THE SPRINTT PROJECT:

TOWARDS A "NEW" GERIATRIC HEALTHCARE

Funding

"The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under *Grant Agreement* n° 115621, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7 / 2007-2013) and EFPIA companies' in kind contribution".

Why GPs should be interested in the SPRINTT?

The SPRINTT project offers the opportunity to investigate the presence of physical frailty and sarcopenia and to have access to state of the art treatments for this conditions. All people enrolled in the RCT will be followed for 3 years by a specialized team of health care professionals. They will undergo medical visits and exams at no cost (e.g. blood analysis, DXA, electrocardiogram). People participating in the intervention group will take part in a multicomponent intervention including exercise classes, nutritional counseling and ICT support.

GPs have an extremely important role. Based on utilizing the knowledge and trust engendered by repeated contacts with patients, they can identify potential candidates who can be referred to the research center. They can mutually discuss the study progress and results with their patients and the research team. Finally, this project aims at developing an intervention that can be applied in primary care Hence, the involvement of GPs and family doctors is fundamental.

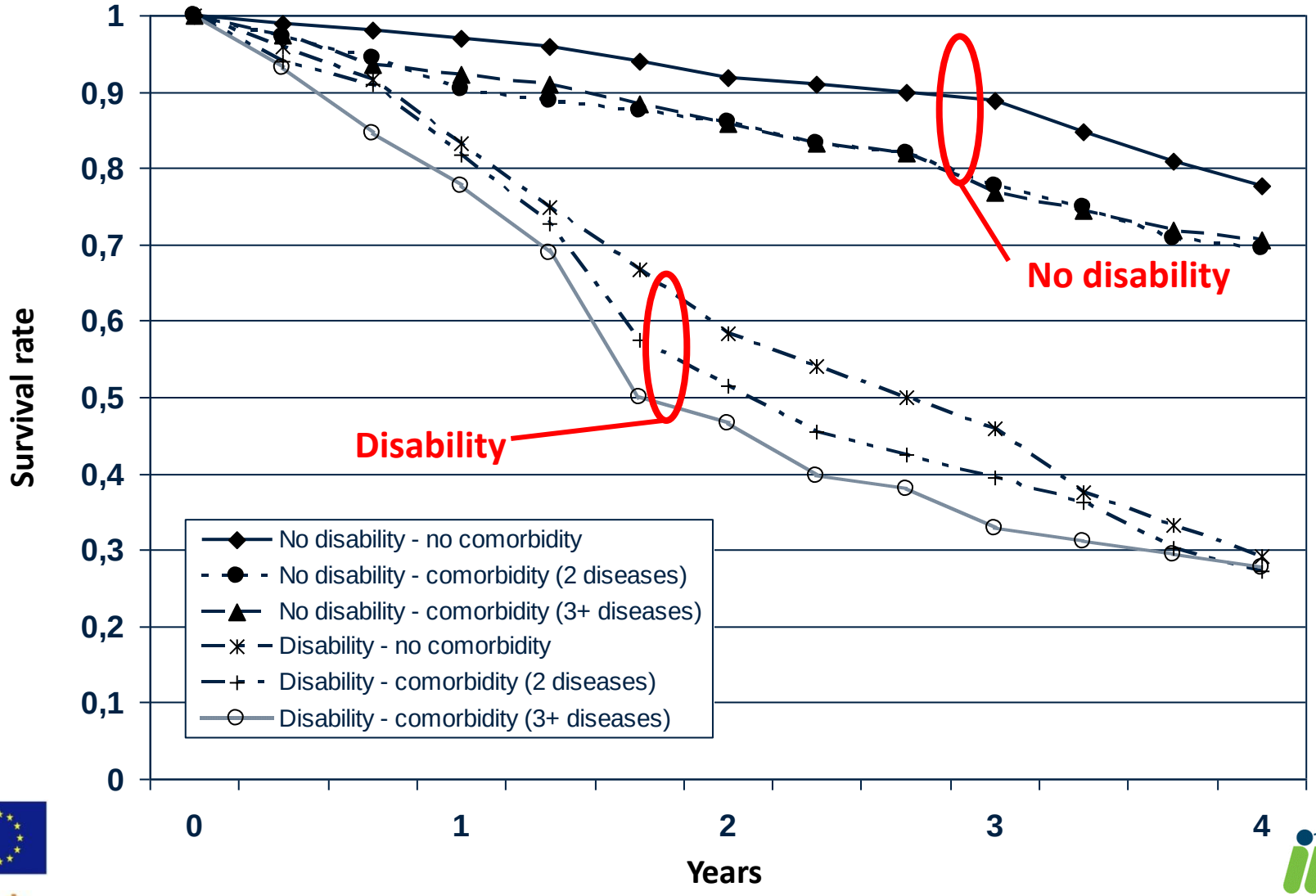
Introduction

From a disease-centred paradigm to a holistic approach for the care of older people

- During ageing the decline in homeostatic reserves may lead to functional impairment, loss of independence and mortality, regardless of disease conditions.

- In older adults, functional impairment is a stronger predictor of adverse health outcomes than the comorbidity burden.

Disability rather than multimorbidity predicts mortality at advanced age



Landi et al., J Clin Epidemiol 2010

Frailty and sarcopenia as a cause of physical function impairment

Frailty and sarcopenia are common causes of physical function impairment.

Identifying an at-risk older population: FRAILTY

- **Frailty** is a common geriatric syndrome associated with aging

- Around 10% of people aged over 65 years have frailty, rising to between a quarter and half of those aged over 85 years.

Based on a recent consensus definition, frailty is a ***"multidimensional syndrome characterized by decreased reserve and diminished resistance to stressors…."***.

Frailty is associated with increased risk of adverse events such as: functional decline, disability, repeated falls, reduction of the quality of life, repeated hospitalizations, nursing home admission and increased risk of death.

Identifying an at-risk older population: SARCOPENIA

Ageing of skeletal muscle is characterized by a progressive decrease in muscle mass.

"Sarcopenia is a syndrome characterized by the progressive and generalized loss of skeletal muscle mass and strength with increased risk of adverse outcomes, such as physical disability, poor quality of life and death."

Its diagnosis is based on criterion 1 plus criterion 2 or 3:

1. Reduced muscle mass
2. Reduced muscle strength
3. Reduced physical performance

Consequences of frailty and sarcopenia in absence of targeted interventions

In the absence of targeted interventions, progression of sarcopenia and frailty is marked by increased morbidity, disability, frequent and often inappropriate healthcare use, nursing home admission, and poor quality of life.

SPRINTT study objectives

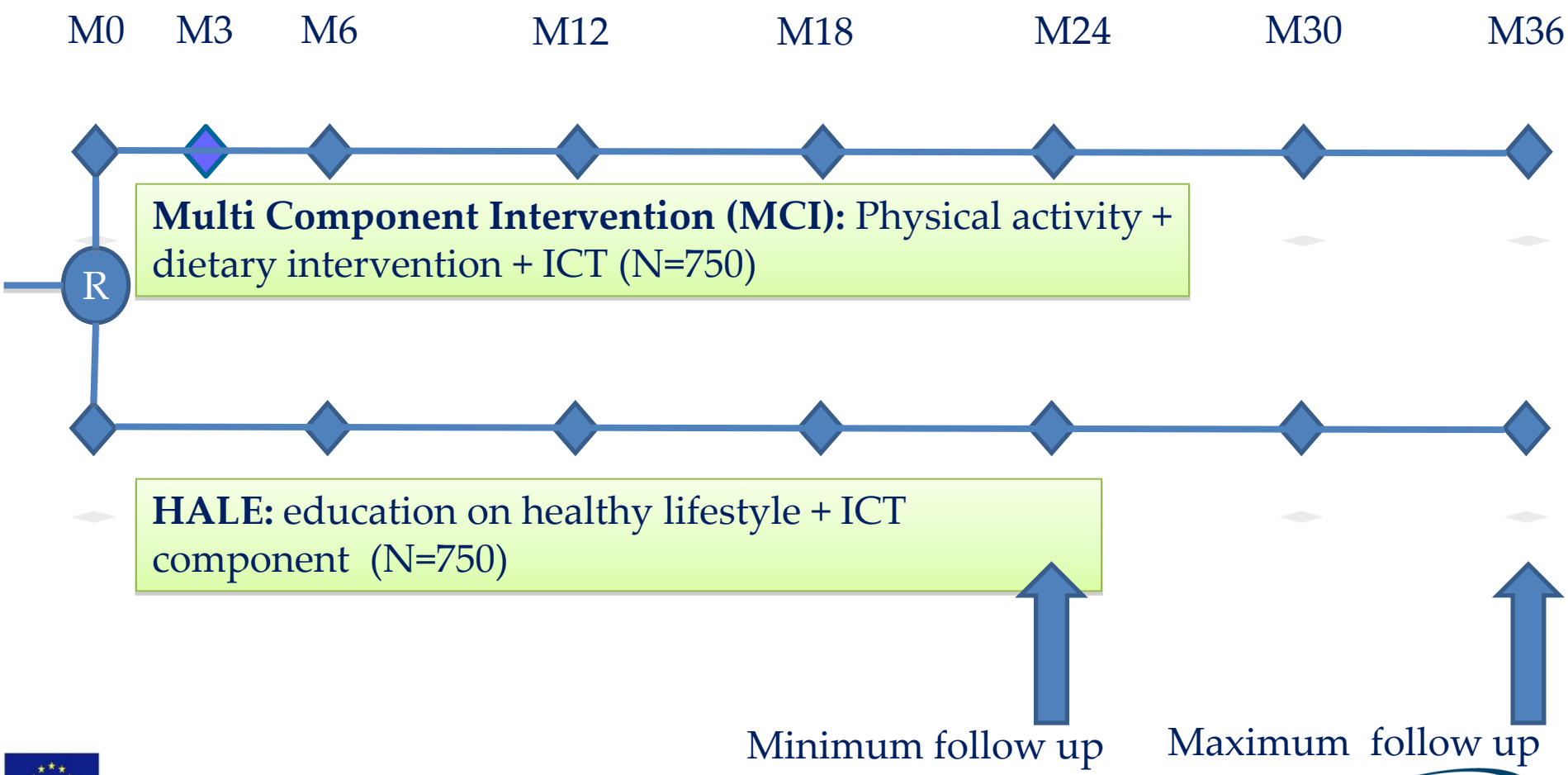
1. Provide a clear operationalisation of the currently vague concept of physical frailty

2. Identify a precise target population with unmet medical needs

3. Evaluate the effectiveness of a multi-component intervention in preventing mobility disability in an older population at risk of disability

4. Identify and validate diagnostic and prognostic biomarkers for physical frailty & sarcopenia

SPRINTT RCT outline



SPRINTT RCT outcomes

Primary outcome

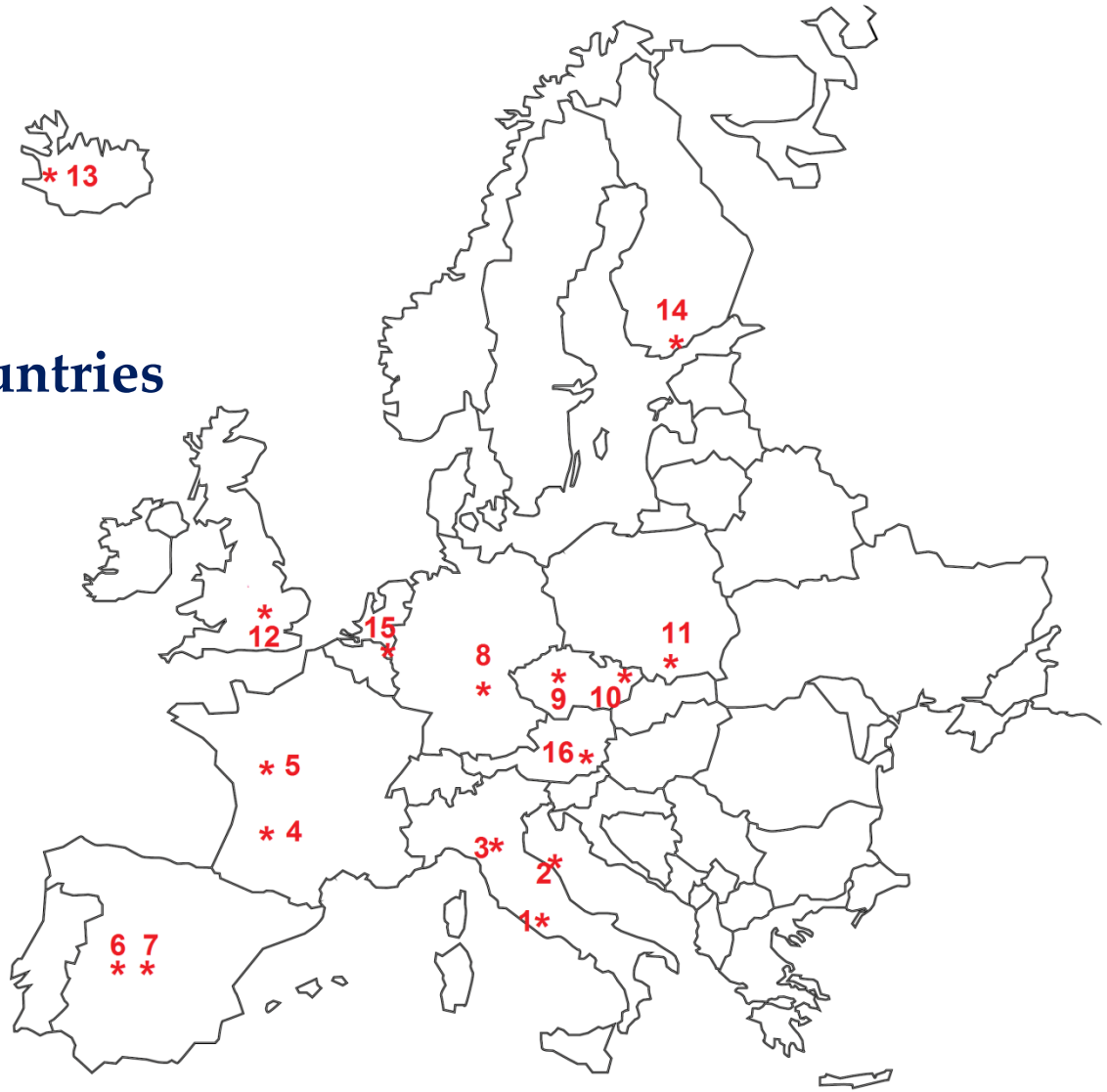
Incidence of mobility disability (inability to complete the 400-m walk test)

Secondary outcomes

- Changes in physical performance (i.e., SPPB, handgrip strength)
- Body composition modifications
- Incidence of falls
- Changes in nutritional status
- Changes in functional status (i.e., ADL, IADL, PAT-D)
- Changes in cognitive function and mood
- Changes in healthcare services utilisation
- Changes in quality of life (i.e., EuroQoL-5D, Participant-Reported)

The SPRINTT RCT clinical centres

16 clinical sites
11 European countries



SPRINTT RCT ELIGIBILITY CRITERIA

- The eligibility criteria in this study are aimed at identifying persons who are physically frail and sarcopenic,

- Candidates for the SPRINTT RCT will also be non-disabled as documented by their ability to walk 400m without sitting or the help of another person. Targeting this subset of the population makes it possible to recruit a non-disabled but at-risk population for a clinical trial of disability prevention.

- The eligibility criteria to be adopted in SPRINTT are very similar to those already implemented in the recently conclude LIFE study.

SPRINTT RCT INCLUSION CRITERIA

- Age ≥70 years
- Able to complete the 400-m walk test within 15 minutes without sitting down, the help of other persons, the use of a walker, or resting for over 1 minute per stop
- Short Physical Performance Battery (SPPB) score between 3 and 9
- Presence of low muscle mass according to results from a dual energy X-ray absorptiometry (DXA) scan (FNIH criteria)
- Willingness to be randomised to either intervention group

SPRINTT RCT
MAIN EXCLUSION CRITERIA

- Unable or unwilling to provide informed consent
- Plans to relocate out of the study area within the next 2 years
- Nursing home residence
- Current diagnosis of schizophrenia, other psychotic or bipolar disorder
- Consumption of more than 14 alcoholic drinks per week
- Difficulty communicating with the study personnel due to speech, language, or (non-corrected) hearing problems
- MMSE lower than 24/30
- Severe arthritis (e.g. awaiting joint replacement) that would interfere with the ability to participate fully

Sprintt
CLINICAL TRIAL

SPRINTT
Sarcopenia & Physical fRailty IN older people: multi-component Treatment strategies

If you want to know more on physical frailty and sarcopenia as well as on the SPRINTT project and RCT, please refer to the next power point presentation

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Disclaimer

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SPRINTT project website

www.mysprintt.eu