TITLE: NON-PHARMACOLOGICAL TREATMENTS FOR THE MANAGEMENT OF BPSD (BEHAVIORAL AND PSYCHOLOGICAL SYMPTOMS OF DEMENTIA) IN SUBJETS SUFFERING FROM ALZHEIMER DEMENTIA

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ABSTRACT

Background.

The therapeutic value of the use of the doll with Dementia-affected patients which exhibit important behavior disturbances, assumes symbolic meaning in relation to the regressive potentialities enhanced by the object *doll*. The doll is an instrument that stimulates the activation of memories by encouraging the motherly care. The applied therapeutic approaches are modulated and proposed after the observation of the behavioral dynamics of patients under test.
The use of the therapeutic doll recalls the relational dynamics typical of infancy and motherhood, especially in people affected by a progressive loss of capabilities and abilities, and with important behavioral problems, such as in advanced dementia. The doll becomes a symbolic instrument which contains the paternal and maternal background and encourages memories and emotions of past life. The doll is the child to care, to nurse, to caress, to look at, to embrace. This way, archaic emotions are stimulated. Patients recognize as real the inanimate object and the care of the doll alleviates the behavior disturbances.

Methodology

20 institutionalized patients suffering from severe degree of Dementia and severe behavior disturbances - such as wandering, agitation and aggressiveness - were selected for the experiment. Dolls produced in Sweden and built with the purpose to encourage the relational contact were adopted. The doll weight, open position of legs, building material, and lateral glance itself, encourages the approach and child-like care.
The study envisaged an observation period, objectified by observation forms filled by the team operators that evaluated the patients, all day long. Afterwards an observation form for the initial evaluation of the relational dynamics patients/doll was activated. The related items explored the relational interactions: she accepts her, she searches her, she speaks to her, she hugs her, she rocks her, she attends her(she rearranges the suits and dresses again her),she smiles when she looks the doll. She smiles toward others, she sings, she plays with her, she seeks the consent, she abandons her ,the contact is continuous or fleeing, she caresses her hair, she holds her without moving her. If the evaluation was positive, patients were admitted to a one-year experimentation. The doll was proposed to the patients both during the acute phase of the behavior disturbance and in other moments, in order to facilitate the therapeutic continuity. The pursued objectives were to investigate both whether the non-pharmacological technique alleviate the behavior disturbance or turned it into a less severe disturbance, f.i. from wandering to bustling around.

Conclusions

The study highlighted interesting potentialities of the therapeutic dolls in the treatment of the **BPSD** resulting in their reduction or lower incidence. This implied:

1. a reduction in the pharmacological load, especially for Neuroleptic patients
2. a better handling of patients from the assistive personnel
3. a higher degree of satisfaction from relatives
4. a less disturbing and slower clinical course of the disease

Therefore, it can be inferred that these methodologies dramatically improve the quality of life of the elderly suffering from dementia, while the results in assistive terms are very interesting.
It was indeed experienced that all the members of the tem were more involved and participative in the assistive process, with a resulting motivation that induced a reduction in the absences due to illnesses and a dramatic reduction of the *burn out* phenomenon.

INTRODUCTION

Data reported in the last Dementia Report (2006) published by Alzheimer Europe, that illustrated the European scenario of the disease spreading, are worrying. In Europe (26 Member States of the European Union plus Island, Norway, Switzerland and Turkey), there are more than 6 millions and half people suffering from dementia, and Italy is classed among the first ones with an alarming data of about one million (905.713) patients affected by Alzheimer. Facing the future, the disease appears as a real healthcare and social emergency. The predictions about the world scenarios estimate about 47 millions of individuals suffering from Alzheimer in 2020, up to 90 millions in 2040.
The Behavioral and Psychological Symptoms of Dementia (BPSD) represent one of the neuro-psychiatric conditions more critical for the elderly affected by dementia. The BPSD appear in about 90% of the cases of dementia and independently from the etiology of the disease. They are associated to an increased risk of morbidity, mortality and institutionalization, and represent a psycho-social and economic emergency for the caregivers and the society of today.
The Dementia, indeed, meant as a syndrome, includes both cognitive aspects (aphasy, agnosy, amnesia, apraxia) and non cognitive neuropsychiatric symptoms (behavior disturbances, psychiatric/psychological symptoms). Both affect the every-day life and relational life.
The definition of the psychic and behavior disturbances, the BPSD, as alterations of the perception, of the contents of the thought**,** of the mood and of the behavior, so often observed in patients affected by dementia, was introduced by the International Psychogeriatric Association (IPA) in 1996. With this specific term a wide spectrum of non cognitive symptoms is labeled. They characterize the course of dementia and include:

- Affective symptoms: *disphory, depression, mania*
- Psychotic symptoms: *delirium, hallucinations*

- Disturbance of the behavior: *sleep, food, sexuality*
- Specific behaviors: *wandering, agitation, aggressiveness*

They can be present in all the phases of the disease and they become more and more severe, with the disease progression.
The BPSD have a high prevalence in all kinds of dementia. They are more precocious in the frontotemporal dementia and the a Lewy body dementia**.** They are more tardy and correlated to their disease evolution, in Alzheimer disease and in vascular dementia.
The first fundamental rule in the medical practice is the Hyppocrates law: "PRIMUM NON NUOCERE". Therefore, before undertaking any treatment is always necessary:

- An accurate evaluation of the effective need of the treatment
- A cost-benefit evaluation
- An evaluation and correction of every possible factor – physical, psycho-social or environmental – that can trigger or maintain the psychical disturbance

Only after having carefully evaluated that the psychiatric symptoms did not originate from specific medical problems, it is possible to consider a psychic and pharmacological intervention.
Used drugs are: **,** Triciclic Antidepressant and the SSRI (Selective Serotonin Receptors Inhibitory), the stabilize tone humour/antiepilectic, the tipical and atypical antipsycotic**,** all moleculas that in the old patient affected by dementia induce important side-effects, both for the presence of comorbidity and politerapies, to which the old patient is often exposed, and due to the pharmacinetic and pharmadynamic modifications, typical of the third age.
Furthermore, in 2002, first indications were published about adverse cerebrovascular events, in old patient affected by dementia and undertaking therapy with atypical antipsychotic drugs:

1. the risk of mortality for patients treated with Olanzapina was double with respect to placebo
2. the risk of adverse cerebrovascular events for patients treated with Risperidone was triple with respect to placebo

Therefore, FDA in US, EMEA in Europe and CUF in Italy, confirmed that the treatment of BPSD associated to dementia cannot be considered an approved therapeutic indication for atypical antipsychotic drugs.
From the analysis of all the studies undertaken at international level, it can be stated that any antipsychotic drug - in particular in the presence of risk factors – determine an increase of adverse cerebrovascular events, while the global risk of mortality is higher for traditional antipsychotic drugs.
This means that, before adopting a drug, it is better, in the light cases, to adopt a non-pharmacological treatment, and to use drugs only if necessary, together to the non

pharmacological treatment in order to reduce their load in moderate and severe cases of the behavior disturbances.
From what stated above, it can be inferred that it is strictly necessary and right to test non-pharmacological methods in the treatment of these behavior disturbances present in dementia-affected elderly.
This study tested the efficacy of an innovative therapy: the Doll Therapy, a therapy that was adopted more than one year ago in Alzheimer Centres (specialized departments in the treatment of dementia) within the Fondazione C. Gusmini in Vertova (Bergamo), a Psychogeriatric Institute which includes a RSA (Assistive Healthcare Residence). Theese Special Care Unit were introduced by the Healthcare Service of Lombardia Region in 1995. They are closed with specific structural requirements, enhancing a prosthesic environment, and quite high level professionality of caregiver personnel.

The Doll Therapeutic Function

The role that the object *doll* will assume inside an affective relationship with the patient, must be considered.
Three possibilities can be envisaged:

- The patient recognizes the doll just as an inanimated object. At the beginning, he/she thus manipulates it, and then he/she forgets it, without considering the doll as a relational element
- The patient looks after the object *doll*, thus recognizing it as a child from any point of view, and cares the doll more or less intensively all the day long
- The patient can alternate moments of intense nursing toward the object *doll* and moment of disattention or indifference or rejection

Some indications
When affectivity is discussed, it is necessary to consider how a person relates herself/himself to the other one. With a severe cognitive degeneration there is no effective recognition of the real event with respect to the imaginary event. There is an incapacity of distinguishing true events from false events, but with a bent to remember and to get excited for situations and/or objects stored in the long-term memory.
In these terms, the object is constituted by the person (doll) towards which the patient addresses his/her first kind of affection.
It is determinant to consider that the capacity of getting in relationship with the object *doll* results from the integration of the instinctual components of the subject, and the capacity of getting in relationship with the other one results from the recognition of her/his identity.
We have to consider the times of the relation patient/doll, to verify the waiting time and research time of the object doll, testifying the care time. All the above must e done according to concrete objectives.

Analysis of possible objectives:

- Decrease of agitation
- Decrease of wandering
- Stimulation of attention and concentration
- Decrease of moments of inactivity

The doll therapy is a therapy that, by means of a doll with specific characteristics - weight, position of arms and legs, dimensions, and somatic characteristics - alleviate some behavior disturbances. By means of the care attitude, the patient activates tactile relations and motherly ones that support the management and sometimes alleviate behavior disturbances such as agitation, aggressiveness, apathy, non adequate motor behavior.

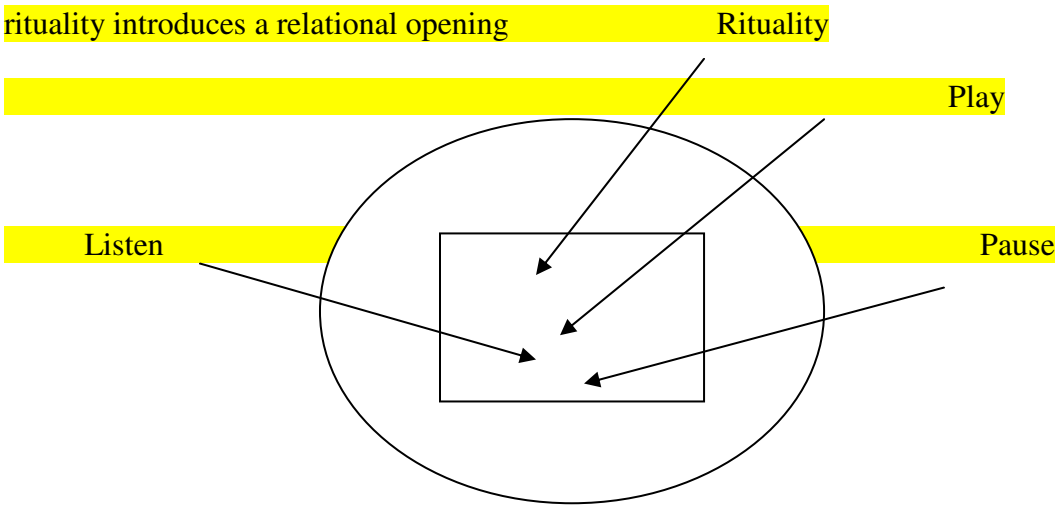
THE DOLL THERAPY: "RITUAL AND EMPATHIC MOMENTS ACTIVATED IN THE EVERY-DAY LIFE SPACES"

The established dynamics (Patient-Doll) in a first moment is connected to a series of ritual moments that encourage the activation of vocal and body response. In this phase, in the patient prevails the availability to carry out shared processes, both at the level of body communication and at the level of relational actions. The empathic-affective relation allows improvised moments with playful dynamics and, at the same time, an important attentive capacity is activated. During the different sessions, the patients altogether alternate moments of openness – often proactive - to moments of relational and postural pause. During the sessions, an evident playful rituality emerges with a curiosity that often turns into empathic moments of improvisation. The doll is explored in a functional way (conventional and non conventional). Proactive and dialogic moments and passivity moments alternate. The attitude to listening should encourage the decrease of situations of relational closure.

Key-words:

- rituality
- game
- listening
- pausa
- corporeity
- dialogue
- glance
- contact
- affectivity

- empathy
- emotion
- wait



EMPHATY (PATIENT DOLL)

METHODS

Preliminary and observational study that analyses the administering of a non pharmacological therapy called "Doll Therapy" to patients suffering from Dementia of different etiology, which exhibit behavior disturbances treated with different symptomatic drugs of the illustrated syndrome.
The 6-months study analyzed 20 patients with observational forms studied by the authors to make the evaluation objective by all the staff.

- **20 patients affected by medium-severe dementia and BPSD** (Behavorial and Psychological Symptoms of Dementia) present in Alzheimer Centres (Special Care Unit of 30 beds) of Fondazione "Card. Gusmini" of Vertova in Bergamo Italy, and under pharmacological treatment with drugs suitable for the illustrated disturbances
- **Comprehensive Geriatric Assessment** of patients and BPSD illustrated by the whole healthcare-assistive team during the meetings to draft the PAI (Individual Assistive Project), when the patient enters the study.
- **Presentation/Introduction of the observational forms** to all the involved personnel.
- **Insertion of patients in the Doll Therapy**; with observation of the behavior one-week long.
- **Definitive Insertion with filling of the form every 15 days**

Observation:

- 1 hour (morning) from 10 to 11
- 1 hour (afternoon) from 16 to 17
- The observation form must be filled at the end of the morning shift and at the end of the evening shift

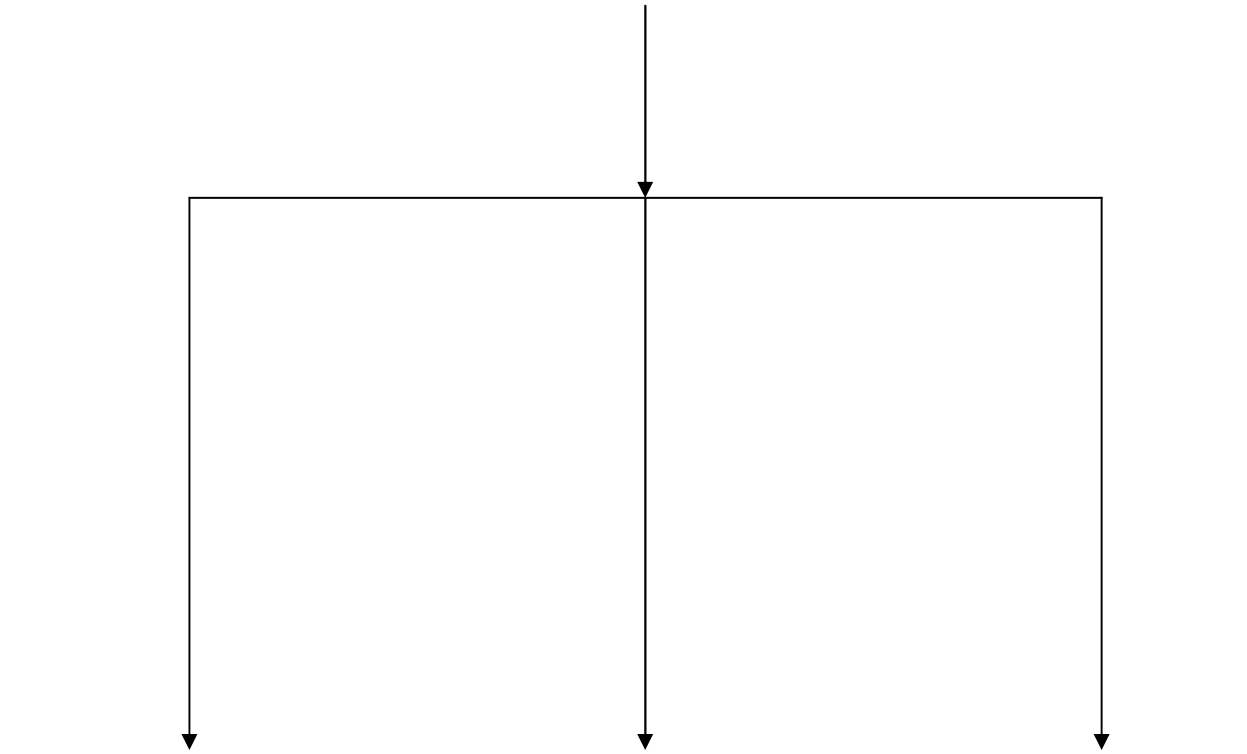
- **Re-evaluation of the methodology at every PAI meeting;** Every three months and when needed (more frequently, if needed).

Phases of therapeutic insertion and evaluation
Administration of observation form
The form must be filled for the first 15 evaluation days of a possible insertion (once a day)

- **If data of the objective evaluation are positive, the patient is inserted in the therapeutic course**
- **During the insertion, the evaluation form of the therapeutic trend was filled (afterwards, two monthly evaluations were performed) for one year.**
- **The considered items enhance the different empathic and relational interactions patient/doll**
- **The body tactile connections and dialogic connections that the different patients activate with the dolls- and throught the dolls among themselves – are highlighted**
- **The conclusive form highlights the numerical level of the interactions.**

PROTOCOL

The insertion is subdivided into 3 phases



Doll providing procedure

- the doll must be provided with the patient possibly in a resting situation, by activating an affective/relational approach
- in case of rejection – f.i. during the morning provision – the provision is shifted to the afternoon. In case of rejection during the afternoon provision, the doll is proposed the day after.

Explanation of Evaluation Form Items

- **Environmental silence**

During the administration of the doll, the environmental silence stresses the sound level of the space surrounding the patient
People close to the patient, indeed, often decrease their verbalization and moment of confabulation, by drawing their attention to the patient with the doll, in a shared silence.

- **Participation**

The term *participation* indicates that the patient with the doll activates verbal evoking finalized and devoted to the moment he/she is living with the child/doll. Memories express the capacity of the patient of remembering events connected to the relation that was activated between him/her and the doll.

- **Tension relaxation**

The terms suggests a decrease in the body and verbal tension, with an initial relaxation, verifiable in an objective way (postural change)

- **Body movements**

This term reminds all the series of movements that the patient activates.
Such movements are related to the relational empathic relationship with the doll.
It is important to verify that these movements are connected to the care of the doll.

- **Voice**

The use of the voice is related to the vocalism that the patient expresses while caring the doll, by singing to it (nursery rhymes, songs, refrains). Furthermore, the dialogic aspect between the patient and the doll is very important

- **Memory activation**

It is related to the memories and moments that the patient expresses verbally (also dialoging with the doll) during the doll administration

- **Crisis – crying**

Crying moments - with or without tears - can be observed during the administration of the doll.

- **Stereotyped**

The term highlights that the patient with the doll activates memories and verbal recollections not addressed to the moment that he/she is living, but that will be recalled in other moments of the day.

- **Communications among patients**

It indicates dialogic moments that are activated between the patients that got the doll with other patients with or without a doll, finalized to express relational and social aspects, by decreasing the isolation of patients (doll as social mediator)

Behavior Disturbances and Doll Therapy

Patients treated by the doll therapy exhibit the following behavior disturbances

- Delirium
- Hallucinations
- **Agitation 7**
- **Depression 2**
- **Anxiety 3**
- **Apathy 2**
- Euphoria
- Disinhibition
- **Irritability 1**
- **Wandering (bastle) 4**
- **Sleep disturbances 2**
- Food disturbances

By means of several tests it was possible to verify that for some disturbances the doll therapy is certainly effective for some behavior disturbances.

The doll therapy was administered with efficacy to patients that exhibited the following behavior disturbances:

- **agitation**
- **apathy**
- **anxiety**
- **wandering (bastle)**
- **depression**
- **sleep disturbances**

The doll therapy is certainly contraindicated for patients that suffer from food disturbances.
In such a case, on one side a condition that guarantees the efficacy of the therapy is certainly the important cognitive decay that implies the recognition of the doll as a child to care, on the other side at the meal time the patient feeds the Doll/child with his/her portion of food, with the practical results of his/her own non-alimentation, thus risking of increasing instead of reducing his/her disturbances.

For the other disturbances (f.i. delirium, hallucinations), in some cases the administration of the doll therapy can be used in the initial phase of the hallucinatory or raving status, but only if the vision of a child appears in the hallucinatory or raving status (initial confirmation reinforced by the doll of the hallucinatory vision or of the raving idea)

Before inserting the patient in the therapeutic course, it is essential to verify that in the patient life no tragic events occurred (premature death of a small child), otherwise the presence of the doll could evoke distressing memories.

The doll therapy was administrated in the space of about 6 months, with a gradual insertion of patients, up to a total of 20 patients.

RESULTS

The study evaluated:
Number of patients: 20
Observation period: 6 months
Number of observation: 4/month
Total number of observations = 20 x 4 x 6 months = 480

The BPSD exhibited by the patients are reported in tab. n. 1
From the synthetic graphs (Tab. n. 2, 3 e 4) it can be inferred that the most important result is that the doll therapy – i.e. the administration of a non pharmacological therapy – certainly modified the behavior of these patients. The action on the mood tone resulted to be the most incisive: 75 reports (Tab. n. 2). There are only 145 out of 480 the reports which describe no variations in the behavior. In other words 30 % (tab.n.3). This means that 70 % of patients had a relapse.
The most meaningful behaviors were the modification of:
mood tone = n. 75 reports, i.e. 16% ,
vocalisation = n. 58 → 12%,
suitale body movements = n. 52 → 11% ,
relaxation of tensions = n. 50 → 10%,
greater participation = n. 40 reports → 8 %.
Up to a total of 70 % . (Tab.n.4)
Taking into account that the most meaningful data was the impact on the mood tone, the mood tone has been better analysed (tab. n. 5).
From the graph it emerges in a very clear way that the patient appears as prevalently relaxed (55%), cheerful (21%), and in a minor measure agitated (12 %), angry (7%) and sad (4 %). Therefore, the mood tone was conditioned more in a positive than in a negative way.

Consequently the disturbances that mainly were reduced by this therapy resulted to be: agitation, depression, anxiety e apathy. Sleep and wandering were not modified.
Furthermore possible variations in the pharmacological therapy obtained during the study lifetime were evaluated. More precisely a reduction in the global pharmacological load was verified (NRL- antipsicotyc and BDZ – benzodiazepines) in most cases i.e. n. 13 patients, no incidence in 4 cases, and only in 3 patients it was verified a further increase of therapy for the exhibited behavior disturbances (agitation and aggressiveness).

CONCLUSIONS

Despite, at present, the validity of non pharmacological therapies for patients suffering from Dementia and with behavior disturbances, was not verified yet, this observational study allows to conclude that non pharmacological therapy which are new and innovative such as the Doll Therapy can affect some disturbances so frequent and disabling like the BPSD, that often lead to institutionalization and administration of drugs as NRL (antipsicotyc) and BPZ (benzodiazepines) that are burdened by important adverse effects on the old patient suffering with dementia.
As it could be noted, in the study just a small group did not get benefits directly from the doll therapy, both because it did not exhibit positive or negative variations, and because it did not get benefits from a considerable reduction of the pharmacological load (7 patients out of 20), despite the clinical history of these patients during this phase of the disease is more frequently characterized by a constant dosage increment or by the introduction of other active principles to reduce the BPSD, and this occurred just in 3 patients.
To a greater extent, on the contrary, it was possible to verify a relevant influence of the method on the patients, that appeared more relaxed and calm, so that to reduce with benefits the pharmacological therapy. *This allowed us to stick to international guidelines that suggest to adopt all the non pharmacological strategies known and suitable to reduce the BPSD, before intervening with typical and atypical neuroleptic drugs*
In any case, the authors verified a **clear improvement in the quality of life** of these elderly suffering from dementia, with a greater participation to relational life and to educational/rehabilitative activities of the ward, organized by the specific healthcare operators (professional educators, physiotherapists, occupational therapists and music-therapists).
Certainly this study, due to the number of patients and the observation period, needs a further widening and verification. To obtain meaningful developments, it is wishable and necessary to continue the study, by involving a higher number of patients for a longer period, and comparing studies from different European healthcare and assistive situations.
This way, it is possible to arrive at certain results and with a scientific approach, without forgetting that, at present, there are no pharmacological strategies really useful and affecting the clinical course of the disease.

This is to demonstrate that “unusual” non pharmacological therapies, such as the doll therapy that is based on the relational approach, meant as empathic relationship, and aim at the environment improvement in a “prosthesis” sense, can be really useful in the most flourishing and disturbing phase of dementia.
Last, but not least, the authors verified that the introduction of this therapy in their medical division dramatically reduced the burn out of the healthcare and assistive operators (professional nurses and ASA = healthcare assistive operators). Furthermore, the requests for changing division due to saturation/workload that usually occurred in this division, disappeared with a dramatic reduction of the personnel turnover. Furthermore, the patient relatives modified their approach to the division, to the patients themselves, and need less psychological support, probably for a reduction in their sense of guilt that the institutionalization had determined
Certainly it would be interesting to study and verify also these interesting side effects on the personnel and patients relatives.