RECage

Towards the conclusion of the project: the Consensus Conference

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The Recage project

Given the unsatisfactory state of the art in this field, the major objective of the project is **to assess the effectiveness of an intervention**, the **SPECIAL CARE UNIT FOR BPSD (*SCU-B*)**, which - although implemented in some countries - is ***not widespread*** and ***has not been sufficiently studied so far***.

We define the **SCU-B** as "*a residential medical structure lying outside a nursing home, e.g. in a general hospital or elsewhere, where* ***persons with dementia (PwD) are temporarily admitted when their BPSD are not amenable to control at home***".

The mission of the SCU-B is to **improve behaviour** and to permit, when possible, their **coming back home**.

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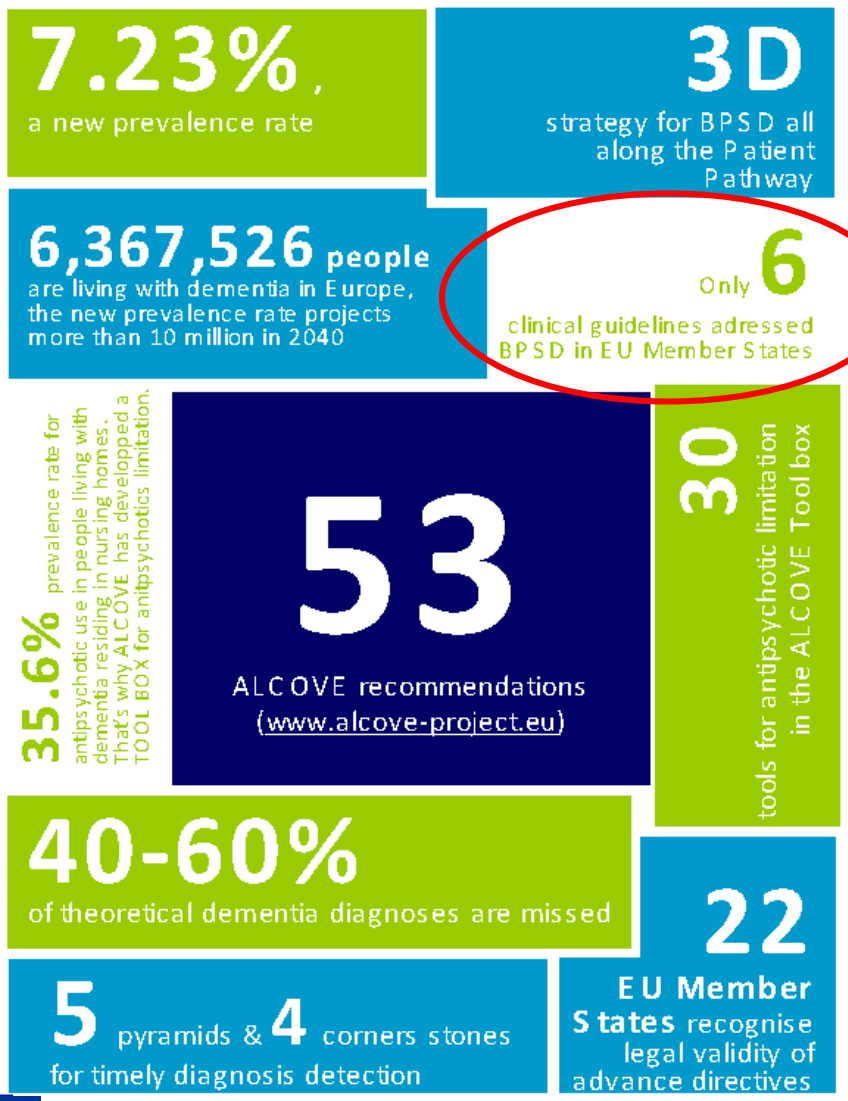
A well-Known recommendation…



alcove
ALzheimer COoperative Valuation in Europe

"**dedicated units for BPSD** in **nursing homes and hospitals** because the development of this kind of nursing or hospitalisation unit ***has already shown to be of dramatic help for people experiencing major BPSD*** in several European countries"

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Care organizations for BPSD

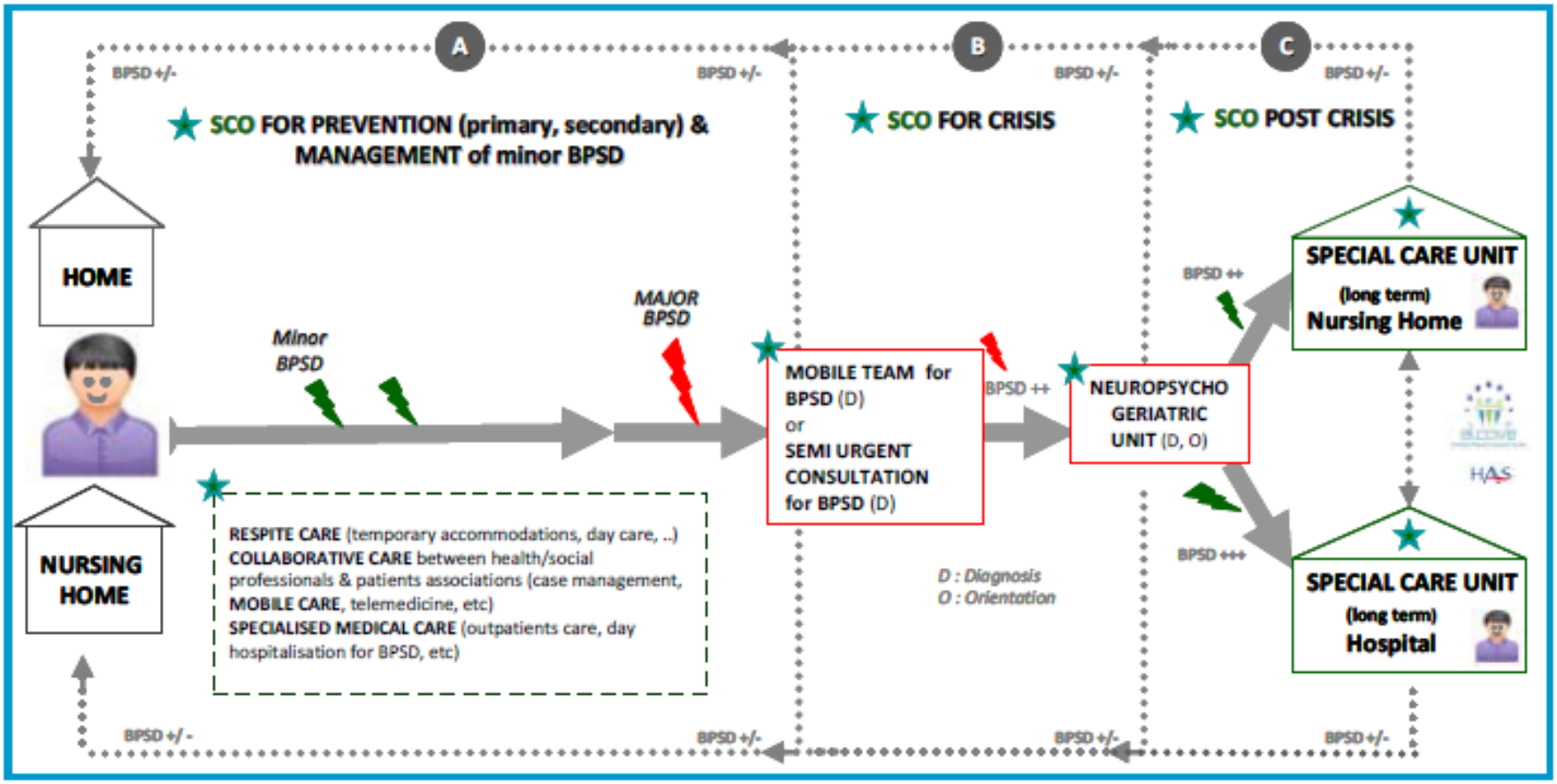
Step A: *minor BPSD prevention and management*

Step B: *maior BPSD crisis management*

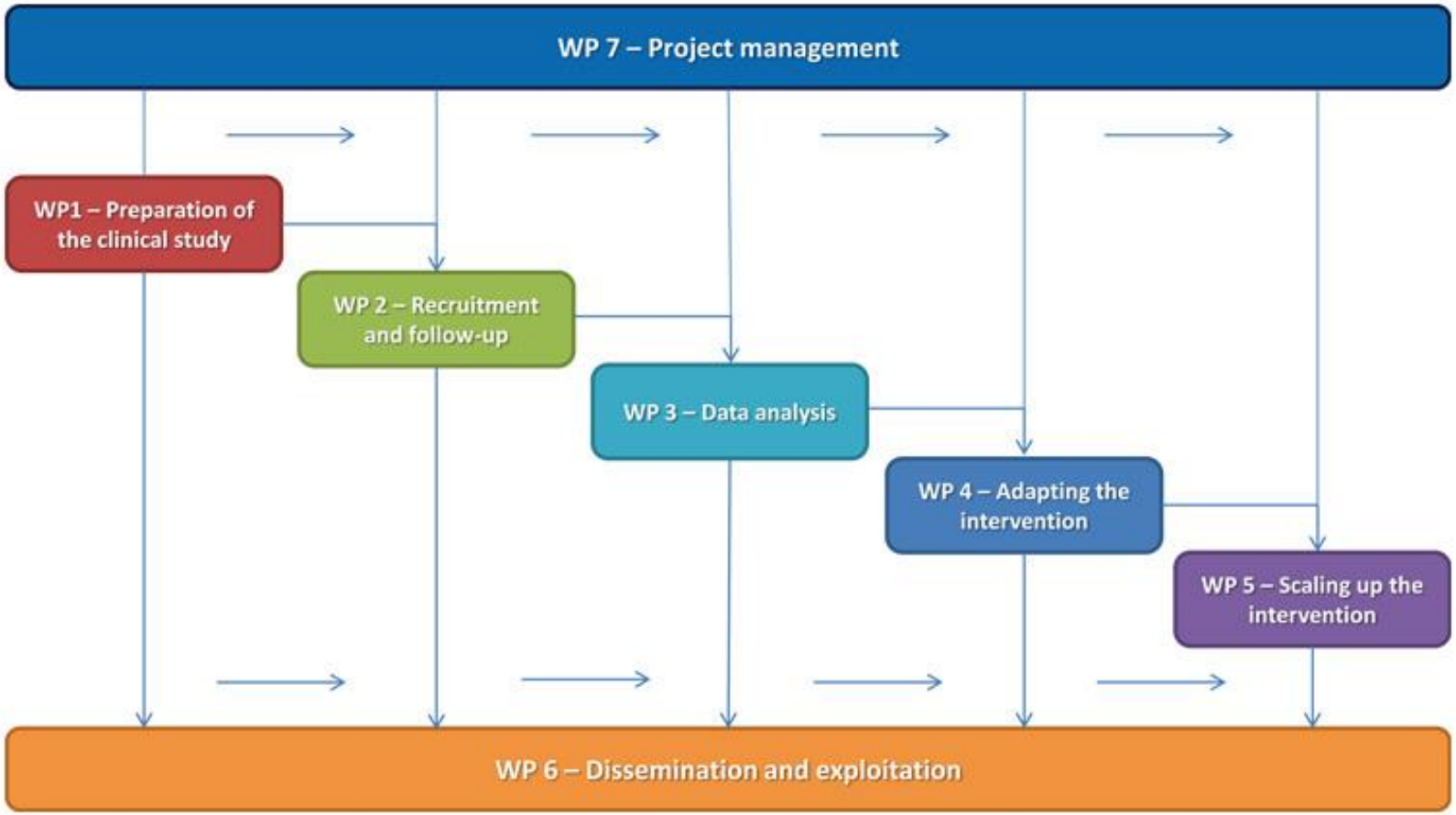
Step C: *BPSD management and prevention*

Figure 1. Structures and Care Organisations for BPSD all along the Patient Pathway

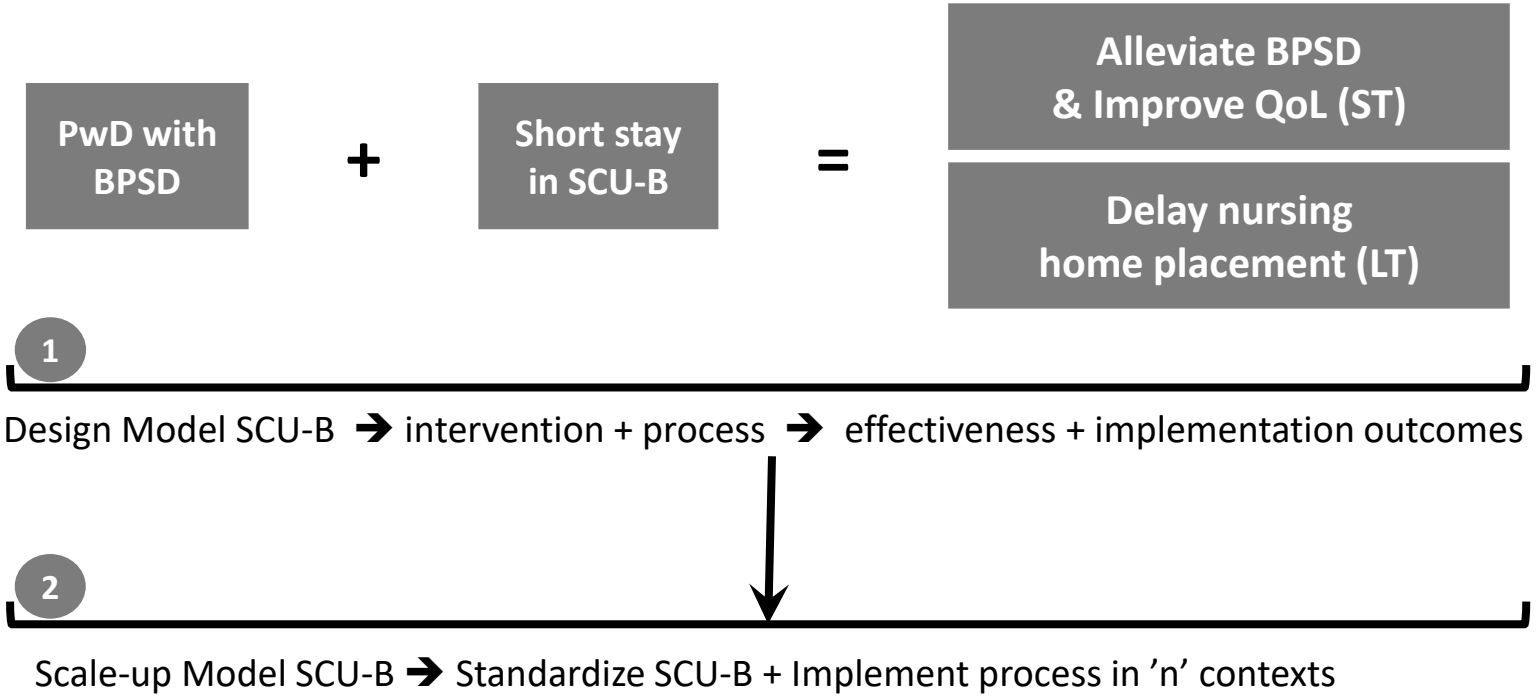
Step A: minor BPSD prevention & management - Step B: major BPSD crisis management - Step C: BPSD management & prevention



Workplan of the project



RECage working hypothesis



*(**Courtesy of Meena Daivadanam, MBBS, MPH, PhD.** Associate Professor, Uppsala university, Sweden)*

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Recage consortium research

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WP4- Adapting the intervention

Objectives of the WP

To reach a **consensus** upon the recommended characteristics of the **SCU-Bs** after the analysis of the **study results**

To know **barriers** and **facilitators** either for **adapting the intervention**

To create a structured communication tecnique (**Nominal Group Technique)**, relying on a panel of experts interacting with the lay Association

To organize an **Consensus Conference (**results of questionnaire about SCU-Bs, panel of expert and Lay Association, discuss with legal experts about laws and emendaments)

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Execution plan

WP4- Adapting the intervention

Task 4.1

- Preparation of the **Nominal Group Tecnique * Conference** (analysis of **study results** and **questionnaire**)

Task 4.2

- The **NGT Conference:** international 3-day meeting (clinical centres, national lay Associations, political members of Consortium : RER and NODAD)

Task 4.3

- Writing the **position paper** (guidelines for the establishment and operation of a **model SCU-B**).

* McMillan S.S., King M, Tully M.P. How to use the nominal group and Delphi techniques Int J Clin Pharm (2016) 38:655–662

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WP4- Adapting the intervention

Risks

Difficulty working out a **synthesis** wich takes account of the various operating ways among the existing SCU-Bs in order to establish a **true consensus** on the position paper

Risk mitigation measures

Discussion among the exisisting **SCU-Bs**

→

Research of **CONSENSUS**

→

VOTING by simple majority (if unanimity is not possible)

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Preparing the closing conference

FERB and **Perugia University** are working on the **results of the qualitative study**, their manuscript is expected before November 2022 and will be circulated

Our experts (Bruno Cesana and Ron Handels) will carry the **analysis of the trial results** (October-December2022) and share them with all of us (WP3)

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Preparing the closing conference

As **Emilia Romagna Region** (member of consortium) we spontaneously proposed to perform a **systematic analysis on the literature on the SCU-Bs**(May-December 2022).

We discussed with the experts (Francesco Nonino, Luca Vignatelli) of the Institute of Neurosciences (Alma Mater Studiorum, University of Bologna, Italy) and **chose to target the analysis**.

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Final conference planning

According to the **NIH Consensus Development Process** (**CDP**), **scientific evidence** is the basis for making judgments and statements.

Panel members will receive a **formal synthesis of the literature** (Systematic Reviews, Evidence Mapping/Scoping Reviews)

*Miake-Lye, I.M., et al. What is an evidence map? A systematic review of published evidence maps and their definitions, methods, and products. Syst Rev **5,** 28 (2016)*

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Final conference planning

Research questions:

A - ***What kinds of SCU-B are there****? With special regard for the "acute" SCU-Bs: what about architectural features, staff compositions, activities, criteria for admission?*

B *- What are the* ***main issues related to the SCU-B*** *(informed consent, restraints, "benevolent" coercion …)*

C *-* ***What is the evidence*** *of* ***clinical effectiveness*** *of the "acute" SCU-B vs usual care?*

D *- What is the evidence of* ***cost-effectiveness of*** *the "acute" SCU-B vs usual care?*

E *-What are the* ***safety issues*** *of physical restraints and neuroleptic treatments?*

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Domain	Question	Type of review
Description and technical characteristics of SCU-B (including description of target population, architectural, organizational, legal aspects)	A - What kinds of SCU-B are there? With special regard for the "acute" SCU-Bs: what about architectural features, staff compositions, activities, criteria for admission?	Evidence mapping review, framing and describing each selected aspect of SCU-B from a qualitative/semi-quantitative perspective
	B - What are the main issues related to the SCU-B (informed consent, restraints, "benevolent" coercion …)	
Effectiveness of SCU-B	C - What is the evidence of clinical effectiveness of the "acute" SCU-B vs usual care?	Systematic review of primary literature
Costs and economic evaluation of SCU-B	D - What is the evidence of cost-effectiveness of the "acute" SCU-B vs usual care?	Systematic review of economic analysis studies
Safety of SCU-B	E -What are the safety issues of physical restraints and neuroleptic treatments?	Systematic review of systematic reviews

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Open questions

QUESTION 1A: **Description and technical characteristics of SCU-B** (including description of target population, architectural, organizational, legal aspects)

First problem: must we change the original definition of the SCU-B

Remember that our definition was "*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*"

Second problem: are there different kind of SCU-B ?

SCU-Bs inside acute hospital or connected with acute geriatris wards (Geneva)

SCU-Bs outside acute hospital : rehabilitation facilities (Gazzaniga, Modena) or psychiatric hospital (Mannheim, Ottestad)

These differences probably explain the different lengths of stay

Open questions

QUESTION 1A: **Description and technical characteristics of SCU-B** (including description of target population, architectural, organizational, legal aspects)

Third problem: we are facing **two alternatives**:

-to develop the minimum common denominator for a SCU-B ward
- the optimal set-up for a SCU-B ward

Fourth problem:

What are the (minimal/optimal) structural requirements of SCU-B ?

Architectural standards

Staff number/Nursing model

Open questions

QUESTION 1B: **what are the main ethical issues related to the SCU-B** (informed consent, restraints, "benevolent" coercion …)

QUESTION 2: What is the evidence of clinical effectiveness of the SCU-B vs usual care?

The participants will have access to:
*- The **data of the RECAGE study** (Bruno Cesana)*
*- The **data of the scoping review** (Silvia Minozzi)*
*- The **draft of the qualitative study** (Anna Giulia Guazzarini)*

QUESTION 3: What is the evidence of cost-effectiveness of the SCU-B vs usual care?

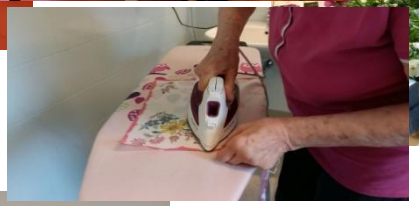
*The participants will have access to the **RECAGE data** (Handels) and to the **scoping review** (Minozzi)*

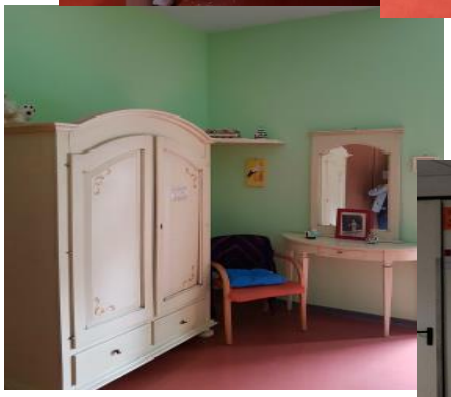
QUESTION 4: What are the main safety issues of restraints and neuroleptic treatments?

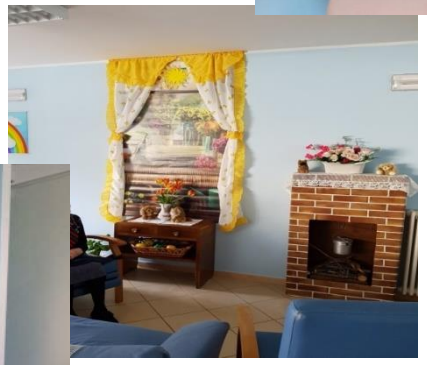
*The participants will have access to the scoping review and, among other papers, the report of Dementia Australia (**the use of restrains** and **psychotropic medications** in PWD, 2014; decision making tool: supporting a restrain-free environment, 2012)*

We need of «3 key words» for Scu-B ? :

Prosthetic environment , **A**ctivities , **S**taff training







= Best practices in dementia care ?

= Better quality of life for People living with dementia who experience behavioral problems ?

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Final conference planning

Patients: patients with dementia and behavioral disorders

Intervention: Special Care Unit, rehabilitation unit, somadem, somatic dementia unit, specialized geriatric unit, specialized psychiatric unit, gerontopsychiatric unit, unitès cognitive-comportamentales

Control: standard of care (admission to emergency room + medical and psychiatric wards)

Outcome: hospitalization, institutionalization, QoL-AD, costs, psycotropic drug consumption, MMSE, ADCS-ADl, NPI, CMAI, CGIS, Euroqol 5, Care Qol, ICECAP-0, ADQ, QUIS, ADQ, CBI, etc

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Final conference planning

Why a systematic analysis?

Please note that we wrote in the **original RECAGE document**:
*"the evidence of short-term efficacy of the SCU-B are not robust, but **rather suggestive**.*

*Some pioneering papers, and some more recent studies demonstrated **marked improvements of BPSD during a short stay in a SCU-B**.*

*In **France** for more than ten years **SCU-Bs** (named **Unités Cognitivo-Comportementales**) have been widely implemented in the framework of a National Alzheimer Plan, but till now France remains the only country to have taken this decision. **The clinical experience (unpublished) of some participants to this study confirms this efficacy**".*

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Final conference planning

Why a systematic analysis?

These statements were based on a non-systematic perusal of the literature. That is why the importance of a new, updated **systematic analysis** can hardly be emphasized.

This analysis, together with the **results of the RECAGE clinical trial** and the **data coming from the qualitative study**, will represent, hopefully, a solid evidence on the basis of which we have to implement the Work Package 4, that is

*"the process of adapting the intervention (the SCU-B) through a conference of the entire Consortium partially conducted in accordance with the Nominal Group Technique, with the **aim to produce a consensus document on the recommended characteristics of the SCU-B".***

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Why a systematic analysis?

How to move in this direction?

Recently a new entry into our Project, the Institute of Neurosciences of Bologna, already mentioned, enrolled by FERB as subcontractor due to their experience in conducting this kind of scientific consensus meeting, suggested to choose the model of **Consensus Conference** **instead of the Nominal Group Technique**, as originally planned.

In fact, **the grade of evidence from the literature** (apart the future data of the meta-analysis) **is not strong**, and the problems we met during the trial (including COVID-19) raise some doubts about the probability of reaching our endpoints.

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Why a systematic analysis?

According to this model, we need to choose:

- **A sponsoring institution** (Alzheimer Europe)
- **A scientific committee**
- **Four/five expert groups requested to answer the main research questions**, each of them composed by experts (clinicians, nurses, medical directors, bioethicists, others..).

Each group shall receive before the Conference the results of the above mentioned studies, and shall prepare **some provisional statements** to be presented by its spoke person during the first Consensus session.

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The project imposes the **need to have a Panel**, composed by persons not directly involved in the project, but sharing an interest in the topic (expert clinicians and non-medical personnel from 2-3 countries, expert methodologists, medical directors, representatives of patient Associations), chaired by a person with previous experiences with such procedures. The composition of the Panel is still to define, in collaboration with its Chairperson

The **Panel will separately** (during a closed session) **discuss the statements proposed** and choose those that seem most appropriate

The Panel Chair will **disclose the statements accepted** before the general public during the second morning of the Conference.

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FERB FONDAZIONE EUROPEA RICERCA BIOMEDICA ONLUS

SYKEHUSET INNLANDET

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Bruxelles, closing and consensus conference ,
February 21-22 , 2023

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How do we imagine the programme of the Closing Conference?

The first day, Tuesday 21 February 2023
(morning 9.30-13.00) could be devoted to:

- **The presentation of the results of the RECAGE trial**
- **The presentation of the results of the collateral qualitative study**
- **The presentation of the results of the meta-analysis**

General discussion.

Afternoon (14.30-16.00)

Presentation on the statements produced by the **four/five expert groups**

Closed session of the panel (16.00)

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How do we imagine the programme of the Closing Conference?

Second day, Wednesday 22 February 2023 (9.30-12.30)

The Chairperson of the panel shall **present the statements** accepted of modified and a general discussion **open to the public will ensue**.

A **final document will be written** after the Conference (involving the Chair and the Project Coordinator) and widely circulated and disseminated.

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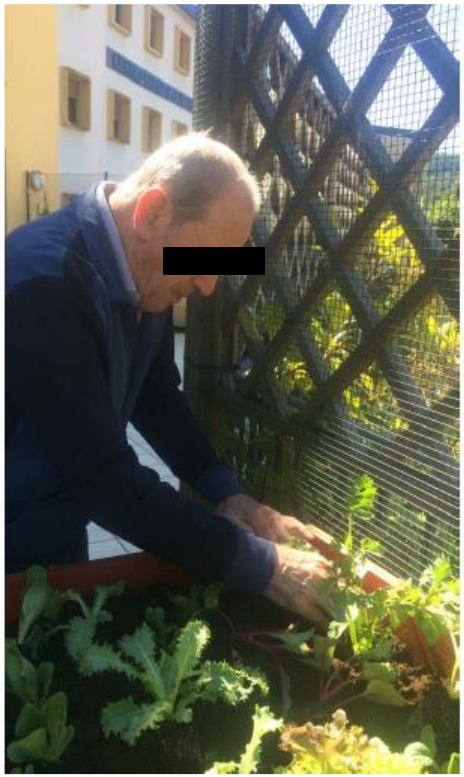
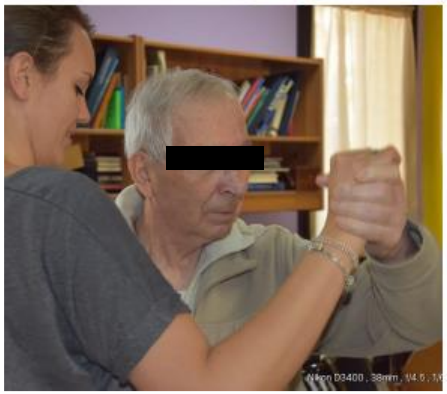
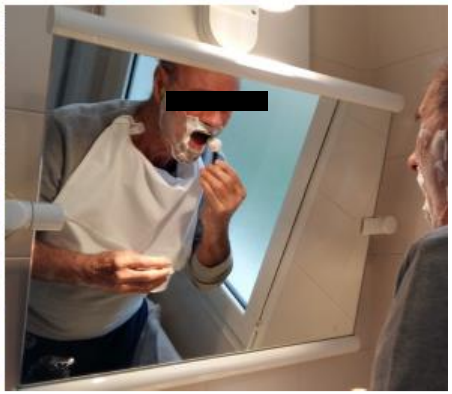
Final conference planning

Thank you for your attention



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