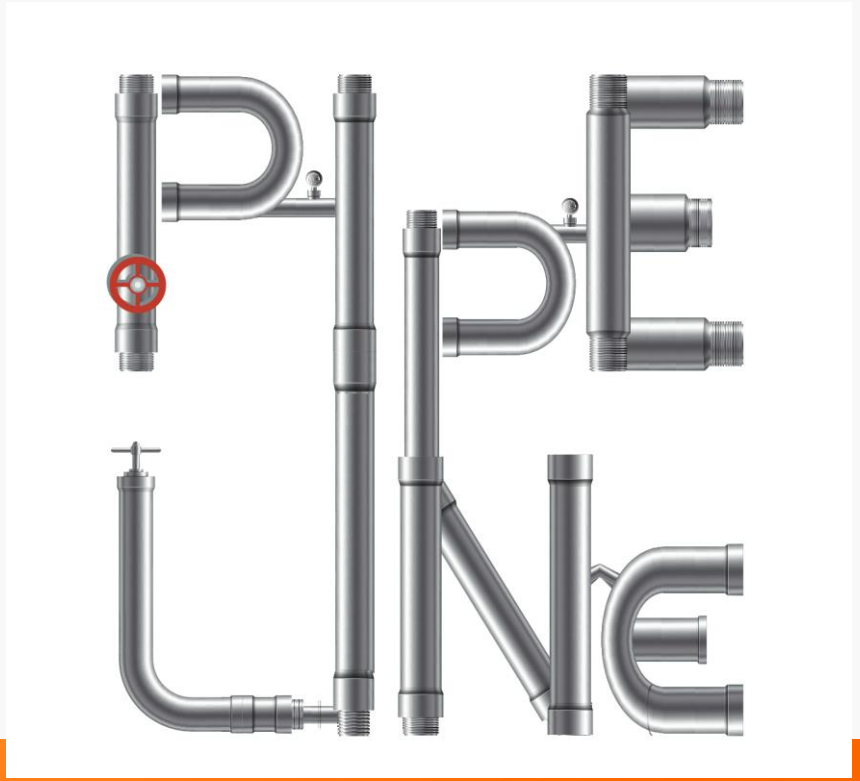
Effectiveness of an early, tailored, Physical activity Intervention in ELderly patients with myocardial INfarction
the PIpELINe randomized clinical trial



Background

- **Elderly patients presenting with myocardial infarction (MI) are the highest risk population with the worst prognosis.**
- **No trial has ever been designed to optimize their outcome through a systematic improvement of their physical performance.**
- **Real-life data shows that older patients are not referred to rehabilitation centers or they have low rate of attendance because of the high number of rehabilitation sessions and of logistic problems.**
- **So, data about effectiveness of rehabilitation programs in older MI patients is lacking.**

Background

- **The HULK pilot study enrolled older MI patients and it demonstrated the feasibility and effectiveness of an**

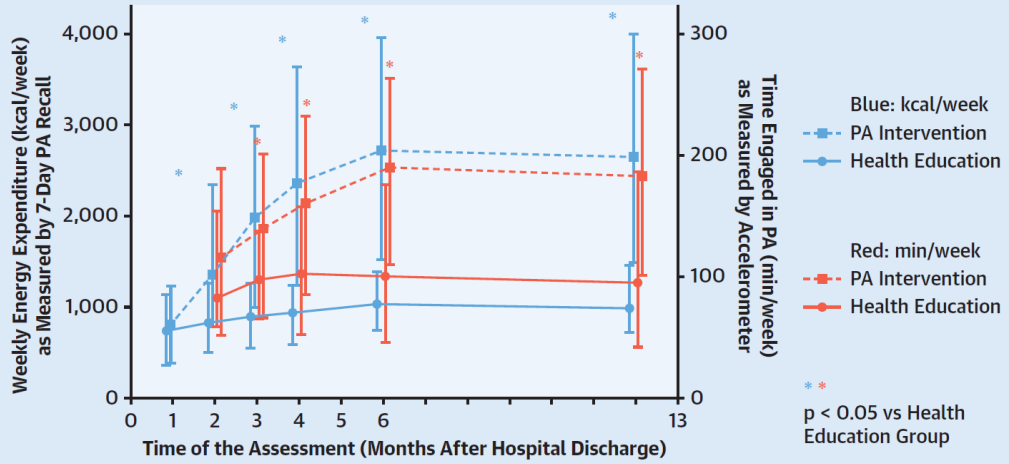
  -early

  -tailored

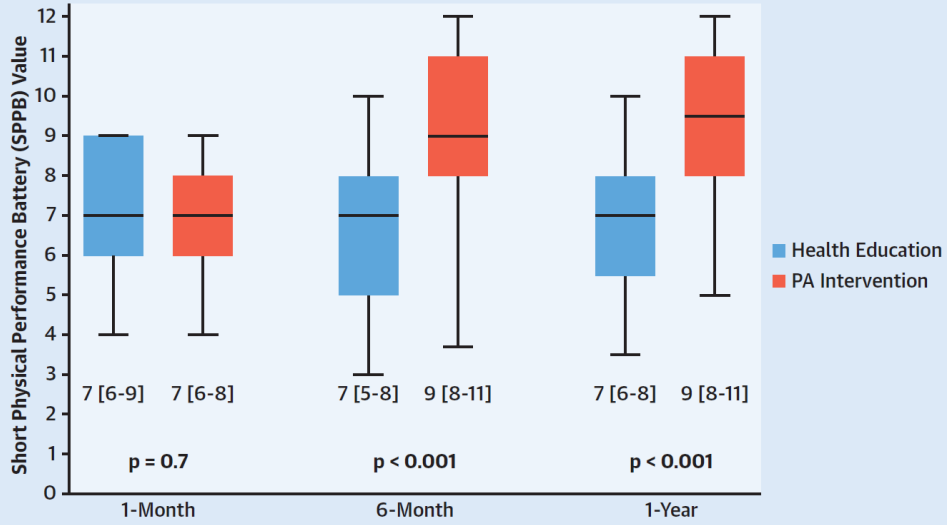
  -low-cost

physical activity intervention in terms of physical performance assessed by the short physical performance Battery (SPPB), that is strongly related to prognosis.

Weekly Energy Expenditure in Physical Activity Measured as kcal/week and min/week



SPPB Value in Study Groups at Different Time Points



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SPPB

SHORT PHYSICAL PERFORMANCE BATTERY (SPPB)

BALANCE TESTS

- **1 point**: feet together side-by side for 10 sec

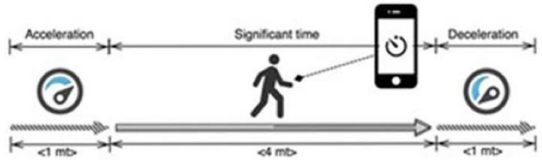
plus

- **1 point**: heel of one foot against side of big toe of the other for 10 sec

plus

- **2 points**: feet aligned heel to toe for 10 sec
- **1 point**: feet aligned heel to toe for 3-9.99 sec
- **0 point**: feet aligned heel to toe <3 sec

GAIT SPEED TEST



Measures the time required to walk 4 meters at a normal pace (use best of times)

- **4 points**: <4.82 sec
- **3 points**: 4.82-6.20 sec
- **2 points**: 6.21-8.70 sec
- **1 point**: >8.7 sec
- **0 point**: unable

CHAIR STAND TEST

Measures the time required to perform 5 rises from a chair to an upright position as fast as possible without the use of the arms

- **4 points**: ≤11.19 sec
- **3 points**: 11.20-13.69 sec
- **2 points**: 13.70-16.69 sec
- **1 point**: >16.7 sec
- **0 point**: 60 sec or unable

0-4 points + **0-4 points** + **0-4 points**

0-1	2	3	4	5	6	7	8	9	10	11	12

- Worst physical performance
- Poor probability of recovery
- Poor probability of improvement
- High mortality

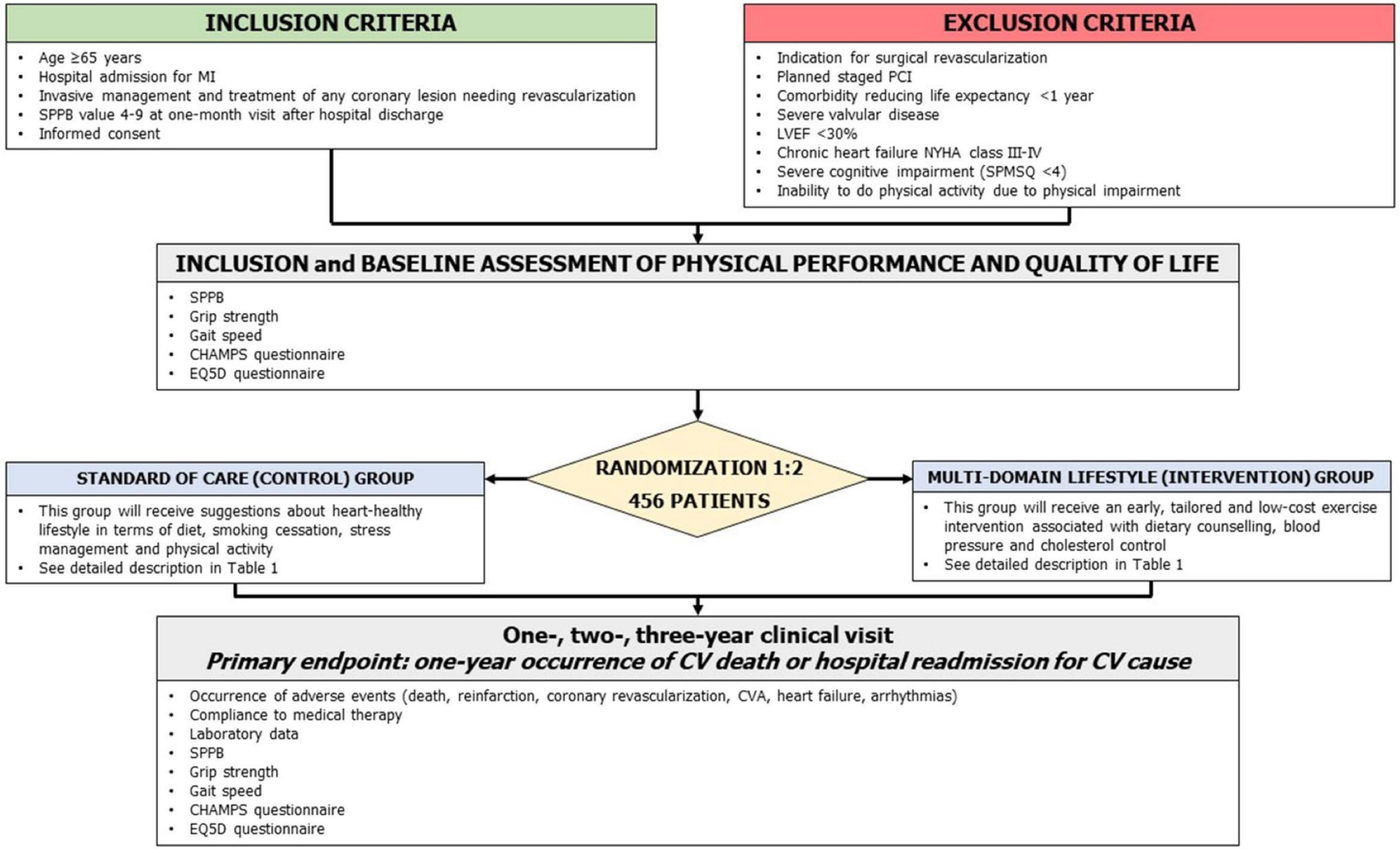
- Reduced physical performance
- High probability of recovery
- Quality of life and mortality related to physical performance improvement

- Best physical performance
- Good quality of life
- Very low mortality

Objective

To assess the superiority of the multi-domain intervention over health education alone in terms of 1-year composite endpoint of cardiovascular death plus hospital readmission for cardiovascular cause.

Flow chart


INCLUSION CRITERIA
Age ≥65 years
Hospital admission for MI
Invasive management and treatment of any coronary lesion needing revascularization
SPPB value 4-9 at one-month visit after hospital discharge
Informed consent
EXCLUSION CRITERIA
Indication for surgical revascularization
Planned staged PCI
Comorbidity reducing life expectancy <1 year
Severe valvular disease
LVEF <30%
Chronic heart failure NYHA class III-IV
Severe cognitive impairment (SPMSQ <4)
Inability to do physical activity due to physical impairment
INCLUSION and BASELINE ASSESSMENT OF PHYSICAL PERFORMANCE AND QUALITY OF LIFE
SPPB
Grip strength
Gait speed
CHAMPS questionnaire
EQ5D questionnaire
RANDOMIZATION 1:2
456 PATIENTS
STANDARD OF CARE (CONTROL) GROUP
This group will receive suggestions about heart-healthy lifestyle in terms of diet, smoking cessation, stress management and physical activity
See detailed description in Table 1
MULTI-DOMAIN LIFESTYLE (INTERVENTION) GROUP
This group will receive an early, tailored and low-cost exercise intervention associated with dietary counselling, blood pressure and cholesterol control
See detailed description in Table 1
One-, two-, three-year clinical visit
Primary endpoint: one-year occurrence of CV death or hospital readmission for CV cause
Occurrence of adverse events (death, reinfarction, coronary revascularization, CVA, heart failure, arrhythmias)
Compliance to medical therapy
Laboratory data
SPPB
Grip strength
Gait speed
CHAMPS questionnaire
EQ5D questionnaire

Inclusion Criteria

1. Patients ≥65 years AND
2. MI (STE or NSTE-MI)
3. Invasive management during index hospitalization including coronary artery angiography (± percutaneous coronary revascularization) AND
4. SPPB value 4-9 at 1-month visit after hospital discharge AND
5. Informed consent

Exclusion critera

1. Multivessel coronary artery disease or left main coronary artery disease candidate to surgical revascularization
2. Planned staged PCI
3. Non-cardiovascular co-morbidity reducing life expectancy to < 1 year
4. Any factor precluding 1-year follow-up
5. Severe aortic or mitral disease
6. Ejection fraction <30%
7. Chronic heart failure NYHA III-IV
8. Severe cognitive impairment (SPMSQ <4)
9. Impossibility to do physical activity due to physical impairment

Experimental group

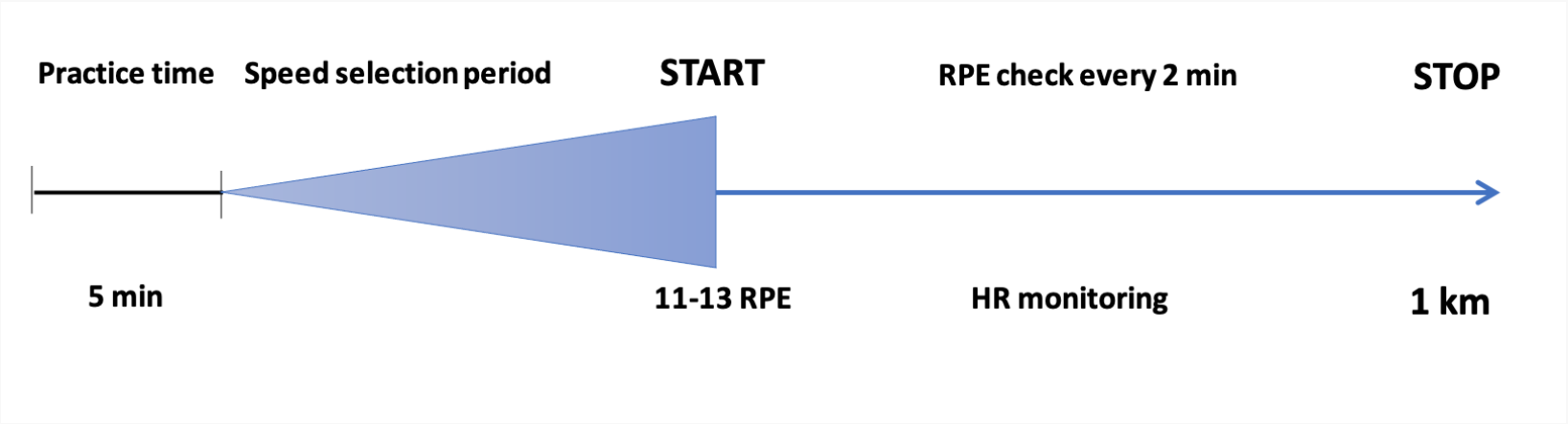
Nutritional interview with a professional	Dietary counselling	Following sessions (60±10, 90±10, 180±10, 270±10 and 360±10 days after T0)
Weight, height, BMI Abdominal circumference, plicometry Bioimpedentiometry by a libra Allergies and medical therapy assessment Blood values evaluation (heamoglobin, kidney function, glicemic and cholesterol levels etc) Patient's dietary habit: - How many meals/day? - Breakfast: sweet or savoury - Preference for meat or fish - Alcohol consumption Agreement on nutritional objectives (weight loss, number of meals/day etc)	Mediterranean diet Recommendation about preference for: -olive oil -at least 2 seasonal, fresh vegetable servings a day -moderate consumption of fresh fruit -fish at least 2 times per week -legumes instead to meat -limiting red meat -limiting sugar and salt -stop smoking	Weight, height, BMI Abdominal circumference, plicometry Bioimpedentiometry by a libra Medical therapy assessment Diet objectives discussion Patient's new diet habit and compliance to suggested diet evaluation

Experimental group

Inclusion visit (T1)	Home-based program	Following activity sessions (60±10, 90±10, 180±10, 270±10 and 360±10 days after T0)
Pre-test: • Questionnaire, measure of blood pressure • Positioning RS100 Polar heart rate monitor to constantly evaluate heart rate • Exercises derived from Otago Exercise Program • Gait speed evaluation **Start: walking on the level at 2.0 km/h or lower according to perceived exertion** **Every 30 seconds: increases of 0.3 km/h up to a walking speed corresponding to a perceived exertion of 11–13 on the Borg scale for 1 km *.** **Every 2 minutes: rate of perceived exertion (RPE) recording** **Post-test: Measure of blood pressure, discussion of test results, counselling on physical activity, counselling on daily activities, distribution of home accelerometry**	• At least 20 min of continuous moderate walking a day (including 5 min warm up and 5 min cool down), preferably 7 days a week, wearing accelerometry. Patients are instructed to follow the same RPE goals. The home-based program is individualized but in agreement with current international guidelines • Exercises derived from Otago Exercise Program	**Pre-test:** • Questionnaire, evaluation of data recorded by accelerometry, measure of blood pressure • Positioning RS100 Polar heart rate monitor to constantly evaluate heart rate. • Exercises derived from Otago Exercise Program **Start: walking at an updated intensity compared to the previous activity session** **Every 30 seconds: increases of 0.3 km/h up to a walking speed corresponding to a perceived exertion of 11–13 on the Borg scale for 1 km *.** **Every 2 minutes: rate of perceived exertion (RPE) recording** **Post-test: Measure of blood pressure, discussion of obtained results, counselling on physical activity and daily activities, distribution of home accelerometry**

Experimental group

-Selection of a pace that they can maintain for 10 to 20 min at a moderate perceived exercise intensity (11–13 on the 6–20 Borg scale).
-Practice time (≈5 min) is allowed to walk comfortably at a light to moderate intensity without support.
-Following this preliminary practice and warm-up phase, patients begin the walk on the level at a walking speed of 2.0 km/h with subsequent increase of 0.3 km/h each 30 seconds up to the target moderate perceived walking intensity.
-RPE is recorded every ≈2 min adjusting walking speed if necessary.
-The time to complete either 1000-m is recorded and average walking speed calculated accordingly.
-Walking HR is averaged every 5 seconds and mean and maximal values during the 1k-TWT are determined.



Control group

Inclusion visit (T1)

- **Questionnaires**
- **Gait speed evaluation**

Study investigators perform a 20-min speech with patient and relatives about the major issues related to a heart-healthy life - style with some suggestions as follows: healthy food choices, weight control in order to achieve and maintain healthy BMI (18.5 - 24.9kg/m2), smoking cessation and referral to special programmes if necessary, stress management technique encouraging help from relatives and care giver, aerobic physical activity.

1. **At least 20 minutes on 5 days/week should be engaged in physical activity, emphasizing that sedentary lifestyle is a risk factor**
2. **Graduation of the physical activity plan**
3. **Variation of activities by changing the type of performance or the way to do it**
4. **Alternation of physical activity with adequate rest breaks**
5. **Wearing the accelerometry while performing physical activity (Accelerometry is provided)**
6. **Association of some calisthenic exercises, calibrating breathes and movements (description and teaching of 3 types of exercises)**

- **Some suggestions to make healthier patent's daily routine: stairs rather than lift should be preferred, getting off the bus one stop earlier and walking for the rest of the way, going out for a walk with friends, for short trips, walking should be preferred**

Endpoints

- **Primary Endpoint: 1-year Cardiovascular death or hospital readmission for cardiovascular cause**

- **Secondary Endpoints:**
  - **1-year and 3-year all-cause death**
  - **1-year and 3-year cardiovascular death**
  - **1-year and 3-year hospital readmission for cardiovascular cause**
  - **1-year and 3-year myocardial infarction**
  - **1-year and 3-year cerebrovascular accident**
  - **1-year and 3-year hospital readmission for any cause**
  - **1-year and 3-year quality of life**
  - **3-year cardiovascular death or hospital readmission for cardiovascular cause**