

Small Nursing Home Management Experience during Covid-19 Pandemic in Italy

G. Noera MD PhD , C. Serafini NP, M. Gaddoni NP DG

TRANSLATION RESEARCH COVID-19 EMERGENCY

Nursing Home	Giardino St Lucia, Massa lombarda
Aim	Area: Ravenna , Emilia Romagna Region, Italy Two stage gate model of interventional management [1]: Application protocols of Centers of Disease Control and Prevention [2]. Nutraceutical on label Trans-Resveratrol-3-O-Glucoside [3,4].
Objective	Infection control.
Population	Cohort of Frail Elderly in care.
Benchmark	Total Residents in Nursing Home Emilia Romagna compliant to Decree and Ordinance.
Primary purpose	Supportive of care.
Period	COVID-19 Pandemic: March 2020- 2021.
Sex/Gender/Ages	Male and female aged > 85 years.

CLINICAL ASSESSMENT AND ADJUSTED OUTCOME

Primary outcome measure	Mortality all cause [Time frame 12 months].
	Mortality COVID-19 [Time frame 12 months].
Secondary outcome measure	Cohort - within subject data retrospective analysis [Time frame March 2019 - '20 vs. March 20- '21].
	Monthly C-Reactive Protein [Time frame 12 months].
	Days/month antibiotics [Time frame 12 months].
	Days/month antipyretics [Time frame 12 months].
	Days/month steroid drugs [Time frame 12 months].
	Days/month hospital all causes [Time frame 12 months].
	Days/month hospital infectious diseases [Time frame 12 months].

CONTEXT DATA & BENCHMARK

Cohort: *n*° 24 frail elderly & *n*° 12 healthcare personnel both vaccination cycles

COVID-19 total 0, death 0 (rate 0 %);

Inhabitants Massa lombarda: *n*° 10.646: density 283 Km²;

COVID-19 total 793, death 12 (rate 1.5 %);

Total Area Residents Nursing Homes of Ravenna: *n*° 7.137 ; 34% > 85 yr;

COVID-19 observed mort. rate 7,3 x 100 Resident [5], lethality 3.4% [6].

Total Residents Emilia Romagna: *n*° 35.978: density 198,9 Km²

COVID-19 total *n*° 9206, death *n*° 2039 [7]

¹ The Stage-Gate Model was created in the 1980s by Robert G. Cooper, a now internationally recognized expert in the field of innovation management. The Stage-Gate Model was the result of an extensive research about the new product development (NPD) practices followed by top performing companies, leading innovators and entrepreneurs,

² www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

³ www. pubchem.ncbi.nlm.nih.gov/compound/Polydatin#section=Safety-anHazards

⁴ **Polidase Sherman Tree under license by Glures srl spinoff CNR- Italy**

⁵ Older People Living in Long-Term Care Facilities and Mortality Rates During the COVID-19 Pandemic in Italy Preliminary Epidemiological Data and Lessons to Learn www.pubmed.ncbi.nlm.nih.gov/33173526/

⁶ www.auslromagna.it/covid-19-aggiornamenti

1. ACTIVITY

Criteria of management

- 1.1. Activity based costing and management (company financial statements turnover);
- 1.2. Investment: Two Stage Gate Model [Time frame 12 months][8]
- 1.3. Benchmark: data source ISTAT 2019, epidemiologic curve of general population by age: official data Emilia Romagna Region , Massa Lombarda AUSI Area Vasta di Romagna [9];
- 1.4. Regulatory affairs for COVID-19 Pandemic: Decree and Ordinance for management of Emilia Romagna Region, Italy;

Methods

- 1.5. Centers of Disease Control and Prevention Recommendation application protocols
- 1.6. Prevention with Trans-resveratrol-3-O-glucoside for Resident [10] Regulatory notes on label use D.Lgs 24/2/2006 n 219;2003/94/CE.
- 1.7. Strengthening of the existing telematic and telemedicine infrastructure [11]

2. RESULTS

- 2.1. **Activity:** total cost percentage of investment onto company turnover = 9,3% [by Resident = 0.38 % , by months = 0.773%]

2.2. Primary outcome

Mortality all cause Cohort: rate $1.36 \pm 2 \times 10^{-2}$ months rate [Time frame 12 months];
Mortality COVID-19 Cohort: rate 0×10^{-2} [Time frame 12 months]

2.2.1. Graphical view period March 2020 – '21 [benchmark Emilia Romagna Region]

Fig 1 Mortality rate - raw data - Nursing Home Residents

Fig. 2 Mortality rate observed Vs expected - Nursing Home Residents

Fig. 3 COVID-19 infection among Nursing Home Residents

Fig. 4 Mortality COVID-19 of infected Nursing Home Residents

⁷ latest data available from Regional Institutions interview, December 2020

⁸ Activity based costing and management programs are extracted from administrative facility data, Microsoft 365 Access database and application of Giardino St Lucia and programmed by Morena Gaddoni NP DG. Statistical analysis :**One-way analysis of variance ANOVA is based on QI Macros and SPC Software for Microsoft Excel.**

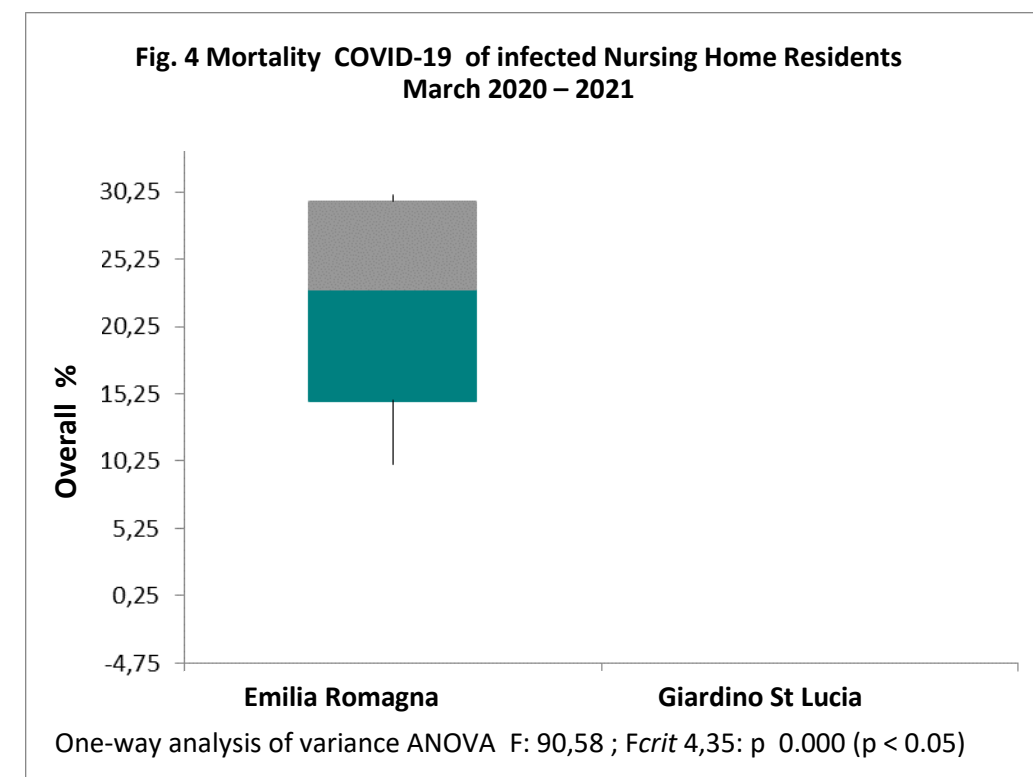
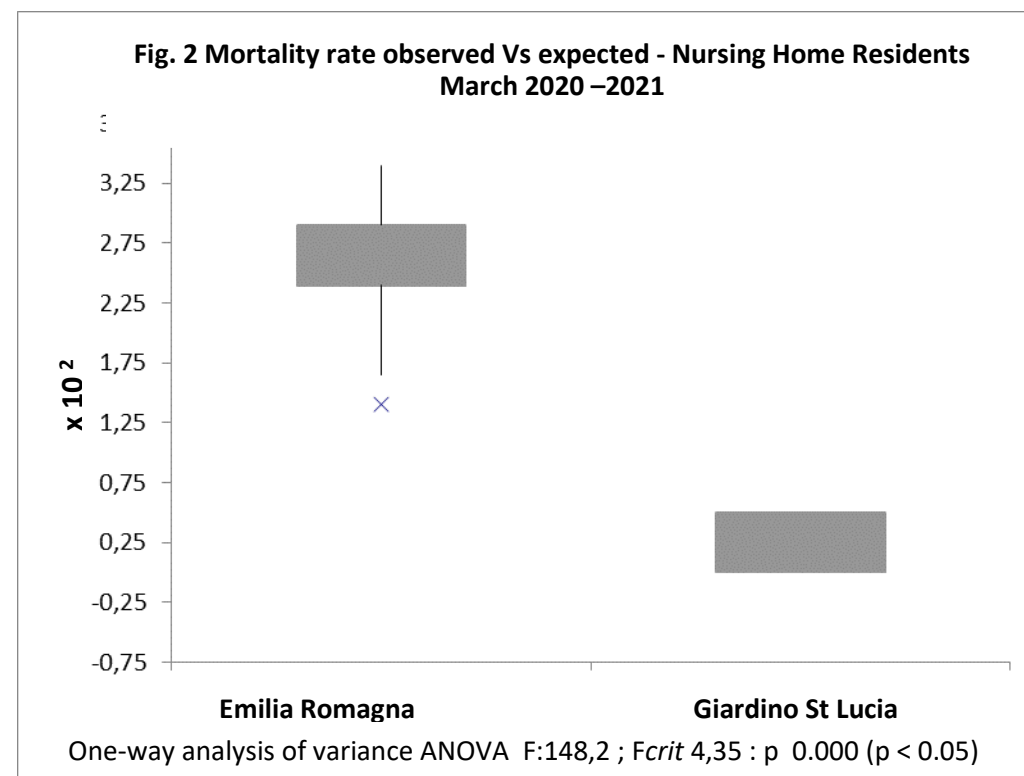
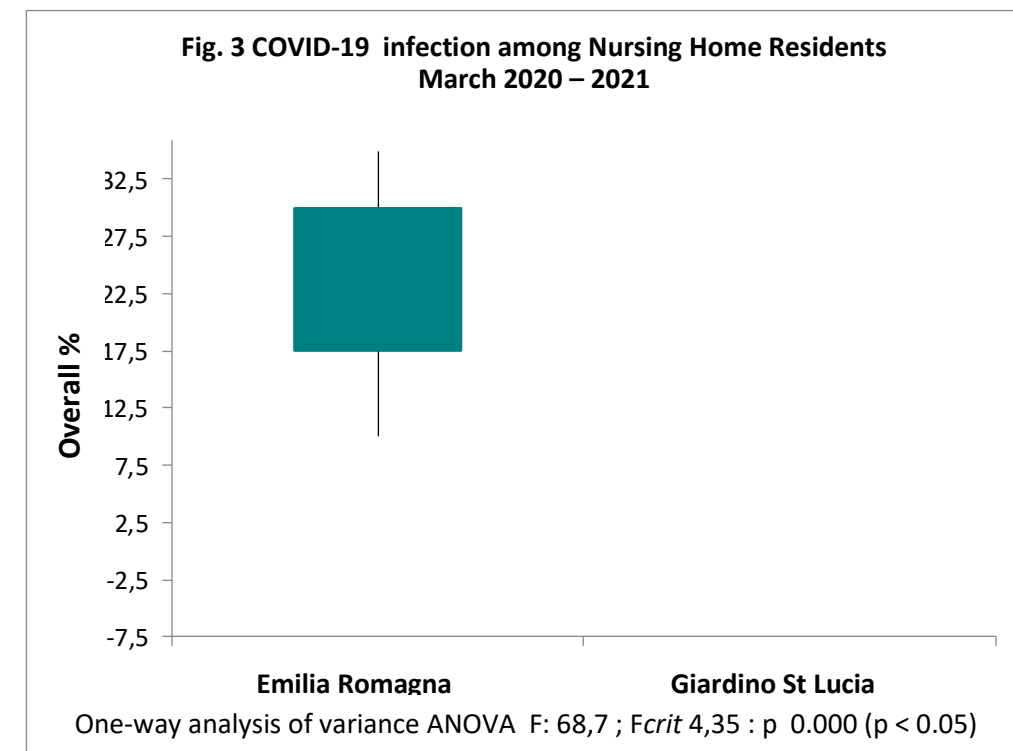
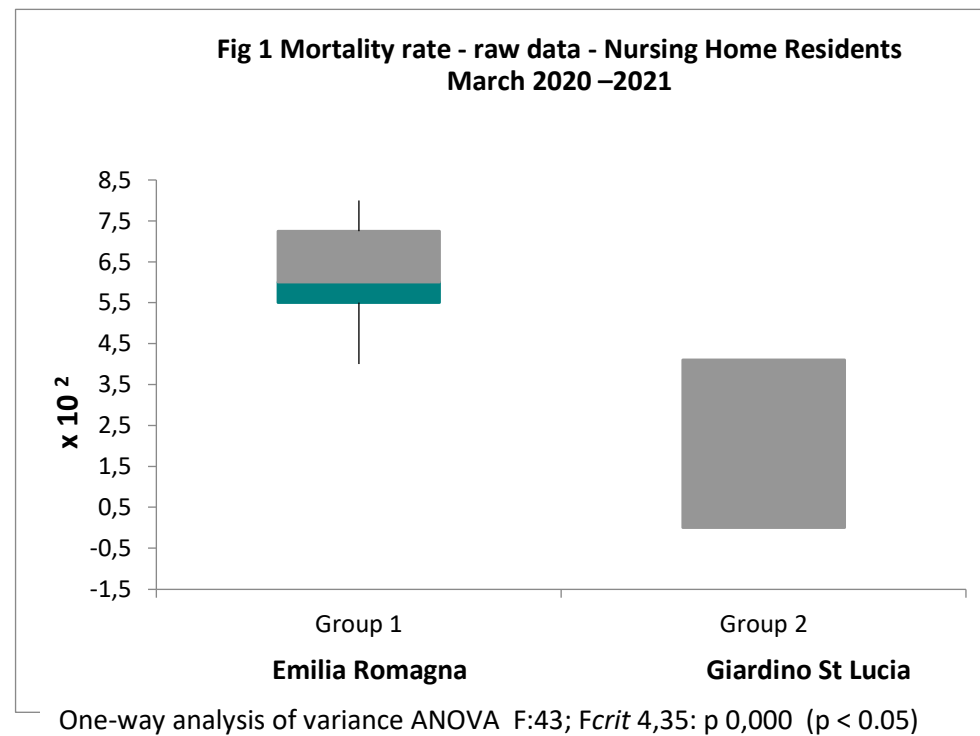
⁹ Limitation: the last three months of epidemiological local area were extracted from a proportional weighted average of the population age and epidemiological incidence

¹⁰ New intriguing possibility for prevention of coronavirus pneumonitis: Natural purified polyphenols doi: 10.1111/odi.13518. Online ahead of print.

¹¹ The nursing Home Giardino St Lucia with Health Ricerca e Sviluppo is accredited as a provider and supplier of hardware and software technologies for digital ECG as well as being a company health facility manager with SUAP _GSL Massa lombarda authorization Prot 40488 Lower Romagna Municipal Union File 2017 / X15 / 20 of 6/7 / 17 for the national territory in compliance for the European digital agenda COM / 2010/0245 / of 26/8/2010, Ministry of Health_ European Commission COM 2008/689 (Electronic health record, personal data and clinical with electronic tools.

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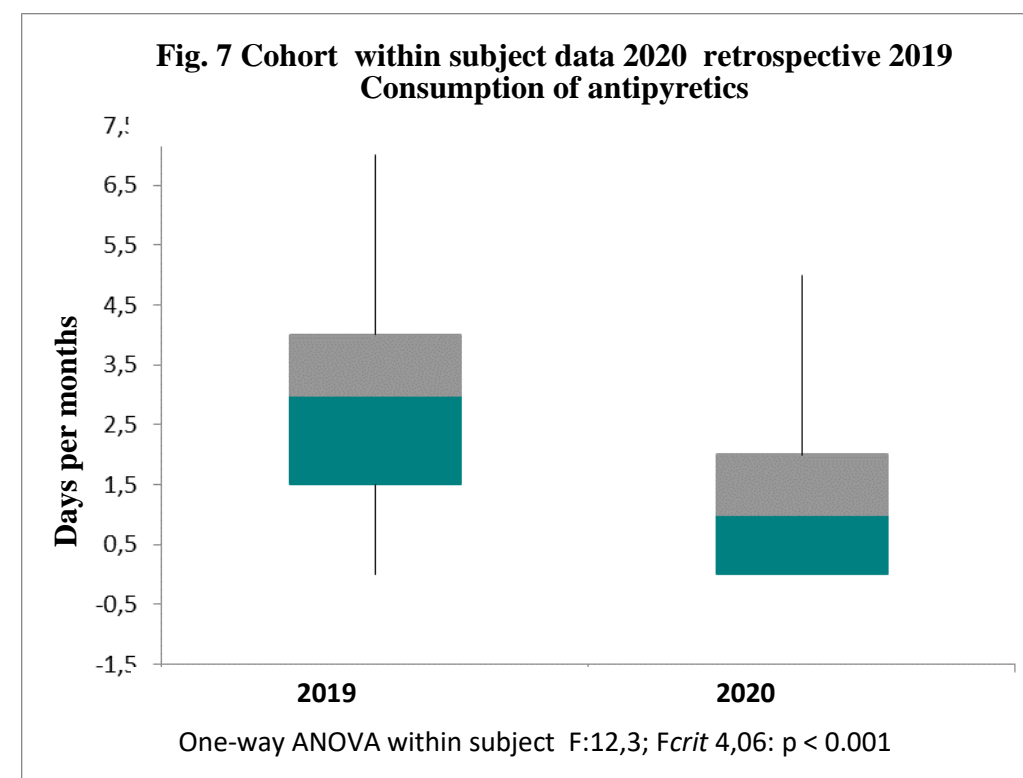
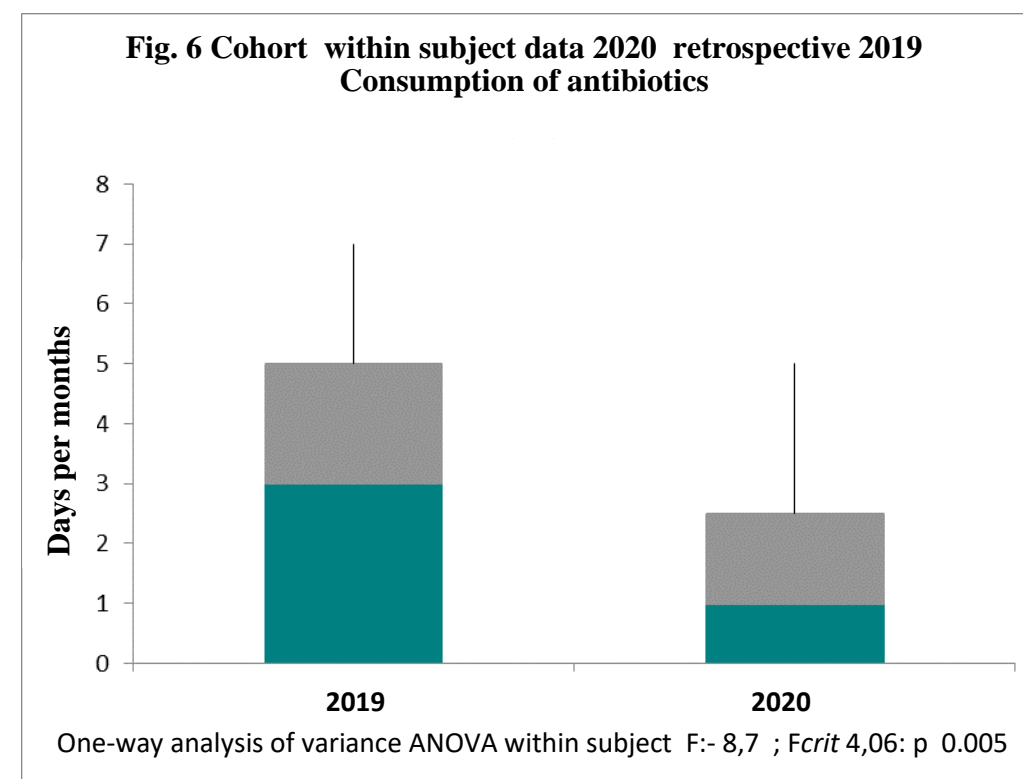
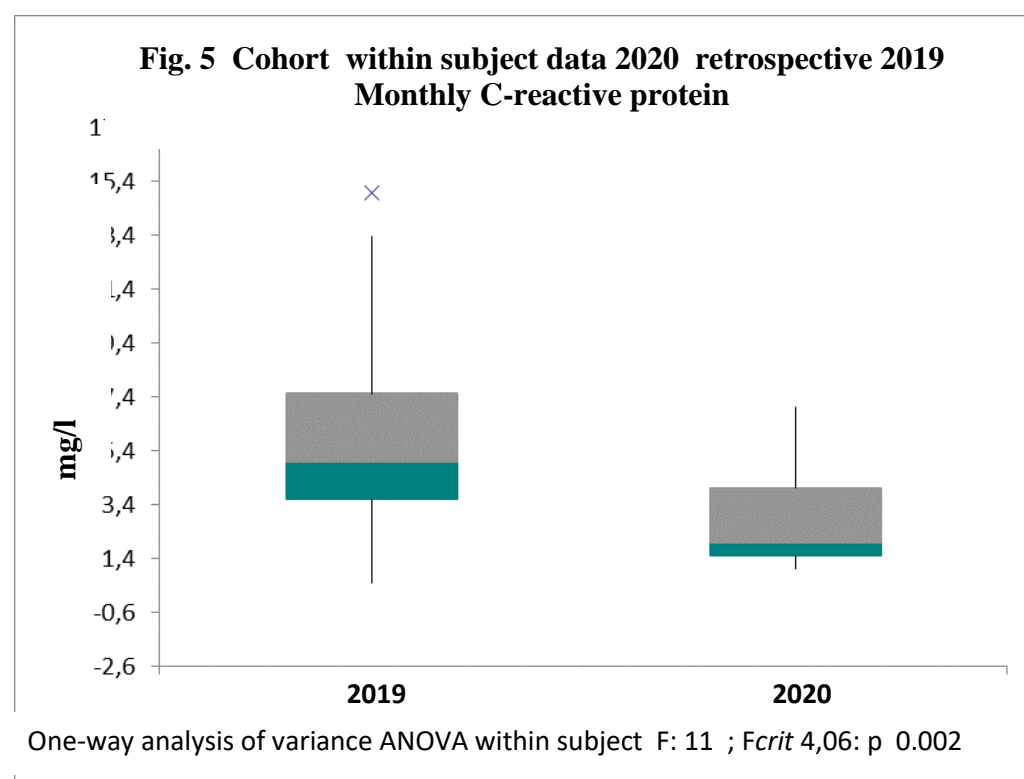


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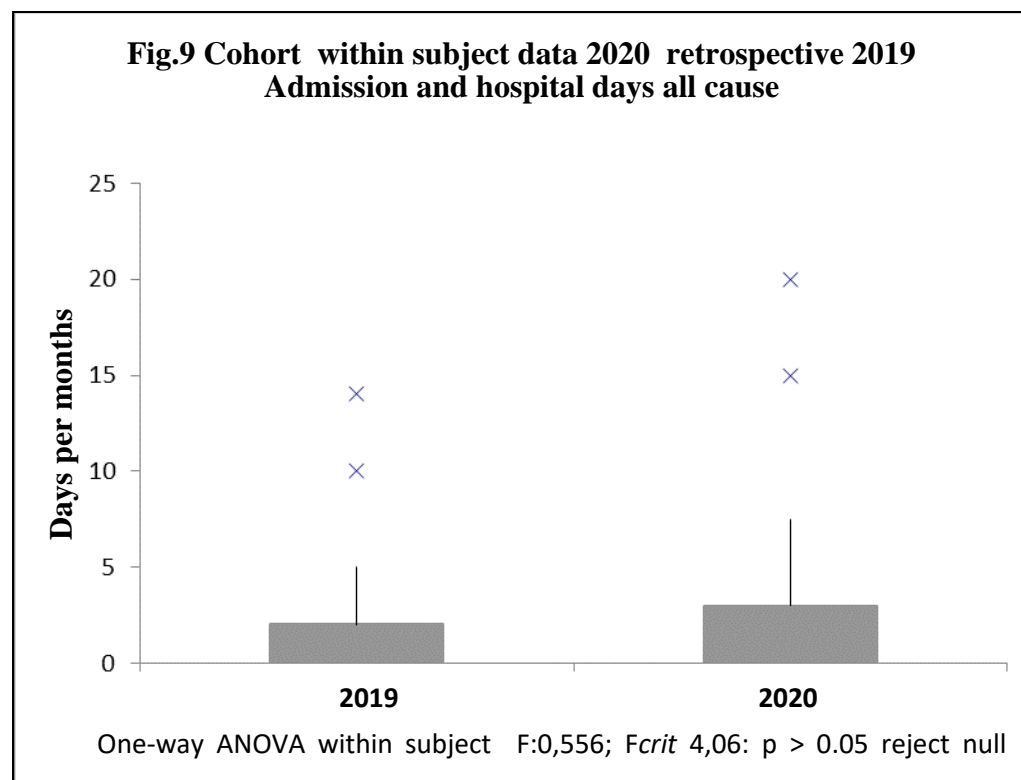
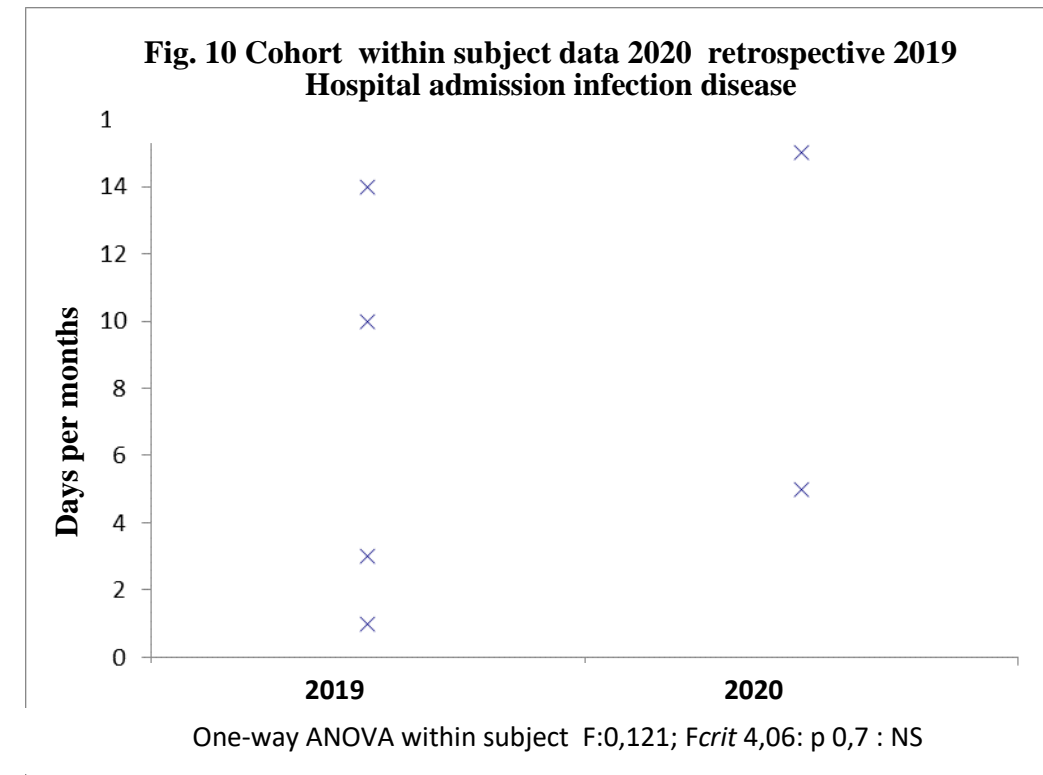
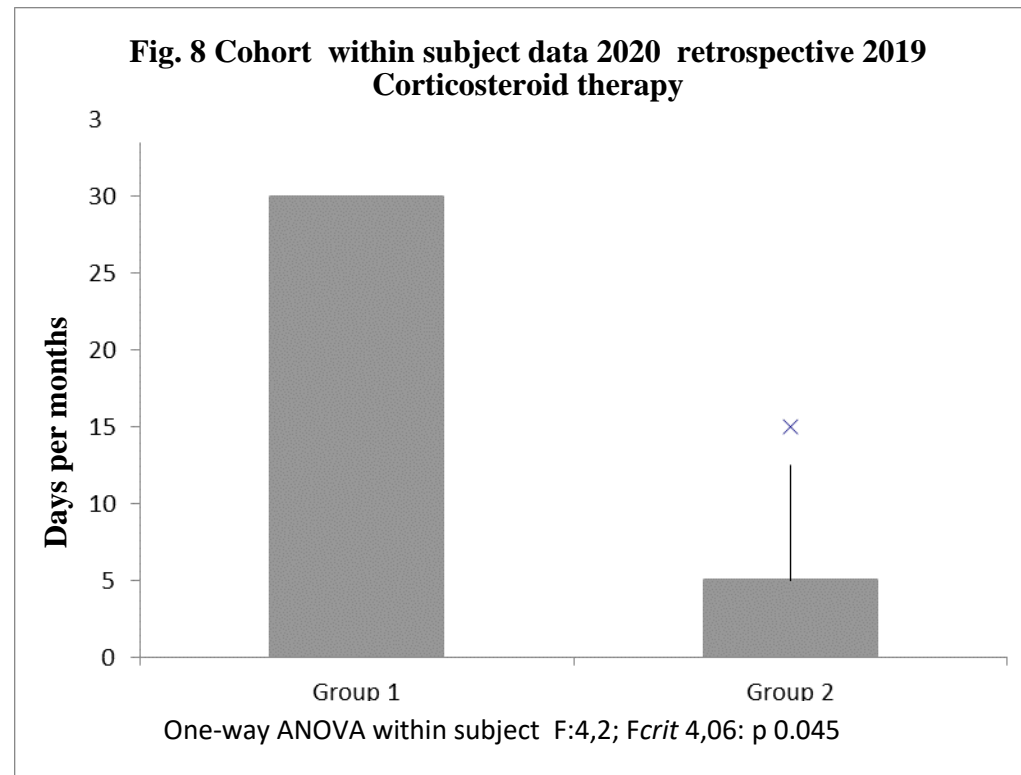
2.3.Secondary outcome

- **Cohort - within subject retrospective analysis**
[Time frame March 2019 - '20 Vs. March 20- '21].
 - 2.3.1. Monthly C-Reactive Protein [Time frame 12 months]:
significant reduction (ANOVA p 0.02);
 - 2.3.2. Days/month antibiotics:
significant reduction (ANOVA p 0.05);
 - 2.3.3. Days/month antipyretics:
significant reduction (ANOVA p< 0.001);
 - 2.3.4. Days/month steroid anti-inflammatory drugs:
significant reduction (ANOVA p 0.045);
 - 2.3.5. Days/month hospital days all causes:
NO significant reduction (ANOVA p > 0.05);
 - 2.3.6. Hospital admissions for infectious diseases:
No significant reduction (ANOVA p 0.7).
- Graphical view Cohort - within subject retrospective analysis
 - 2.3.1. Fig. 5 Monthly C-Reactive Protein
 - 2.3.2. Fig.6 Consumption of antibiotics days per months
 - 2.3.3. Fig.7 Consumption of antipyretics days per months
 - 2.3.4. Fig.8 Corticosteroid therapy days per months
 - 2.3.5. Fig. 9 Admission and hospital days all cause days per months
 - 2.3.6. Fig 10 Hospital admission infection disease



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3. CONCLUSION

The stage-gate model for quality of care development during COVID-19 epidemic , was carried out through several process including risk management and business plan concept for cost benefit ratio. The tests and experience were characterized by three intentions : **a)** to extend CDC protocols as a closed loop to individual risk management within training for health worker and his/her family; **b)** to create a virtual perimeter using a logistic centralization of all the needs as laboratory tests, telemedicine and telematic system for medical advice networking; **c)** to introduce a literature-based nutraceutical logic for prevention of cytokine storm in frail elderly with trans-resveratrol-3-O-glucoside.

The cost of investments for chapters **a)** and **b)** were 8.5 % of turnover while for chapter **c)** was 0.8 %. All chapters were measured by the form of related outcome of Residents. Up to date, the results show an high overall benefit of management over the risk of COVID-19 infection in Nursing Homes and its dramatic side effects observed in the local area. **The infection and mortality zero due for COVID -19 compared to observed rates in Nursing Home of Emilia Romagna, are interpedently to management and in minor manner to luck.** The model adopted for **response capacity including the nutraceutical component provides significance** with respect to retrospective data for the consumption of antibiotic, anti-pyretic and anti-inflammatory drugs. The causal prevalence cannot be attributed to a single component due to the presence of interdependence of concausal factors.