

Research Paper

Conceptual Development of Cognitive Behavioral Restructuring Intervention Programme of Well-Being for Alzheimer's Patients and Their Caregivers

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ABSTRACT

Background: Ageing related problems are not only one of the most burdensome worry for sufferers and their caregivers but also one of the biggest challenges for many countries of the world and their health care systems. The complexity and multi-factorial nature of Alzheimer's disease (AD) related to pathology, phases, progression, life expectancy, risk factor, diagnosis has been discussed in details with reference to AD patients and caregivers.

Aim: The present study focuses on development of a cognitive-behavioral program that combines theory based, multi-domain training and restructuring intervention strategies of Alzheimer's patients well-being for whose efficacy is to be determined in randomized controlled case studies with state-of-the-art trial methodology on Alzheimer patients and their caregiver in India. The research tries to develop a generalized as well as individualized cognitive behavioral therapy model for Alzheimer patients and their caregivers in Indian context by restraining the shortcomings of worldwide previous researches in several respects.

Design: The Pre-test post-test non-equivalent control group research design will be used. A diagnosis of Alzheimer's disease will be made in consensus including the neurologist, neuro-psychiatrist and neuro-psychologists based on the review of the clinical, neurological and investigation results. **Discussion:** The cognitive-behavioral restructuring program of well-being for AD patients will consists of *fourteen modules* in following **six sessions:** diagnosis and goal setting; psycho-education, engagement in pleasant activities; cognitive restructuring; training of the caregiver in behavior management techniques and intervention for the caregivers. It will be individualized according to individual problems of the subject and the caregiver.

Keywords: *Alzheimer's disease, Cognitive Training and Restructuring, Intervention Program, Cognitive Behavioral Therapy, Well-Being, Caregiver.*

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Ageing is an inevitable dynamic biological process since birth to death with regular changes and impairments in appearances, physical activities and cognitive functions which may cause considerable distress to the individual. The impairments of cognitive functions are commonly accompanied and occasionally preceded by deterioration in emotional control, social behavior or motivation. Dementia is such type of a syndrome characterized by disturbance of multiple brain functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgment. Alzheimer's disease (AD) is most prevalent form of dementias, accounting for approximately 60 % of all dementias.^[1] AD is a progressive neuro-degenerative disease that causes the brain to shrink (Atrophy) and brain cells to die, which results in continuous decline in thinking, behavioral and a social skill that affects the person's ability to function independently and slowly becomes more severe and eventually incapacitating. This complexity and multi-factorial nature of AD has led some leading AD researchers to hypothesize that AD is not a disease in the technical sense, but more like a syndrome, a collection of pathologies which manifest themselves as common symptoms classically described as age-related memory loss and personality changes.^[2] Overall, they land up with decline in memory (amnesia), absence of sensory functions, awareness (agnosia), disorientation in time, place and person leading to loss of personality, blunting of emotions (apathy), impaired judgments, reasoning, concentration, inability to carry out motor activity (apraxia), problem in speech (dysphasia or aphasia), unable to name objects, things (dysnomia), problems in walking (asterixis), problems in writing (dysgraphia), absence of muscle tone (atonia) and absence of muscle power (akinesia) or increased muscle tone (hypertonia). Problem behaviors include agitation, aggression, sleep disturbance, wandering, apathy, anxiety, depression, delusions and hallucinations.

Pathology -AD pathology presents a complex interplay between several biochemical alterations, including changes in amyloid precursor protein metabolism, phosphorylation of the tau protein, oxidative stress, impaired energetics, mitochondrial dysfunction, inflammation, membrane lipid dysregulation and neurotransmitter pathway disruption.^[3] People with familial forms of AD have an autosomal dominant mutation in either one of the presenilin genes located on chromosomes 1 and 14 or in the amyloid precursor protein (APP) gene located on chromosome 21. In addition, individuals with down's syndrome (trisomy 21) have an increased risk of developing early-onset AD. The genetics of sporadic AD are more complex and less well understood. It is known that the epsilon four allele of the apolipoprotein E (APOE) gene located on chromosome 19 is a risk factor for the development of sporadic AD.^[4] The pathological hallmark of Alzheimer's disease is the presence of Amyloid plaques and Neurofibrillary tangles (NFT). There is diffuse atrophy of the cerebral cortex and secondary dilatation of the ventricles. The deposits are found more at the hippocampus, temporal cortex and nucleus basalis of Meynert. There is loss of neurons due to the pathological changes leading on to reduced levels of neurotransmitters especially acetylcholine causing cognitive deficits in these patients. The basic pathological cause of Alzheimer's disease is not fully understood and a lot of research is being done to elucidate the basic pathological process. With the current understanding many hypothesis are put forth for the pathogenesis of AD. The widely accepted among them are, Amyloid Cascade Hypothesis, Tau Hypothesis and Mitochondrial Cascade Hypothesis.

Amyloid Cascade Hypothesis is the most widely accepted hypothesis. The deposition of A β 42 - amyloid plaques in the brain is considered the basic pathology. A β 42 is derived from Amyloid Precursor Protein (APP) by the sequential action of β -secretase and γ -secretase.

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A β 42 is insoluble and aggregates to form plaques which causes oxidative damage and initiates inflammatory processes leading on to neuronal death. There is hyper phosphorylation of tau proteins and their deposition as neurofibrillary tangles secondary to amyloid deposition. Alzheimer's disease occurs in two forms - familial and sporadic forms. Familial forms have an early onset and are associated with mutations in APP gene (chromosome 21), Presenillin-1 (chromosome 14) and Presenillin-2 genes (chromosome 1). The late onset of familial form and sporadic forms of AD are associated with the presence of APOE4 allele. APOE is involved in cholesterol transport and has three alleles - 2, 3 and 4. APOE4 allele is present in 40 - 80 % of the Alzheimer's patients, though the normal distribution in Caucasian population is only 24 - 30 %. APOE4 is shown to increase the production and decrease the clearance of amyloid. *Tau Hypothesis* -The amyloid cascade hypothesis does not satisfactorily explain sporadic cases of AD and the level of amyloid deposits does not correlate with the degree of cognitive decline. This lead to the Tau hypothesis which asserts that the deposition of tau and formation of neurofibrillary tangles is the basic pathology and the amyloid deposition occur secondary to it. Tau is a microtubule associated protein which binds to and stabilizes the microtubules involved in intracellular transport. The hyper phosphorylation of tau reduces the binding of tau to microtubules, and the sequestration of hyper phosphorylated tau into neurofibrillary tangles (NFTs) reduces the amount of tau that is available to bind microtubules. As a result, the microtubules disintegrate leading to reduced axonal transport and cell death. *Mitochondrial Cascade Hypothesis* - The reduced mitochondrial function to handle the free-radicals is considered the initiating step in AD.

Phases -There are three phases of AD, the *first phase* is the forgetfulness phase in which there is usually a difficulty in recalling recent events and a tendency to forget where the objects have been placed. The second phase is the confusional phase resulting in increasingly poor attention span and a decline in generalized intellectual performance with deteriorating memory i.e., disorientation in place, word finding and change in speech is observed. The third phase is the dementia phase characterized by lack of purpose in person's behavior which appears disjointed and sometimes bizarre. Remaining intellectual and self-care abilities require constant supervision as people in this phase undergo further deterioration in memory capacity, calculating ability (dyscalculia) and aspects of language are severely affected and eventually lost. Hence, constant assistance is required by caregivers for carrying out the self-care skills such as grooming, dressing, toileting and feeding. Sometimes one or two years of life will follow in an almost vegetative state until death.

Progression and Life Expectancy of AD Patient: The rate of progression from mild to late is highly variable from individual to individual and ranges from 3 to 20 years. ^[5] Studies indicate that people of age 65 and older survive an average of 4 to 8 years after a diagnosis of Alzheimer's disease, yet some survive as long as 20 years. This indicates the slow, insidious nature of progression of disease. ^[6] The mean life expectancy following diagnosis is approximately seven years. ^[7] Regarding mortality in AD, risk was 2.3 times more for older people with Dementia and linearly correlated with the severity of cognitive impairment. ^[8] Another study showed higher mortality risk by 2.65 times in patients with post-stroke dementia than in stroke survivors without cognitive dysfunction. ^[9] AD is ultimately fatal. Between 2000 and 2019, the death rate from Alzheimer's increased 33% for people age 65 to 74, but increased 51% for people age 75 to 84 and 78% for people age 85 and older. ^[10]

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Diagnosis of AD: According to Alzheimer's association only 1-in-4 people with Alzheimer's disease have been diagnosed. The diagnosis "probable" or "possible" AD is made by clinical criteria established by National Institute of Neurologic and Communicative Disorder and Stroke - Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA). The AD patients should have dysfunction of at least two or more areas of cognition (orientation to place and time, memory, language, praxis, attention, visual perception, and problem-solving skills) with progressive worsening of memory and other cognitive functions, no disturbance of consciousness and onset between ages 40 and 90, most often after the age of 65. ^{[11][12][13]}

Risk factors in AD: Older Age is the primary and strongest risk factor for the AD. ^[14] Reduced synthesis of the neurotransmitter acetylcholine, lifestyle, and environmental factors are risk factors of Alzheimer's, an insidious disease. Risk of AD increases with age, approximately 33% of women and 23% of men will have developed Alzheimer's disease by age 90, the lifetime risk for Alzheimer's in women are at age 55 is approximately 17 percent and in men about 9%; thus 1 in 6 women compared with 1 in 10 men who live past 55 years of age will develop in their remaining life years. ^[15] Significant advances in research identified that AD is caused by genetic components such as apolipoprotein E (APOE) allele. ^[16] Familial AD accounts for about 1-5% of all Alzheimer's disease cases. ^[17] Alzheimer's and other dementias are the top cause for disabilities, illness, impaired quality of life and reduced life expectancy.

Caregivers -Alzheimer's caregivers are those who care for someone who has AD. A Caregiver is broadly defined as one who provides informal care to a family member - including basic Activities of Daily Living (ADL) such as bathing and dressing or Instrumental Activities of Daily Living (IADLs) such as cooking and housework. In the context of AD, the individuals of the neurodegenerative disease both the patient and the caregiver are vulnerable to poor well-being. Though, the AD patients externally look physically normal with no impairments but, in the brain internally they are afflicted with progressive patterns of cognitive and functional impairments. The morbid person will not be able to understand in any circumstance and won't be a cooperative recipient of care with the caregiver rather only provoke/produce/ create the thought /stimulate the mind of caregivers to think that the afflicted is intentional, purposive, pretending, stubborn and adamant. This scenario in care giving creates enormous strain and burden to the family members who are the caregivers, which include physical, psychological, social, or economic aspects. Thus, the care giving by a family member for AD patient demands a range of skills, patience, good health and mental ability to cope with continued stresses. Theoretically, evaluation of the impact of care is still dormant and is in its infancy in home care.

Subjective Well-Being (SWB) includes three components: 1) life satisfaction-a cognitive evaluation of one's overall life, 2) the presence of positive emotional experiences, and 3) the absence of negative emotional experiences. Thus, a person is described as enjoying a high level of SWB if one is satisfied with one's life, frequently experiences positive emotions (such as joy, affection), and seldom feels negative emotions (such as anxiety, sadness). One hallmark of SWB is that it is judged from the individual's own perspective. Thus, in SWB, a person's *subjective* perception about his own well-being is of paramount importance, which is shaped in complex ways by cultural factors. Though it is always difficult to interpret any psychological construct into mathematical way, but a serious thought has been given which

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will answer and simplify the notion of wellbeing as used in different cultures depicted by an equation as follows:

$$V(x)\{N+M\} = U1(x)M + U2(x)N + U3(x)N + U4(x)M + U5(x)N + U6(x)M + U7(x)M + U8(x)N + U9(x)M + \dots Un(x) N+M \text{ ----- Where}$$

V = Periodic Well-Being of individual

U = Index of individual's well-being in different periodic state of affairs x

N = Dimensional space of growth & welfare of the individual

M = Dimensional space of obstacle & non-welfare of the individual

Thus, well-being over time and across is measured by above expression. ^[18] This expression involves the subjective and mediating concerns of an individual in a particular culture. U(x) may assume positive or negative value depending on the individual's state of affairs. If U1(x)...Un(x) is added then total V(x) will be obtained. This V(x) will give integrated well being of the individual at particular period of time, which will be holistic view of well being of an individual. In light of this evidence and global trends in the incidence of AD, there is a growing need to intensify and refine the study of SWB in this population. Following researches have studied the SWB in the subjects of AD are as follows, memory rehabilitation training had positive effects on the well-being of patients with AD, ^[19] musical interventions may improve the well-being of patients with AD, ^[20] walking on treadmill training is effective treatment improving quality of life, controlling systematic inflammation and enhancing psychological well-being in people with AD ^[21] preserved cognitive skills improve psychological well-being in AD ^[22] and the nostalgia intervention boosted self-reported psychological well-being, positive affect and meaning in life ^[23], psychosocial intervention had no effect on well-being and diseases progression or AD symptoms. ^[24]

Cognition is a combination of processes, including paying attention, learning and reacting to objects in the environment, and using language and memory. If cognition becomes impaired, an individual may have difficulty performing everyday tasks. If those tasks become very hard or impossible to perform, AD or another type of dementia is diagnosed, in which case cognitive training may be in order. The key question here is whether training basic cognitive abilities will transfer to everyday abilities, such as managing one's finances or medicines and improving the basic survival skills like toileting, bathing, dressing and eating etc. *Cognitive training* is based on the idea that the brain, even in old age, can change for the better. What we know about the brain suggests that it resembles muscles in the same way that physical training improves physical abilities, cognitive training (or brain training) improves cognitive abilities.

Cognitive training uses guided practice on a set of tasks related to memory, attention, or other brain functions. This training can take many shapes. For instance, it can be conducted on the computer or delivered in person, either individually or in small groups. But it typically involves using repetitive exercises designed to improve single (e.g., memory) or multiple (e.g., memory and reasoning) cognitive abilities. Cognitive training programs contain multiple cognitive strategies (e.g., the use of imagery to aid memory and repetition), and grow more challenging as performance improves. It progresses through cognitive training to cognitive stimulation and cognitive rehabilitation, all of which aim to increase general cognitive and social function. *Cognitive restructuring* is a generic term that describes a variety of psychological interventions directed at replacing maladaptive, self-defeating thoughts with healthier adaptive one. These interventions are aimed at breaking the vicious cycle of negative thinking which distorts perception of everyday events and

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prevents adaptive coping behaviors. [25] Typical forms of treatment involve teaching individuals to reinterpret their thoughts in a less negative way and to raise their awareness of distorted and maladaptive thinking.

Assessment Instruments: Psychometric assessment and cognitive state of the subjects will be determined namely in four areas, activities of daily living, behavior, cognition, and severity or stage of AD. *Instrumental Activities of Daily Living (IADL)* [26] is an appropriate instrument to assess independent living skills. *Geriatric Depression Scale (GDS)* [27] is an instrument to measure depression used extensively with the older population. *State Trait Anxiety Inventory (STAI)* [28] is used to measure both state and trait anxiety. *Mini Mental State Examination (MMSE)* [29] either used alone or combined with more comprehensive instruments. This test allows assessing cognitive function and screening of dementia conditions. *Addenbrooke Cognitive Assessment (ACE)* [30] consists of the global cognitive scale mini mental status examination (MMSE), tests for episodic memory, verbal fluency, confrontation naming, constructional praxis, the clock-drawing test, tests for language and remote memory. *Dementia Assessment by Rapid Test (DART)* [31] is based on the clinical observation in Out Patient Department (O.P.D) and Clinical Neuropsychology for cognitive domains of impairment commonly encountered in MCI and possible dementia cases. *Global Deterioration Scale (GDS)* [32] provides caregivers an overview of the stages of cognitive function for those suffering from a primary degenerative dementia such as Alzheimer's disease.

Cognitive-Behavioral Restructuring Intervention Program: The cognitive-behavioral restructuring program comprising of multi-domain training and restructuring intervention strategies of well-being consists of *fourteen modules* in following *six sessions*: diagnosis and goal setting; psycho-education, engagement in pleasant activities; cognitive restructuring; training of the caregiver in behavior management techniques and intervention for the caregivers. It will be individualized according to individual problems of the subject and the caregiver. Each subject or caregiver will receive at least three out of the six interventions; 1) psycho-education on dementia and its treatment (oral and written); 2) appropriate medical advice; 3) social counseling; 4) memory training; 5) a self-help strategies for the subject; and 6) a self-help strategies for caregivers. In this control condition, the likelihood of a significant effect will be expected to be smaller than that in the intervention experimental condition. The subjects in both conditions will be assessed before and after the intervention. Subsequently, Follow-up assessments will take place.

Participants: Alzheimer patients and their caregivers of Madhya Pradesh and Rajasthan will be included from three main sources; 1) the psychiatric/ neurology department of government hospital and private clinics, 2) general practitioners in the area of Geriatrics and 3) old age homes or families with patient of Alzheimer disease. The target sample size will be 60 subjects both male and female, 30 subjects for each control and experimental group.

Inclusion and Exclusion Criteria: All participants will undergo baseline screening in the Prevalence Survey (PS). The Addenbrooke's Cognitive Examination (ACE) along with Instrumental activities of Daily living for Elderly (IADL-E) will be administered to the participants and caregivers. Patients must meet the criteria of the National Institute of Neurological and communicative Disorders and Stroke-Alzheimer's disease and Related Disorders Association (NINCDS-ADRDA) for probable or possible Alzheimer's disease. Mixed Alzheimer's disease and vascular dementia cases will also be included. The cases of

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Alzheimer disease with mild to moderate severity of dementia will be included as determined by the Mini mental state examination (MMSE). A diagnosis will be made in consensus including the neurologist, neuro-psychiatrist and neuro-psychologists based on the review of the clinical, neurological and investigation results. A caregiver, partner or a good friend must be available to take part in most of the sessions. Exclusion criteria will be concomitant alcohol or drug addiction and a history of a malignant disease, severe organ failure, metabolic or hematological disorders, neurosurgery or a neurological condition, such as Parkinson’s disease, epilepsy, post-encephalitic or post-concussion syndrome.

Informed Consent: The objectives and detailed information about the study program will be explained to the subjects. The information will also be given in printed form to the subjects. Written informed consent will be obtained from all participants and caregivers prior to inclusion. Subjects who cannot give their informed consent will not be included in the research study. Participation in the study will be voluntary. There will not be negative consequences for non-participants or dropping out. The research scholar and supervisor will preserve the confidentiality of the participants in the study.

Restructuring Intervention Domains: There will be mainly three approaches adopted to improve cognitive abilities, (1) *cognitive training* uses repetitive exercises keyed to specific cognitive abilities. May be computer-assisted or delivered in person individually or in small groups, (2) *Cognitive stimulation* engagement with enjoyable activities involving some mental processing in a social context, (3) *Cognitive rehabilitation* tailored to the individual and involves working on personal goals, often using external cognitive aids in real-world settings. The majority of the restructuring intervention stems from the CBT literature, including behavioral analysis, psycho-education, advice on establishing pleasant activities, guidance on self-reward to motivate oneself, mutual dialogue for guided discovery, training in behavior management, problem solving, stress management, resilience building and social support will be adopted for the following described module in Table 1.

Session content: The cognitive-behavioral based multi-component restructuring program will consist of six sessions, flexible in duration as per the requirement. Table 1 delineates the content of all sessions. Most of them will be joint sessions, but some will be separate sessions either for the patient or the caregiver.

Table 1: Description of Sessions and Module Program

Session	Module	Module No.	Module Description	Restructuring Intervention Program	Setting
First	Diagnosis and goal setting	1	Diagnosis investigation	Comprehensive assessment of affective and behavioral symptoms with the help of diagnostic instruments and interview. Burden of caregiver and resources availability will also be assessed	Joint
		2	Behavioral analysis and goal setting	Analysis of situation, behaviors, emotion, cognition, and willingness to participate in the study; setting of individual goals, planning intervention for joint and separate session.	Joint
Second	Psycho-	3	Awareness	Providing information about	Joint

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	education			disease, course, cause, medication, intervention and psychosocial support.	
Third	Engagement in pleasant activities	4	Setting the stage for pleasant activities	Explaining inactivity, mood, neural degeneration and cognitive decline. Developing a personal list of pleasant activities in a structured schedule.	Possibly without caregiver
		5	Planning of pleasant activities	Selection of social, physical and leisure pleasant activities. Planning these pleasant activities in a structured schedule.	Joint
		6	Establishing regular activities	Discussing problems related activities and developing motivation to form new habits like reinforcing by rewards and positive self talk.	Joint
Fourth	Cognitive restructuring	7	Setting the stage for cognitive restructuring	Assessing typical negative and positive thoughts for restructuring and finding alternative thoughts.	Joint
		8	Challenging negative thoughts	Challenging dysfunctional thoughts and introduce thought control techniques.	Possibly without caregiver
		9	Practicing helpful thoughts	Discussing problems and progress. Practicing helpful thoughts.	Joint
Fifth	Training caregiver in behavioral management techniques	10	Setting the stage for behavior management	Identifying problem behaviors, their precursors and consequences; planning and describing the restructuring intervention program; evaluating methods and intervention to change	Only caregiver
		11	Changing problem behavior	Discussion on methods, progress, change precursors and consequences of change on behavior	Possibly without patient
Sixth	Intervention for the caregivers	12	Stress management and emotional regulation	Identification and monitoring of stressors, thoughts, emotional and behavioral reactions. Training in effective problem solving and relaxation techniques.	Only caregiver
		13	Pleasant activities	Selection, planning and discussion on pleasant activities. Developing a personal list of pleasant activities and keeping record of the same in activity notebook.	Only caregiver
		14	Social support	Analyzing social support network and grooming formal or informal communication with social support.	Only caregiver

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Follow Up: After successful administration of the entire module program on patients and caregivers, they shall be approached or called for review of condition after first 3 months and 6 months respectively.

CONCLUSION

Several descriptive and inferential statistical strategies are planned to test the efficacy of the restructuring intervention program. Initially all descriptive statistics like mean, standard deviation and error will be calculated, individual growth curves depicting progressive rate and shape of changes will be drawn for comparison and investigation of differences. Further, ANOVA will be conducted to compare the mean outcomes and covariates within and between group performances. The multivariate analyses will be used to test the effect of the restructuring intervention program. Based on statistical analysis the result of the research will be prepared in graphical and table form. The efficacy and future prospects of restructuring intervention program will be discussed. All limitations keeping the risk, protective, ethical and adverse factors in mind will be reported.

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Conflict of Interest

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