



## CONSENSUS CONFERENCE ON THE SPECIAL CARE UNIT FOR BPSD SCU-B

RECAGE Project (GA No: 779237)  
*Project funded by the European Commission*  
H2020-SC1-2017-Single-Stage-RTD

**Carlo A. Defanti**

***Bruxelles, 21-22 February, 2023***



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## A definition of the SCU-B.

The Special Care Unit for patients with dementia and Behavioural Disturbances is defined as “a residential medical structure lying outside of a nursing home, in a general hospital or elsewhere, e.g. in a private hospital, where patients with BPSD are temporarily admitted when their behavioural disturbances are not amenable to control at home. The mission of the SCU-B is to improve patient’s behaviour and its goal is to permit, when possible, her/his coming back home”.

Poptsi et al. 2021

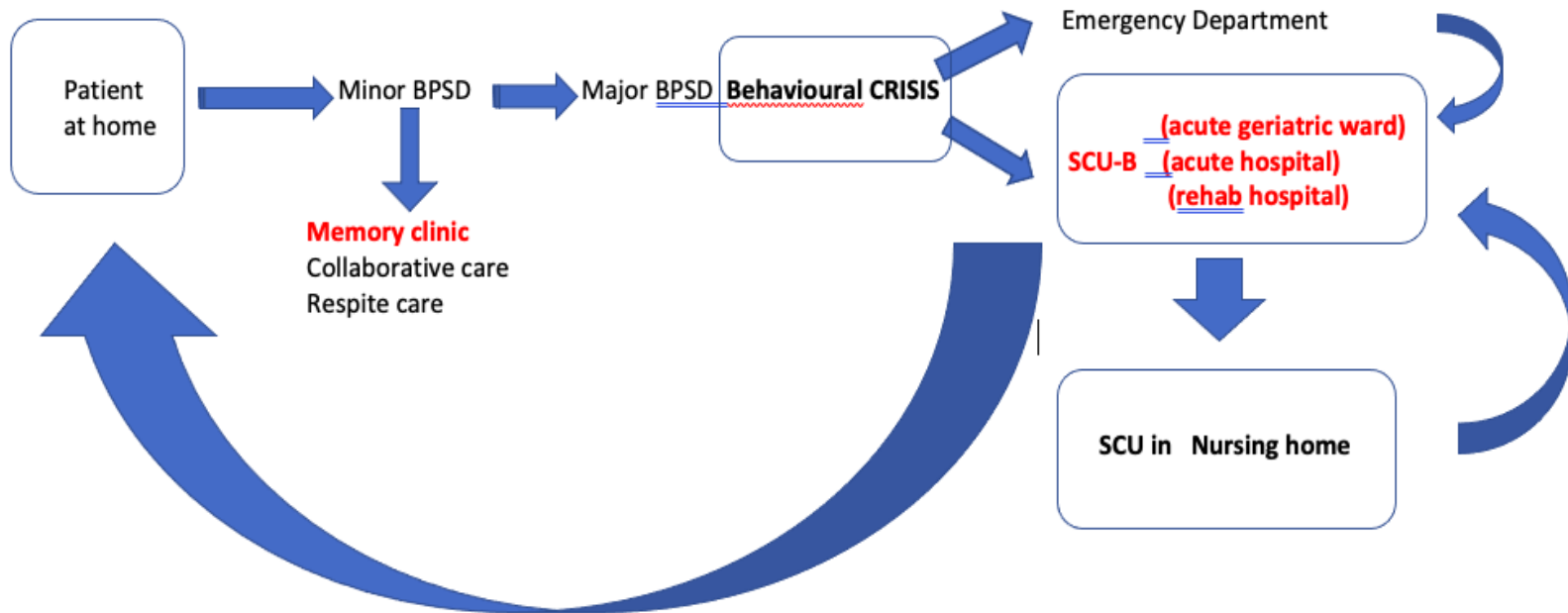


This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779237



## After the ALCOVE Project

Structure and care organization for BPSD along the care pathway of the patient (modified from the ALCOVE Project)





**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## The RECAGE Project

The leading idea was threefold:

1. *to look for stronger evidence of effectiveness and cost-effectiveness of the SCU-B*
2. *to adapt the model through a consensus conference;*
3. *to scale up the intervention in the countries who would take part in our Project where these units are absent or only sporadic.*



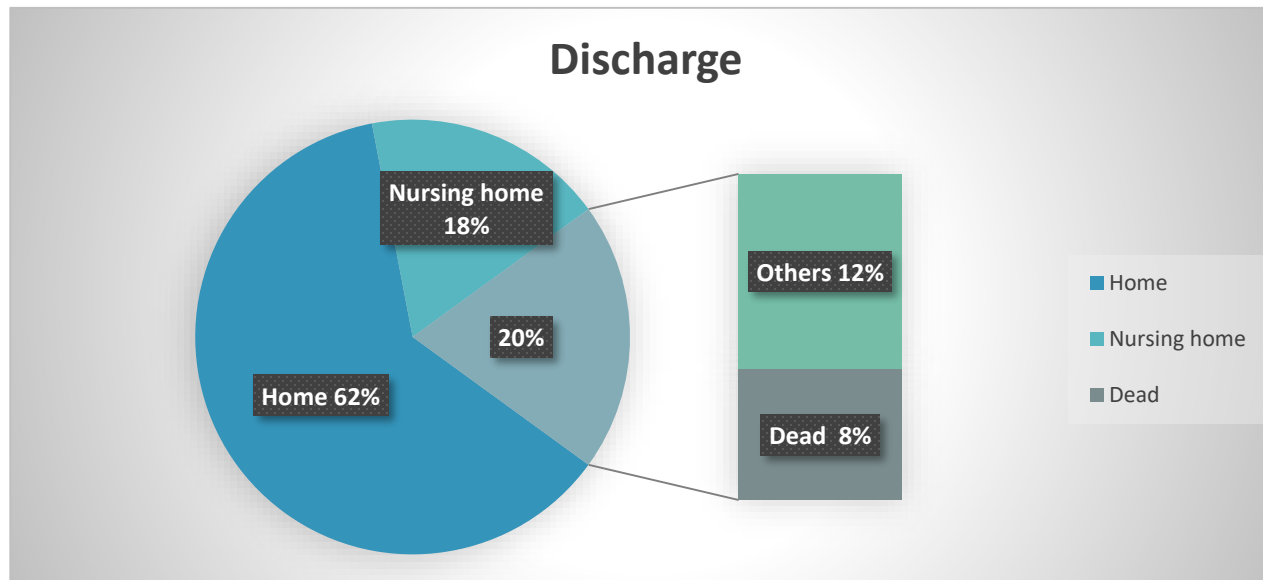
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



## Some historical data

M. Soto-Martin JAMDA 13 (2012) 486.e1e486.e6

A report on the pioneering Specific Acute inpatient Care Unit (SACU) of the Toulouse hospital. 6299 consecutive patients with dementia admitted (1996-2006) to a 20-beds acute care inpatient unit located at the Department of Geriatric Medicine.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## The French Literature

Soto-Martin: *"Despite the existence of special care units in nursing homes .. BPSDs are still difficult to manage, especially agitation and aggressiveness, and that the SACU could play a key role within the Alzheimer care system, in collaboration with the assisted living facilities"*.

Koskas et al *A pilot Psychogeriatric Unit for BPSD management* Alzheimer Dis Assoc Disord 2011; 25:184-6

Delphin-Combe et al *Experience of a care pathway for psychological and behavioral symptoms of dementia*  
Geriatr Psychol Neuropsychiatr Vieil 2013 ; 11 (4) : 416-22



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



REcage

## The Goldberg RCT 2013

Patients over 65 admitted to an acute hospital and identified by physician of the admission units as “confuse” were randomized either to a specialist medical and mental health unit, designed to deliver best practice care for people with delirium or dementia, or to standard care (acute geriatric or general medical wards).

*Conclusions: specialist care for people with delirium and dementia improved the experience of patients and satisfaction of carers, even though they weren't able to demonstrate convincing benefits in health status or service use.*

Goldberg et al: *Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial)*  
BMJ 2013;347:f4132 doi: 10.1136/bmj.f4132



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## The Australian model

Later on (2016), an intervention similar to the French one has been implemented in Australia, where the units are named *Special Dementia Care Units (SDCU)*.

The Sax Institute Review (2017, accompanying the Australian strategy), acknowledged that the evidence basis for the decision to implement the SDCUs is rather low.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237





**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## The design of the RECAGE trial

### Population

- One cohort followed up by centers provided with a SCU-B (N=250)
- One cohort followed up by centers with no SCU-B (N=250)

### Inclusion criteria

- Any age
- Males, females
- Diagnosis of primary dementia (DSM IV)
- MMSE score  $\leq 24$
- **NPI global score  $\geq 32/144$**
- Availability of a caregiver (informal/family member or formal caregiver) committed to follow the patient along the 3-year course of the study
- Living at home (nursing home residents were excluded).



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## The design of the REcAGE trial

Patients were treated by the participating centers according to their usual procedures. No alteration of the routine of the centres was requested and no additional therapy was recommended.

Admission to a SCU-B (either to the unit pertaining to the centre or another one external to it) was indicated only when a behavioural crisis arose, not amenable to control at home.

Total duration of the follow-up was **three years**.

Regular visits every 6 months, and – if needed – additional visits in between



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECAGE**

## The design of the RECAGE trial

### Outcomes

**Primary:**

- change over time of NPI and CMAI scores

**Secondary:**

- quality of life
- psychotropic drugs consumption
- change of caregivers' attitude toward dementia
- cost-effectiveness

**Tertiary:**

- delayed institutionalisation

*The main research hypothesis was that the care pathways of patients with BPSDs including a SCU-B would be superior in the long term to the pathways lacking this facility.*



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## Side hypotheses

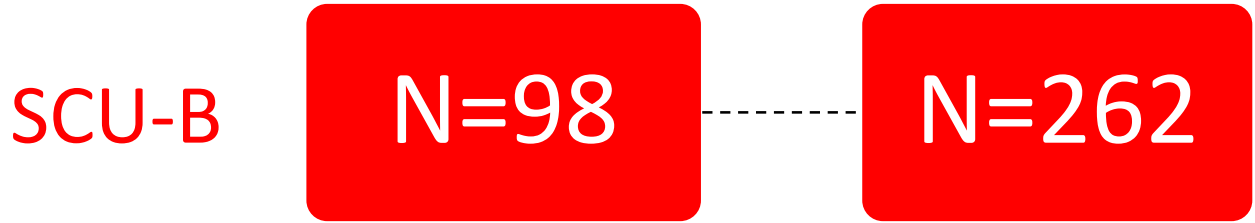
- 1: BPSDs would be better mitigated via the SCU-B pathway compared to the no-SCUB one.
- 2: QoL of patients and their caregivers cared for by centers endowed with a SCU-B would be improved compared to the QoL of patients followed by centers lacking a SCU-B.
- 3: The attitude of caregivers toward dementia would possibly be improved, due to the psychoeducation they will have in SCU-Bs.
- 4: SCU-Bs would be a cost-effective solution for both people with BPSD and their caregivers.
- 5: People with BPSDs followed by SCU-B centers would have lesser psychotropic drug consumption.
- 6: People with BPSDs followed by no SCU-B centers would be prone to earlier admission to institutions than people cared for by SCU-B centers.



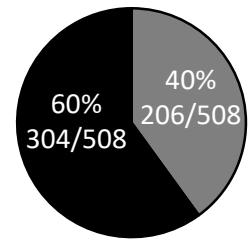
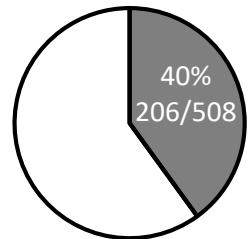
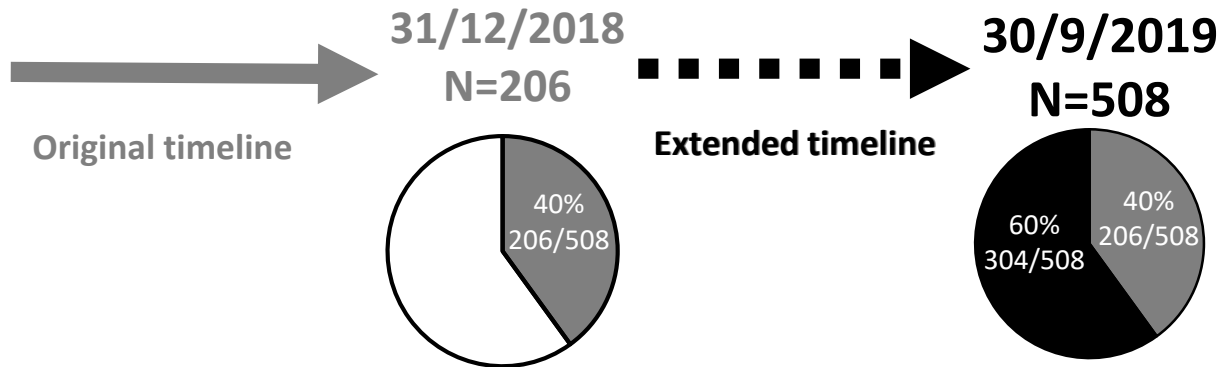
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



# Recruitment of 508 participants



April 2018  
Study start



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## The COVID 19 pandemic

The COVID-19 pandemic began in Europe at the end 2019 and that it was specially devastating in Italy, where two SCU-Bs (Gazzaniga and Modena) with a high recruitment rate (150/262) are located, with ensuing mortality (total of 15 COVID-19 related death with 14 in SCU-B and only 1 in non-SCU-B arm).

The coordinating centre of this Project (Gazzaniga) was located in the very epicentre of the pandemic



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



Bergamo, March 2020



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## The COVID 19 pandemic

The pandemic may have had an impact in many ways:

- Direct effects of the disease (e.g. mortality)
- Indirect effects, e.g. social isolation due to the prolonged lockdowns
- Negative impact on the conduct of the study leading to several visits being conducted over the phone, with impossibility to perform a number of assessments



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237





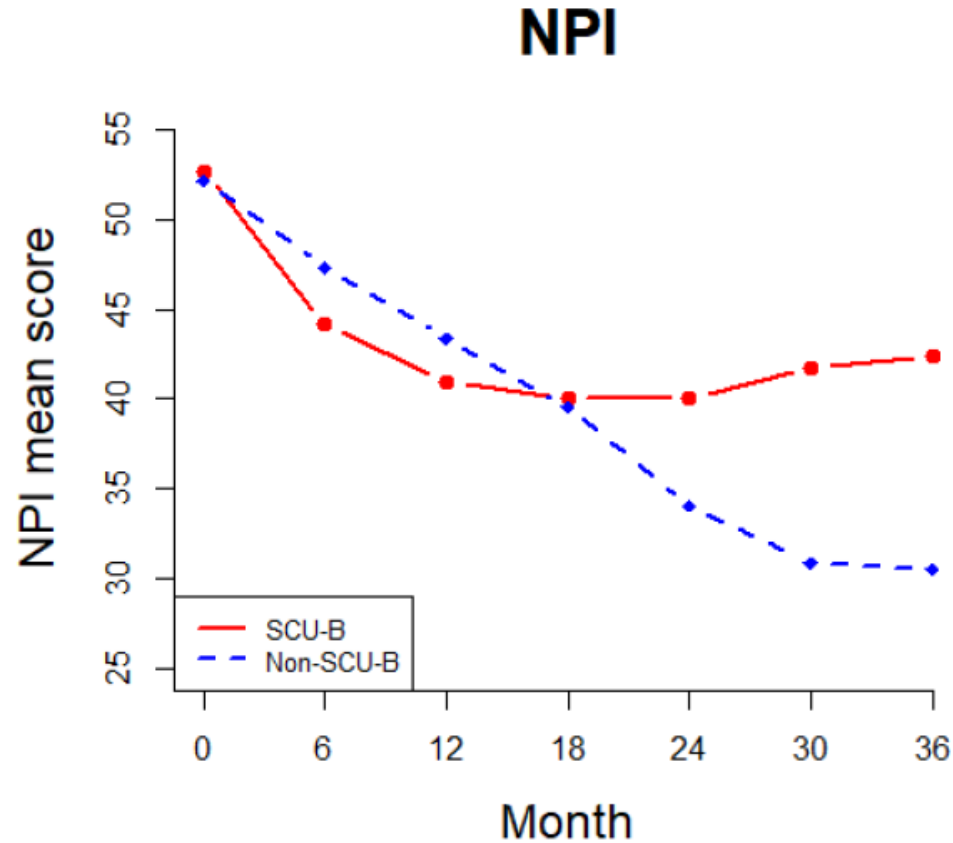
**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

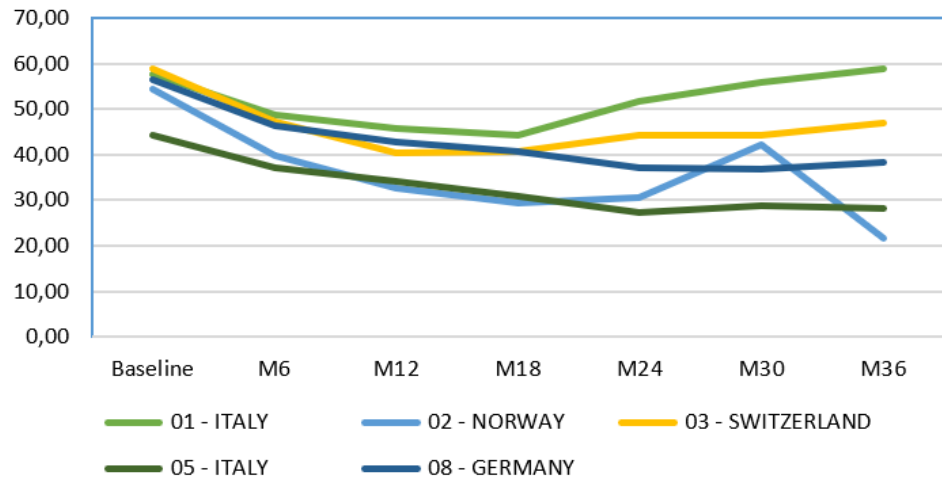
## The results of RECage clinical Trial: the Primary Outcome



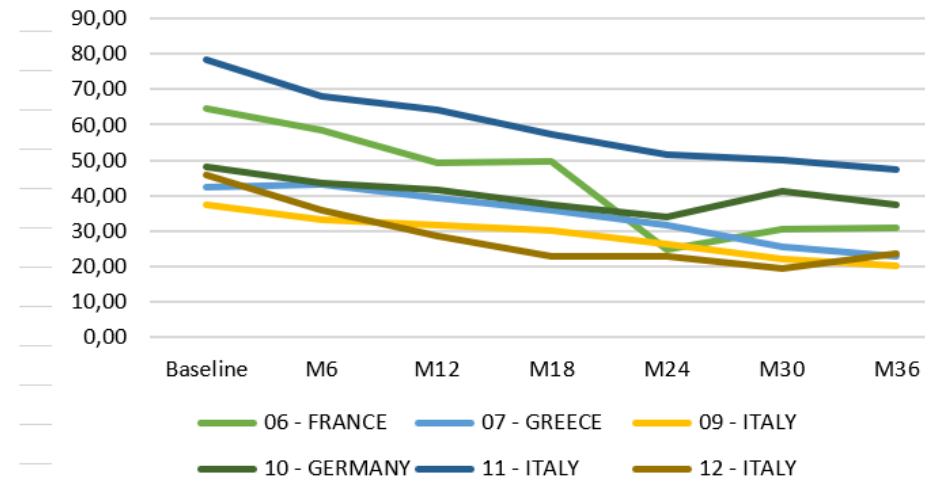
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237

## NPI score: time course in all centres

SCU-B



NON SCU-B



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**

## Other endpoints

### As to the *secondary endpoints*:

No significant differences as regards functional status (ADCS-ADL), quality of life (QoL-AD scale), and caregiver's burden (CBI)

Small significant difference of QoL (EQ-5D-5L index proxy rated) and ACQoL (Adult Quality of Life Carer) was found in favour of the noSCU-B cohort. Equally small difference in favour of the SCU-B cohort were found as regards the Dementia Attitude Scale (DAS).

### As to the *tertiary endpoint (time to institutionalization)*:

No significant difference between the cohorts



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



REcage

***Should we conclude that the SCU-B is ineffective?***

*No evidence in the effect is very different from evidence in no effect*



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## Our clinical impression

Notwithstanding the disappointing results of RECAGE, the (albeit scarce) evidence found in the extant literature on acute effectiveness, as well as the shared common experiences from physicians running SCU-Bs across Europe, seem to show that these structures can tackle during acute phase challenging clinical situations not easily amenable to solution at home.

*Certainly SCU-Bs, at least taken in isolation, are not able to influence long-term evolution and especially nursing home placement.*



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REAge**

## What lessons can we learn from all that?

A first general consideration: it is very difficult to reach strong evidence in real-world clinical trials.

The RCT model was not chosen because of ethical reasons, and a comparative longitudinal study as ours is subject to many confounding factors.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

# What next?



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237

## The Consensus Conference methodology

- A specific way of producing definitions/statements/recommendations through a **formal consensus process** between different stakeholders
- It revolves around a **public debate** in which clinical experts and other stakeholders exchange views
- **Purpose:** to provide patients with the best quality of care in relation to available resources
- Appropriate in specific situations:
  - **Controversial topic requiring public debate**
  - **Scanty evidence, no evidence**

**Definition:** to explain

**Statement:** to express a position

**Recommendation:** operational indication







**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## Consensus Conference Workflow

- Summary of the available evidence (systematic review of scientific literature or surveys)
- Panel of renowned experts (multidisciplinarity with respect to the topic) synthesize the available evidence and develop a report for each topic
- The panel listens to the reports and discussion with the public and develops recommendations/statements



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237

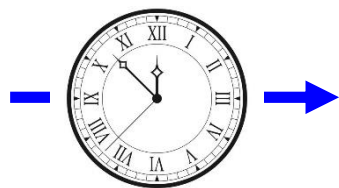


**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**REcage**



*Closed  
session*

**Consensus document**

## Panel

multistakeholder



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECage**

## Panel

Name	Role, Affiliation
<b>Iva Holmerová</b>	<b>Gerontologist, University of Prague, Panel Chair</b>
Maria Do Rosário Zincke Dos Reis	Chairperson of Alzheimer Europe
Ninoslav Mimica	Psychogeriatrician, University of Zagreb
Marina Boccardi	Neuropsychologist, University of Rostock
Pierre Jean Ousset	Geriatrician, University of Toulouse
Frans Verhey	Psychiatrist, University of Maastricht
Marco Canevelli	Neurologist, Istituto Superiore di Sanità, Sapienza University, Rome
Katalina Tudose	Psychiatrist, University of Bucharest
Francesco Nonino	Methodologist, Institute of Neurological Sciences of Bologna



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



## What questions for the Panel?

Domain	Research Question	Questions for the panel
Description and technical characteristics of SCU-B (including description of target population, architectural, organizational, legal aspects)	What kinds of SCU-B are there? With special regard for the SCU-Bs: what about architectural features, staff compositions, activities, criteria for admission?	<b>1. Which types of SCU-B can be identified ?</b> <b>2. What are the characteristics of different types of SCU-B in terms of target population, structural and organisational aspects ?</b> <b>3. What are the main ethical issues to be addressed by the staff of a SCU-B?</b>
	What are the main issues related to the SCU-B (informed consent, restraints, “benevolent” coercion ...)	
Effectiveness of SCU-B	What is the evidence of clinical effectiveness of the SCU-B vs usual care?	<b>4. What are the recommended effectiveness and safety outcomes to be considered when assessing/auditing a SCU-B?</b>
Costs and economic evaluation of SCU-B	What is the evidence of cost-effectiveness of the SCU-B vs usual care?	<i>(see question 4 – Effectiveness component of cost-effectiveness)</i>
Safety of SCU-B	What are the safety issues of physical restraints and neuroleptic treatments?	<b>5. What are the main safety issues to be addressed by the staff of a SCU-B in relation to restraint measures?</b>



This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



REAge

## What «product» do we want after the CC?

- A list of definitions – statements – recommendations (as appropriate, based on what we know from the available evidence)
- Clear, unambiguous
- Preceded by a one-page executive summary
- «Usable» in different settings (healthcare management, as well as political)
- With broad endorsement by researchers, clinicians (scientific societies) and advocacy groups



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237



**FERB**

FONDAZIONE  
EUROPEA  
RICERCA  
BIOMEDICA  
ONLUS



**RECase**

**THANKS FOR YOUR ATTENTION!**



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 779237