RESPECTFUL CARING FOR THE AGITATED ELDERLY (RECage)

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DEFANTI C, FASCENDINI S, BAROCCO F, SANGIOVANNI C, ZANNI M.

Fondazione Europea di Ricerca Biomedica (FERB Onlus), Gazzaniga, Italy

RECage tackles one of the most challenging problems arising in the course of dementia: the **BEHAVIORAL AND PSYCHOLOGICAL SYMPTOMS OF DEMENTIA (BPSD)**

Given the unsatisfactory state of the art of the treatment 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, especially in France (the so-called UCC) - 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.

OBJECTIVES OF THE CLINICAL STUDY (FIRST PHASE OF RECage)

- The *primary objective* is to evaluate the efficacy, both short-and long-term, of the SCU-Bs as components of the care pathways for persons with dementia.
- The *secondary objectives* are to assess the quality of life both of PwD and their caregivers, to estimate the psychotropic drug consumption and the cost-effectiveness of the SCU-B.
- The *tertiary objective* is to evaluate the capacity of SCU-B to delay institutionalization.

MATERIALS AND METHODS

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

The total number of persons will be 500, divided in two cohort of 250 each.

The follow-up will last 3 years; the follow-up visits are scheduled every 6 months.

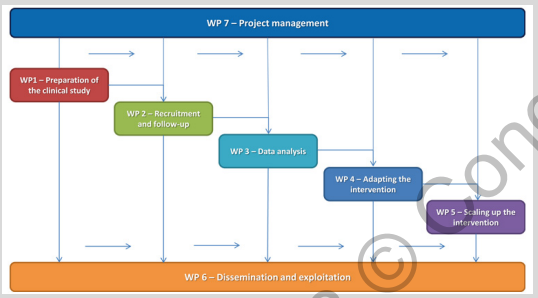
Each person must have a primary caregiver committed to stand by the her/him during the study.

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 primary endpoint will be measured through the NPI and CMAI scales.
- The secondary endpoint will be estimated through QoL-AD (patient) and ACQoL, EQ-5D-5L, CBI (carer); the comparison of the drug consumption between cohorts will be measured through the number of psychotropic drugs used.
- The tertiary endpoint will be estimated through survival methods.

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).

WORKPLAN OF THE PROJECT



THE SECOND AND THE THIRD PHASE OF RECage

2. 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.

3. 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.