THE SPECIAL CARE UNIT FOR BPSD (SCU-B) AND THE RECAGE PROJECT

A NEW LINK IN THE CHAIN OF ALZHEIMER SERVICES

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Our experience, since 2005, inside the FERB Alzheimer Centre (Gazzaniga), a clinical unit located in a rehabilitation hospital pertaining to the ASST Bergamo Est, convinced us of the utility of such a structure, which allows the admission, for a limited period of time, of persons with dementia when they face a behavioural crisis not amenable to control at home. We decided to call this structure "Special Care Unit for patients with dementia and Behavioural disturbances (SCU-B)".

The short-term results, as regards the behavioural symptoms (the so-called BPSD), are good in the large majority of patients, but there are no solid data in the scientific literature showing that the possibility to have resort to a SCU-B is able to modify the long-term course of dementia.

Starting from this uncertain situation, we presented to the European Commission a project, named RECage (Respectful Caring for the AGitated Elderly), which succeeded in obtaining a grant in the frame of the H2020 Projects.

RECage

RESPECTFUL CARING FOR THE AGITATED ELDERLY

A PROJECT FUNDED BY THE EUROPEAN COMMISSION H2020

REC*age* tackles one of the most challenging problems arising in the course of dementia: the **BEHAVIORAL AND PSYCHOLOGICAL SYMPTOMS OF DEMENTIA (BPSD)** and explores the clinical efficacy and the cost-effectiveness of the SCU-Bs

WHAT IS A SPECIAL CARE UNIT FOR BPSD (SCU-B)?

Our definition is: "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"

DISTINCTION FROM OTHER SCU

A SCU-B must be carefully distinguished from the much more common **SCU or special area for PwD existing in many nursing homes, where PwD are cared for permanently** by specially trained staff, in wards appropriately endowed with locking systems and safety devices. The usefulness of this last facility, although widespread, is not entirely uncontroversial, even though a recent review demonstrated a trend towards a better functional status and a better quality of life in the SCU group compared to the traditional nursing home (non-SCU) group.

Kok JS, Berg IJ, Scherder EJA *Special care units and traditional care in dementia: relationship with behavior, cognition, functional status and quality of life – a review* Dement Geriatr Cogn Disord Extra 2013; 3:360–375

HOW DOES A SCU-B WORK?

The therapeutic approach in most existing SCU-B is a mix of cautious pharmacological treatment, non-pharmacological therapies (such as occupational therapy, physiotherapy, doll therapy, sensory room and so on), appropriate environment and, above all, experienced geriatric/gerontopsychiatric doctors and nurses; in some existing SCU-B the approach to the patients is in line with the Gentlecare or to the Person-Centred Dementia Care approach.

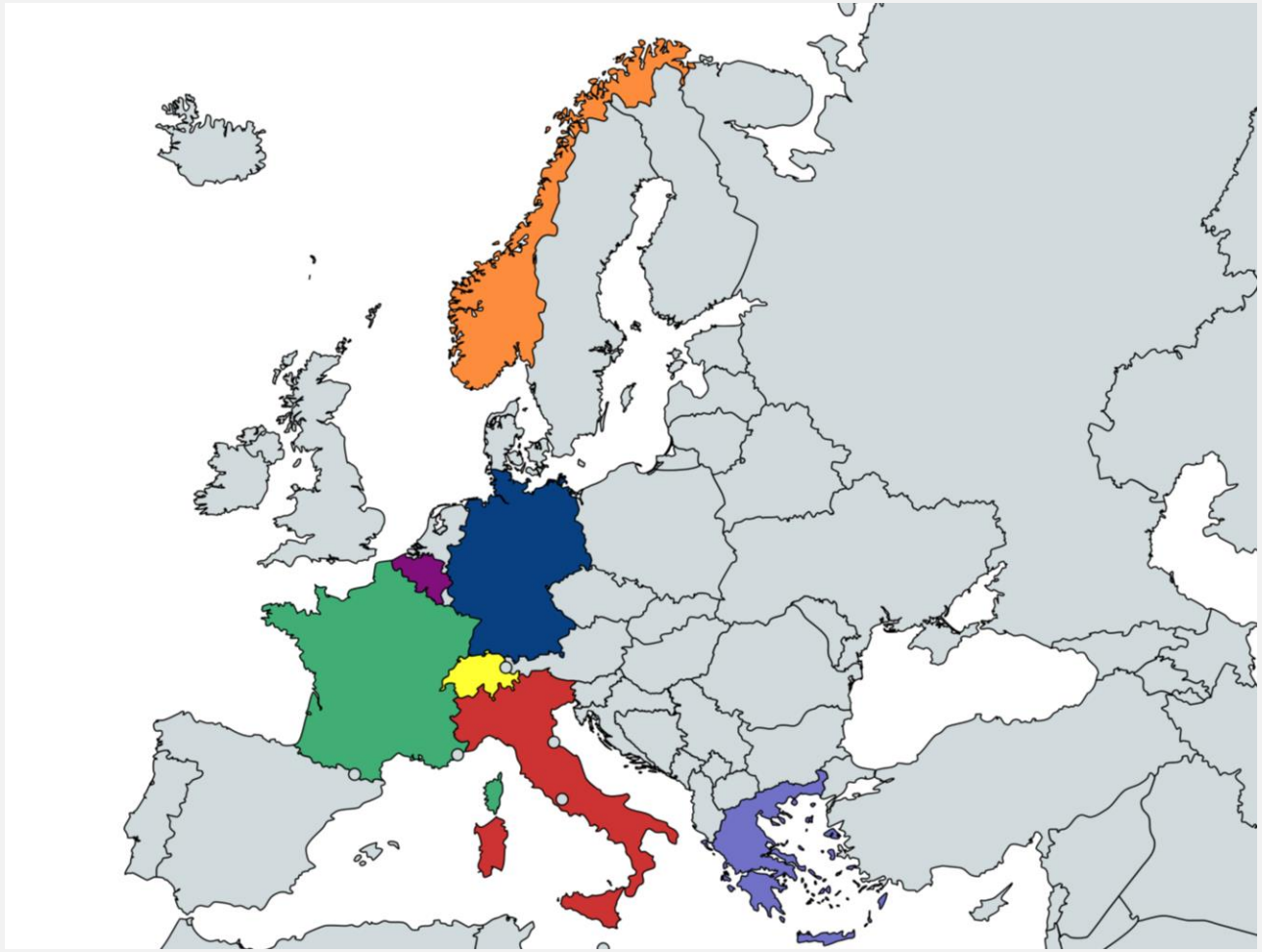
THE FIRST PHASE OF THE RECAGE PROJECT: THE CLINICAL STUDY

THE CONSORTIUM

The Consortium encompasses 12 clinical centres located in **7 European Countries** (Italy, France, Germany, Belgium, Greece, Switzerland and Norway), a CRO, a health economist, two Alzheimer Associations (from Italy and Greece) and two health Authorities (from Italy and Greece).

Horizon 2020
European Union Funding
for Research & Innovation

RECage



THE PARTICIPATING CENTRES AND THEIR SOCIAL CONTEXT

- The French situations is unique, insofar as in that country a formal network of SCU-B (called UCC) ha been implemented for 10 yrs
- The Swiss situation changes across the cantons.
- A rather similar situation exists in Norway, where the presence of SCU-B vary across regions.
- Germany and Italy don't have a formal network of SCU-Bs (the former country have several, Italy only a few).
- Greece has no such unit and therefore could be a good starting point for implementing this intervention

CHOICE OF THE STUDY DESIGN

Two alternatives:

- a randomized controlled trial performed only by the Centres endowed with a SCU-B and comparing an active group, which could have access, if necessary (e.g. during a behavioural crisis), to the SCU-B and a control group without this option
- a prospective observational study comparing two cohorts: the one followed by the Centres with SCU-B and the other by the Centres lacking this facility.

CHOICE OF THE STUDY DESIGN

- Mainly for ethical reasons we opted for a comparative cohort study, whose main goal – as stated above – is to measure the efficacy and the cost-effectiveness of the SCU-B; at the same time we shall evaluate the quality of life of the patients/relatives and the ethical aspects of care in the SCU-B (attitude of the staff/relatives to the patient)
- The patients will be followed up by the participating centres according to their usual procedures. No alteration of the routine of the centres is requested, no additional therapy recommended.

DESIGN OF THE STUDY

RECage is a prospective observational study (follow-up duration: 3 years) comparing two cohorts of community-dwelling PwD with a diagnosis of dementia (MMSE ≤ 24) of any etiology and significant BPSD (NPI ≥32)

DESIGN OF THE STUDY

- Total number of persons: 500, divided in two cohorts of 250 each.
- Follow-up: 3 years; the follow-up visits are scheduled every 6 months.
- Each person must have a primary caregiver committed to stand by the her/him during the study.
- The first cohort will be followed up by 6 centres endowed with a SCU-B and the second one by 6 centres without a SCU-B.

THE WORKING HYPOTHESIS

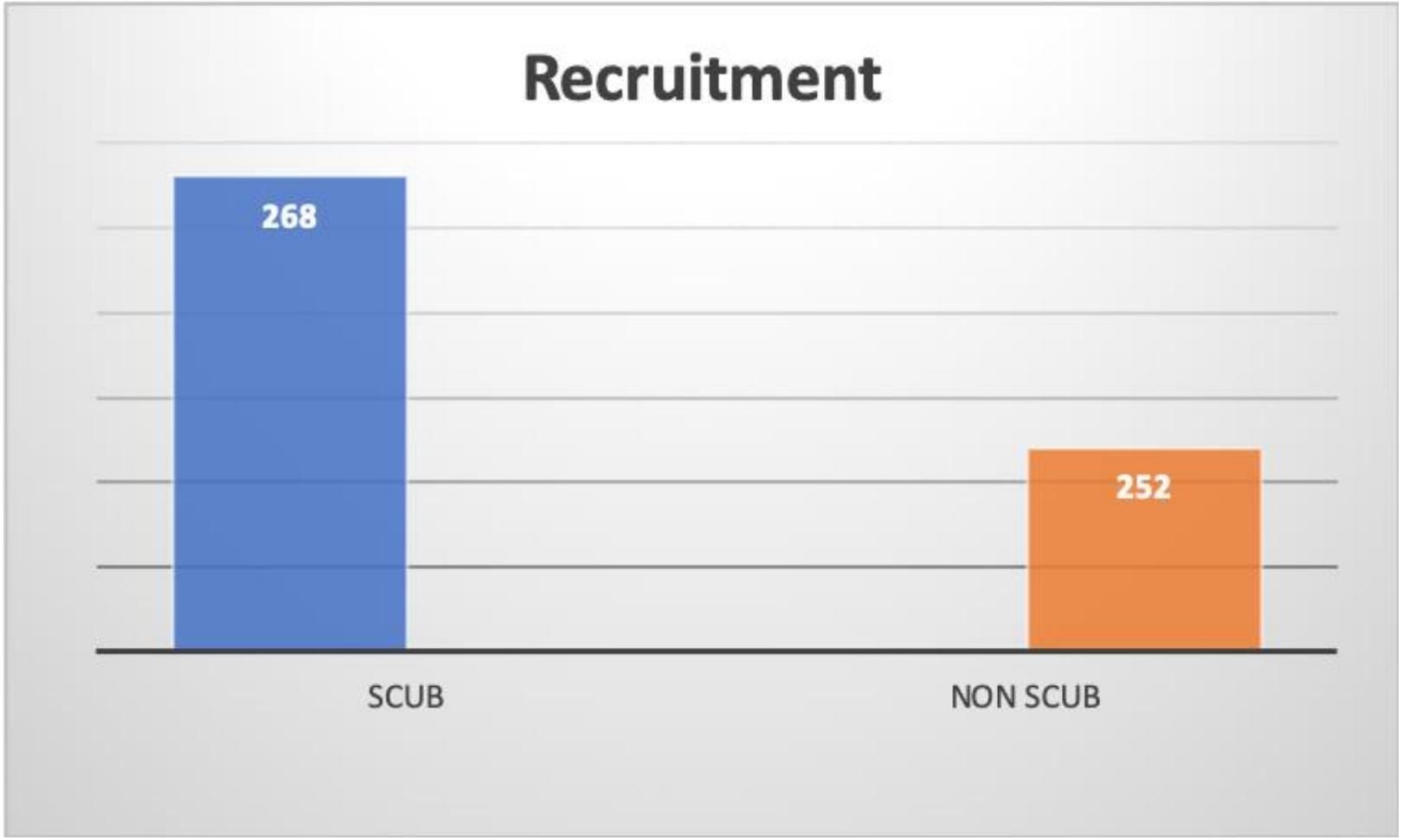
- **Our working hypothesis is the superiority of the care pathways comprising a SCU-B over those lacking it.**
- **The (expected) superiority of the pathways with SCU-B over the others is linked to the availability of this facility, not to the routine admission to it.**

Objectives	Endpoints
Primary	
• To estimate the clinical efficacy, both short- and long-term, of the SCU-B	• To compare the two cohorts in the change of BPSD (NPI, CMAI) over time (at time 0, 6, 12, 18, 24, 30, 36 months)
Secondary	
• To assess the quality of life of the patients and their caregiver • To estimate the cost-effectiveness of SCU-Bs • To estimate psychotropic drug consumption over time • To assess the change of attitude of caregivers toward dementia	• To compare QoL of PwD over time (Qol AD and EQ-5D-5L, at time 0, 6, 12, 18, 24, 30, 36 months) between the two cohorts • To compare QoL (total) of caregivers over time (AC-QoL,EQ-5D-5L, CBI at time 0, 6, 12, 18, 24, 30, 36 months) between the two cohorts • Change in care costs over time (at time 0 [baseline], 6, 12, 18, 24, 30, 36 months): RUD • Incremental cost-effectiveness ratio RUD, ICECAP-O, EQ-5D-5L • To compare drug consumption between the two cohorts • Dementia Attitude Scale (DAS)
Tertiary/Exploratory	
• To assess the capacity of the SCU-B to delay institutionalisation	• Time of the (final) admission to a nursing home (Survival methods)

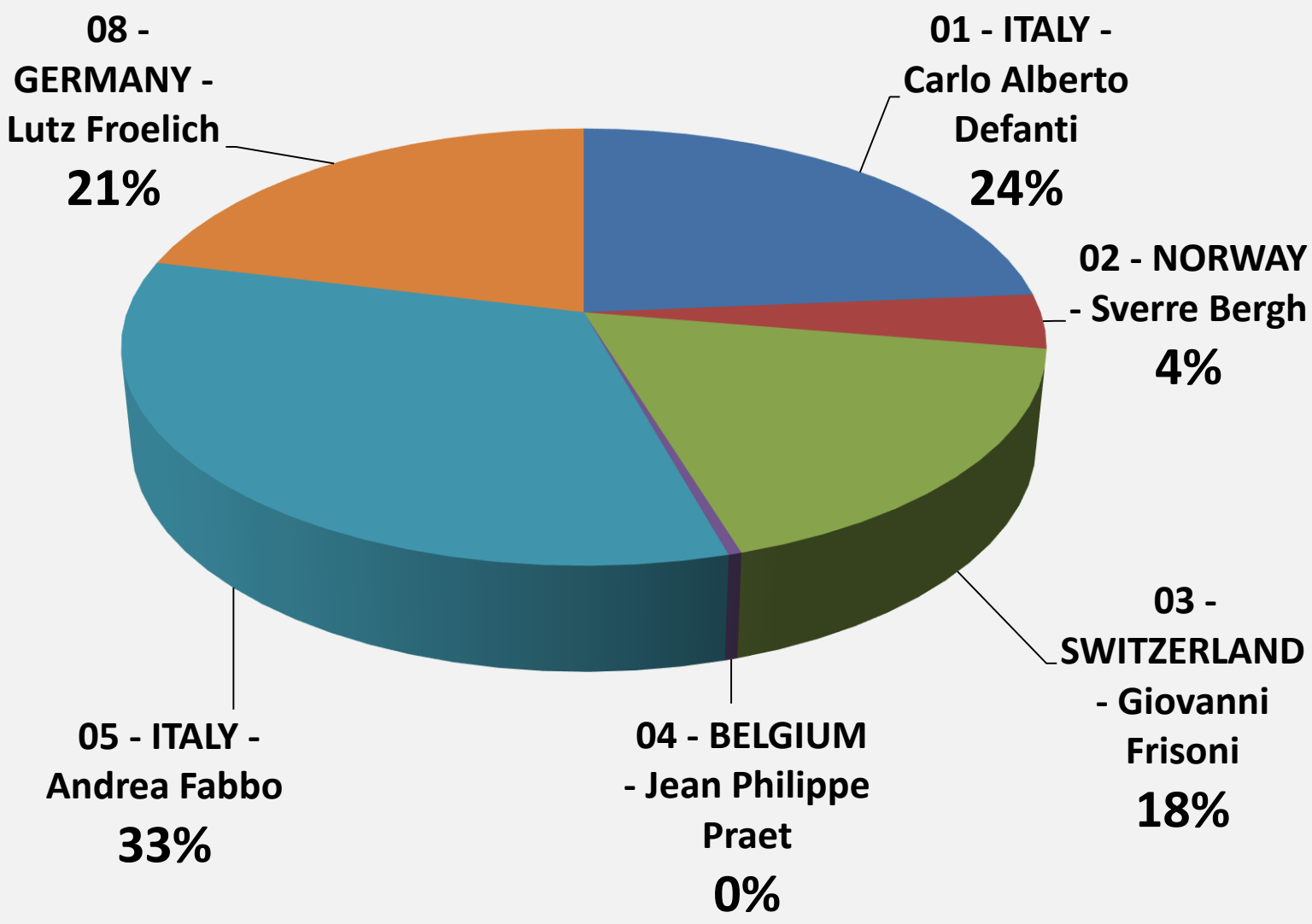
THE CLINICAL STUDY: BASELINE DATA

PROBLEMS OF RECUITMENT

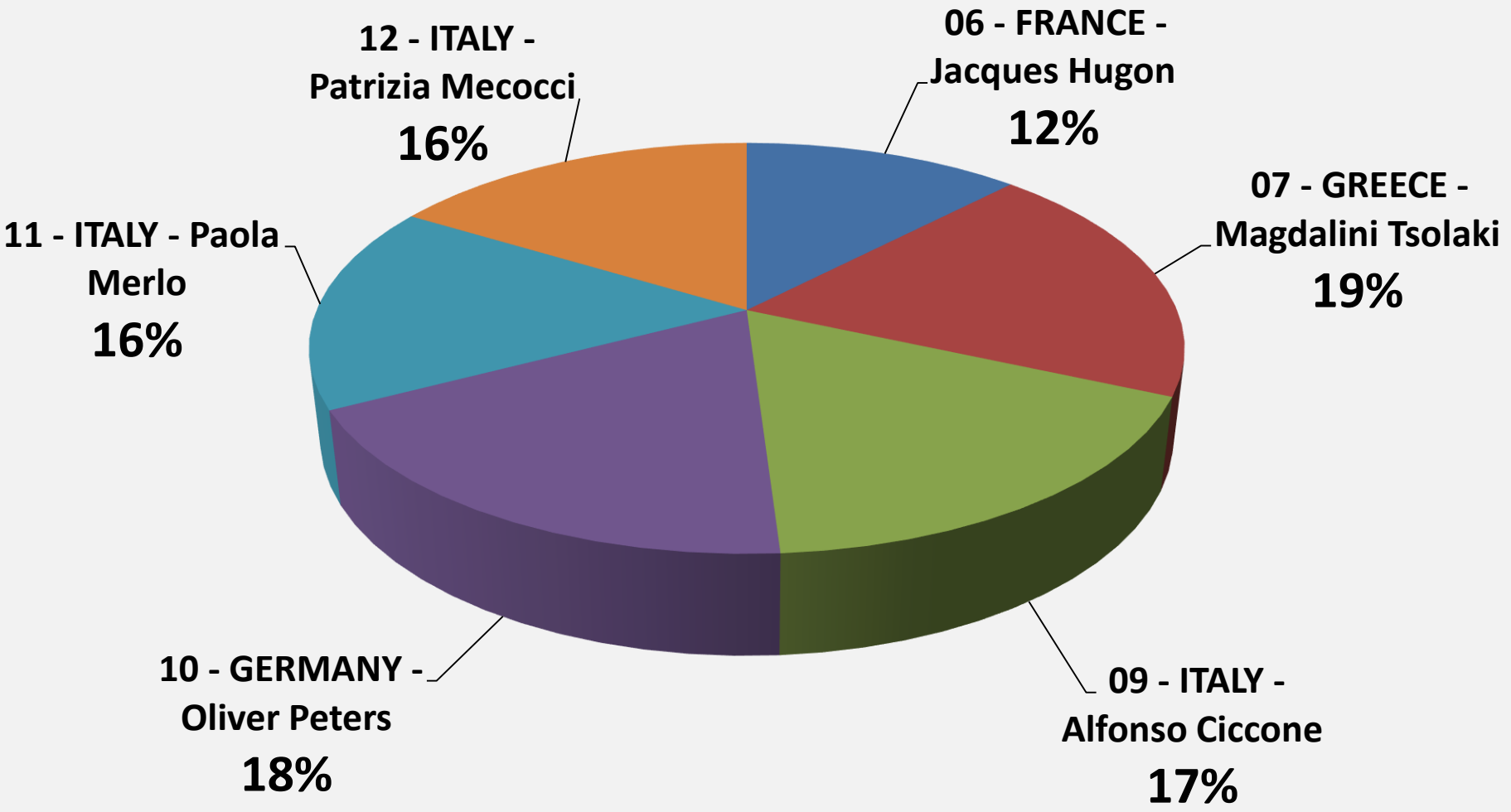
- Delays in obtaining the Ethics Committee's approval
- Exit of the Bruxelles Centres → imbalance between SCU-B and non SCU-B centres → competitive recruitment
- Prolongation of the recruitment period (from 31° December 2018 to 30° September 2019)


Recruitment
268
252
SCUB
NON SCUB

SCU-B (N=268)

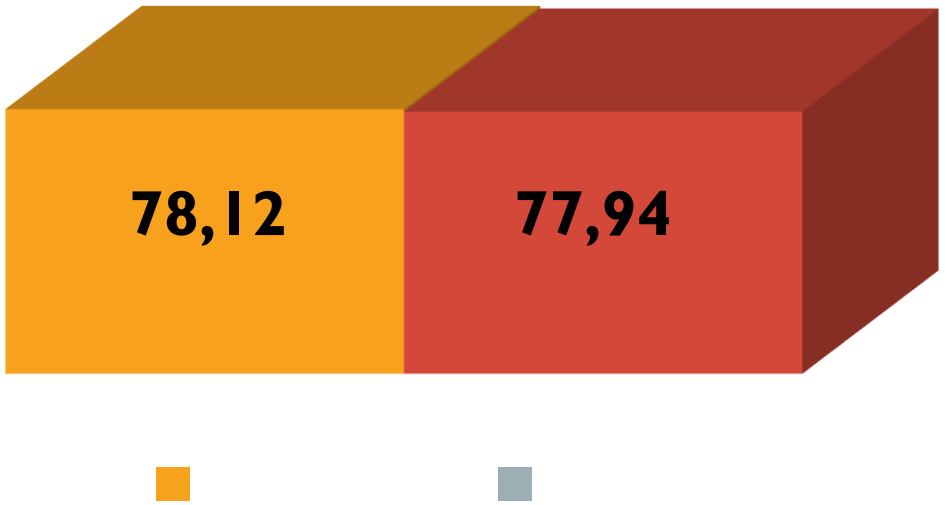

08 - GERMANY - Lutz Froelich
21%
01 - ITALY - Carlo Alberto Defanti
24%
02 - NORWAY - Sverre Bergh
4%
03 - SWITZERLAND - Giovanni Frisoni
18%
04 - BELGIUM - Jean Philippe Praet
0%
05 - ITALY - Andrea Fabbo
33%

NON SCU-B (N=252)



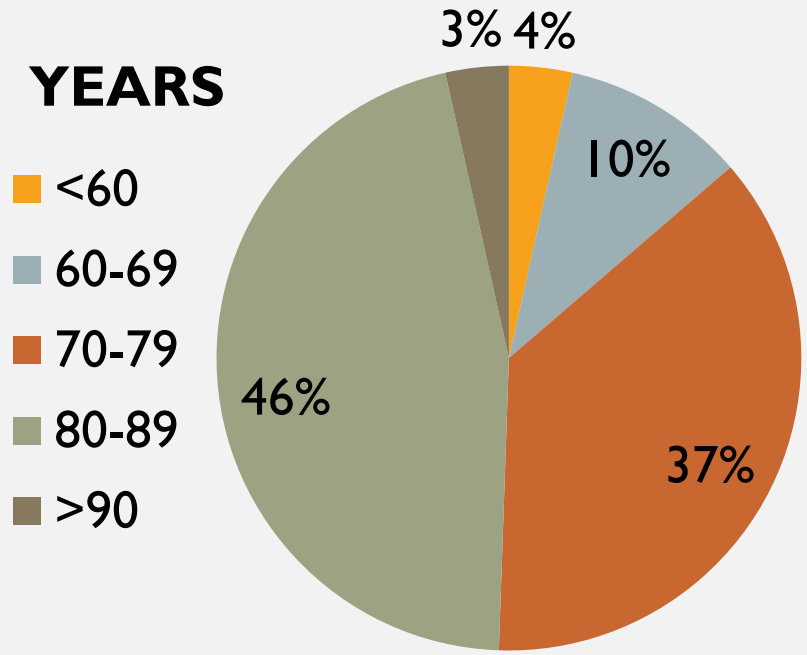
MEAN AGE

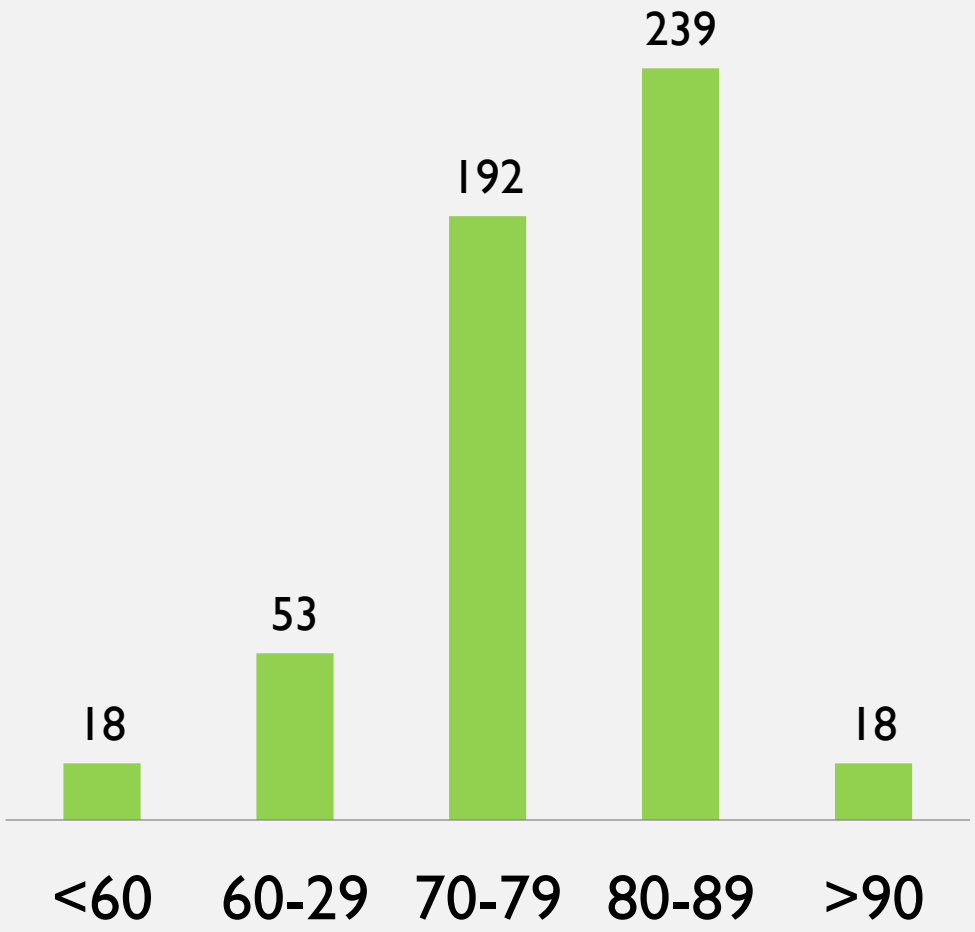
AGE	SCU-B (N=268)	Non SCU-B (N=252)
Mean (SD)	78,12	77,94



AGE ALL PATIENTS (N=520)

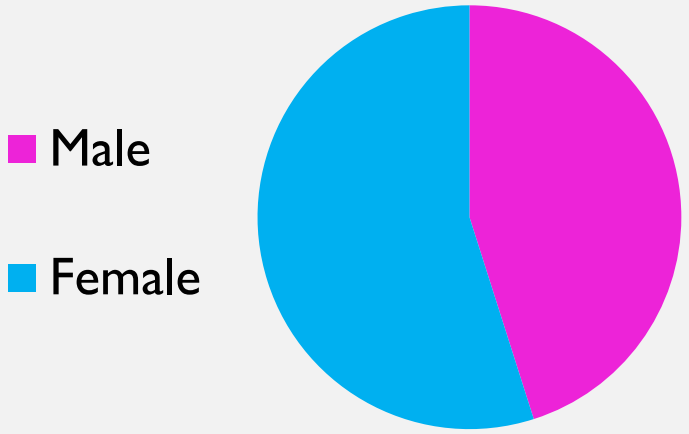
YEARS	N	%
<60	18	3,5%
60-29	53	10,2%
70-79	192	36,9%
80-89	239	46%
>90	18	3,5%

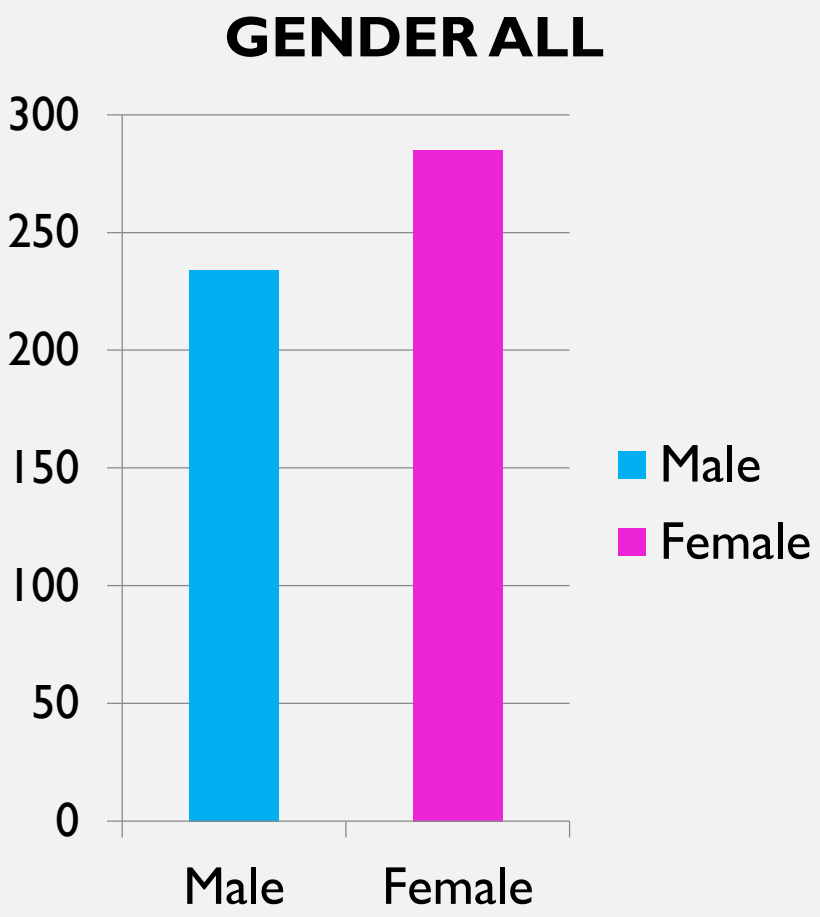




GENDER: ALL (N=520)

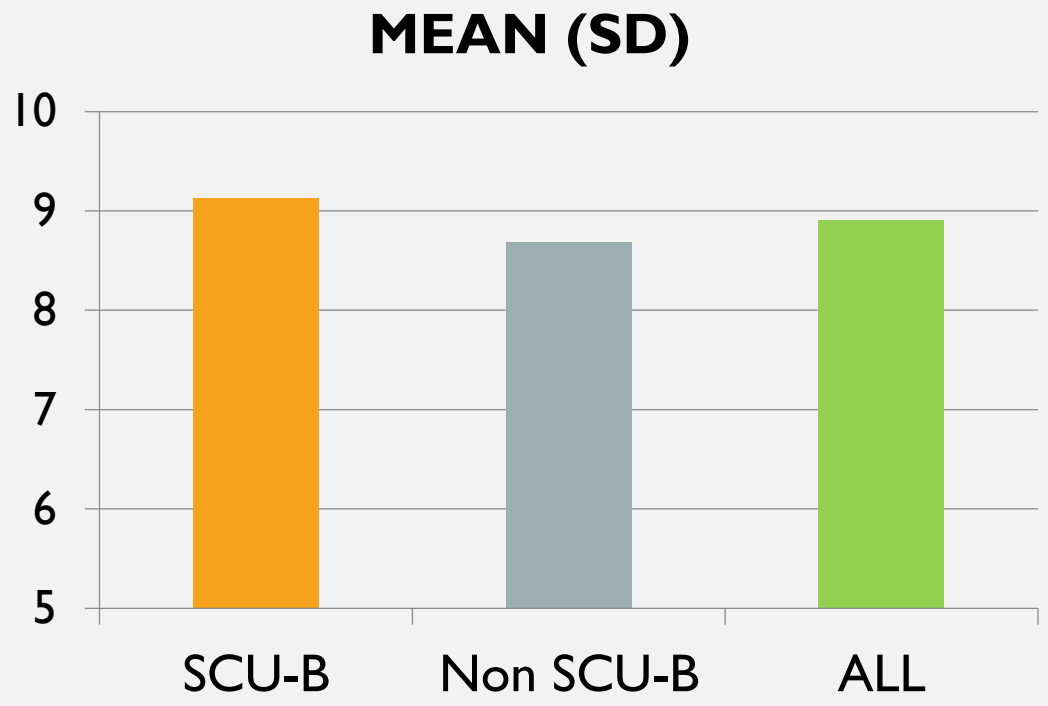
GENDER	ALL (N=520)	
Male	234	45%
Female	285	54,8%
Missing	1	





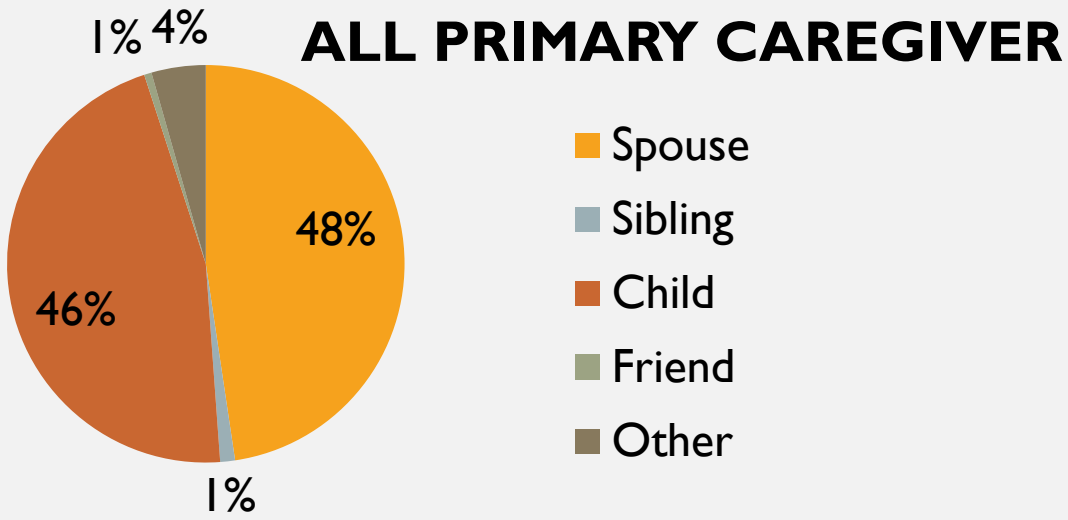
EDUCATIONAL LEVEL (YRS)

EDUCATIONAL LEVEL	N	%	MEAN (SD)
SCU-B (N=268)	266	99,3%	9,13
Non SCU-B (N=252)	249	98,8%	8,68
ALL (N=520)	515	99%	8,91



PRIMARY CAREGIVER

PRIMARY CAREGIVER	SCU-B (N=268)		Non SCU-B (N=252)		ALL (N=520)	
Spouse	136	50,7%	111	44%	247	47,5%
Sibling	1	0,4%	5	2%	6	1,2%
Child	114	42,5%	125	49,6%	239	46%
Friend	3	1,1%	0	0%	3	0,6%
Other	12	4,5%	11	4,4%	23	4,4%

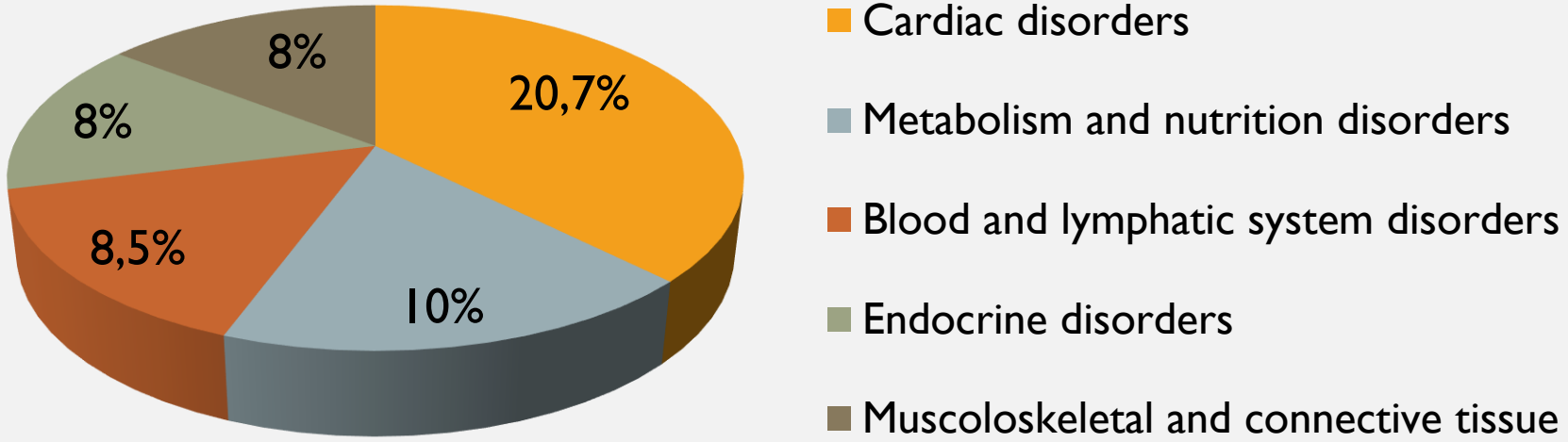


DIAGNOSIS OF DEMENTIA

DIAGNOSIS OF DEMENTIA	SCU-B (N=268)		Non SCU-B (N=252)		ALL (N=520)	
Alzheimer	162	60,4%	133	52,8%	295	56,7%
Vascular Dementia	28	10,4%	3	1,2%	31	6%
Lewy Body Dementia	14	5,2%	9	3,6%	23	4,4%
Parkinson-Dementia	1	0,4%	5	2%	6	1,2%
Frontotemporal Dementia	19	7,1%	19	7,5%	38	7,3%
Dementia due to multiple etiologies	34	12,7%	52	20,6%	86	16,5%
Dementia non otherwise specified	6	2,2%	27	10,7%	33	6,3%

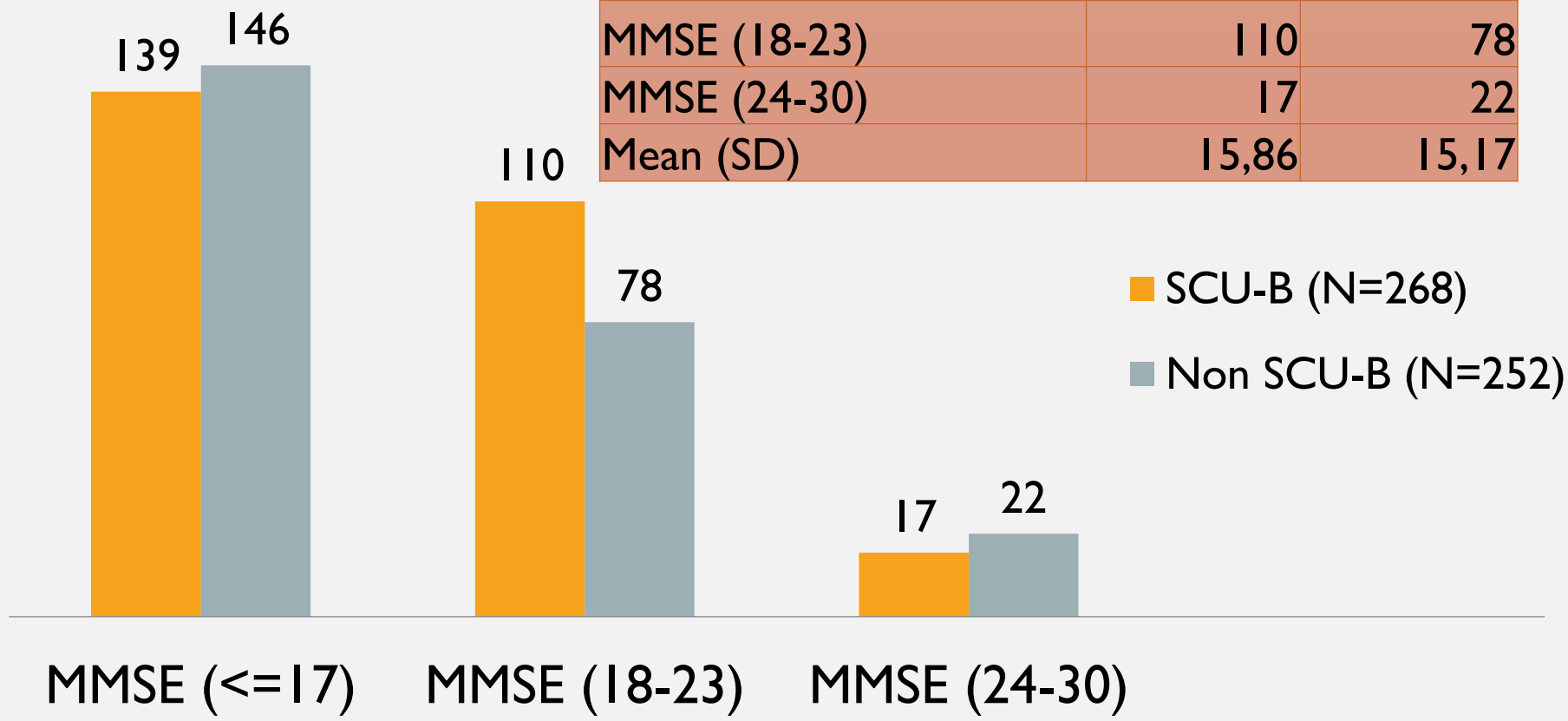
ALL (N=520) BODY SYSTEM

BODY SYSTEM	N	%
Cardiac disorders	257	20,7%
Metabolism and nutrition disorders	124	10%
Blood and lymphatic system disorders	105	8,5%
Endocrine disorders	99	8%
Muscoloskeletal and connective tissue	99	8%



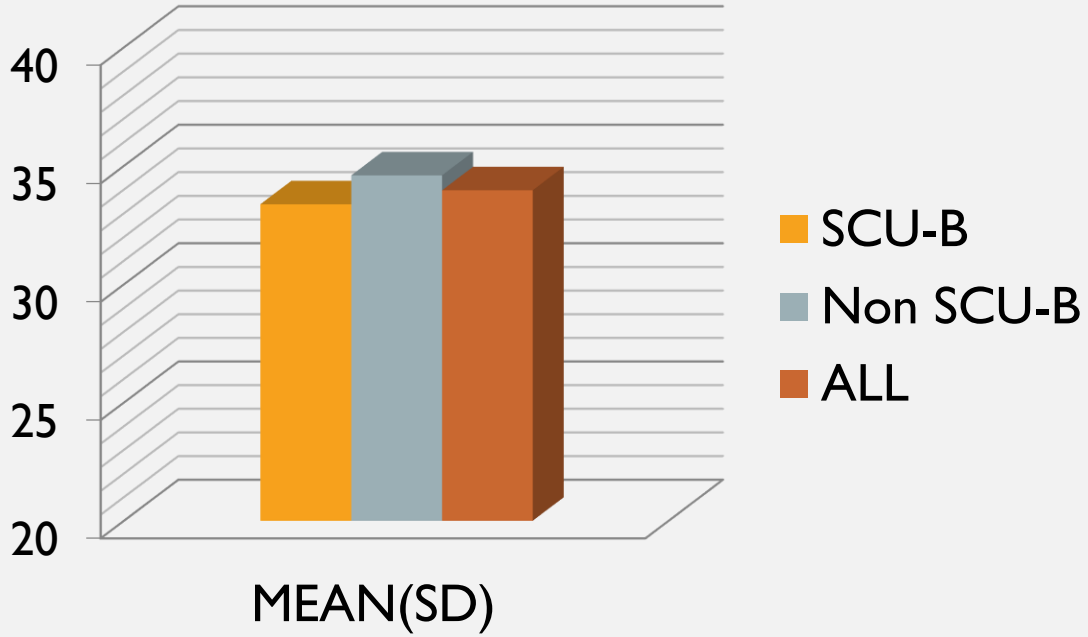
MMSE: TOTAL SCORE

MMSE DISTRIBUTION BY SEVERITY	SCU-B (N=268)	Non SCU-B (N=252)
MMSE (≤17)	139	146
MMSE (18-23)	110	78
MMSE (24-30)	17	22
Mean (SD)	15,86	15,17



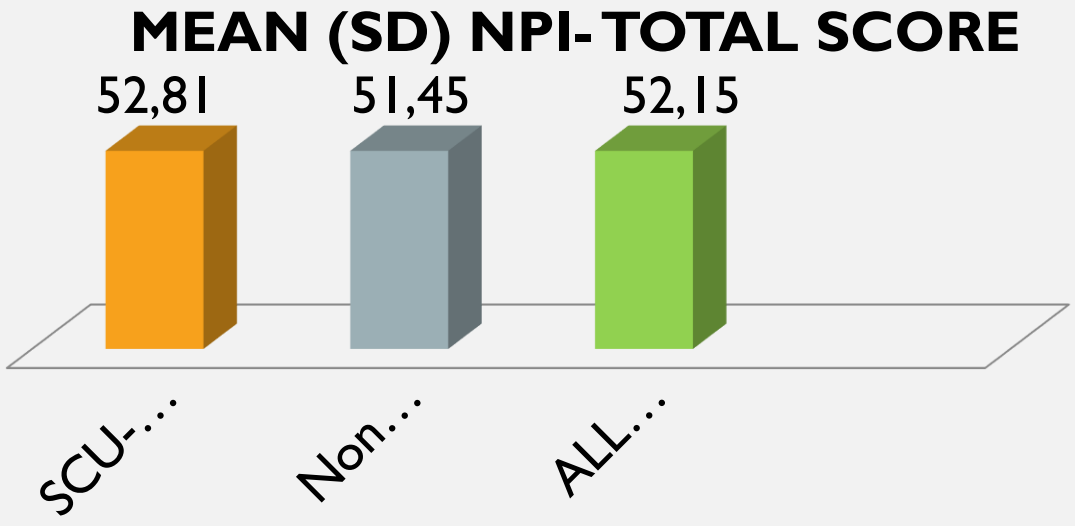
FUNCTIONAL STATUS: ADCS-ADL

ADCS-ADL	SCU-B (N=268)		Non SCU-B (N=252)		ALL (N=520)	
	N	%	N	%	N	%
N	263	17,8%	247	17,0%	510	17,4%
MEAN (SD)	33,38		34,6		33,97	



NPI- TOTAL SCORE

NPI-TOTAL SCORE	SCU-B (N=268)		Non SCU-B (N=252)		ALL (N=520)	
	N	%	N	%	N	%
N	266	16,4%	248	21,1%	514	18,8%
Mean (SD)	52,81		51,45		52,15	



THE SECOND PHASE OF THE RECAGE PROJECT

To **adapt the model in accordance with the results of the cohort study**, not only regarding the main endpoints, but also comparing the experience and the different ways to work of the participating centres and the different socio-political context in which they act.

THE SECOND PHASE OF THE RECAGE PROJECT

- **Data analysis**
- **Conclusive meeting →**
- **Position paper with recommendations for new SCU-B to be implemented**
- **Meanwhile: qualitative studies (interviews, focus groups) in all clinical centres**

THE THIRD PHASE OF THE RECAGE PROJECT

To scale up the intervention in the countries who take part in the study, but where SCU-B are sporadic or even absent, as Italy and Greece.

We plan to advocate implementation with policy-makers, government officials, general managers of the hospitals and other influential individuals, groups or institutions.

The (expected) evidence of clinical efficacy and cost-effectiveness → strong argument to be put forward by the clinicians, by the Scientific societies (Geriatrics, Psychogeriatrics, Neurology etc.) and the lay Associations in order to justify the extra-costs of implementing a SCU-B

B. Abdeljalid: the French situation

E. Ulshöfer: the Mannheim experience

A. Mendès: the Geneva experience

S. Bergh: the Norwegian experience

Round table with the healthcare service Authorities

THE MORNING SESSION