Clinica Luganese
Moncucco

The elderly patient demented in an acute geriatric department: pilot study, monocentric, randomized on the use of aromatherapy as a complementary treatment tool to psychopharmacology in behavioral and psycological symptoms of dementia (BPSD)

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INDEX

1. SYNOPSIS

The elderly patient demented in an acute geriatric department: pilot study, monocentric, randomized on the use of aromatherapy as a complementary treatment tool to psychopharmacology in psychological disorders and behavior (BPSD).

Rationale

Behavioral and psycological symptoms of dementia (BPSD) are a big issue for families, paramedics, physician and the patient itself (1,2,3,4).

In absence of universally recognized guidelines, the standard of treatment of these disorders involves the use of psychotropic drugs (typical/atypical neuroleptics, antidepressants, benzodiazepines) that are often found to have a reduce efficacy and induce a number of side effects such as sedation, impaired motor neurons slowdown, cardiac electrical alterations and extrapyramidal syndrome (5,6,7,8,9). In consideration of this, it is important to check for treating alternative ways, which can reduce psychological and behavioural disorders and at the same time can reduce the use of psychotropic drugs.

Concerning the aromatherapy [10], the therapeutic use of natural essential oils, there are decades of clinical experience, especially in France, accompanied by increasing scientific evidence with significant increase in publications regarding its use of psychological disorders and dementia-related behavior context (11,12,13,14).

Based on the available scientific publications, it has been therefore decided to use two essential oils (*Citrus sinensis*, *Lavandula angustifolia*) in environmental diffusion within the Geriatric Department of the Clinic Luganese Moncucco.

Objectives

Primary objectives: through the execution of the Neuropsychiatric Inventory – Nursing Home Version (NPI-NH), the neuropsychiatric and psychopathological symptoms of dementia patients will be evaluated in order to assess how the use of aromatherapy can improve the management of BPSD, reducing, where there is clinical indication, psychotropic therapy and secondary side effects. The score is considered positive if the presence of BPSD is greater than or equal to 1 (15, 16,17); the improvement of the score is represented from decrease of the NPI-NH respect to the initial assessment (19, 20).Performing neuropsychological tests is not an additional attention to enrolled patients, but it is part of clinical practice (18).

Secondary objectives: to validate the hypothesis that through the use of aromatherapy will improved the management of Behavioral and psycological symptoms of dementia (BPSD) in the dementia patient, with a concomitant reduction of the clinical staff stress who take care of patients (physician, nurses, care assistants), determined by the results reported by the Neuropsychiatric Inventory – Nursing Home Version (NPI-NH), In the specific section concerning

the distress measurement; improvement of the score is represented from decrease of the NPI-NH respect to the initial assessment (19, 20).

Project duration: 2 months of enrollment.

Number of patients: 32, 16 patients for the control group and 16 patients for the group" aromatherapy".

Inclusion criteria:

- patients age ≥ 70 years;

- patients admitted to the acute geriatrics ward;

- patients with known diagnosis of dementia associated with BPSD or diagnosis performed during hospitalization.

Exclusion criteria:

- patients with alcohol-based dementia;

- patients with Mild Cognitive Impairment (MCI) – paragraph 4;

- patients with language barriers;

- patients already being treated with aromatherapy.

Protocol design: prospective data collection of psychological disorders and behaviour in patients with diagnosis of dementia with associated behavioral and psycological symptoms of dementia (BPSD)- diagnosis already performed using neuropsychological tests (below), according Evidence Based Medicine, and/or patients who BPSD diagnosis performed during the hospital stay in the Geriatric Competence Centre, Clinica Luganese Moncucco.

The enrollment will be performed in May and June 2018.

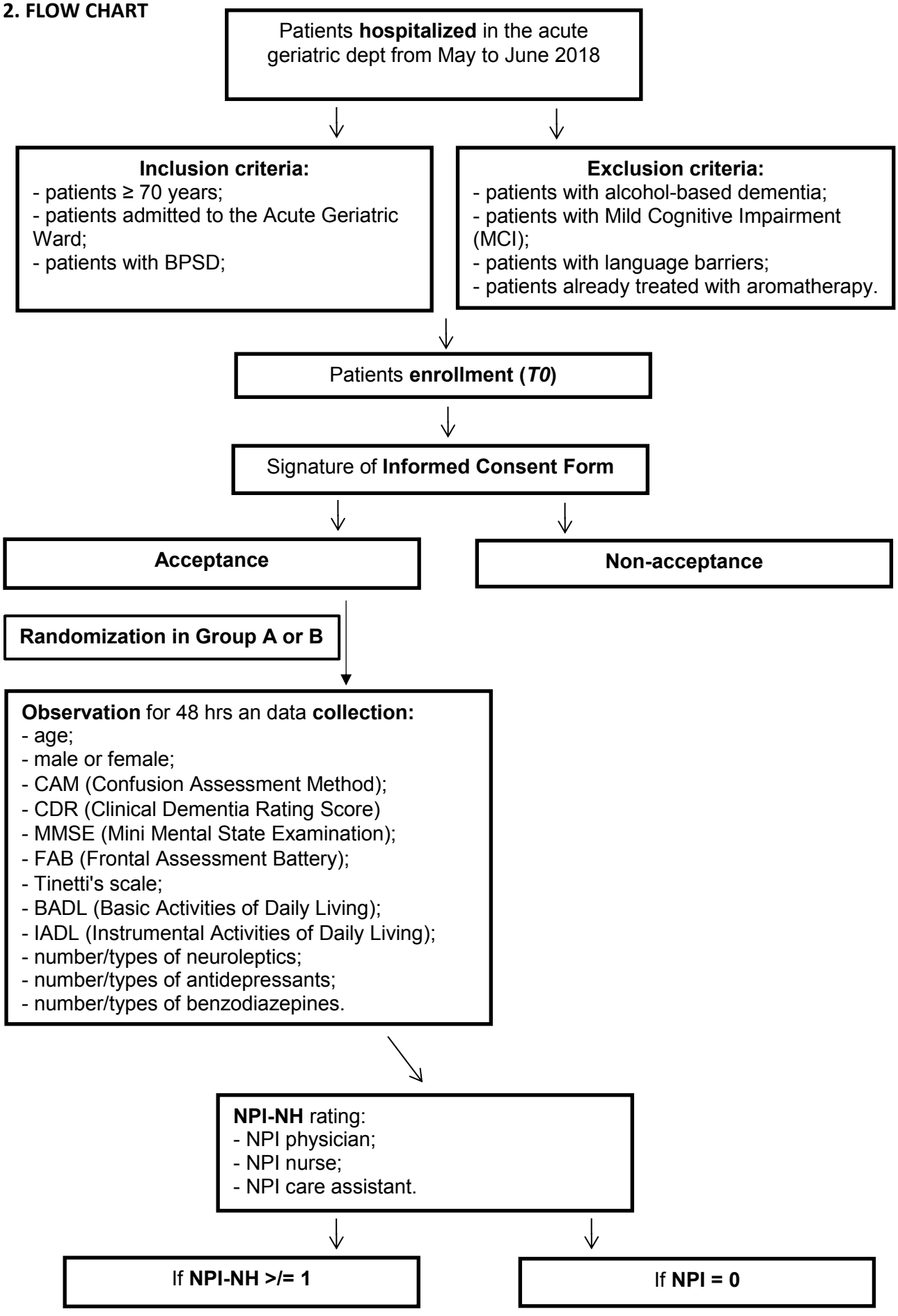
Enrolled patients will be treated with psychotropic drugs vs psychotropic drugs with aromatherapy in environmental diffusion. It is expected to use neuropsychological specific tests to assess dementia, motor and functional status patient status **(**CAM - Confusion Assessment Method -, CDR - Clinical Dementia Rating -, MMSE - Mini Mental State Examination -, FAB - Frontal Assessment Battery -, Tinetti Scale, BADL - Basic Activities of Daily Living -, IADL - Instrumental Activities of Daily Living -, NPI-NH – Neuropsychiatric Inventory – Nursing Home Version)).

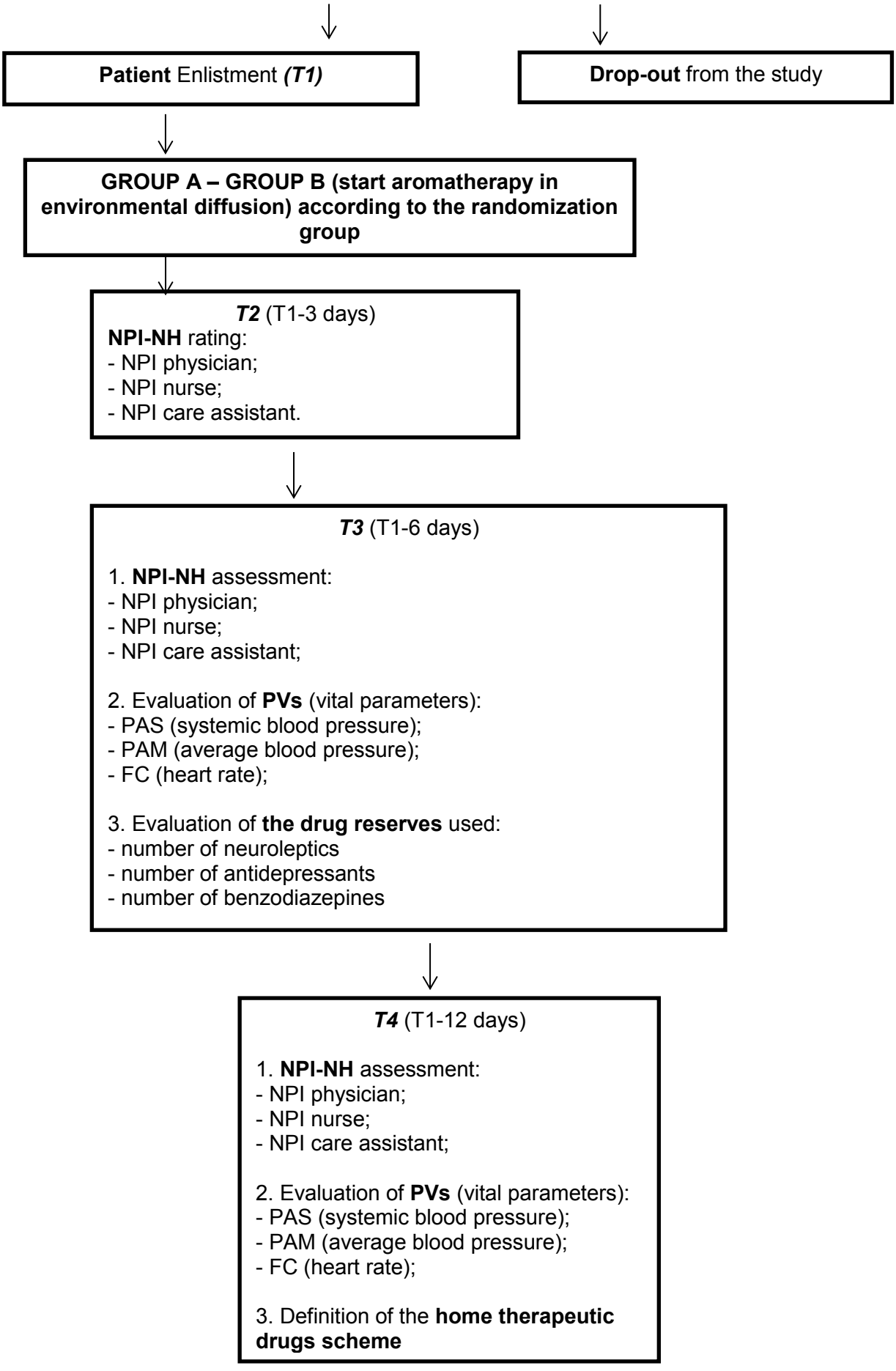
Patients enrolled in the project will not undergo to additional tests; the performed test are required in the standard clinical practice [18].

GROUP A: 16 patients, following the inclusion criteria, will be enroll and they will be treated with psychotropic drugs.

GROUP B: 16 patients, following the inclusion criteria, will be enroll and they will be treated with psychotropic drugs and, in a complementary way, with aromatherapy in environmental diffusion.

2. FLOW CHART


Patients **hospitalized** in the acute geriatric dept from May to June 2018
Inclusion criteria:
- patients ≥ 70 years;
- patients admitted to the Acute Geriatric Ward;
- patients with BPSD;
Exclusion criteria:
- patients with alcohol-based dementia;
- patients with Mild Cognitive Impairment (MCI);
- patients with language barriers;
- patients already treated with aromatherapy.
Patients **enrollment (*T0*)**
Signature of **Informed Consent Form**
Acceptance
Non-acceptance
Randomization in Group A or B
Observation for 48 hrs an data **collection:**
- age;
- male or female;
- CAM (Confusion Assessment Method);
- CDR (Clinical Dementia Rating Score)
- MMSE (Mini Mental State Examination);
- FAB (Frontal Assessment Battery);
- Tinetti's scale;
- BADL (Basic Activities of Daily Living);
- IADL (Instrumental Activities of Daily Living);
- number/types of neuroleptics;
- number/types of antidepressants;
- number/types of benzodiazepines.
NPI-NH rating:
- NPI physician;
- NPI nurse;
- NPI care assistant.
If **NPI-NH >/= 1**
If **NPI = 0**


Patient Enlistment *(T1)*
Drop-out from the study
GROUP A – GROUP B (start aromatherapy in environmental diffusion) according to the randomization group
T2 (T1-3 days)
NPI-NH rating:
- NPI physician;
- NPI nurse;
- NPI care assistant.
T3 (T1-6 days)
1. **NPI-NH** assessment:
- NPI physician;
- NPI nurse;
- NPI care assistant;
2. Evaluation of **PVs** (vital parameters):
- PAS (systemic blood pressure);
- PAM (average blood pressure);
- FC (heart rate);
3. Evaluation of **the drug reserves** used:
- number of neuroleptics
- number of antidepressants
- number of benzodiazepines
T4 (T1-12 days)
1. **NPI-NH** assessment:
- NPI physician;
- NPI nurse;
- NPI care assistant;
2. Evaluation of **PVs** (vital parameters):
- PAS (systemic blood pressure);
- PAM (average blood pressure);
- FC (heart rate);
3. Definition of the **home therapeutic drugs scheme**

3. STUDY CHARACTERISTIC

Monocentric, randomized, pilot study which consists in the prospective data collection related to psychological disorders and behavior in the patient with dementia using neuropsychological tests in order to define the possible effectiveness of two essential oils (*Citrus sinensis*, *Lavandula angustifolia*) in the disorders control of psychological sphere and behavior of patients with degenerative or mixed type of dementia, admitted in the Geriatric Department of Clinica Luganese Moncucco in May and June 2018.

In the proposal for therapeutic process of dementia patients in this project there is no disaccording with Evidence Based Medicine.
Patients enrolled in the project will not undergo additional tests; the performed tests will follow the standard procedures of clinical practice [18].

4. PROTOCOL RATIONALE

Behavioral and psycological symptoms of dementia (BPSD) are a major problem for families, physicians and the patient itself [1,2,3,4].
Performing neuropsychological tests is not an additional source of distress for enlisted patients, but is part of clinical practice [18].
The standard treatment of these disorders involves the use of psychotropic drugs (typical/atypical neuroleptics, antidepressants, benzodiazepines) which are often ineffective and have a number of side effects such as sedation, reduction in cognitive performance, cardiac electrical alterations and extrapyramidal syndrome [5,6,7,8,9].

Within the scientific community, it is therefore mandatory to identify alternative ways of managing BPSDs, which can have a beneficial effect on patient life and, at the same time, a reduction in the used of psychotropic drugs.

The therapeutic use of natural essential oils has decades of clinical experience, especially in France, accompanied by an increase numbers of publications in their use in BPSD [11,12,13,14].

The knowledge of alternative treatments of BPSD (such as aromatherapy) are the basis of our study project, which involves the introduction of essential oils in the BPSD management, while maintaining conventional psychotropic therapy (typical/atypical neuroleptics, antidepressants, benzodiazepines) in a prefixed form of ProReNata (PRN) (paragraph 5).

The identified oils (*Citrus sinensis, Lavender angustifolia*) were selected on the degree of purity defined by the mass spectrophotometry available by the supplier.999

The choice of adjuvant therapy with essential oils could allow, in accordance with the 3rd principle of Medical Ethics to administer natural treatment to patients with distress with BPSD reducing, if possible, use of psychotropic drugs and their major side effects.

The use of essential oils in treatment of BPSD can also have a positive impact on patient economic management due to limited costs, allowing a distribution of treatments according to IV Principle of Ethics Medical: principle of justice.

Mild Cognitive Impairment (MCI) patients were excluded from the protocol as a form of pre-dementia.[21].

MCI is a neurological syndrome characterized by a cognitive impairment greater than that statistically expected based on age and education level, but who are still able to carry out their daily activities (BADL and IADL tests). The Mild Cognitive Impairment is considered a form of pre-dementia, situated in a transition point between normal aging and dementia.

5. STUDY POPULATION

The population that will be evaluated within the project is constitute by patients with diagnosed dementia with BPSD (diagnosis carried out using, according to Evidence Based Medicine, the neuropsychological tests below) and/or by patients who the diagnosis of dementia with BPSD will be performed at the Geriatric Competence Centre of the Clinica Luganese Moncucco.

The enrollment will be performed in May and June 2018.

All patients mentioned above, within 48 hours after the admission at the Geriatric Department or the manifestation of BPSD, will be assessed to neuropsychological and functional tests (CAM - Confusion Assessment Method -, CDR - Clinical Dementia Rating Score -, MMSE - Mini Mental State Examination -, FAB - Frontal Assessment Battery -, scala di Tinetti, BADL - Basic Activities of Daily Living -, IADL - Instrumental Activities of Daily Living -), as required by Good Clinical Practice[18]. Subsequently, patients who can be enrolled in the study will be randomized into two groups, described below.

Here is the study population on which we will focus:

GROUP A – controls -: will be enrolled 16 patients eligible for criteria of inclusion, treated with psychotropic drugs.

GROUP B – aromatherapy –: will be enrolled 16 patients eligible for criteria of inclusion, treated with psychotropic drugs and aromatherapy in air-diffusion.

Based on the randomization, patients will be divided into group A – controls – and group B – aromatherapy in air diffusion.

Neuropsychiatric Inventory (NPI) is a validated and useful tool for characterizing and assessing the BPSD frequency and seriousness.

A Resident Physician will perform the NPI in our study protocol.

The physician, by interview with patient's nurse, in absence of patient himself, will fill out the NPI-NH.

The above mentioned physician, formerly operating in the Geriatric Department – who knows the geriatric assessments - and currently active in the Rheumatology Department, will therefore respect the blind study procedure.

The geriatric nurse was chosen for the close relationship of care that is created with the patient; during the test, BPSD frequency and seriousness will be evaluated.

The psychological distress induced by BPSD patients, will be evaluated on the three figures who have in charge the patient, which are nurses, care assistants and the resident physicians.

The psychological distress assessment is part of the NPI-NH test with a scale of severity from 0 to 5.

Nurses will be undergo to NPI – NH test within 48 hours after patient admission or at first appearance of BPSD **(T1), T2 (T1-3 days)** 3 days after enrollment, at **T3 (T1-6 days)** 6 days after enrollment, at **T4 (T1-12 days)** at 14th day. According to the same timing, NPI-NH will also be performed to the resident physicians, the nurses and the care assistants to assess the psychological distress. The NPI-NH test will be performed following the Good Clinical Practice.

The tests results performed to the two groups of patients will be considered in order to assess a possible reduction in BPSD. As the project is a pilot study, a descriptive analysis will be performed.

Here the schemes defined for treatment with aromatherapy and psychotropic drugs, according to scientific publications in the first case and scientific publications and Evidence Based Medicine in the second:

Aromatherapy

Route of administration: air diffusion with ultrasonic diffuser in a single room and for about an hour.

Doses:

- *Citrus sinensis*: 6 drops at 8, 12 and 18 in nebulization

and

- *Lavender angustifolia*: 6 drops 8 p.m. in nebulization

PRN PSYCOPHARMACOTHERAPY

Drug:

- in case of psychomotor agitation:

Haloperidol 1 mg PO 10 times in 24 hours

1 mg SC/IM 5 times in 24 hours

Reperidone 0.5mg - 2mg PO in 24 hours
Olanzapine 2.5 mg – 5 mg PO in 24 hours

Clozapine 6.25 mg – 25 mg PO in 24 hours

Quetiapine 12.5mg - 150mg PO in 24 hours

- in case of sleep disturbance:

Valerian 1 tb - 2 tbs PO in 24 hours

Melatonin 1 tb - 2 tbs PO in 24 hours

Lorazepam 0.5 mg - 3mg PO in 24 hours

Oxazepam 7.5mg - 45mg PO in 24 hours

Clomethiazole 1 tb -3 tbs PO in 24 hours

- in case of anxiety/depression:

Trazodone 25 mg – 150 mg PO in 24 hours

Escitalopram 10 mg – 20 mg PO in 24 hours

Mirtazapine 15 mg – 45 mg PO in 24 hours

Citalopram 10 mg – 20 mg PO in 24 hours

Paroxetine 20 mg – 50 mg PO in 24 hours

The control group is treated with psychopharmacological therapy, defined by the PI, according to the Evidence Based Medicine criteria.

Patient can withdraw the ICF at any time.

The investigators could decide to withdraw a patient for safety and health.

The withdrawn patients will not be evaluated unless they have been treated for 8 days, useful to evaluate the aromatherapy efficacy.

In bibliography reported that essential oils in air diffusion are effective in 3 days. Additional 5 days of treatment allow to stabilize patient's condition and collect, through the NPI-NH test, changing in BPSD data.

Withdrawn patients will be followed according to the standards of care provided by the Clinica Luganese Moncucco.

6. PROJECT OBJECTIVES

The goal of this project is to evaluate the effectiveness of aromatherapy in air diffusion in addition to psychotropic drugs in order to evaluate a possible reduction in BPSD.

The project's hypothesis is that GROUP B patients show an improvement in their BPSD. The performed neuropsychological tests will provide the answer to the project hypotesis.

Primary objectives*:* validate the hypothesis that the use of aromatherapy in air diffusion can improve the BPSD management, allowing a reduce in psychotropic therapy prescribed and its secondary side effects. The patient’s nurses will be tested with NPI-NH, that will characterize

frequency and seriousness of BPSD [15,16, 17]. A score greater or equal to 1 is considered positive for presence of BPSD.

Secondary objectives: validate the hypothesis that the use of aromatherapy will improve the management of BPSD patients, with a simultaneously reduction of physicians, nurses and care assistants stress. The last aspect will be evaluated with a specific part of NPI-NH test. The decrease of the initial score represented an improvement [19.20]. The NPI-NH test will be performed according to the time points defined in paragraph 7.1.1

The obtained results could be interesting to the future implementation of the use of essential oils in air diffusion in acute geriatric departments and in all facilities with BPSD patients.

7. RANDOMIZATION

Enrolled patients with BPSD will be randomized according to the following randomization scheme (AABB, ABAB, BBAA, BABA, ABBA, BAAB).

A repetition of the first 4blocks will be performed, for a total of 32 patients, 16 each group, according to the following scheme:

AABB, ABAB, BBAA, BABA

AABB, ABAB, BBAA, BABA

8. PROJECT DESIGN

The project will be managed in the acute geriatric department of the Clinica Luganese Moncucco. Enrolment and treatment scheme is present in the flow chart (chapter 2).

After randomization patients will be enrolled in the two groups GROUP A, control group, and GROUP B, treatment group.

The enrollment will be performed in 2 months.

GROUP A: 16 patients, following the inclusion criteria, will be enroll and they will be treated with psychotropic drugs.

GROUP B: 16 patients, following the inclusion criteria, will be enroll and they will be treated with psychotropic drugs and, in a complementary way, with aromatherapy in environmental diffusion.

The project hypothesis will be validated using the following neuropsychological and functional tests:

- CAM (Confusion Assessment Method);
- CDR (Clinical Dementia Rating Score)
- MMSE (Mini Mental State Examination);
- FAB (Frontal Assessment Battery);

- Tinetti's scale;
- BADL (Basic Activities of Daily Living);
- IADL (Instrumental Activities of Daily Living);
- NPI-NH (Neuropsychiatric Inventory – Nursing Home Version);

Neuropsychological tests are part of clinical practice [18].

Scientific reports show that essential oils in air diffusion are effective in 3 days. A final timepoints of 14 days represent the mean hospital stay:

2 days for the collection of behavioral data;

6 days to observe the possible effectiveness of aromatherapy in air diffusion;

6 days to adapt the therapy with oils and psychotropic drugs and stabilize patient's condition for a possible discharge.

Enrolled patients and nurses will be tested according to the following times:

8.1.1 Observation for 48 hours with data collection and execution of the NPI-NH (T1): in the 48 hours after patient admission at the Geriatric Department or at the diagnosis of dementia, the information collection will be performed: sensitive data (age, gender), dementia condition (CAM, CDR, MMSE, FAB), functional status (IADL, BADL, Tinetti scale) and the used number of psychotropic drugs. As a result of this evaluation, patient will be assessed for the presence of BPSD using the NPI-NH assessment scale, nurses will be undergo to NPI – NH test within 48 hours after patient admission. In case of a score greater than or equal to 1, patient will be followed within the study project, otherwise it will follow the standard process.

8.1.2 Assessment of NPI-NH at T2 (T1-3 days): 3 days after enrollment, patient will be re-evaluated with NPI-NH to assess BPSD progress. In addition, the distress level of on the three health caregivers is also measured with the NPI-NH test.

8.1.3 Assessment of NPI-NH at T3, assessment of vital parameters and use of drug reserves (T1-6 days): 6 days after enrollment, NPI-NH will be re-executed, with associated assessment of patient's vital signs (PAS, PAM, FC) and the use of psychotropic drug reserves.

8.1.4 Final T4 assessment (T1-12 days): NPI-NH scale will be performed in association with vital signs.

The physician in charge of dispensing the NPI-NH questionnaires to nurses to collect BPSD patients status, will also submit the questionnaires to the referring physician, nurse and care assistants with the aim to assess the level of stress in the clinical staff (see "Distress" column in NPI-NH questionnaire in the appendix).

9. ELEGIBILITY CRITERIA

Inclusion criteria:

- patients ≥ 70 years;

- patients admitted to the Acute Geriatric Ward;

- patients with known diagnosis of dementia associated with BPSD or diagnosis performed during the hospitalization.

Exclusion criteria:

- patients with alcohol-based dementia;

- patients with Mild Cognitive Impairment (MCI) – paragraph 4 -;

- patients with language barriers;

- patients already being treated with aromatherapy.

Patients admitted to the Geriatric Competence Centre of the Clinica Luganese Moncucco who do not respect inclusion criteria at the time of admission but develop them in the course of stay in the Clinic (for example: patient without psychological disorders and behavior at the entrance that manifest BPSD during hospitalization) could be enrolled.

10. CODIFY AND REGISTRATION PROCEDURES

A unique and increasing patient number (UPN) will be assigned to each patient. The clinical research unit of Clinica Luganese Moncucco will keep the dataset containing the correspondence between the UPN and the patient's personal and clinical data. All the analyzed data, available for scientific discussions or publishing, will be encoded.

11. PROJECT DURATION

Patients enrolment will be performed during May and June 2018.

12. RISKS AND BENEFITS

This project involves the use of essential oils, which are natural and with no collateral risks; the only risks the patient might present are hypersensitivity to essential oil [22].

If aromatherapy results efficacious in the management of BPSD, patients benefit would result in a reduction of the use of psychotropic therapy with a consecutive reduction in the side effects.

At the same time as the effectiveness of aromatherapy, possible benefits will also be available for caregivers (doctors, nurses, patient care assistant, family members).

13. STATISTICAL CONSIDERATIONS

This is a pilot study which required the enrollment of 32 patients. For this reason, the statistical considerations will be purely descriptive.

Patients will be enrolled, according to the described randomization, in GROUP A, control group in which patients will be treated exclusively with traditional psychotropics drugs, or in group B, in which they will be treated with aromatherapy integrated with psychotropics drugs.

14.ETHICS CONSIDERATIONS

This protocol has been designed and written in accordance with the Helsinki Agreement, the International Good Clinical Practice ICH Guidelines and the arrangements of the European and Swiss regulatory authorities [23, 24, 25].

In consideration of the presence of potentially vulnerable subjects, in order to ensure the inalienable principle *of patient autonomy* (I principle of Medical Ethics), informed consent will be explained and requested to a relative/legal representative of the patient who has lost the ability to discern.

15. DATA PUBLISHING POLICY

The ownership of the data is of Clinica Luganese Moncucco. The results are also expected to be published in the event of negative results and the authors of the scientific work will be chosen according to their contribution.

16. INSURANCE COVERAGE

No specific insurance coverage is required.

17. FUNDING

The funding for this pilot project comes from the aromatherapy fund of the Geriatric Competence Centre of Clinica Luganese Moncucco.This fund is funded by private donations. No companies participated in the financing.

18. CONFLICTS OF INTEREST

The authors and collaborators of the study declare that they do not present any conflict of interest.

19. ADDITIONAL INFORMATION

As agreed with the Cantonal Ethics Committee, in order not to harm the sensitivity of patients and relatives involved in the study, the title of the protocol was changed only in informed consents, replacing the term "demented" with "with dementia." This measure has also not been applied to the protocol as it is a document that is not provided to relatives or involved patients, but is tool for the staff participating an the study.

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21.APPENDIX

21.1 Scores used for evaluation

21.1.1 Confusion Assessment Method (CAM)

Confusion Assessment Method (CAM) Diagnostic Algorithm	**Date of assessment**	
	Time of assessment	
		Yes or No
1. Acute onset and fluctuating course? (Acute change in mental status from baseline, fluctuating behaviour through the day)		
2. Inattention? (Difficulty focusing attention, easily distracted, difficulty keeping track of what is being said)		
3. Disorganised thinking? (disorganized or incoherent thinking, rambling or irrelevant conversation, unclear or illogical flow of ideas)		
4. Altered level of consciousness? (This feature is shown by any answer other than "alert", including: hyper-alert, lethargic, stupor, or coma)		
The diagnosis of Delirium by CAM requires the presence of features 1 and 2 *AND EITHER* 3 or 4		
Delirium detected?		**YES NO (Circle)**

Reference: Inouye SK, Van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI (1990) Clarifying confusion: the Confusion Assessment Method. *Annals of Internal Medicine* 113: 941-8

21.1.2 Mini Mental State Evaluation (MMSE)

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

Interpretation of the MMSE:

Method	Score	Interpretation
Single Cutoff	<24	Abnormal
Range	<21	Increased odds of dementia
	>25	Decreased odds of dementia
Education	21	Abnormal for 8th grade education
	<23	Abnormal for high school education
	<24	Abnormal for college education
Severity	24-30	No cognitive impairment
	18-23	Mild cognitive impairment
	0-17	Severe cognitive impairment

Interpretation of MMSE Scores:

Score	Degree of Impairment	Formal Psychometric Assessment	Day-to-Day Functioning
25-30	Questionably significant	If clinical signs of cognitive impairment are present, formal assessment of cognition may be valuable.	May have clinically significant but mild deficits. Likely to affect only most demanding activities of daily living.
20-25	Mild	Formal assessment may be helpful to better determine pattern and extent of deficits.	Significant effect. May require some supervision, support and assistance.
10-20	Moderate	Formal assessment may be helpful if there are specific clinical indications.	Clear impairment. May require 24-hour supervision.
0-10	Severe	Patient not likely to be testable.	Marked impairment. Likely to require 24-hour supervision and assistance with ADL

Source:

- Folstein MF, Folstein SE, McHugh PR: "Mini-mental state: A practical method for grading the cognitive state of patients for the clinician." *J Psychiatr Res* 1975;12:189-198.

21.1.3 Frontal Assessment Battery (FAB)

Frontal Assessment Battery

Purpose
The FAB is a brief tool that can be used at the bedside or in a clinic setting to assist in discriminating between dementias with a frontal dysexecutive phenotype and Dementia of Alzheimer's Type (DAT). The FAB has validity in distinguishing Fronto-temporal type dementia from DAT in mildly demented patients (MMSE > 24). Total score is from a maximum of 18, higher scores indicating better performance.

1. Similarities (conceptualization)
"In what way are they alike?"

- A banana and an orange

(In the event of total failure: "they are not alike" or partial failure: "both have peel," help the patient by saying: "both a banana and an orange are fruit"; but credit 0 for the item; do not help the patient for the two following items)

- A table and a chair
- A tulip, a rose and a daisy

Score (only category responses [fruits, furniture, flowers] are considered correct)

Three correct: 3 Two correct: 2 One correct: 1 None correct: 0

2. Lexical fluency (mental flexibility)
"Say as many words as you can beginning with the letter 'S,' any words except surnames or proper nouns."

If the patient gives no response during the first 5 seconds, say: "for instance, snake." If the patient pauses 10 seconds, stimulate him by saying: "any word beginning with the letter 'S.' The time allowed is 60 seconds.

Score (word repetitions or variations [shoe, shoemaker], surnames, or proper nouns are not counted as correct responses)

> 9 words: 3 6 -9 words: 2 3 -5 words: 1 < 3 words: 0

3. Motor series "Luria" test (programming)
"Look carefully at what I'm doing."

The examiner, seated in front of the patient, performs alone three times with his left hand the series of "fist–edge–palm."
"Now, with your right hand do the same series, first with me, then alone."
The examiner performs the series three times with the patient, then says to him/her:
"Now, do it on your own."

Score

Patient performs six correct consecutive series alone: 3
Patient performs at least three correct consecutive series alone: 2
Patient fails alone, but performs three correct consecutive series with the examiner: 1
Patient cannot perform three correct consecutive series even with the examiner: 0

4. Conflicting instructions (sensitivity to interference)
"Tap twice when I tap once."
To ensure that the patient has understood the instruction, a series of 3 trials is run: 1-1-1.

Frontal assessment battery_SVUH_MedEl_tool 1/2

"Tap once when I tap twice."
To ensure that the patient has understood the instruction, a series of 3 trials is run: 2-2-2.

The examiner then performs the following series: 1-1-2-1-2-2-2-1-1-2.

Score No errors: 3 1 -2 errors: 2 > 2 errors: 1
Patient taps like the examiner at least four consecutive times: 0

5. Go–No Go (inhibitory control)
"Tap once when I tap once."
To ensure that the patient has understood the instruction, a series of 3 trials is run: 1-1-1.

"Do not tap when I tap twice."
To ensure that the patient has understood the instruction, a series of 3 trials is run: 2-2-2.

The examiner then performs the following series: 1-1-2-1-2-2-2-1-1-2.

Score No errors: 3 1 -2 errors: 2 > 2 errors: 1
Patient taps like the examiner at least four consecutive times: 0

6. Prehension behaviour (environmental autonomy)

"Do not take my hands."

The examiner is seated in front of the patient. Place the patient's hands palm up on his knees. Without saying anything or looking at the patient, the examiner brings his own hands close to the patient's hands and touches the palms of both the patient's hands, to see if he will spontaneously take them. If the patient takes the examiner's hands, try again after asking the patient: "Now, do not take my hands."

Score

Patient does not take the examiner's hands: 3
Patient hesitates and asks what he/she has to do: 2
Patient takes the hands without hesitation: 1
Patient takes the examiner's hand even after he/she has been told not to do so: 0

Interpreting results
A cut off score of 12 on the FAB has a sensitivity of 77% and specificity of 87% in differentiating between frontal dysexecutive type dementias and DAT

ReferenceS
Dubois, B. ; Litvan, I.; The FAB: A frontal assessment battery at bedside. Neurology. 55(11): 1621-1626, 2000.

Slachevsky, A; Dubois, B. Frontal Assessment Battery and Differential Diagnosis of Frontotemporal Dementia and Alzheimer Disease. Archives of Neurology. 61(7): 1104-1107, 2004.

21.1.4 Tinetti

TINETTI BALANCE ASSESSMENT TOOL

Tinetti ME, Williams TF, Mayewski R, Fall Risk Index for elderly patients based on number of chronic disabilities. Am J Med 1986:80:429-434

PATIENTS NAME _____ D.o.b. _____ Ward _____

BALANCE SECTION

Patient is seated in hard, armless chair;

		Date		
Sitting Balance	Leans or slides in chair Steady, safe	= 0 = 1		
Rises from chair	Unable to without help Able, uses arms to help Able without use of arms	= 0 = 1 = 2		
Attempts to rise	Unable to without help Able, requires > 1 attempt Able to rise, 1 attempt	= 0 = 1 = 2		
Immediate standing Balance (first 5 seconds)	Unsteady (staggers, moves feet, trunk sway) Steady but uses walker or other support Steady without walker or other support	= 0 = 1 = 2		
Standing balance	Unsteady Steady but wide stance and uses support Narrow stance without support	= 0 = 1 = 2		
Nudged	Begins to fall Staggers, grabs, catches self Steady	= 0 = 1 = 2		
Eyes closed	Unsteady Steady	= 0 = 1		
Turning 360 degrees	Discontinuous steps Continuous	= 0 = 1		
	Unsteady (grabs, staggers) Steady	= 0 = 1		
Sitting down	Unsafe (misjudged distance, falls into chair) Uses arms or not a smooth motion Safe, smooth motion	= 0 = 1 = 2		
	Balance score		/16	/16

TINETTI BALANCE ASSESSMENT TOOL

GAIT SECTION

Patient stands with therapist, walks across room (+/- aids), first at usual pace, then at rapid pace.

		Date		
Indication of gait (Immediately after told to 'go'.)	Any hesitancy or multiple attempts No hesitancy	= 0 = 1		
Step length and height	Step to Step through R Step through L	= 0 = 1 = 1		
Foot clearance	Foot drop L foot clears floor R foot clears floor	= 0 = 1 = 1		
Step symmetry	Right and left step length not equal Right and left step length appear equal	= 0 = 1		
Step continuity	Stopping or discontinuity between steps Steps appear continuous	= 0 = 1		
Path	Marked deviation Mild/moderate deviation or uses w. aid Straight without w. aid	= 0 = 1 = 2		
Trunk	Marked sway or uses w. aid No sway but flex. knees or back or uses arms for stability No sway, flex., use of arms or w. aid	= 0 = 1 = 2		
Walking time	Heels apart Heels almost touching while walking	= 0 = 1		
	Gait score		/12	/12
	Balance score carried forward		/16	/16
	Total Score = Balance + Gait score		/28	/28

Risk Indicators:

Tinetti Tool Score	Risk of Falls
≤18	High
19-23	Moderate
≥24	Low

21.1.5 Addiction index in everyday activities (BADL)

Hygiene	Autonomous	0
	Partial assistance for one part of the body	1
	Assistance for several parts of the body or toileting impossible	2
Dressing	Autonomous	0
	Dresses but needs assistance with shoes	1
	Needs assistance in choosing clothing, getting dressed, and remains partially or completely undressed	2
Toileting	Autonomous	0
	Needs to be accompanied; needs assistance	1
	Does not go to the toilet; does not use the toilet or urinal	2
Locomotion	Autonomous	0
	Needs assistance	1
	Bedridden	2
Continence	Continent	0
	Occasional incontinence	1
	Permanent incontinence	2
Meals	Autonomous	0
	Needs assistance to cut meat or peel fruit	1
	Total assistance or artificial feeding	2
Total		

Scale of Basic Activities of Daily Living (ADL)

21.1.6 Addiction index in the instrumental activities of daily life (IADL)

Patient Name:_____ **Date:**_____
Patient ID #_____

LAWTON - BRODY
INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)

Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).

A. Ability to Use Telephone		**E. Laundry**	
1. Operates telephone on own initiative-looks up and dials numbers, etc.	1	1. Does personal laundry completely	1
		2. Launders small items-rinses stockings, etc.	1
2. Dials a few well-known numbers	1	3. All laundry must be done by others	0
3. Answers telephone but does not dial	1		
4. Does not use telephone at all	0		
B. Shopping		**F. Mode of Transportation**	
1. Takes care of all shopping needs independently	1	1. Travels independently on public transportation or drives own car	1
2. Shops independently for small purchases	0	2. Arranges own travel via taxi, but does not otherwise use public transportation	1
3. Needs to be accompanied on any shopping trip	0	3. Travels on public transportation when accompanied by another	1
4. Completely unable to shop	0	4. Travel limited to taxi or automobile with assistance of another	0
		5. Does not travel at all	0
C. Food Preparation		**G. Responsibility for Own Medications**	
1. Plans, prepares and serves adequate meals independently	1	1. Is responsible for taking medication in correct dosages at correct time	1
2. Prepares adequate meals if supplied with ingredients	0	2. Takes responsibility if medication is prepared in advance in separate dosage	0
3. Heats, serves and prepares meals, or prepares meals, or prepares meals but does not maintain adequate diet	0	3. Is not capable of dispensing own medication	0
4. Needs to have meals prepared and served	0		
D. Housekeeping		**H. Ability to Handle Finances**	
1. Maintains house alone or with occasional assistance (e.g. "heavy work domestic help")	1	1. Manages financial matters independently (budgets, writes checks, pays rent, bills, goes to bank), collects and keeps track of income	1
2. Performs light daily tasks such as dish washing, bed making	1	2. Manages day-to-day purchases, but needs help with banking, major purchases, etc.	1
3. Performs light daily tasks but cannot maintain acceptable level of cleanliness	1	3. Incapable of handling money	0
4. Needs help with all home maintenance tasks	1		
5. Does not participate in any housekeeping tasks	0		
Score		**Score**	

Total score_____

A summary score ranges from 0 (low function, dependent) to 8 (high function, independent) for women and 0 through 5 for men to avoid potential gender bias.

21.1.7 Neuropsychiatric Inventory NPI-NH

NPI-NH

Neuropsychiatric Inventory – Nursing Home Version

Scoring Summary

CENTER #	SCREENING #	PATIENT #	PATIENT INITIALS	VISIT	DATE
☐☐☐	☐☐☐☐☐	☐☐☐☐	☐☐☐ (F M L)	☐☐	☐☐☐ (M D Y)

Please transcribe appropriate categories from the NPI-NH Worksheet into the boxes provided.

For each domain:
- If symptoms of a domain did not apply, check the "N/A" box.
- If symptoms of a domain were absent, check the "0" box.
- If symptoms of a domain were present, check one score each for Frequency and Severity.
- Multiply Frequency score x Severity score and enter the product in the space provided.
- Total all Frequency x Severity scores and record the Total Score below.
- If symptoms of a domain were present, check one score for Occupational Disruptiveness; total all occupational disruptiveness scores for a summary score.

Rater's Initials: ☐☐☐

DOMAIN	N/A[1]	ABSENT	FREQUENCY	SEVERITY	FREQUENCY X SEVERITY	OCUPATIONAL DISRUPTIVENESS
		0	1 2 3 4	1 2 3		0 1 2 3 4 5
A. Delusions	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
B. Hallucinations	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
C. Agitation/Aggression	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
D. Depression/Dysphoria	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
E. Anxiety	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
F. Elation/Euphoria	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
G. Apathy/Indifference	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
H. Disinhibition	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
I. Irritability/Lability	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
J. Aberrant Motor Behavior	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
TOTAL SCORE:					☐☐☐	☐☐
K. Sleep and Nighttime Behavior Disorders	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐
L. Appetite/Eating Changes	☐	☐	☐☐☐☐	☐☐☐	☐☐	☐☐☐☐☐☐

NPI-NH	Neuropsychiatric Inventory – Nursing Home Version
	Worksheet

Directions: Read all items from the NPI-NH "Instructions for Administration of the NPI-NH". Mark Caregiver's responses on this worksheet before scoring the Frequency, Severity, and Occupational Disruptiveness.

A. DELUSIONS: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Fear of harm ☐ 2. Fear of theft ☐ 3. Spousal affair ☐ 4. Phantom boarder ☐ 5. Spouse imposter ☐ 6. House not home ☐ 7. Fear of abandonment ☐ 8. Talks to TV, etc. ☐ 9. Other _____	**B. HALLUCINATIONS**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Hears voices ☐ 2. Talks to people not there ☐ 3. Sees things not there ☐ 4. Smells things not there ☐ 5. Feels things not there ☐ 6. Unusual taste sensations ☐ 7. Other _____
C. AGITATION/AGGRESSION: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Upset with caregiver; resists ADL's ☐ 2. Stubbornness ☐ 3. Uncooperative; resists help ☐ 4. Hard to handle ☐ 5. Cursing or shouting angrily ☐ 6. Slams doors; kicks, throws things ☐ 7. Hits, harms others ☐ 8. Other _____	**D. DEPRESSION/DYSPHORIA**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Tearful and sobbing ☐ 2. States, acts as if sad ☐ 3. Puts self down, feels like failure ☐ 4. "Bad person", deserves punishment ☐ 5. Discouraged, no future ☐ 6. Burden to family ☐ 7. Talks about dying, killing self ☐ 8. Other _____
E. ANXIETY: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Worries about planned events ☐ 2. Feels shaky, tense ☐ 3. Sobs, sighs, gasps ☐ 4. Racing heart, "butterflies" ☐ 5. Phobic avoidance ☐ 6. Separation anxiety ☐ 7. Other _____	**F. ELATION/EUPHORIA**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Feels too good, too happy ☐ 2. Abnormal humor ☐ 3. Childish, laughs inappropriately ☐ 4. Jokes or remarks not funny to others ☐ 5. Childish pranks ☐ 6. Talks "big", grandiose ☐ 7. Other _____

NPI-NH	Neuropsychiatric Inventory – Nursing Home Version Worksheet

G. APATHY/INDIFFERENCE: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Less spontaneous or active ☐ 2. Less likely to initiate conversation ☐ 3. Less affectionate, lacking emotions ☐ 4. Contributes less to household chores ☐ 5. Less interested in others ☐ 6. Lost interest in friends or family ☐ 7. Less enthusiastic about interests ☐ 8. Other _____	**H. DISINHIBITION**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Acts impulsively ☐ 2. Excessively familiar with strangers ☐ 3. Insensitive or hurtful remarks ☐ 4. Crude or sexual remarks ☐ 5. Talks openly of private matters ☐ 6. Inappropriate touching of others ☐ 7. Other _____
I. IRRITABILITY/LABILITY: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Bad temper, "flies off handle" easily ☐ 2. Rapid changes in mood ☐ 3. Sudden flashes of anger ☐ 4. Impatient, trouble coping with delays ☐ 5. Cranky, irritable ☐ 6. Argues, difficult to get along with ☐ 7. Other _____	**J. ABERRANT MOTOR BEHAVIOR**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Paces without purpose ☐ 2. Opens or unpacks closets or drawers ☐ 3. Repeatedly dresses and undresses ☐ 4. Repetitive activities or "habits" ☐ 5. Handling, picking, wrapping behavior ☐ 6. Excessively fidgety ☐ 7. Other _____
K. SLEEP AND NIGHTTIME BEHAVIOR DISORDERS: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Difficulty falling asleep ☐ 2. Up during the night ☐ 3. Wanders, paces, inappropriate activity ☐ 4. Awakens others at night ☐ 5. Wakes and dresses to go out at night ☐ 6. Early morning awakening ☐ 7. Sleeps excessively during the day ☐ 8. Other _____	**L. APPETITE/EATING CHANGES**: ☐Yes ☐No ☐N/A Frequency_____ Severity_____ Occupational Disruptiveness _____ ☐ 1. Loss of appetite ☐ 2. Increased appetite ☐ 3. Weight loss ☐ 4. Weight gain ☐ 5. Change in eating habits ☐ 6. Change in food preferences ☐ 7. Eating rituals ☐ 8. Other _____

21.1.8 Clinical Dementia Rating (CDR)

CLINICAL DEMENTIA RATING (CDR™):	0	0.5	1	2	3

	Impairment				
	None 0	Questionable 0.5	Mild 1	Moderate 2	Severe 3
Memory	No memory loss or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented to time, often to place	Oriented to person only
Judgment & Problem Solving	Solves everyday problems & handles business & financial affairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, and differences	Moderate difficulty in handling problems, similarities, and differences; social judgment usually maintained	Severely impaired in handling problems, similarities, and differences; social judgment usually impaired	Unable to make judgments or solve problems
Community Affairs	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities although may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside home Appears well enough to be taken to functions outside a family home	Appears too ill to be taken to functions outside a family home
Home and Hobbies	Life at home, hobbies, and intellectual interests well maintained	Life at home, hobbies, and intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home
Personal Care	Fully capable of self-care		Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

Score only as decline from previous usual level due to cognitive loss, not impairment due to other factors.