







Enlarged Partnership 8 – Consequences and Challenges of Ageing



A novel public-private alliance to generate socioeconomic, biomedical and technological solutions for an inclusive Italian ageing society

XVII Convegno

I CENTRI PER I DISTURBI COGNITIVI E LE DEMENZE E LA GESTIONE INTEGRATA DELLA DEMENZA Luca Cuffaro









- **Dementia** - Special Reports - Aug 29TH 2020

"Nowhere in the world is ready to cope with the global explosion of dementia", writes Simon Long









WORLDWIDE DEMENTIA CASES TO TRIPLE BY 2050 TO OVER 150 MILLION PEOPLE

The number of people with dementia would increase from 57-4 (95% uncertainty interval

50·4–65·1) million cases globally in 2019 to 152·8 (130·8–175·9) million cases in 2050









Comment

The personal economic burden of dementia in Europe



Linus Jönsson

Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Stockholm, Sweden

Dementia is a syndrome characterized by progressive cognitive and functional impairment, most commonly caused by Alzheimer's disease and other neurodegenerative and cerebrovascular disorders. Costs of care increase dramatically with progressing disease severity, and increasing dementia prevalence due to ageing populations is raising concerns about the sustainability of future costs of dementia care. A new study shows that social welfare systems in

balance the dataset to counter this effect. As the survey did not measure costs for dementia care beyond out-of-pocket expenditures, total costs (including costs paid by government or insurance, such as long-term care) were estimated by assuming that the proportion of total spending to out-of-pocket spending is the same for persons with dementia as the national average in each country - this may result in underestimation of the total costs of dementia care.

The Lancet Regional Health - Europe 2022;20: 100472 Published online 25 July 2022 https://doi.org/10.1016/j. lanepe.2022.100472 In 2019, dementia cost economies globally
1.3 trillion \$

Approximately **50% of these costs** are attributable to care provided by informal carers (e.g. **family members and close friends**), who provide on **average 5 hours of care and supervision per day**

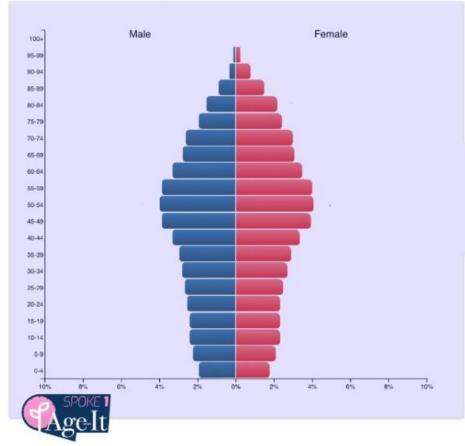




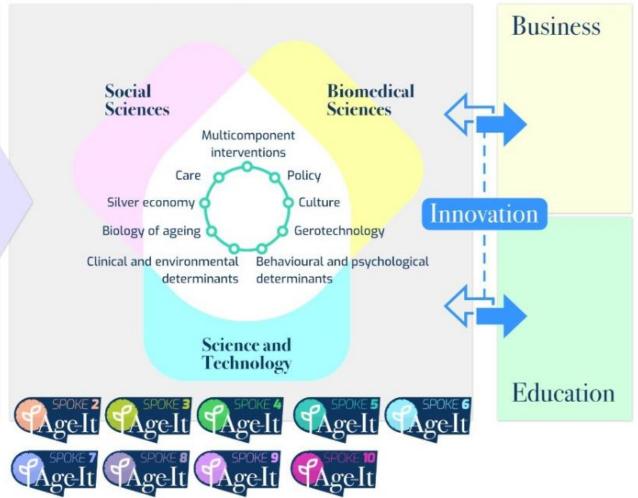




Italian 2021 population pyramid



Holistic, problem-solving and interdisciplinary approach



















SPOKE 2 Age-It

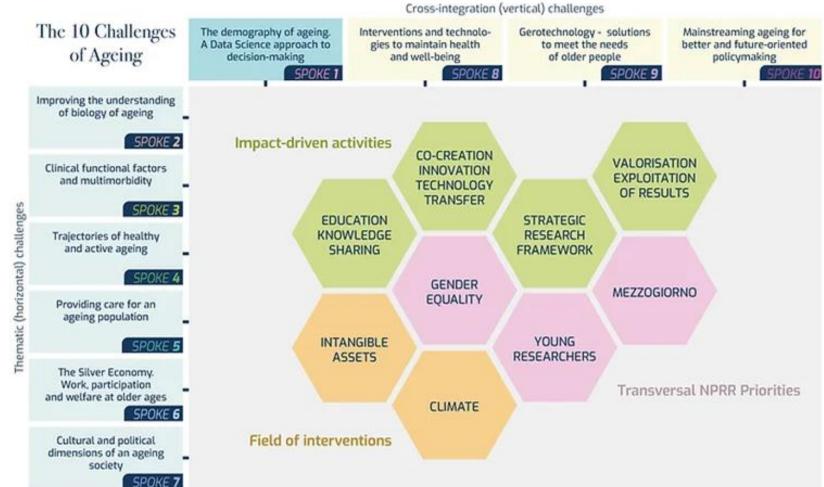






















Interventions and technologies to reduce the burden of agerelated diseases, disorders and disabilities

PI: Prof. C. Ferrarese, UNIMIB

Structure (six WPs):

- both "horizontal" (focused on *three settings* of multicomponent interventions; WP 1 to 3)
- "vertical" (data collection and analytics, technologies, and cost-effectiveness; WP4 to 6)

Disciplines:

 Medicine (neurology, geriatrics), neuroscience, neuropsychology, computer science, genetics, bioengineering, biostatistics, economics









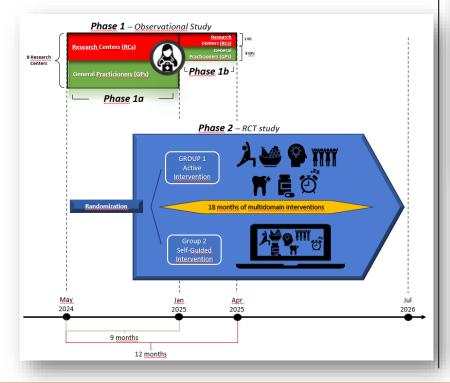


Horizontal WPs

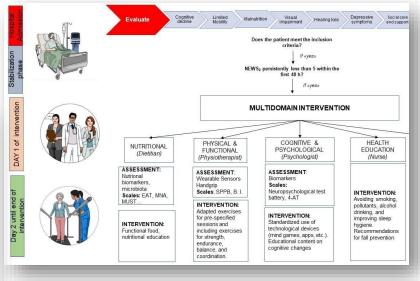
Project (WP1) In-TEMPO (community-dwellers)

Phase 1 (population study): **3000 pz** Pahse 2 (efficacy study): **1340 pz**

9 research centers (2 Nord, 2 Center, 5 Sud)



Interventions and technologies to reduce the burden of age-related diseases, disorders and disabilities



Project (WP2) OPTIMAge-IT (hospitalised)
Efficacy and feasibility study: 240 pz
Hospital phase, then home-based treatments
8 research centers (3 Nord, 2 Center, 3 Sud)



Project (WP3) I-COUNT (nursing-home)
Sample size: 120 pz
3 research centers

ENDPOINTS: functional, cognitive, biomarkers, hospitalisation rates **OUTPUTS**: new protocol of health care system organization for elderly











Vertical WPs

Interventions and technologies to reduce the burden of age-related diseases, disorders and disabilities



WP4: **Informatic resources and artificial intelligence** tools to collect, analyse and share data



WP5: Advanced and innovative technlogies able to adapt in several settings (app-web, wearable devices)



WP6: Cost-effective and sustainability analysis to optimise and rethink the assistance to elderly people







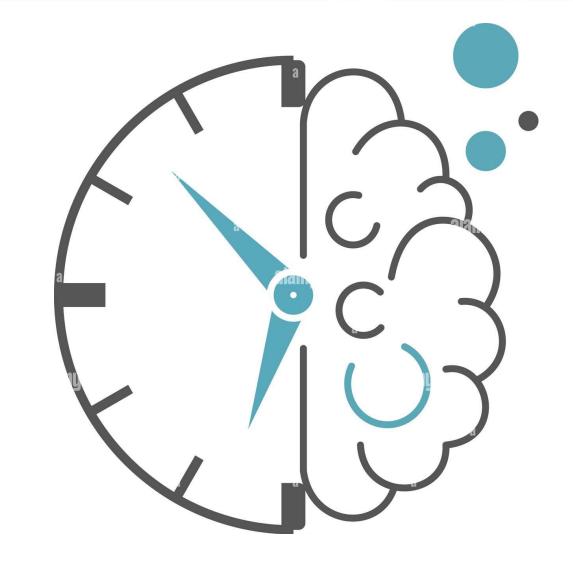


IN-TeMPO study

ItaliaN study with Tailored
Multidomain interventions to Prevent
functional and cognitive decline in
community-dwelling Older adults

www.clinicaltrials.gov: NCT06248723















Alzheimer's & Dementia 9 (2013) 657–665

Alzheimer's & Dementia

The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER): Study design and progress

Miia Kivipelto^{a,b,c,d,*}, Alina Solomon^{a,c,d}, Satu Ahtiluoto^b, Tiia Ngandu^{b,d}, Jenni Lehtisalo^b, Riitta Antikainen^{e,f}, Lars Bäckman^c, Tuomo Hänninen^g, Antti Jula^b, Tiina Laatikainen^b,

A 2 year multidomain intervention of diet, exercise, cognitive $\mathfrak{F}_{\mathscr{O}}$ training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial

Tiia Ngandu, Jenni Lehtisalo, Alina Solomon, Esko Levälahti, Satu Ahtiluoto, Riitta Antikainen, Lars Bäckman, Tuomo Hänninen, Antti Jula, Tiina Laatikainen, Jaana Lindström, Francesca Mangialasche, Teemu Paajanen, Satu Pajala, Markku Peltonen, Rainer Rauramaa, Anna Stiqsdotter-Neely, Timo Strandberg, Jaakko Tuomilehto, Hilkka Soininen, Miia Kivipelto

Findings Between Sept 7, 2009, and Nov 24, 2011, we screened 2654 individuals and randomly assigned 1260 to the intervention group (n=631) or control group (n=629). 591 (94%) participants in the intervention group and 599 (95%) in the control group had at least one post-baseline assessment and were included in the modified intention-to-treat analysis. Estimated mean change in NTB total Z score at 2 years was 0.20 (SE 0.02, SD 0.51) in the intervention group and 0.16 (0.01, 0.51) in the control group. Between-group difference in the change of NTB total score per year was 0.022 (95% CI 0.002-0.042, p=0.030). 153 (12%) individuals dropped out overall. Adverse events occurred in 46 (7%) participants in the intervention group compared with six (1%) participants in the control group; the most common adverse event was musculoskeletal pain (32 [5%] individuals for intervention vs no individuals for control).

Interpretation Findings from this large, long-term, randomised controlled trial suggest that a multidomain intervention could improve or maintain cognitive functioning in at-risk elderly people from the general population.







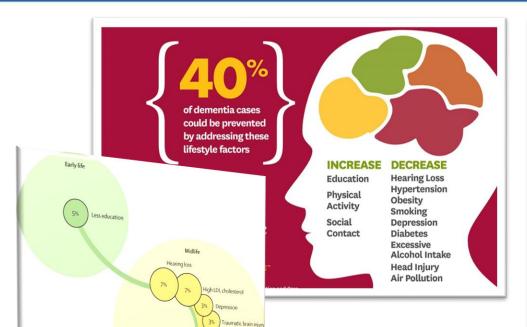
Late life

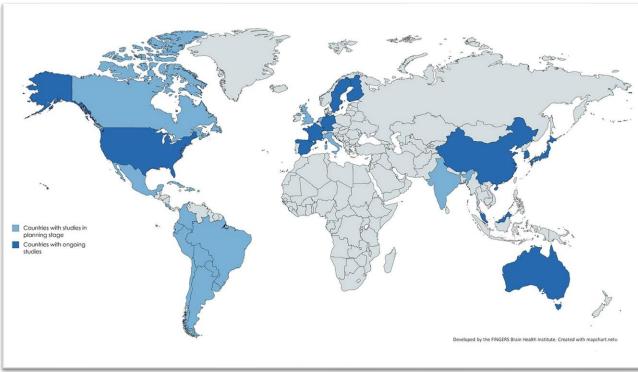
n Percentage reduction in cases of dementia if this risk factor 45% potentially modifiable

















MULTIDOMAINS INTERVENTIONS











OBJECTIVES

- **□ Primary** Objective
 - Evaluate the 18-month effect of multidimensional interventions on cognitive performance through a battery of neuropsychological tests (mNTB)
- **□ Secondary Explorative** Objectives:
 - Assess the effect of multidimensional interventions on functional efficiency.
 - Assess the effect of multidimensional interventions on the degree of multidimensional impairment.
 - Evaluate the effect of multidimensional interventions on scales of physical performance.
 - Assess the impact of multidimensional interventions on the level of independence in activities of daily living.
 - ...









INCLUSION CRITERIA:

- Age => 60 years
- Mild/moderate vulnerability (Primary Care Frailty Index score between 0.07 and 0.21)
- Cardiovascular Risk Factors, Aging, and Dementia Risk Score (CAIDE) => 6
- Clinical Dementia Rating scale (CDR) <= 0.5
- Presence of an increased risk of developing dementia due to **family history** (≥ 1 family member with dementia) and/or at least one modifiable risk factor, with a **Lifestyle Index ≥ 2** (each yes = 1 point):
 - **Physical activity** less than 2.5 hours per week (defined as physical activity intense enough to lead to sweating and breathlessness)*
 - **Diet**: less than 5 servings of fruits and vegetables per day
 - **Diet**: less than 2 servings of fish per week
 - **Hypertension**: diagnosed by a doctor or on pharmacological therapy, or SBP > 140 mmHg, or DBP > 90 mmHg)
 - **Diabetes**: type 1 or type 2 diagnosed by a doctor, or on pharmacological treatment, or HbA1C ≥ 7% in the previous 6 months
 - Sleep disorders, depressive symptoms, or psychophysical stress symptoms for at least one month, judged by the doctor as disabling in daily life
 - <u>BMI</u> ≥ 25 kg/m2
 - **Alcohol** consumption > 21 units per week









2 North:

UNIMIB, UNIPO

2 Center:

• UNIFI, UNI Roma La Sapienza

3 South:

• UNIBA, UNIMO, UNINA

2 satellite South centers

UNIPA, UNICT





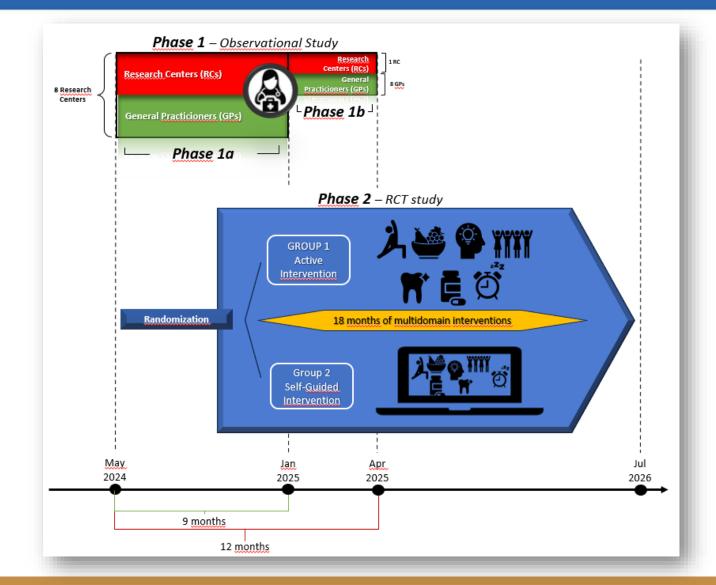






Phase 1 (screening)

- observational study population-based
- total 12 months
- first six months to enrol subjects
- last six months just for screening



Phase 2 (efficacy)

- longitudinal randomised controlled trial (RCT)
- total 18 months









Phase 1 (screening)

Average estimate of subjects under the care of GPs (1237)

31% aged ≥ 60 yrs

Average estimate of subjects ≥ 60 yrs under the care of GPs (383)

25% excluded in line with exclusion criteria

Average estimate of subjects ≥ 60 yrs recruitable under the care of GPs (288)

Assuming the value by default and applying a positive response rate of 30%

Average estimate of subjects ≥ 60 yrs

recruitable and keen to participate

under the care of GPs

(84)

Population screening (3000)

~ 66% from GPs patients

Screening of GPs' patients (2000)

Divided among the 7 research centers involved

Screening GPs' patients ≥ 60 yrs
recruitable in the area of each
research center
(285)

Divided among the 10 General Practitioners (GPs) affiliated with each research center, assuming an additional 50% dropout

Screening GPs' patients ≥ 60 yrs
recruitable and keen to participate
(36)

~ 33% from direct access to research center access

Screening direct access (1000)

Divided among the 7 research centers involved

Screening subjects directly accessed to care ≥ 60 yrs recruitable and keen to participate
(143)









Screening visit with GPs

Phase 1 (screening)



| Phase of screening | Time |
|--|--------|
| Signing of the informed consent, and subsequent general medical examination and inclusion/exclusion criteria | 10 min |
| Fragility via PC-FI | 3 min |
| Risk of Dementia via CAIDE | 2 min |
| Cognitive performance via RAVL-I | 10 min |
| Functional status via (SPPB) | 10 min |
| Cognitive performance via RAVL-D | 2 min |
| Collection of self-administered scales for cognitive performance (TYM-I) | 1 min |
| Total | 38 min |



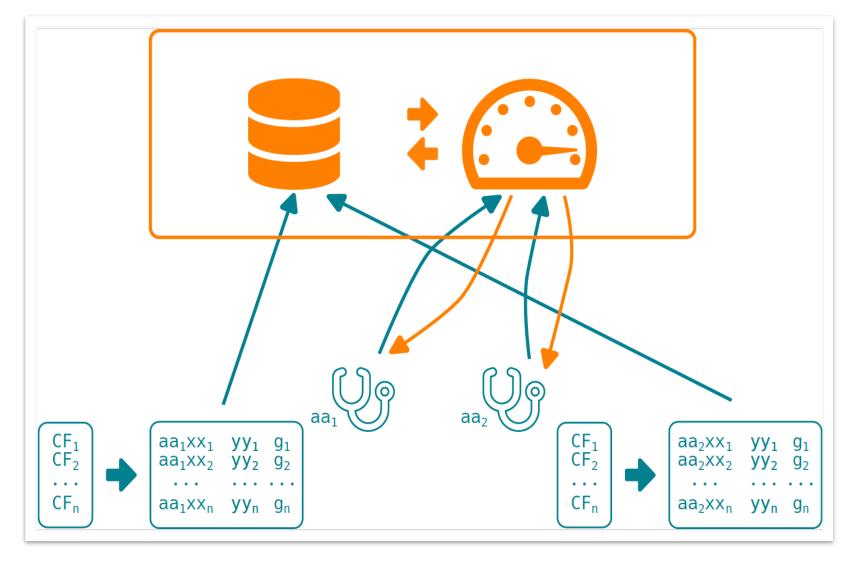






Phase 1 (screening)

- Software for balanced stratification of GP patients
- MMG local server that decodes the CFs:
 - aa= identification code
 - xx= sex
 - yy= age
 - g= group by age/sex group



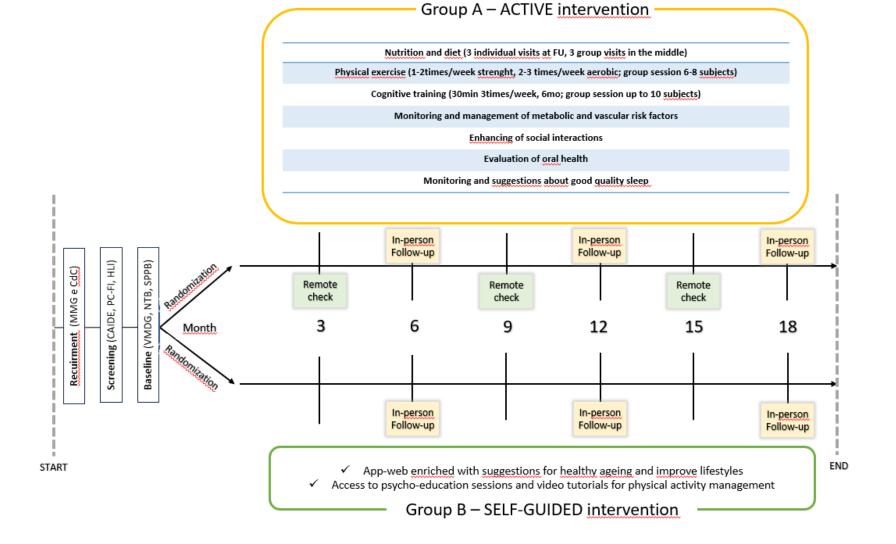








Phase 2 Efficacy

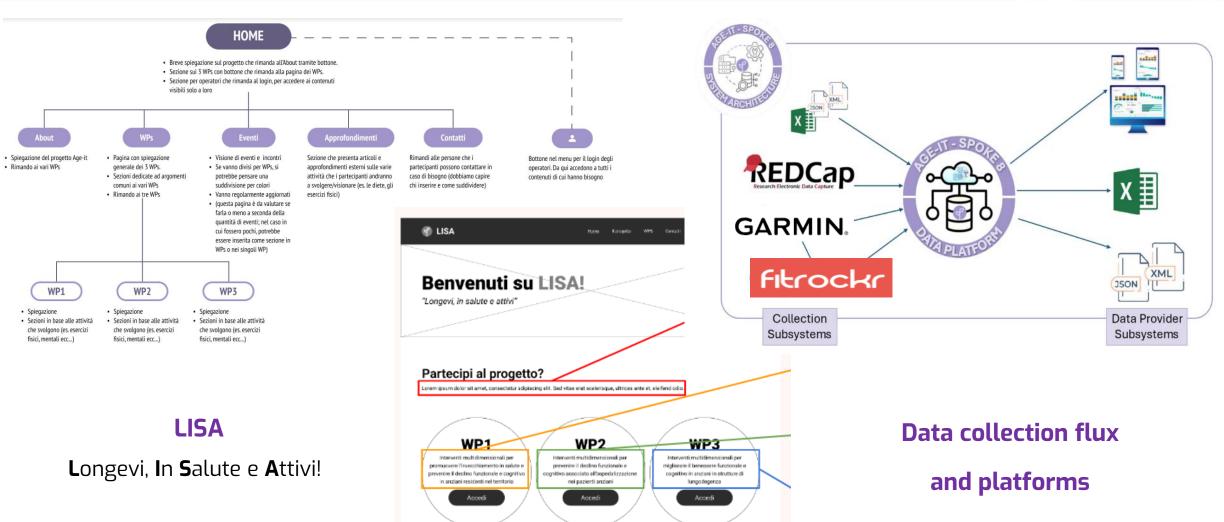












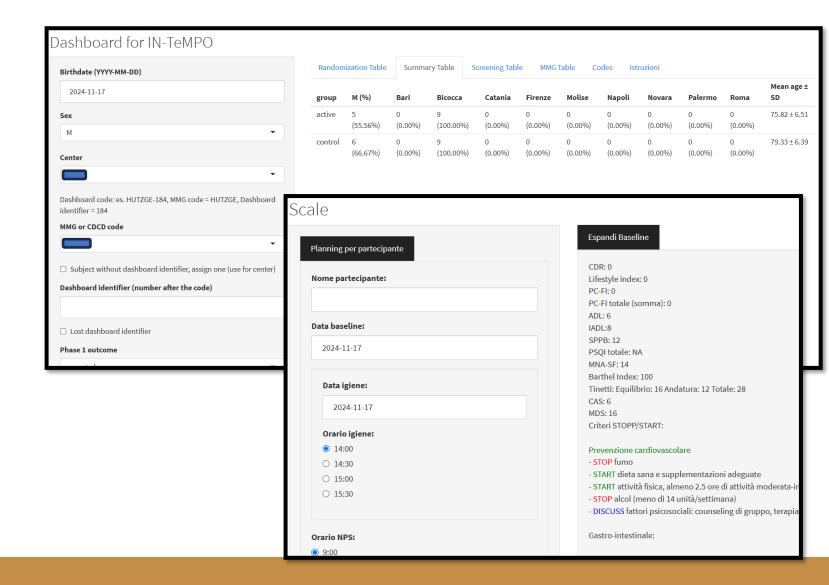








Apps dedicate













IN-TEMPO

| | | Sogg | getto | | Extra (recuperi) | | | | | | | | |
|-------|----------|----------|----------|----------|------------------|------------|------------|------------|------------|-----------|--|--|--|
| | 1 | 2 | 3 | 4 | 7 | 8 | 9 | 10 | 11 | 12 | | | |
| 09:00 | NPS | NPS | | | | | | | | | | | |
| 10:30 | | | NPS | NPS | | | | | | | | | |
| 13:00 | Prelievo | Prelievo | Prelievo | Prelievo | | | | | | | | | |
| 14:00 | Visita | | lgiene | | Igiene | | Nutrizione | | | | | | |
| 14:30 | | Visita | | Igiene | | Igiene | | Nutrizione | | | | | |
| 15:00 | Igiene | | Visita | | Nutrizione | | Igiene | | | | | | |
| 15:30 | | Igiene | | Visita | | Nutrizione | | Igiene | | | | | |
| 16:00 | | | | | | | | | Nutrizione | | | | |
| 16:30 | | | | | | | | | | Nutrizion | | | |

WORKFLOW & SUBJECT JOURNEY
Sede Milano-Bicocca

| Giorno | Orario | 711 | n | 712 | N | 709 | n | 711 | n | Igienisti | n | Carate | n |
|-----------|-------------|--------|----|-----|---|------------|----|----------------|---|-----------|----|---------|----|
| Lunedì | 9:00-12:00 | NPS | 2 | NPS | 2 | Study C | | | | | | | |
| | 14:00-16:00 | Visite | 4 | NPS | | Nutrizione | 6 | Prelievo 13:00 | 6 | | | Visita | |
| Martedì | 9:00-12:00 | NPS | 2 | NPS | 2 | Study C | | | | | | | |
| | 14:00-16:00 | Visite | 4 | NPS | | Nutrizione | 6 | Prelievo 13:00 | 6 | Igiene | 8 | Visita | |
| Mercoledì | 9:00-12:00 | NPS | 2 | NPS | 2 | Study C | | | | | | | |
| | 14:00-16:00 | Visite | 4 | NPS | | Nutrizione | 6 | Prelievo 13:00 | 6 | Igiene | 8 | Visita | |
| Giovedì | 9:00-12:00 | NPS | 2 | NPS | 2 | Study C | | | | | | | |
| | 14:00-16:00 | Visite | 4 | NPS | | Nutrizione | 6 | Prelievo * | 6 | | | Visita | |
| Venerdì | 9:00-12:00 | NPS | 2 | NPS | 2 | BHS | | | | | | | |
| | 14:00-16:00 | Visite | 4 | NPS | | | | Prelievo 13:00 | 6 | | | Visita | |
| | | Visite | | | | Nutrizione | | | | Igiene | | Motorio | |
| n/mese | | | 80 | | | | 48 | | | | 64 | | 12 |











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