oncologica, da parte di un gruppo di pazienti (n=10) e di esperti (n=20)
• Metodologia: indagine quantitativa (cross-sectional)

FASE 3
• Obiettivo: verifica della preliminare efficacia della guida;
• Metodologia: interventistico (prospettico longitudinale)
Run with cancer at “Run for Science”: a qualitative study to evaluate the barriers and the motivations in running

“Sfida” legata alla storia passata di malattia
Dare speranza agli altri pazienti
Supporto da parte degli amici e del personale sanitario
Programma organizzato e strutturato

Infortuni ed effetti collaterali legati al trattamento
Istruttori poco qualificati
Ambiente inquinato
Cultura tradizionalista

Avancini A, et al. Re-submitted to PLOS One after revisions

↑ Adeherence to running program
↑ Compliance to running program
**Aims:** Examine the change of physical activity, weight management and emotional functioning during and after adjuvant therapy for early stage breast cancer.

**Physical activity level**

- Baseline: Low = 71%, Moderate = 43%, High = 41%
- Follow-up: Low = 0%, Moderate = 16%, High = 0%

**Body Mass Index**

- Baseline: <18.5 = 0%, 18.5-24.9 = 9%, 25-29.9 = 51%, >30 = 56%
- Follow-up: <18.5 = 18%, 18.5-24.9 = 25%, 25-29.9 = 31%, >30 = 18%

**Emotional functioning**

- Baseline
- Follow-up

Avancini A, et al. SISMES 2019
## PROSPECTIVE LIFESTYLE (PHYSICAL ACTIVITY, NUTRITION AND PSYCHOLOGICAL ASPECT) ASSESSMENT IN EARLY STAGE BREAST CANCER

<table>
<thead>
<tr>
<th></th>
<th>Body mass index at baseline</th>
<th>Emotional functioning at baseline</th>
<th>Energy expenditure at follow-up</th>
<th>Emotional functioning at follow-up</th>
<th>Body mass index at follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy expenditure at</strong></td>
<td>-0.393</td>
<td>0.195</td>
<td>0.175</td>
<td>-0.0109</td>
<td>-0.381</td>
</tr>
<tr>
<td><strong>baseline</strong></td>
<td>P&lt;0.001</td>
<td>P=0.0575</td>
<td>P=0.0625</td>
<td>P=0.908</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td><strong>Body mass index at</strong></td>
<td>-0.528</td>
<td>-0.088</td>
<td>-0.152</td>
<td>0.833</td>
<td></td>
</tr>
<tr>
<td><strong>baseline</strong></td>
<td>P&lt;0.001</td>
<td>0.351</td>
<td>P=0.106</td>
<td>p&gt;0.001</td>
<td></td>
</tr>
<tr>
<td><strong>Emotional functioning</strong></td>
<td>-0.112</td>
<td>-0.112</td>
<td>0.221</td>
<td>-0.443</td>
<td></td>
</tr>
<tr>
<td><strong>at baseline</strong></td>
<td>P=0.275</td>
<td>P=0.275</td>
<td>P=0.0308</td>
<td>P&lt;0.001</td>
<td></td>
</tr>
<tr>
<td><strong>Energy expenditure at</strong></td>
<td></td>
<td></td>
<td>0.247</td>
<td>-0.0444</td>
<td></td>
</tr>
<tr>
<td><strong>follow-up</strong></td>
<td></td>
<td></td>
<td>P=0.0083</td>
<td>P=0.642</td>
<td></td>
</tr>
<tr>
<td><strong>Emotional functioning</strong></td>
<td></td>
<td></td>
<td></td>
<td>-0.155</td>
<td></td>
</tr>
<tr>
<td><strong>at follow-up</strong></td>
<td></td>
<td></td>
<td></td>
<td>P=0.102</td>
<td></td>
</tr>
</tbody>
</table>
## A Multidisciplinary Intervention in the Management of Metastatic Pancreatic Cancer: A Case Report

<table>
<thead>
<tr>
<th>Measure</th>
<th>At baseline</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resting blood pressure and heart rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting systolic blood pressure (mmHg)</td>
<td>103</td>
<td>109</td>
</tr>
<tr>
<td>Resting diastolic blood pressure (mmHg)</td>
<td>70</td>
<td>61</td>
</tr>
<tr>
<td>Resting heart rate (bpm)</td>
<td>68</td>
<td>61</td>
</tr>
<tr>
<td>Six minutes walking test (m)</td>
<td>416.0</td>
<td>525.6</td>
</tr>
<tr>
<td>Handgrip strength (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right arm</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Left arm</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>RPE</td>
<td>4.0</td>
<td>5.5</td>
</tr>
<tr>
<td>Anthropometric parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>49.0</td>
<td>53.2</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>18.0</td>
<td>19.5</td>
</tr>
<tr>
<td>Waist (cm)</td>
<td>67.1</td>
<td>70.5</td>
</tr>
<tr>
<td>Hip (cm)</td>
<td>89.3</td>
<td>92.0</td>
</tr>
<tr>
<td>NRS-2002 score</td>
<td>3.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

### Measure

<table>
<thead>
<tr>
<th>Quality of life (score 0-100)</th>
<th>At baseline</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>73.3</td>
<td>80.0</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>75.0</td>
<td>83.3</td>
</tr>
<tr>
<td>Social functioning</td>
<td>33.3</td>
<td>66.7</td>
</tr>
<tr>
<td>Fatigue</td>
<td>55.6</td>
<td>66.7</td>
</tr>
<tr>
<td>Pain</td>
<td>33.3</td>
<td>50.0</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>33.3</td>
<td>66.7</td>
</tr>
<tr>
<td>Insomnia</td>
<td>33.3</td>
<td>66.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical activity level (min/week)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Light</td>
<td>210.0</td>
<td>420.0</td>
</tr>
</tbody>
</table>

### Psychological status (score 0-21)

| Hospital Anxiety and Depression Scale – anxiety | 16 | 9 |
| Hospital Anxiety and Depression Scale – depression | 18 | 11 |
| Distress Thermometer                  | 8  | 4  |

| Nutritional impact symptoms         |     |                   |
| Dysphagia                          | Yes | No                |
| Oral mucositis                     | Yes | No                |
| Dyspepsia                          | Yes | No                |
| Nausea or vomiting                  | Yes | No                |
| Xerostomia                         | Yes | No                |
| Diarrhea                           | Yes | No                |

There is new ammunition in the war against cancer. These are the bullets.

Revolutionary new pills like GLEEVEC combat cancer by targeting only the diseased cells. Is this the breakthrough we've been waiting for?

GOP Makeover / Drone Morality / The Marriage Test

How to Cure Cancer

*Yes, it's now possible—thanks to new cancer dream teams that are delivering better results faster. By Bill Saporito*
Impact of a comprehensive lifestyle intervention on immunological parameters and outcome in non-small-cell lung cancer

**Hypothesis:** A comprehensive lifestyle intervention including:
1) nutritional management
2) physical activity and
3) psychological support
may modulate immunological parameters and improve immunotherapy outcome in NSCLC patients.
Impact of a comprehensive lifestyle intervention on immunological parameters and outcome in non-small-cell lung cancer

RETROSPECTIVE & PROSPECTIVE PHASE

**Task:** aims to build a signature for predicting the outcome of immunotherapy-treated NSCLC patients

- Tissue-based
- Blood-based

**Task:** aims to evaluate the effect of our comprehensive lifestyle approach on the outcome of immunotherapy-treated NSCLC patients

- Nutritional status
- Muscle wasting
- Physical activity level
- Psychological state
Impact of a comprehensive lifestyle intervention on immunological parameters and outcome in non-small-cell lung cancer

INTERVENTIONAL PRECONDITIONING TRIAL

Comprehensive lifestyle approach

Recommendations according to guidelines

Immunotherapy