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RESEARCH ARTICLE

The "Continu-A-mente" project: an interdisciplinary program to promote the continuity of care between hospital and community for people with dementia and their caregivers. Study Protocol.

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ABSTRACT

Background: Nonpharmacological approaches are recommended as first-line treatment for the neuropsychiatric symptoms of persons living with dementia. Tailored Activity Program is a non-pharmacological approach which has shown to reduce neuropsychiatric symptoms and functional dependence of persons living with dementia at the community, as well as caregiver's distress. The aim of the study is to assess the feasibility of a project in which the Tailored Activity Program is delivered partially at an acute hospital ward and partially at the patient's home.

Material and Methods: The study is aimed at enrolling 50 dyads (patients/caregivers) from the memory clinic, acute geriatric ward, or short-stay emergency department at the IRCCS San Gerardo dei Tintori, Monza (Italy). Inclusion criteria are: the patient's clinical diagnosis of dementia, clinically detectable neuropsychiatric symptoms (Neuro Psychiatric Inventory, NPI score ≥ 6 in at least one item), the ability to participate in activities of daily living (Katz's index ≥ 2), the presence of a caregiver (aged ≥ 21 years; minimum 4 hours of daily care), and the willingness of the dyad patient/caregiver to participate in the project. Treatment is delivered both i) in hospital (2 sessions) and ii) at home (6 sessions), including occupational therapy, telemedicine and nursing care provided once a week. The following variables are measured: Neuro Psychiatric Inventory, Time Up and Go Test, Katz's Index and the level of caregiver's sense of competence with the Sense of Competence Questionnaire. Data are collected both at baseline, at the end of the treatment, with a follow-up scheduled at 4 months after enrollment. Primary outcome measure is the dyad's retention rate at 4-month follow-up. Secondary outcomes are the reduction in the patient's frequency and severity of NPS; the improvement in the patient's Time Up and Go Test score; the improvement in the patient's levels of autonomy and participation in activities of daily living and improvement in the caregiver's Sense of Competence Questionnaire score.

Results and Conclusion: We seek to evaluate whether the Tailored Activity Program is well-received by the patient/caregiver dyad and, consequently, whether our project is feasible. If this objective is achieved, and if we also report some improvement in the secondary outcomes, we can then plan a larger multicenter study aimed at evaluating the effectiveness of this approach, partly delivered at the hospital and partly at patient's home.

Keywords: dementia care; hospital discharge; primary care; occupational therapy; tailored activity program

1. Introduction

Dementia is a progressive neurodegenerative syndrome characterized by a progressive decline in individual's brain and cognitive functions¹. There were over 55 million people worldwide living with dementia in 2020, and this number is expected to almost double every 20 years, reaching 78 million in 2030 and 139 million in 2050². Dementia adversely affects patients, resulting in a loss of autonomy, difficulties in daily functioning, and increased dependence on families and society in the course of their routine activities³.

Neuropsychiatric symptoms (NPS) are a well-known complication of dementia that often emerge due to dysfunction in brain circuits crucial for cognition and emotion⁴. This breakdown in brain circuitry may render the patient unable to interact effectively with both caregivers and the environment, particularly in response to stressful events⁵. NPS are highly prevalent in people living with dementia (PLWD), even in the early stages⁶, and are associated with several adverse events, including accelerated cognitive decline, premature nursing home placement, reduction in the individual's and caregiver's quality of life, caregiver's burnout and stress, and, ultimately, to increased cost of care^{4,7}.

It is commonly accepted that NPS do not respond well to medications, which should be therefore avoided as a first-line approach. Guidelines and scientific societies recommend indeed to manage them through non-pharmacological approaches under the guidance of trained and educated caregivers⁸. However, this occurs only rarely, and PLWD are frequently treated with psychotropic drugs⁹, attend inappropriate outpatient visits¹⁰ and refer to emergency departments¹⁰.

This breakdown in brain circuitry may result in the patient being the patient unable to interact effectively with both caregivers and the environment, particularly in response to stressful events¹¹. Moreover, in the absence of effective pharmacotherapies that slow disease progression, there is an urgent need to develop and test the effectiveness of well-tolerated treatments that improve NPS and thereby enhance quality of life of PLWD and their caregivers¹¹.

Nonpharmacological approaches have been identified as a first line treatment for managing patient's NPS and functional dependence, potentially reducing caregiver distress^{8,12}. One promising nonpharmacological approach for reducing NPS is the Tailored Activity Program (TAP), which tailors activities to the abilities and interests and instructs caregivers in their use in addition to perform stress reduction techniques. TAP is a standardized occupational therapy (OT) program based on occupation and centered on the patient's motivation and abilities.

In a randomized control trial (RCT), 160 dyads of community-dwelling veterans with dementia and caregivers underwent 8 sessions with a TAP. At 4 months, the TAP group showed reductions in number of behavioral symptoms, number of activities needing assistance, functional dependence level, and pain levels, in comparison to controls. Furthermore, caregivers of veterans in TAP reported less behavior-related distress than before treatment¹³. Another RCT was conducted on 250 dyads of patient/caregivers (124 assigned to TAP and 126 to usual care), with assessments at baseline, 3 and 6 months. The study found a significant improvement in ADLs as well as in caregiver well-being¹⁴.

Only one study, to our knowledge, was carried out in a hospital. This was a feasibility study conducted in a 22-bed unit, specifically designed to provide comprehensive in-patient care to older adults with complex medical needs and specialty consultation to address psychiatric conditions. Eleven in-hospital sessions to develop activities tailored to patient interests and capabilities and train staff/families in their use were provided to 20 PLWD and caregivers. Observational data revealed an increase in pleasure and positive gestures and a decrease in anxiety/rage, negative verbalizations, and negative nonverbal behaviors from baseline to intervention sessions. Furthermore, staff improved their helpfulness and families expressed high satisfaction with the program, with 59.4% of activities used at home¹⁵.

Overall, studies regarding TAP have been conducted exclusively either within the community or within an acute hospital ward, while no study has evaluated yet whether an approach with TAP conducted partly in the hospital and partly at home is feasible and can have positive effects on patient's and caregiver's status. We seek to evaluate whether an 8-session TAP, delivered by OTs in continuity between hospital and community, is well-accepted by the patient/caregiver dyad and, consequently, is feasible. We will also aim to evaluate whether this approach can lead to a reduction of patient's NPS and functional dependence as well as in caregiver's distress. Results of this study could have significant implications for health care organizations. In fact, if this approach proves to be useful, TAP could be proposed in PLWD attending the emergency rooms to avoid improper hospitalizations and allow adequate recognition of individual's needs.

2. Material and Methods

2.1 Study Design and Setting

The "Continu-A-mente" project is a single-arm experimental study, based on a pre test – post test design, to evaluate feasibility and secondary outcomes of a TAP approach delivered partly at a hospital ward and partly at patient's home. The sample size includes 50 dyads of PLWD and caregivers.

The trial is monitored by a data and safety monitoring board and overseen by a Milano-Bicocca University. Written informed consent is obtained from caregivers and PLWD, or by the proxy if PLWD is unable to consent. The data collection includes outcome measurements/assessment tools and descriptive quantitative data. The study protocol follows "the Standard protocol items: recommendations for intervention trials 2013 statement"¹⁶.

The study received Comitato Etico Brianza – Monza approval on 12.01.2023 No.4173. Informed consent will be obtained from all the participants.

The TAP has several scientific studies with different methodological designs including 6 randomized controlled trials demonstrating its validity in various geriatric care settings (hospital, nursing home, home care). However, there are currently no experimental studies regarding the use of this strength-based rehabilitative approach in occupational therapy, in conjunction with hospital and community based systems of care. Our approach involves a total of 8 sessions deliverable partially in the hospital and partially at the patient's home by two different occupational therapists who remain in communication with the other. The experimental

idea is quite interesting with both clinical and financial management implications. However, the first step is to understand feasibility of our approach. Through the collected data, we will evaluate the dropout rate of enrolled dyads, clinical outcomes, and the number of adverse events recorded during the experimental period. Additionally, the subjective satisfaction level of the project will be recorded from the perspective of PLWD and their caregivers

2.2 Study population and eligibility criteria

PLWD eligible for the study are recruited from either the memory clinic, the Acute Geriatric Unit (AGU) or the Short-Stay Emergency Department Observation Unit at the IRCCS San Gerardo dei Tintori, Monza (Italy). Eligibility criteria are patient's ability to speak Italian, age of 65 years old or above; prior diagnosis of dementia (mild, moderate, severe), presence of significant NPS and independence in at least two basic activities of daily living; presence of a caregiver aged ≥ 21 years or more, and willingness of caregiver to take care the PLWD to home. Both PLWD and caregivers should give informed con-sent to participate in the study. Exclusion criteria are a diagnosis of schizophrenia, bi-polar disorder, dementia secondary to traumatic head injury, inability to walk or pro-longed wheelchair use (12+ hours a day) and life expectancy <6 months, as determined by the attending physician.

2.3 Interventions

The intervention is based on the original TAP protocol, comprising 8 sessions, each with a duration of 1 to 1½ hour, spanning over a three-month period. We adapted the original protocol, providing 2 sessions at the hospital (either at the memory clinic or at the AGU) and

6 sessions at patient's home. Two OT are involved in this project: one is based at the hospital, and another is based at the Meridiana cooperative providing care at patient's home. Both OTs have been previously trained in the use of TAP. The online course was provided by Drexel University in Philadelphia, USA¹⁷.

The first two sessions are carried out in the hospital, and include the assessment of PLWD preserved abilities, functional challenges (fall risk, executive function, sensory impairments), interests (roles, occupations, routines, activities), caregiver communication style, availability, and readiness to use activities, and the physical environment (lighting, seating, noise, clutter).

After 24-72 from discharge, PLWD are taken care of by a team, including a nurse and a geriatrician, in addition to one the OT. The continuity of care from the hospital to home is maintained through verbal (phone) and written handovers, which include sharing the results of the multidimensional assessment between OTs.

Subsequently, a meeting is scheduled to be held at patient's home, involving PLWD, caregivers, geriatricians, OTs and nurses. Additionally, video call consultations between patients, caregivers and care team are facilitated through telemedicine. In total, the team conducts 6 home visits: four sessions are dedicated to identifying three specific activities of interest for everyone, which are then tailored to the functional profile of PLWD and to caregiver and environmental profiles. Caregivers are then provided with instructions on how to set-up these activities, communicate effectively, offer verbal or physical cues and/or supervise as needed.

Environmental changes, such as decluttering, seating, and optimizing lighting, are implemented to support active participation in the prescribed activities. To familiarize themselves with these activities, caregivers begin by observing OTs as they trigger PLWD engagement in the TAP. During each session, OTs explain the process and seek inputs by PLWD. Then, caregivers take on the role of engaging PLWD in the same activity, with OTs observing, providing prompts, and offering support as required. Before the next session, caregivers are encouraged to attempt the activity themselves. This learning process for caregivers involves both observation and hands-on experience, with written instructions available as a reference in the form of TAP Activity Prescription for each prescribed activity. In each subsequent session, the previously introduced activity is reviewed and a new activity prescription is provided and practiced.

The third phase, known as generalization, includes up to two sessions with caregivers alone. During these sessions, OTs assist caregivers in applying strategies acquired during activity-related sessions to broaden care challenges, such as helping with bathing or dressing. For example, techniques used to facilitate engagement in the activities can be employed to aid PLWD in self-care. Adapting the physical environment to promote activity engagement can also be extended to everyday tasks such as bathing or grooming. Throughout the TAP sessions, caregivers receive education on dementia, including that behavioral symptoms are not intentional, and they can practice various strategies and techniques to reduce stress.

TAP is person-centered, meaning that activities are tailored to the interests and capabilities of PLWD. Since activities align with individual interests, use familiar objects, and are graded based on PLWD functional profiles, the range of activities provided is quite vast. Any single activity can be adjusted to suit the person's cognitive and functional abilities.

Table A1: Overview of TAP in "Continu-A-Mente" Project

N sessions	Setting	Contents
1	Hospital	Phase 1: assessment, daily routine review, interest inventory review, screen for capabilities, caregiver stress reduction. Session Goals: To provide an orientation to TAP, the importance of activities and begin the assessment process to identify areas of strength and activity interests.
2	Hospital	Phase 1: assessment, screen for capabilities, falls risk assessment, Brainstorming activities. Session Goals: To provide support, education, and complete assessment process.
3	At Home	Phase 2: Implementation, assessment scores review, introduce activity 1. Session Goals: To introduce activity prescription 1 which is tailored to individual profiles based on results from Phase I and train caregiver in effective use.
4	At Home	Phase 2: Implementation, introduce activity 2. Session Goals: To review the use of Activity Prescription 1 and modify if indicated. To introduce Activity Prescription 2, which is tailored to individual profiles based on the results from phase I and train the caregiver in their effective use.
5	At Home	Phase 2: Implementation, introduce activity 3. Session Goals: To review the use of Activity Prescription 2 and modify if indicated. To introduce Activity Prescription 3, which is tailored to individual profiles based on results from phase I and train the caregiver in their effective use. To review use of Activity Prescription 3 and modify if indicated.
6	At Home	Phase 2: Implementation, Check in and review. Session Goals: To reinforce the use of Activity Prescriptions and problem solve challenges caregivers may have in using them.
7	At Home	Phase 3: generalization, ways to modify activities as disease progresses. Session Goals: To review basic strategies for using activity in daily care routines, troubleshoot and generalize specific learned strategies (e.g. relax the rules).
8	At Home	Phase 3: generalization, ways to generalize the strategies to other care challenges. Closure of treatment. Session Goals: To review the use of Activity Prescriptions in daily care routines, troubleshoot and generalize the specific learned strategies to other care challenges

2.4 Measures

At the hospital the OTs performs the following assessments:

- a) Neuropsychiatric symptoms, using the NPI¹⁸. The NPI consists of 12 items that are assayed with questions, sub questions, and ratings of frequency and severity. The NPI has been shown to be valid and reliable. The NPI is a useful instrument for capturing behavioral changes for PLWD.
- b) Motor function with the TUG¹⁹. TUG is a functional measurement tool to assess

and monitor walking ability and fall risk especially for people with physical and mental health risk factors.

- c) Independence in ADLs with the Katz index²⁰. Katz index is a rating scale that measures a patient's ability to perform ADLs.
- d) Persons living with dementia (PLWD) occupational performance using the ACLS Allen Cognitive Level Screen²¹. The ACLS is a cognitive test. PLWD will perform some threading tasks using a string, a needle, and a piece of leather with holes around the edges. The levels

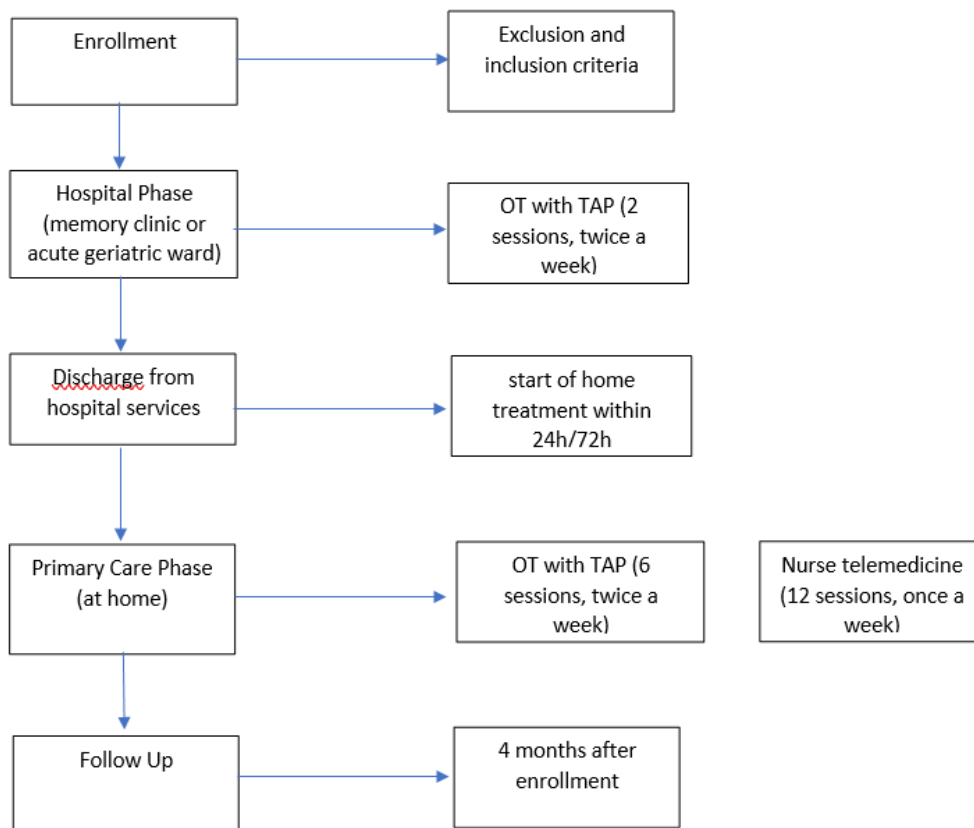
are on a scale of 0 to 6. Each number corresponds to a level of cognitive ability and function.

- e) Caregiver's sense of competence with the SCQ²². The SCQ has developed to assess a caregiver's feeling of being capable of caring for their charge.

A follow-up is planned at 4 months after enrolment, with the OT and the geriatrician to

the baseline data. During the follow-up visit, we collect information on the occurrence of new hospitalizations or ED access, and functional and motor dependence (using the Katz Index and the TUG). Caregivers' sense of competence in delivering care is also measured. Finally, we assess whether new social or health services are initiated to en-sure optimal care at home. The flowchart of the study is shown in figure A1.

Figure A1: Flowchart of the "Continu-A-mente" project



2.5 Outcomes

Primary outcome is the retention rate of dyads at the follow-up. Secondary outcomes are the change between baseline and follow up in the frequency and severity of NPS, de-pendence in ADLs; walking ability; and in the caregiver's sense of competence in the assistance. In addition, the number of hospital readmissions

between baseline and fol-low-up or any new admissions to the emergency department will be assessed.

2.6 Statistical analysis

The data collection forms will be analyzed using descriptive statistics and quantitative content analysis to delineate refusal rate and

treatment adherence among the PLWD and families. Patterns of changes within the group will be determined by descriptive statistics, and nonparametric comparative tests on all the outcome measures. The data will be analyzed over two time points (baseline and four month follow up). Data will be recorded in an Excel database (Microsoft Office 2016) and analyzed using STATA 16 software.

3. Expected Results

From the "Continu-A-mente" project, we expect to understand whether the use of the TAP program in continuity between the hospital and the local area can promote the containment of NPS in PLWD and foster an increase in the sense of competence of the caregiver living with the person with dementia or providing care. The results will show us any improvement or worsening in the functional status of the PLWD (autonomy in ADL and walking ability) and record any adverse events encountered during the project (lasting a total of 4 months from hospital service discharge to the date of follow-up) such as hospital readmissions, emergency room access, or increased daily care. These outcomes will have great relevance from a public health and economic resource utilization perspective.

4. Discussion

Hospitalization is usually a sentinel event leading to disability, especially in older adults^{23,24}. Although the hospitalization process provides the opportunity to solve the acute phases of the disease in order to restore the state of health, it can considerably negatively impact functional capacity of older patients. A growing number of studies are emerging

examining the iatrogenic effects and nosocomial disability developed during hospitalization, and currently these consequences are relevant in clinical practice. The iatrogenic nosocomial disability is mainly characterized by prolonged bed rest episodes, sedentary behaviours and lack of appropriate cognitive stimulation during the entire hospital stay. These low-mobility behaviours coupled with the impaired intrinsic capacity of older people precipitate many adverse effects, such as loss of independence of ADLs, cognitive impairment, reduced caloric intake, sarcopenia, higher risk of falls and social isolation; thus, increasing the likelihood of developing new disabilities and death^{24,25}.

At the same time, the hospital and especially the emergency room and sometime thereafter, the geriatrics departments of hospitals are frequently an important point of contact for the population that needs health or social interventions and often in emergencies. The use of hospitals and emergency rooms becomes part of the care pathway of many PLWD. Thus, offering evidence-based home-based interventions and connecting hospital to home and territorial services in a structured way is a critical goal in dementia care and of the "Continu-A-mente" project. To do this, it is necessary to equip the geriatrics department with interprofessional staff prepared and trained in a rehabilitative approach with people with dementia and NPS. With this improvement in mind through the "Continu-A-mente" project, it was possible to integrate an OT with expertise in psychogeriatrics within the staff of the geriatric department. Realistically, this process of integrating the skills of the occupational therapist with TAP training can potentially be extended in other hospital departments to improve the care of PLWDs and their families (e.g., emergency departments).

This increased psychogeriatric expertise in various hospital departments would lead to a qualitative and quantitative improvement in defining multidimensional needs, thereby ensuring a greater ability of the healthcare system to address clinical and psychosocial needs. Ensuring continuity of care between the hospital and the community will be particularly challenging. Currently, home care for PLWD and their families is highly fragmented. For example, in Italy and especially in the Lombardy region, there is a home care assistance program provided by the national healthcare system. However, this service does not cater to people with disabilities and is primarily focused on delivering advanced nursing and/or rehabilitative services (such as those for individuals with hip fractures, stroke sequelae, exacerbated chronic obstructive pulmonary disease) with the goal of recovery. That is why the "Continu-A-Mente" project seeks to respond to these two main difficulties: the care and treatment of PLWDs with NPSs and the integration of new skills in two care settings such as the hospital and the local area, particularly as PLWDs transition from hospital to home-based care.

The "Continu-A-Mente" project evaluates a flexible approach which is, at the same time, structured and specific for PLWDs with NPSs returning from the hospital (memory outpatient setting or acute geriatrics ward or Short Observation Unit of the IRCCS San Gerardo dei Tintori Emergency Room) to the home. The data from this re-search will show how an innovative model such as the "Continu-A-Mente" project, can improve care for people with disabilities and their caregivers. The model we will evaluate is supported by epidemiological studies that project an exponential increase in the number of people living with a diagnosis

of dementia. More than 55 million people worldwide are living with dementia, a leading cause of disability and among the elderly and this number will increase to 150 million within 30 years².

In this scenario, health care spending will also increase considerably as dementia and the various comorbidities related to it lead to the need for specialist examinations, emergency department presentations and hospitalizations. To reduce this cost, it is increasingly important to develop comprehensive dementia care approach that integrates and links therapeutic interventions. Based on these premises, our experimental project will provide preliminary data on the feasibility of combining hospital and community services through the TAP program: data on the dropout rate to treatment, hospital readmissions between baseline and follow-up (4 months) and emergency room admissions have the potential to inform both policy and practices.

The novelty of this experimental design is embedding an evidence-based program, TAP, between two different treatment settings to bridge hospital to home and evaluate its impact both from the point of view of NPS containment and functional and psychological outcomes for both PLWDs and their caregivers. This approach may be better able to support the challenging transition from hospital discharge to home with the potential of reducing possible readmissions.

The use of TAP may ensure better communications between different teams and settings, more efficient and effective sharing of clinical documentation, and the involvement of the person with dementia and his or her caregiver in treatment choices to meet different

clinical and social needs. Improving the coordination and quality of transitional processes may lead to a reduction in re-hospitalizations and less use of the emergency department to address the clinical-management difficulties related to NPSs. As NPS can escalate with such transitions, our model holds great promise. In previous randomized trials, TAP has shown improvements in a range of behavioral symptoms, e.g., agitation²⁶. This positive impact of TAP on NPSs has been reported in studies conducted in the United States^{14,27}, Brazil²⁸, and Australia²⁹. As mentioned, these studies were conducted in single care settings (hospital, community, nursing home). Our experimental intent is to evaluate whether such improvements can similarly be achieved when TAP is situated between two different settings.

But why can engagement in activities tailored to the cognitive abilities and interests of PLWDs result in reduced symptoms? One explanation could be that activities fill a void, improve role identity, and help people express themselves positively. This may allow control of self-identity by increasing self-esteem³⁰. TAP can introduce activities that preserve pre-disease roles and identities (e.g., watering plants in the home, using elegant clothing, or using nail polish related to employment history). Whole-life activities will be modified by simplifying them to fit the patient's abilities, thus minimizing frustration and providing positive engagement. The goal will also be generalization of strategies for using activities to other types of self-care and instrumental activities of daily living¹⁴.

Another explanation could be that the intervention may reduce allostatic load, defined as overload of sensory and information

processing capacity^{14,31}. Recent conceptualizations of behaviors as reflecting the interaction between neurological, socio-psychological, and environmental factors suggest that external conditions can overload patients' abilities, with very negative consequences³². Simplifying the task and the environmental context in which the activity takes place, and consequently "personalizing" the activity, can reduce physiological stress responses and agitated type behaviors. Caregivers can benefit from TAP in several ways: a major concern of families is how to occupy their family members and sustain personal identity. Caregivers are particularly distressed by their family members' apathy and distress¹⁴. TAP will be able to offer enjoyable activities, and caregivers can observe the benefits. In addition, TAP will seek out activities that are enjoyable and easy to do and that, rather than requiring additional time, will reduce the time dedicated to daily caregiving^{4,15,27,29}.

In addition, important clinical implications will be drawn from TAP: the TAP assessment included in the "Continu-A-mind" project combines neuropsychological testing and observations of occupations to gain insight into skills and deficits. Families often underestimate or overestimate the capabilities of PLWD.

5. Conclusions

If our scientific hypotheses are confirmed by experimental data, this study will provide foundational knowledge from which to conduct multi-center national and international trials and in other transitional contexts. Potentially "Continu-A-mente" may be a way forward to facilitate transitions and/or the discharge of this population from any care setting back to

home. Training in the psychogeriatric field of the team and the presence of the OT with TAP training would be crucial. In addition, it is important to understand whether the number of OTs in Italy - 2624 OTs, 4.45 OTs per 100,000 population³³ - could support a possible diffusion of this promising method. As in other European states, the shortage of health professionals could be a limitation for project implementation.

The researchers acknowledge the limitations of the current trial protocol, especially as it concerns sample size and the absence of a control group. However, this study will lay the foundation for further methodologically more advanced studies. This section may be divided by subheadings. It should provide a concise and precise description of the experimental results, their interpretation, as well as the experimental conclusions that can be drawn.

Conflict of Interest Statement:

The authors declare no conflicts of interest.

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