Multi-domain Rehabilitation for Older Patients with Myocardial Infarction

The PIpELINe trial

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On behalf of the PIpELINe investigators

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Background

- Despite advancements in acute care, older patients presenting with myocardial infarction (MI) are the highest risk population with the worst prognosis[1]
- Older adults represent the least physically active group with often experiencing functional decline, frailty and disability after MI[2]
- Traditional cardiac rehabilitation programs show several limitations such as low participation rate, early withdrawal and high costs, especially in older patients[3]

1. JACC 2018; 2. J Gerontol A Biol Sci Med Sci. 2020; 3. NEJM 2024.

Research Question

To evaluate whether, in older patients (65+ years old) admitted to hospital for MI and with impaired physical performance, an early, tailored, multi-domain rehabilitation intervention was superior as compared to standard of care in improving outcomes.

Organization

Country: Italy

7 centers

Study PI: Gianluca Campo

Study Chair: Giovanni Grazzi

Executive Committee: Elisabetta Tonet, Stefano Volpato, Andrea Raisi, Gianni Mazzoni






CEC: Rita Pavasini, Paolo Cimaglia

DSMB: Simone Biscaglia, Roberta Campana

ARO: Veronica Lodolini, Chiara Manzalini, Cecilia Chiarelli, Elisa Mosele, Martina Viola, Alice Santoni

Stats: Donato Martella, Nicola Pesenti

The Physical Activity Intervention in Elderly Patients with Myocardial Infarction (PIpELINe) trial was an **investigator-initiated, multicenter, prospective, superiority, randomized trial**.

Sponsor

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Ferrara

Università degli Studi di Ferrara

Supporter

Ministero della Salute

Ricerca Finalizzata 2018

GR 2018-12367114

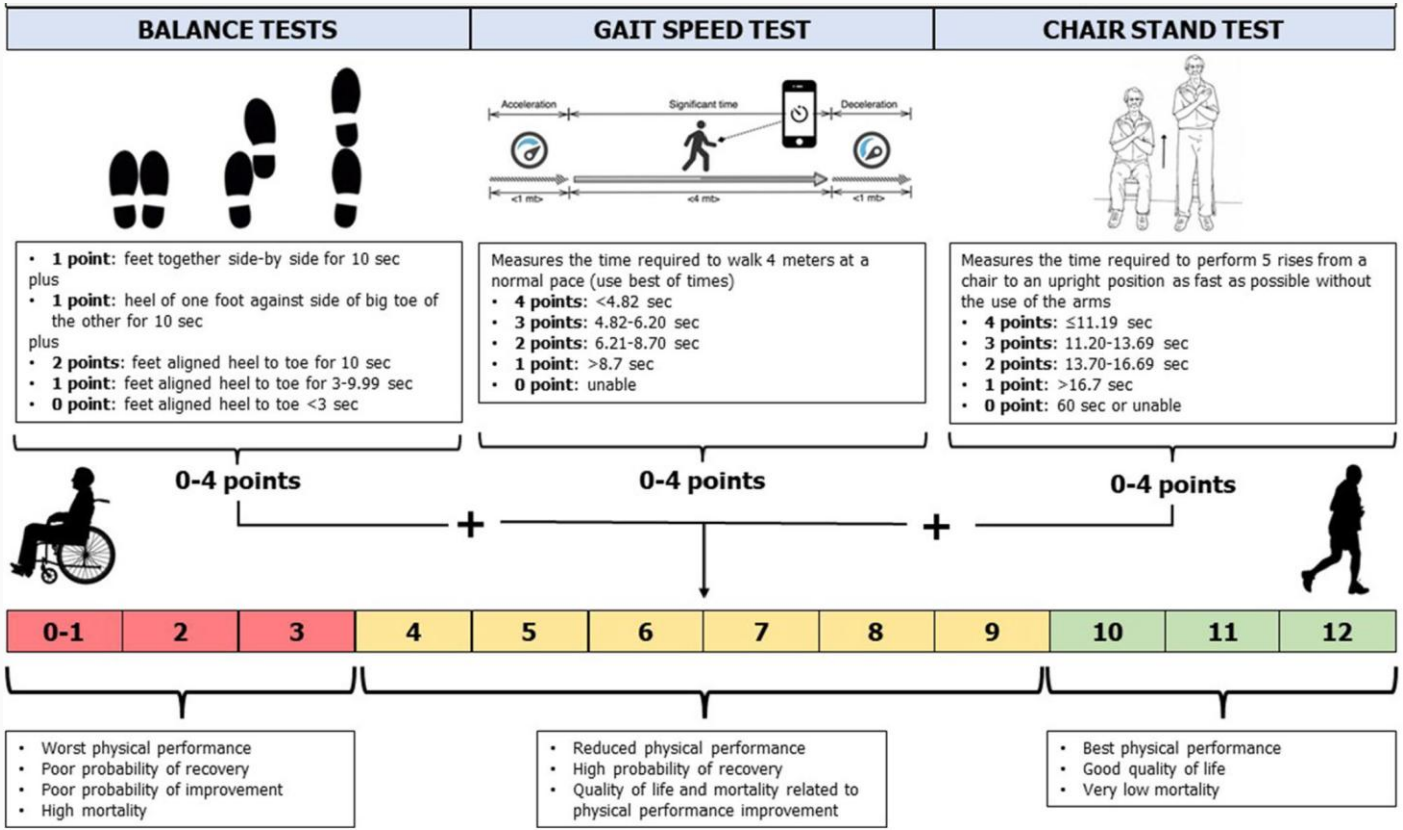
RegioneEmilia-Romagna

Inclusion and Exclusion Criteria

- 65+ years old
- MI (STE or NSTE-MI)
- Indication to invasive management
- SPPB value 4-9 at 1-month

- Planned coronary revascularization
- Life expectancy to < 1 year
- Severe aortic or mitral disease
- Ejection fraction <30%
- NYHA class III-IV
- Severe cognitive impairment
- Physical impairment

Short Physical Perfomance Battery [1, 2]

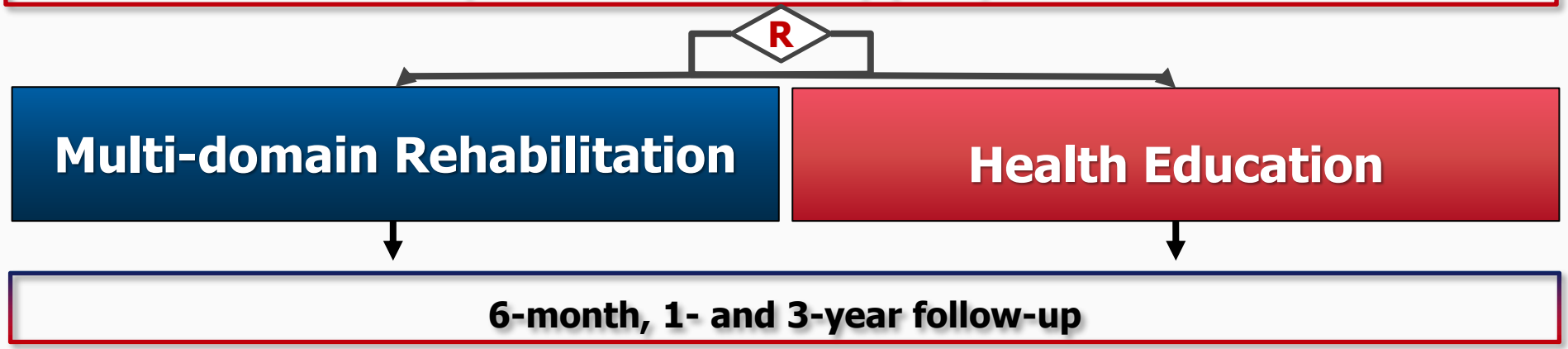


1. J Gerontol 1994; 2. BMC Med 2016

Study Design

Pts ≥65 ys hospitalized for MI (STE or NSTE) with indication to invasive management

Short Physical Performance Battery (SPPB) 4-9 at 1-month



Sample Size

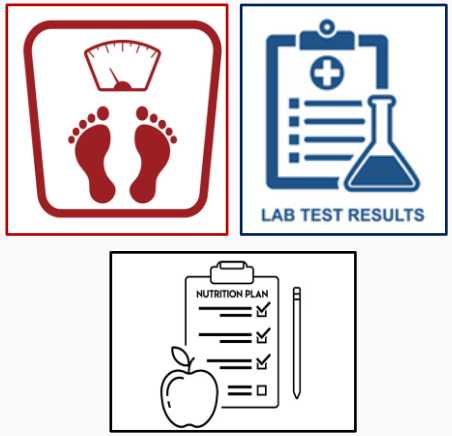
We assumed that 25% of patients in the control group would experience a primary-outcome event. With an anticipated relative risk reduction of at least 40% in the interventional group, we determined that enrolling at least 435 patients would provide the trial with 80% power to demonstrate the superiority of the intervention over usual care, at an alpha of 5%. To account for an anticipated 5% attrition, the final sample size was increased to at least 456 patients.

Intervention

Metabolic Risk Factors Control

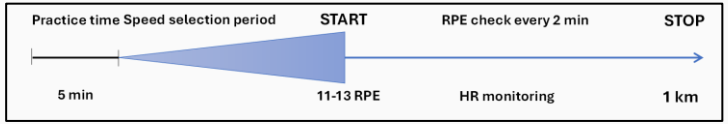
Risk factor management at each visit, targeting improvements in blood pressure, lipid profiles, blood glucose, and smoking cessation.

Diet Counselling



A nutritional status assessment was performed and each patient received a tailored diet plan

Exercise Training



Supervised sessions
(1-, 2-, 3-, 6-, 9-,12-month)

Tailored home-based exercises
20 minutes x3-5 days moderate walking

6 on-site supervised ambulatory individual sessions combined with an individualized home-based exercise prescription. Exercise intensity and progression were individualized based on patient performance at each session. [1,2,3]

1. Heart 2016; JACC 2019; 3. Heart 2020

End Points (at 1-year)

Primary

CV death or unplanned hospitalization for CV causes

Secondary

Death, HF, MI, revasc, CVA, Unplanned hospitalization

Other

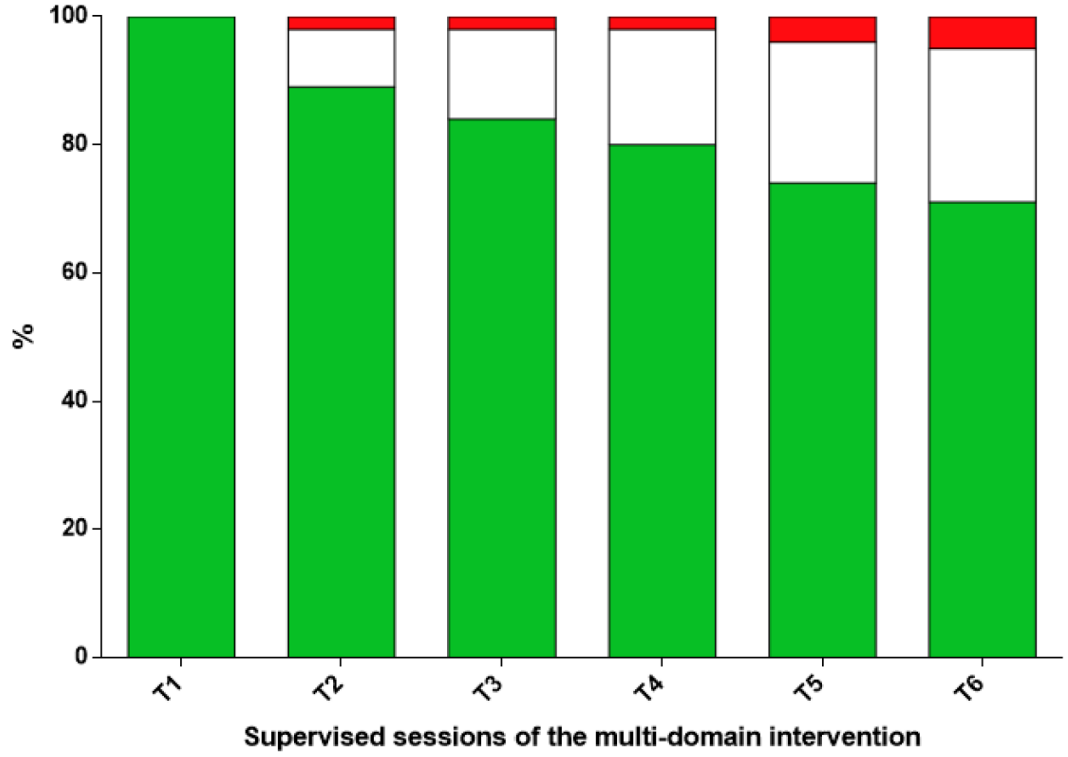
SPPB, gait speed, handgrip strength, QoL

Baseline Characteristics

Characteristic	Control (N=170)	Intervention (N=342)
Age (IQR) – yr	80 (76-83)	80 (75-84)
Female sex	65 (37.6)	122 (35.7)
Comorbidities		
Hypertension	148 (87.1)	294 (86)
Diabetes	50 (29.4)	87 (25.4)
Prior MI	45 (26.5)	81 (23.7)
eGFR <60 ml/min	33 (19.4)	56 (16.4)
PAD	35 (20.6)	74 (21.6)
Clinical presentation		
STEMI	63 (37.1)	127 (37.1)
NSTEMI	107 (62.9)	215 (62.9)

Characteristic	Control (N=170)	Intervention (N=342)
Nutritional Status		
Normal	118 (69.4)	232 (67.8)
At risk for malnutrition	47 (27.6)	96 (28.1)
Malnourished	5 (2.9)	14 (4.1)
Physical performance		
SPPB score	8 (6-9)	7 (6-9)
Gait speed	0.6 (0.5-0.8)	0.7 (0.5-0.8)
Handgrip strength		
Men	30 (22-36)	30 (25-37)
Women	21 (17-32)	20 (15-28)

Compliance to Intervention

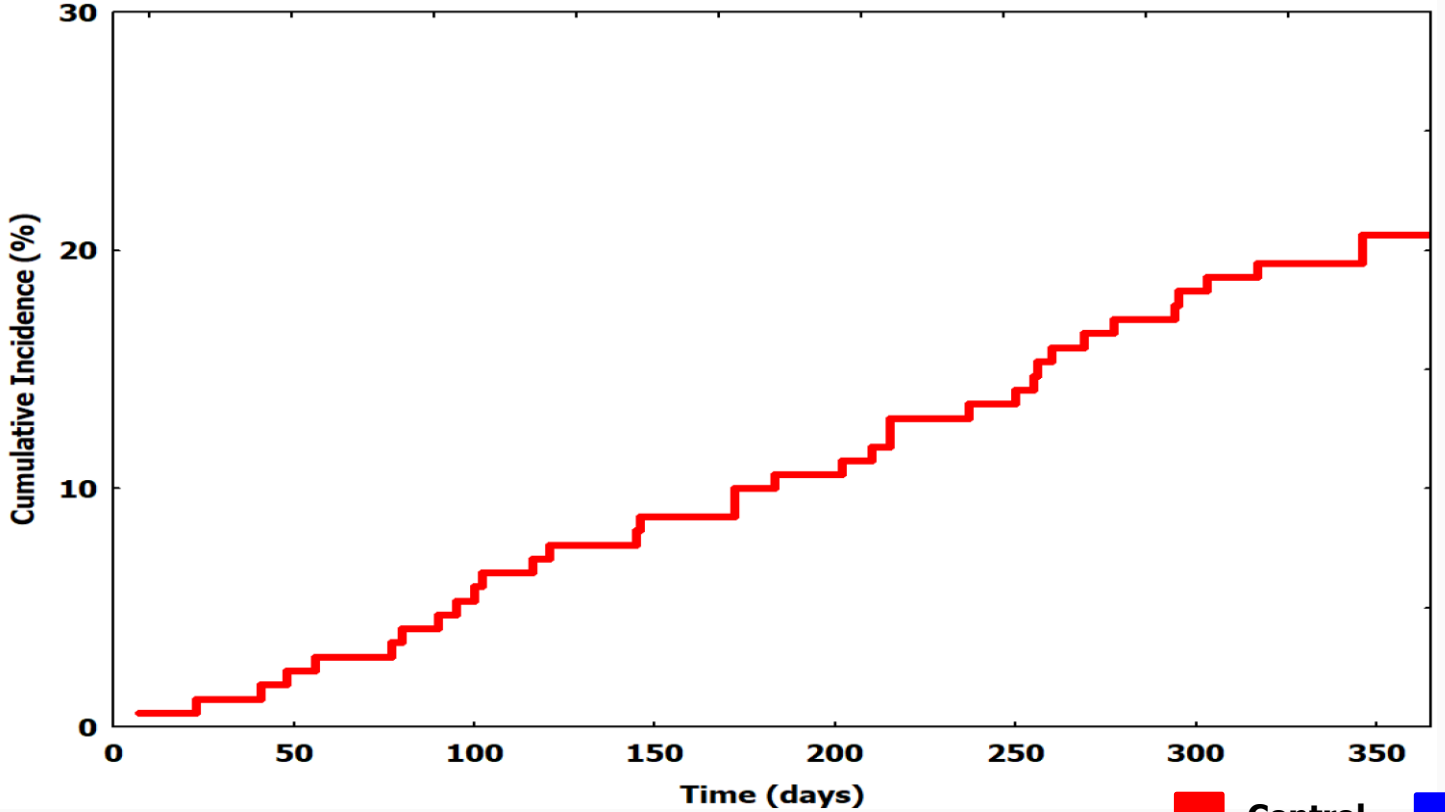


There were no serious adverse events reported during the supervised training sessions.

The overall compliance with the intervention was

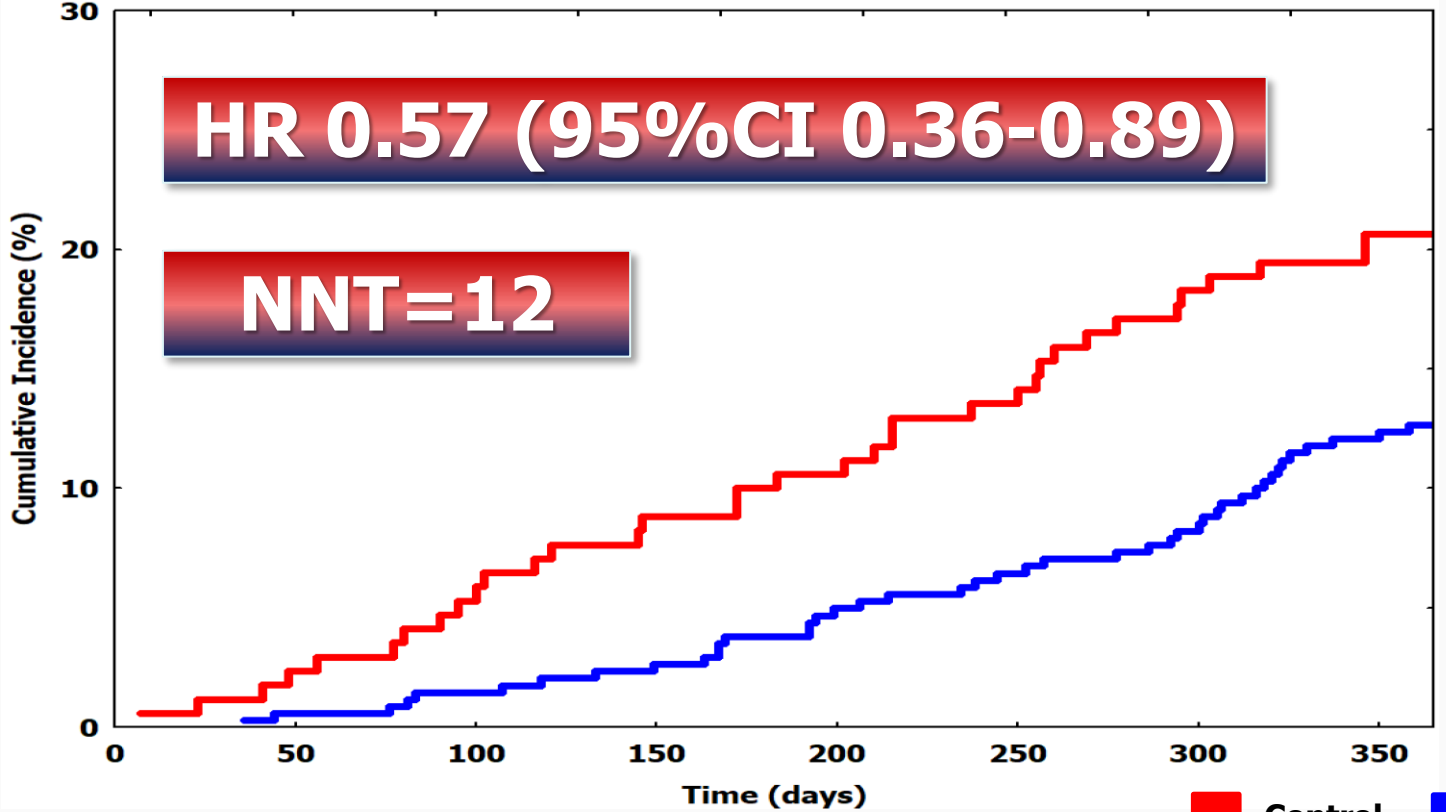
71% (95%CI 65%-75%)

Primary End Point



20.6%

Primary End Point



20.6%

12.6%

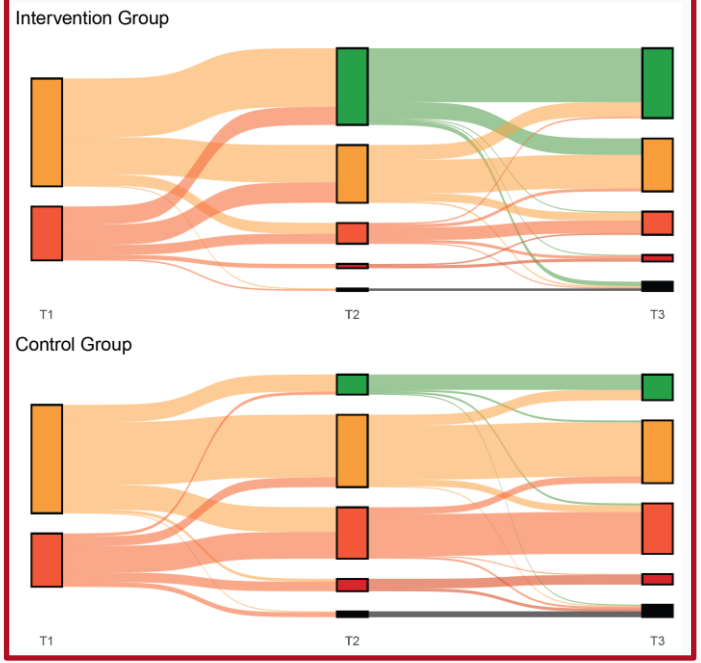
p=0.013

Secondary End Points

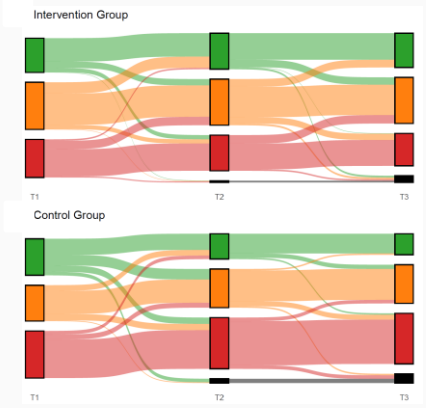
Outcome	Control (n=170) no. (%)	Intervention (n=342) no. (%)	Hazard Risk (95% CI)	P
Death	13 (7.6)	19 (5.6)	0.72 (0.35-1.45)	0.36
Cardiovascular death	10 (5.9)	14 (4.1)	0.69 (0.31-1.55)	0.37
Unplanned CV hospitalization	30 (17.6)	31 (9.1)	**0.48 (0.29-0.79)**	**0.004**
- Heart failure	12 (7.1)	5 (1.5)	**0.20 (0.07-0.56)**	**0.002**
- Myocardial infarction	10 (5.9)	13 (3.8)	0.63 (0.28-1.44)	0.26
- Revascularization	8 (4.7)	13 (3.8)	0.80 (0.33-1.93)	0.62
- Stroke	2 (1.2)	3 (0.9)	0.74 (0.12-4.43)	0.74
Unplanned hospitalization for any cause	39 (22.9)	56 (16.4)	0.67 (0.44-1.01)	0.06
Unplanned non-CV hospitalization	13 (7.6)	28 (8.2)	1.06 (0.55-2.02)	0.86

Other End Points

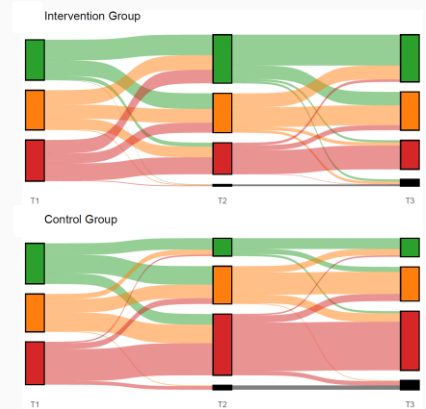
SPPB



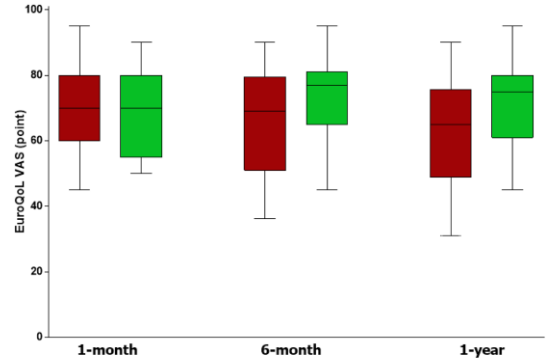
Handgrip



Gait Speed



Quality of Life



Intervention group demonstrated greater improvements in functional status with higher progression to better SPPB functional classes compared to the control group, higher gait speed and handgrip strength and better quality of life.

Limitations

- Open-label design
- Selection bias (1-month survivors)
- Multi-domain rehabilitation (impact each component)
- Supervised vs. home-based sessions
- Preserved cognitive function
- Longer-term follow-up is needed

Conclusions

- **A multi-domain rehabilitation reduces CV death or unplanned hospitalization for CV causes in older MI patients with impaired physical performance**
- **CV care in older MI patients is now based on RCT data!**

1. NEJM 2024; 2. NEJM 2023

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ORIGINAL ARTICLE

Multidomain Rehabilitation for Older Patients with Myocardial Infarction

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