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Online Programme "Symparastasi": A Comparison of Psychoeducation and Multicomponent Exercise for the Caregivers of Patients with Mild Dementia. An Original RCT

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Abstract

Objectives: *As there are many patients with dementia and their caregivers who do not have access to the third age centers, there is a need for creating an online platform which aims to educate the informal caregivers on matters regarding dementia. The aim is to educate the caregivers in order to be able to provide to their patients with the best care, safely and effectively.*

Methods*: This is an original randomized controlled trial with 60 participants. 30 participants were randomly assigned to group a, which received only the multicomponent exercise programme or group b, which received only the psychoeducation. Caregivers had access to the platform with their special username and password and received the instructions from the neuroscientist or the fitness specialist. The programme lasted for 24 weeks and every new lesson was released after 2 weeks. The 12th session was a private meeting with the neuroscientist and the fitness specialist in order for every participant to ask any question. Measurements used were: For physical performance, the Timed Up and Go test (TUG), for assess balance ability, the Berg Balance Scale (BBS), and Muscle strength, measured by a 30second Sit to Stand Test. Mini Mental State Examination (MMSE) and Addenbrooke's Cognitive Examination- Revised (ACE-R). For the neuropsychiatric problems Neuropsychiatric Inventory (NPI) was used. For the daily functioning the Clinical Dementia Rating–Sum of Boxes (CDR_SB) was used. For the caregivers the study used the following scales: State Trait Anxiety Inventory (STAI-S) in order to record the anxiety levels, Beck Depression Inventory (BDI) for the depression and NPI and Zarit Burden Interview (ZBI) in order to record caregivers' burden. All tests were applied in the beginning of the programme, before any intervention occurred (T1), after 6 months of receiving the intervention (T2), and 3 months after the end of the programme as a follow-up (T3).*

Results: *Important improvements were shown in decreasing behavioral and psychological symptoms (BPSD) and improving the quality of life.*

Conclusions: *Both interventions can effectively reduce BPSD and improve quality of life for both patients and caregivers, however none of these interventions could effectively improve the cognitive abilities of the patients. The general conclusion from the caregivers was very promising as they claimed that the programme was very helpful.*

Keywords: Dementia, Mild Dementia, Non-pharmacological Interventions, Psychoeducation, Online Education, Multicomponent Exercise, Physical Exercise, BPSD, Quality of Life, Caregivers.

Abbreviations

- **ACE-R:** Addenbrooke's Cognitive Examination (Revised)
- **AD:** Alzheimer's Disease
- **BDI:** Beck Depression Inventory
- **BPSD:** Behavioral and Psychological Symptoms in Dementia
- **CDR_SB:** Clinical Dementia Rating Scale
- **CVD:** Cardiovascular Dementia
- **DLB:** Lewy Body Dementia
- **FTD:** Frontotemporal Dementia
- **MCI:** Mild Cognitive Impairment
- **MMSE:** Mini Mental State Examination
- **NPI:** Neuropsychiatric Inventory
- **PDD:** Parkinson's Dementia
- **PwD:** Patients with Dementia
- **RCT:** Randomized Controlled Trial
- **STAI-S:** State Trait Anxiety Inventory
- **ZBI:** Zarit Burden Interview

Introduction

Dementia is a progressive neurodegenerative disorder that affect cognitive functions [1]. In 2019 there were approximately 57 million patients with dementia (PwD) globally and in 2050 the number is estimated to triple, with 153 million PwD, due to population growth and ageing [1]. A transitional stage in early dementia is often characterized as Mild cognitive impairment (MCI), which is commonly considered to be a key stage for preventing dementia [2]. MCI patients have a few cognitive declines; however, they are totally able to live independently and function well in their daily activities [3]. Disease progression has as a start MCI and spans in different stages to mild, middle and severe stages of dementia. Mild dementia differs from MCI in terms that patients with mild dementia have extended cognitive deficits than MCI patients and they are not able to live independently and they need support for accomplishing their daily activities [4]. At the same time, Behavioural and Psychological Symptoms in Dementia (BPSD) is another crucial problem, because they affect almost the 90-95% of the PwD. BPSD are an early symptom of cognitive decline and their severity increases over the progress of the disease. They are associated with several negative outcomes, such as reduced independency, early hospitalization, faster cognitive decline, and increased anxiety and depression levels in dementia caregivers. The etiopathogenesis of BPSD remains complex and it is probably a result of multiple factors, such as biological, psychological and social factors. According to Cummings (1994) the BPSD can be categorized in the following 12 behaviors: delusions, hallucinations, agitation/aggressive behavior, depression, anxiety, euphoria, apathy, disinhibition, irritability, wandering, sleeping disorders and eating problems. Currently there are some pharmacological solutions for the management of the BPSD, such as? antidepressants, antipsychotics, mood stabilizers etc., but they have some remarkable side effects, such as dizziness, headaches, xerostomia, fatigue, heart arrhythmia, gastrointestinal problèmes, constipation and confusion [5].

As the current pharmacological solutions for the cognitive decline, such as acetylcholinesterase inhibitors and memantine and psychiatric drugs for the treatment of BPSD have side effects, there is a significant attention in non-pharmacological interventions [6]. Non-pharmacological interventions have no side-effects, most of them are no money consuming and they seem to have a positive impact on the dementia caregivers, as well. Dementia caregivers, also called "second patient", because they experience high levels of anxiety and depression, in comparison with other adults who are not caregivers [7]. Because dementia is a progressive disease the caregiving necessitates a higher level of attention and personal time and money primarily 3often provided by family members. The caregiving often results in high costs, psychological stress, social isolation, financial difficulties and general bad health [8]. Thus, there is a need for non-pharmacological interventions that can effectively maintain cognitive abilities, reduce BPSD and increase the quality of life of the PwD and the caregiver, too. Psychoeducational programmed have been shown positive results in PwD and them caregivers and they aim to be a non-pharmacological intervention that can effectively support the patients and their caregivers, as well [9]. The programmed differ from one another, but their similar goal is to offer knowledge about dementia to the caregivers, support them psychologically and advise them on how to manage the daily problems.

Furthermore, another effective non-pharmacological intervention is physical exercise (PE). PE has shown positive results in terms of preventing dementia and managing some BPSD, such as depression, anxiety, apathy, wandering, aggressive behavior and sleeping disorders [10]. Individuals who consistently exercise have significantly benefits in mood improvement, reduction of depression symptoms, brain plasticity and neurotransmitters' production [11]. More specifically, PE seems to reduce the risk factor of cognitive decline by 18% [12]. An amount of 150min per week of moderate intensity exercise, or 75min per week of intense exercise seems to be effective in delaying the cognitive declines due to aging [13]. A range of research have investigated the benefits of various forms of exercise including aerobic exercise, resistance training, coordination training in people with MCI and the results were very promising [14]. New evidence has shown that multicomponent exercise training, a training model that combines physical (resistance and cardiovascular training) and motor (balance, co-ordination, reaction time and dual exercises) components, can improve cognitive performance and seems to be a promising non- pharmacological intervention for early stages of dementia [12]. At the same time, physical activity has also proven beneficial in enhancing the quality of life and general psychology of the dementia caregivers, too [15].

The aim of this study is: 1) to compare the two non-pharmacological interventions, Psychoeducational programme and Multicomponent exercise to patients with MCI and mild dementia and explore which intervention is most effective in a) maintain cognitive abilities, b) decrease BPSD and c) improve quality of life in PwD and their caregivers.

Methods

Design and Participants

The study is a randomized, controlled trial. A total of 60 participants (N=60) with MCI and mild dementia and their primary caregivers were chosen from all over Greece. The participants were randomly divided into two equal groups of 30, the experimental group (N=30) and the control group (N=30). Participants were randomly assigned to either the experimental or control

group using an independent randomization service (randomization with a 1:1 ratio). Both groups executed physical and cognitive tests in the beginning (T1), after 6 months (T2) and after 9 months (T3), to detect a possible detraining.

The experimental group, after the initial measures (T1), executed a 6month intervention. The
inclusion criteria include patients with MCI or mild dementia, their caregivers who have access on the internet, and none or mild kinesthetic problems in order to be able to perform
the multicomponent exercise programmed.

Subjects

60 patients with MCI and mild dementia and their caregivers were included.

Interventions

Participants in the experimental group (N=30) received either multicomponent exercise training for 24 weeks or psychoeducational programme for the same period of time. The multicomponent training was done twice per week through video surveillance, that was made from the fitness specialist. More specifically, the fitness specialist was uploading in the online platform that was created especially for the programme "Symparastasi" the training video of the week. There were 11 videos in total, that were released to the participants every 2 weeks. Each video had the same structure: in the beginning the fitness specialist was showing exercises for warm-up, then the trainer was performing the main exercises and explaining the key points of every exercise and in the end, there were stretching exercises in order to avoid any injury. On the other hand, the other group received psychoeducational lessons by a neuroscientist. There were also 11 videos in total, that were released every 2 weeks, as well. Each video had the same structure: the video was divided into two categories, the theoretical background and the practical part. In the theoretical background the neuroscientist was informing the participants about dementia. The lessons captured a wide range of what is dementia, and the possible problems of the disease. In the practical part the neuroscientist was giving advices and guidance on what the caregiver should do in some special occasions, such as; should the PwD drive, what to do if the PwD 5does not want to shower, what to do if the PwD has an aggressive behavior, what to do if the PwD does not dress properly etc. The caregivers were watching the videos and then they perform either the multicomponent exercise programme or the non-pharmacological interventions (such as music therapy, aromatherapy, massage, validation therapy, orientation therapy, dance therapy, etc) to their patients. The 12th session was an online one to one session with either the fitness specialist or the neuroscientist in order for the caregivers to have the opportunity to talk in private with the instructor and share their experience. However, every week, there was continuous communication between participants and the instructors in order to solve any problems and explain again the physical exercises and the non-pharmacological interventions, in order to ensure that the participants perform everything correctly.

Multicomponent Exercise

The multicomponent exercise is a training model that combines aerobic training, resistance training, balance and coordination exercises. In this particular exercise plan, the first part of every workout consists of 5 – 25 minutes of stationary bike or walking. In the first week the participants were asked to do 5 minutes of low intensity aerobic exercise (stationary bike or walk) and every two weeks the fitness specialist was increasing the duration of aerobic exercise up to 2 minutes until the total duration of 25 minutes. After that, the participants perform strengthening, balance, postural and coordination exercises. Participants in the control group did not receive any kind of physical exercise, but they were performing other non-pharmacological interventions.

Psychoeducational Programme

The psychoeducational programme included lessons about dementia, its progress, non- reversible dementias, BPSD, current pharmacological solutions, prevention, daily problems in dementia, BPSD, non-pharmacological interventions for the reduction of BPSD, non- pharmacological interventions for the cognitive abilities etc. The non-pharmacological interventions that were recommended in the psychoeducational programmed were: music therapy, aromatherapy, massage, validation therapy, orientation therapy, dance therapy, reminiscence therapy, cognitive therapy, behavioral therapy). Participants in the control group did not receive any kind of the afore-mentioned interventions and/ or the theoretical lessons, but they were only performing the multicomponent exercise programme.

Measurements

All measurements and questionnaires were performed in the beginning (T1), after 6 months (T2) and after 9 months (T3) for both, the experimental and the control group. For physical performance, the Timed Up and Go test (TUG) were used to estimate functional mobility and fall risk. Participants were instructed to stand up from a chair, walk as fast as possible for 3 meters, then turn, walk back to the chair and sit down [16]. For assess balance ability, the Berg Balance Scale (BBS) was performed. The BBS is the best-known balance measurement tool and it consists of qualitative measures in several postural and every day movements. Each item is scored according to a 5-point scale, from 0 (which indicates the lowest level of function) up to 4 (which indicates the highest level of function). Nagging from 0 to 4 (in which 0 indicates the lowest level of function and 4 indicates the highest level of function). The total possible score is 56 points, and 41–56 suggests a low fall risk, 21–40 a medium fall risk and 0–20 a high fall risk [17]. Muscle strength, measured by a 30second Sit to Stand Test. The participants were asked to stand up and sit down for a high armless chair as many times as possible during a 30sec phase [18].

However, all participants were tested in order to record their cognitive abilities, neuropsychiatric problems and daily functioning. For the cognitive abilities the following tests were used: Mini Mental State Examination (MMSE) and Addenbrooke's Cognitive Examination- Revised (ACE-R). For the neuropsychiatric problems Neuropsychiatric Inventory (NPI) by Cummings 1994 was used. For the daily functioning the Clinical Dementia Rating–Sum of Boxes (CDR_SB) was used. For the caregivers the study used the following scales: State Trait Anxiety Inventory (STAI-S) in order to record the anxiety levels, Beck Depression Inventory (BDI) for the depression and NPI and Zarit Burden Interview (ZBI) in order to record caregivers' burden. All tests were applied in the beginning of the programme, before any intervention occurred (T1), after 6 months of receiving the

intervention (T2), and 3 months after the end of the programme as a follow-up (T3).

Results

Group A which received the multicomponent training programme had better results in all physical exercise scales, but no statistically significant differences in cognitive scales. Group A had a statistically significant improvement in CST test in T2 test, but the group could not maintain the good results 3 months after stopping the intervention. The same result referred to TUG test, as well. Multicomponent exercise programme enhanced the ability of functional mobility 6 months after the training programme, but could not maintain the result 7after stopping the invention. Lastly, BBT test measures the balance of the PwD. Group A had statistically significant improvements in this test, and it is important that it maintained the good results in T3 follow up test, as well. On the other hand, group B received psychoeducation programme, which means that the patients received all other forms of non- pharmacological interventions, but no multicomponent training programme. In all fitness tests, group B had aggravated the results. In terms of the other tests, both groups did not mention and statistically significant change in ACE-R and MMSE. Statistically significant improvements were shown in NPI test, but the good results did not maintain, NPI test for the caregiver, STAIS, BDI and ZBI test. No statistically significant changes were mentioned in CDR_SB scale. Tables show the results analytically.

Discussion

The cognitive abilities of the PwD did not change after either the multicomponent training programme nor the psychoeducation. Nevertheless, group B reported a change between T2 test and T3 test in ACE-R cognitive examination. However, an important improvement was shown in NPI inventory. Both groups have decreased the unwanted behavior's and this had an impact on the caregivers, as well. This is important because BPSD is a crucial problem in dementia, and its progress leads to institutionalization, poor prognosis and cognitive decline [19]. Dementia caregivers suffer from anxiety and depression more than other people who are not caregiving [20]. The fact that both groups decreased the caregivers' distress is of great importance, because in dementia we have to think about the caregivers as well, as they suffer a lot. Moreover, according to the results, the whole quality of life of the dementia caregivers was improved. The general psychological condition of the caregivers seemed to increase in both groups. This is also very important because the non-pharmacological interventions seem to not only have a promising impact on the PwD, but also to the caregivers, as well. In terms of the results in the exercising part, the results are interesting, too. Group A which received the multicomponent exercise programme had improvements in all exercising tests, in contrary with group B which did not receive a physical exercise programme and had an essential reduction in the fitness abilities. This result is a logical outcome, as group B did not receive any specific training programme and considering the age of the patients, their fitness abilities decreased after some months. The critical result here, is that the fitness abilities decrease after some period of time, if the patients do not receive any training programme, and this underlies the importance of physical exercise, which should be regular and consistent. Physical exercise is very important for the health, because it can delay 8institutionalization, improve quality of life, enhance the general mood of the patient and prevent from falls [21]. Hence, it is fundamental for the PwD to receive some kind of physical exercise.

Our results are in accordance with previous studies. The BPSD which is a tremendous problem in dementia can be effectively decreased after PE and psychoeducation. PE has been examined previously in numerous studies and it has shown promising results in the reduction of some BPSD, such as; agitation/ aggressive behavior, depression, anxiety, apathy, wandering, irritability and sleeping problems [22-24]. On the other hand, psychoeducation has also proven beneficial to PwD in terms of decreasing some unwanted behaviors. The result is in accordance with previous studies, which have studied the impact of several non-pharmacological interventions in the reduction of the BPSD. Both sensory and cognitive stimulation therapies, as well as behavioral techniques such as psychoeducation have been proven beneficial in reducing some BPSD and thus improve the quality of life [25, 26]. In addition, according to a recent review which included all the original studies, that have combined the psychoeducation programme with a multicomponent training programme, our results show positive outcomes. According to Skov et al. they used an intervention with 2 weekly training sessions, lasted for 15 weeks and 3 hours per session. Each group consisted of 7-10 participants and the programme included 1,5 hours of physical exercise combined with either 1 hour of CST or 1 hour of psychoeducation. The programme took place in Copenhagen and consisted of 44 participants. The measurements for the cognitive functions were MMSE, and Quality of Life in Alzheimer's Disease (QoL-AD) scale [27]. Two psychotherapists applied the physical exercise in a workout room, including warm up, cycling, short breaks and strength exercises. The psychoeducational programme lasted for 1 hour and included themes regarding dementia. The study found positive results and the combination of psychoeducation and physical exercise showed promising results.

Additionally, our results are in accordance with another study as well. Prick et al. [28] with a follow up test, included 57 patients and 54 participants in a comparison group, who received a minimal intervention. The study from the Netherlands included a personal trainer with 8 sessions, lasted 1 hour, for 3 months, and the training programme included exercises for flexibility, strength, endurance and balance. The psychoeducationaln programme aimed to educate the caregivers and encourage communication between caregiver and patient. Even though the programme did not find significant differences in executive functions, however it reported positive outcomes in terms of attention.

Moreover, another study of Teri et al. examined the combination of psychoeducation and multicomponent training programme [29]. The psychoeducation included topics regarding dementia and the study had a large sample size of 255 participants. The programme lasted 9for 4 months and the study reported better physical activity and beneficial effects even after 13 months after the end of the programme. Lastly, Brewster et al. examined the combination of these two non-pharmacological interventions in a sample of 153 participants [30]. The patients received a psychoeducation programme 2 hours for 6 times, another group received psychoeducation with exercise (aerobic and resistance training) for a minimum of 30m, and the attention control group

attended one group session focused on some aspects of nutrition, stretching exercises and flexibility [31-35]. The study used some measurements such as PROMIS emotional distress-depression instrument for measuring the depressive symptoms and the the Zarit Burden Interview (ZBI) for measuring caregivers' burden and PROMIS emotional distress-anxiety for the anxiety symptoms. According to the results of the study the anxiety and depression have improved. In contrary with our results the trial found no significant differences in caregivers' distress.

Our results are in accordance with these previous studies. Both groups showed improvements in decreasing the BPSD, and improving the quality of life of the patients and their caregivers, as well. However, both groups could not improve the cognitive abilities of the patient, which is an important result, too. The main problem in dementia is the cognitive decline, and it seems that the non-pharmacological interventions cannot improve the cognitive abilities. However, it is important that there was no deterioration in the cognitive abilities while performing the interventions, which is something very essential because the realistic expectation in dementia, is not to improve the cognitive abilities, but to maintain them in a good condition for a longer period of time. In that terms, the fact that we did not find improvements in both MMSE and ACE-R cognitive tests is not disappointing, but rather realistically [36-39].

In addition, our results did not maintain after some period of time. Our follow up test did not show improvements. This is an expected result because good outcomes require constant effort. The promising results of the non-pharmacological interventions cannot maintain if the intervention does not take place anymore. Hence, the caregivers should be encouraged to continue the interventions for as long as they can and their patient can perform them well and safely.

The study has some strengths. Our methodology is strict and we had a control group in order to compare the groups. Both groups have received a specific and very well organized programme of how to perform the multicomponent exercise programme and the non- pharmacological interventions that were suggested in the psychoeducation. The study used several questionnaires in order to evaluate the cognitive abilities, the unwanted behaviours, the daily functioning of the PwD, and the general psychology of the caregivers.

Furthermore, the two non-pharmacological interventions were instructed by specialists, who know their science in depth. On the other hand, there are some limitations, as well. Future studies should focus on larger samples, strong methodology, and extend the duration of the interventions. Follow up tests should be made necessarily. It is important to identify the duration of the non-pharmacological interventions and the consistency that they require in order to offer best results [40-42].

Conclusion

Both groups are effectively in order to decrease some BPSD and improve the quality of life of the PwD and their caregivers. Unfortunately, none group showed improvements in cognitive abilities, however there was no deterioration, as well, which is something very important, too. Both multicomponent exercise programme and psychoeducation can be two effective non-pharmacological interventions that can be used in PwD and their caregivers, in order to decrease some unwanted behaviours and improve the general quality of life. Both interventions can be applied by the informal caregivers, if they have been trained properly and systematically by specialists. The interventions are inexpensive, safe, and without side-effects.

The Authors Declare No Conflict of Interest

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