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The Impact of Multicomponent Intervention on Cognition in Older Adults with Subjective Cognitive Decline: A Randomised Controlled Trial

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Abstract

Background:*Subjective cognitive decline (SCD) is the self-perceived deterioration in cognitive function in the form of more frequent confusion or memory loss, in comparison to a previously normal state. Developing strategies to improve cognitive function and slow the rate of cognitive decline is essential to prevent further dementia.*

Purpose:*The objective of the study was to investigate the impact of the multicomponent intervention encompassing physical, cognitive, and psychosocial components (PCP protocol) on the cognitive function of the older adults having SCD.*

Participants:*The study involved 130 older adults having SCD. Participants were randomized into two groups; an experimental group received PCP protocol while a control group received regular Occupational Therapy (OT) program.*

Methods:*A randomized controlled trial (RCT) design was employed. The intervention's efficacy was assessed using the Montreal Cognitive Assessment (MoCA) and Addenbrooke's Cognitive Evaluation (ACE-III) at baseline, 12th week, and 24th week, later the data was analyzed.*

Results:*One-way ANOVA was conducted to compare the means of MOCA and ACE III scores across the three assessment sessions separately for the control and experimental groups. The experimental group showed significant improvement in MOCA ($p = .013$) and ACE II ($p = .006$) scores.*

Conclusions:*A PCP protocol significantly improved cognitive outcomes in older adults with SCD. The findings will benefit both the patients and clinicians in cognitive health.*

Keywords: *Cognitive decline, Cognitive impairment, Cognitive motor, Physical activities, Psychosocial*

1. INTRODUCTION:

As people age, cognitive abilities undergo natural changes that can impact daily functioning. Dementia is the most severe level of cognitive impairment with a prior stage of mild cognitive impairment (MCI). MCI is preceded by a stage where individuals experience a subjective decrease in cognitive function but shows no evidence of objective cognitive decline or daily functioning. This condition was termed as Subjective Cognitive Decline (SCD) [1]. It is described as the self-perceived deterioration in cognitive function in the form of more frequent confusion or memory loss, in comparison to a previously normal state [2]. SCD is one of the major issues faced by the older individuals with a ratio of one in four cognitively unimpaired persons above 60 years of age [3]. Crucially, while age is the strongest known risk factor for cognitive decline, others are lifestyle-related risk factors, such as physical inactivity, tobacco use, unhealthy diets, and harmful use of alcohol. Hypertension, diabetes, hypercholesterolemia, obesity, and depression are also associated with increased risk of developing dementia. Other potentially modifiable risk factors include social isolation and cognitive inactivity [4].

It has been ascertained that SCD is considered as one of the earliest clinical symptoms of Alzheimer's disease (AD). As a preclinical stage of AD and Mild Cognitive Impairment (MCI), SCD may represent an important opportunity for therapeutic intervention to slow down or prevent cognitive decline.

Initiating intervention early has the potential to reverse cognitive deterioration and reduce the chances of progressing to AD [5]. Due to the limited success of drug therapies in improving cognitive abilities in individuals with SCD, as well as the risk of side effects, there has been significant focus on non-pharmacological interventions (NPI) for their impact on improving cognition in SCD (6). Studies indicate that the use of NPIs in the context of SCD shows promise, and interventions addressing multiple domains may offer greater preventive benefits compared to those focusing on a single domain. This implies that integrating various therapeutic approaches could enhance opportunities for fostering healthy aging in individuals experiencing SCD [7, 8]. Multi-domain lifestyle intervention strategies like diet/nutrition, cognitive training, and physical exercise interventions are effective in delaying cognitive decline in healthy older adults. It is recommended to begin engaging in these activities consistently as early as midlife to potentially influence cognitive function in their later years [9]. In addition, lifestyle intervention (nutrition, exercises, behaviour modification, counselling), and frequent social activity are recommended to delay cognitive decline [10].

Physical activity/exercise, as a form of non-pharmacological intervention, can influence the electrical activity of neurons that is linked to cognitive abilities, promote brain structural plasticity [11], and encourage the formation of new neurons and synapses associated with learning and memory [12, 13].Cognitive training improves cognition in ageing as indicated by a meta-analysis in which cognitive training had a substantial impact on memory and subjective cognition functioning [14]. A socially engaged lifestyle can assist to prevent cognitive deterioration in old age. A study's compelling data with an average follow-up of five years revealed that frequent social interaction was linked to subsequently lower rates of cognitive impairment. The rate of cognitive deterioration of most socially active people was only one-fourth as compared that of the least socially active people [15].

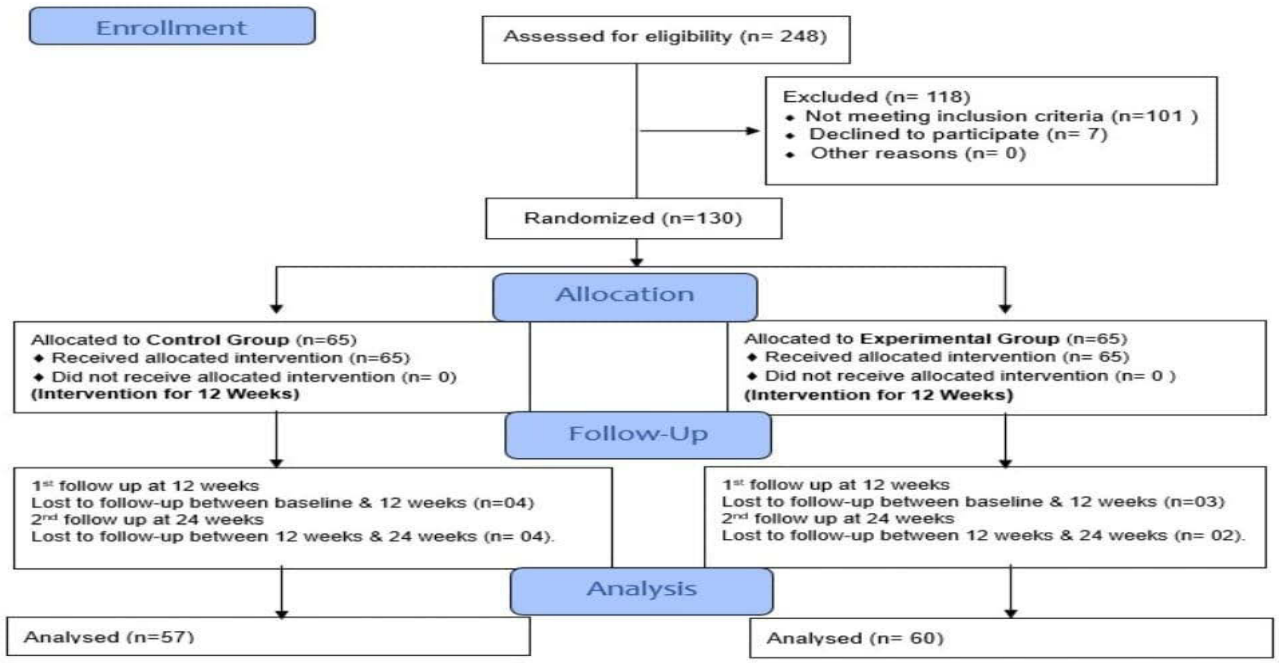
This study aims to assess the impact of a structured Physical-Cognitive-Psychosocial (PCP) protocol on cognitive function in older adults with SCD compared to a standard Occupational Therapy program [16].

2. METHODS

2.1. Study design and settings

The design of this study was a single-blinded randomised controlled trial with two parallel groups in a 1:1 allocation ratio. All the screened patients were randomly assigned to one of the two groups i.e. a control group and an experimental group. The study protocol adhered to the principles of the Standard Protocol Items Recommendation for Interventional Trials (SPIRIT). The process of reporting of the RCT was as per the guidelines of The Consolidated Standards of Reporting Trials (CONSORT) (Figure 1). Assessment was done 3 times, at baseline, 12 weeks, and 24 weeks of intervention.

Figure 1- CONSORT 2010 Flow Diagram



Older adults were enrolled in this study, who attended the outpatient department (OPD) of a national rehabilitation Institution in Delhi from July 2023 to April 2024 and had answered positive to a simple question; "Do you think you have any difficulties with your memory or cognition, like forgetting important dates, or names of people or confusion in planning things as compared to last 1year, or 2year?".Inclusion criteria were, subjects of age 60 years and above, willing to participate in the trial, having self-reported cognitive complaints or their caregivers' complaints, having Montreal cognitive assessment scoring of minimum 26 or having Lawton IADL score 8, no medical/ psychiatric history with cognitive impairment (Dementia, TBI, Stroke), and can hear, read, and write simple sentence with or without any aids. Exclusion criteria were dementia or objective cognitive impairment, any neurological or psychiatric diseases, acute musculoskeletal diseases or recent fractures, malignancy and MOCA score below 26. A total of 130 older adults were recruited out of 248 older adults (Table-1).

Table -1: Characteristics of Participants enrolled in the study

Participants characteristics	Control group n=65	Experimental group n=65
Female	26	23
Male	39	42
60-70 years	39	49
70-80 years	25	14
80 years above	01	02
Mean Age	67.49 (±6.51)	66 (±6)
MoCA	26.70 ± 0.981	26.49 ± 1.393
ACE III	82.75 ± 5.159	81.89 ± 8.707

2.3. Randomisation and Allocation Procedure

Participants had been randomly allocated to the experimental and control group using a computer-generated block randomisation method, performed in blocks of four, resulting in 32 blocks, with the last block containing two participants. Allocation concealment was done by the sealed envelope method. An independent assessor performed the randomisation and allocation. Different raters were involved for baseline and post-intervention assessments.

2.4 Sample size estimation

A sample of minimum 130 individuals was calculated keeping in mind the follow-up time duration of 06 months and according to the expected patient inflow. However, utilizing the findings of a study conducted by Cohen-Mansfield et al (2015), which showed improvement in mean cognitive score in the intervention group, as compared to control group among >70-year-old patients. A minimum sample of 57 per group was calculated. However, to compensate for the patients lost to follow up, nearly 15% extra cases were added, which computed the minimum sample size to 130 (65 per group) [17].

2.4. Ethical considerations

This study followed the 2017 National Code of Ethics for Biomedical Research Involving Human Participants and the 2013 revised Declaration of Helsinki. Informed consent and participant information sheet were obtained from all the participants, in which a detailed information about the study purpose, procedure, potential risks, benefits and the principle of confidentiality were discussed. It was approved by the Institutional Ethical Committee (IEC), Amity University, (AUUP/IEC/AUG/2021/10, dated April 19, 2022) as well as by the PDUNIPPD Institutional Ethics Committee (IEC) (IEC11/2022/RP1, dated December 13, 2022). The study was registered in the Clinical Trial Registry – India with Registration number: CTRI/2022/10/046602.

2.5. Study intervention

After the participants were randomly allocated to the experimental and control group, distinct intervention protocols were given. The experimental group received the PCP protocol, a multicomponent protocol that included physical, cognitive, and psychosocial components (Table 2), while the control group received a standard occupational therapy program (Table 3) [16]. A baseline assessment was done before the start of the intervention.Intervention was provided by a qualified Occupational Therapist to both the groups that lasted 50 minutes each day, twice a week for a period of 12 weeks. The first reassessment was conducted after completion of 12 weeks of intervention, which was followed by a period of no contact for another 12 weeks.Every participant, was invited to return for a

second evaluation after the no contact period. Second reassessment was done after 12-week period of no contact i.e. at 24thweekafter baseline evaluation.

Table- 2: Physical-Cognitive-Psychosocial (PCP) Protocol for Experimental group

Activity	**Frequency**	**Intensity**	**Time**	**Type**
Shoulder wheel (1kg resistance) in Shoulder flexion & abduction. Dumbbell (1kg) in Hip flexion & abduction. (Above activities are 01 set)	Twice weekly for 12 weeks	10 repetitions/min X 2 sets with 2minute rest time in between sets.	10 minutes	**PHYSICAL** Strengthening and Stretching of U/L & L/L.
Static cycle Theraband (Hip abd- hip add in sitting and standing). (Above activities are 01 set)	Twice weekly for 12 weeks	10 repetitions/min X 2 sets with 2minute rest time between sets.	10 minutes	
S3T: Tandem walk in a straight line while counting backwards in steps of 3 i.e., 100-3, 97-3, 94-3,.. (Above activities are 01 set)	Twice weekly for 12 weeks	3meters of going forwards and coming back to start position X 2 sets	08 minutes	**COGNITIVE-MOTOR** (Dual activities) Improving balance, coordination, and alertness of mind.
Square Stepping Exercise (SSE) is performed on a non-skid mat having 10 rows with 4 equal sized squares. SSE is a group-based intervention, to be carried out in groups not more than 6. (Above activities are 01 set)	Twice weekly for 12 weeks	Each pattern X 02 sets (to & fro) for 2 weeks. Six patterns- (simple to complex) elementary1, elementary2, intermediate1, intermediate2, advanced1, & advanced2.	12 minutes	Improving mental focus as well as motor activity. It involves concentration, coordination, attention, and memory along with stepping.
8. Interactive session/ educative session- at 1st week, 5th week & 12th week. Individual/ Group activity at week 2nd, 3rd,, 4th, 6th, 7th, 8th, 9th, 10th, 11th (above activities are 01 set)	Twice weekly for 12 weeks	Discussion with subjects coping with life stressors, sense of achievement, happiness, and improving QOL.	10 minutes	**PSYCHOSOCIAL** Enhancing socialising skills, executive function, promoting mental health,

Table- 3: Standard Occupational Therapy program for Control group

2.6. Measurement

Baseline assessment of the participants was done by taking demographic characteristics of the participants such as age, gender, education, marital status, living arrangement, socioeconomic status, personality traits, and lifestyle. Outcome measure assessment utilising Montreal Cognitive Assessment (MOCA) score, and Addenbrooke's Cognitive Examination (ACE III) were done at baseline, first reassessment and second reassessment. The MoCA has been described as a good tool to detect cognitive impairment in older adults. The MOCA test was used for quickly screening. It has good to excellent test-retest reliability (r = 0.80-0.90), inter-rater reliability (r = 0.90-0.95), convergent validity (r = 0.70-0.80) [18]. The ACE-III is one of the widely used cognitive assessment tools. It is primarily used for detecting

and screening for dementia and MCI in individuals over 50 years. It has good to excellent test-retest reliability (r = 0.95; 95% CI: 0.93-0.97), inter-rater reliability (r = 0.98; 95% CI: 0.97-0.99), convergent validity (r = 0.85; 95% CI: 0.80-0.90) [19].

2.7 Data analysis

Statistical analysis was conducted with IBM SPSS version 24.0. Descriptive statistics such as mean, standard deviation wasobtained for variables MoCA, and ACE-III. Using one-way analysis of variance (ANOVA), baseline variables were compared across the groups to identify systematic differences. P value less than 0.05 was considered as statistical significance.All analyses will follow the intention-to-treat principle.

3. RESULTS

The mean scores and standard deviations were increased for the MOCA and ACE-III for both the control and experimental groups, across the three assessment sessions (Table -4).MOCA scores are consistently in a narrow range across all time points, with means generally between 26 and 28, and with low standard deviations i.e 1.03. Whereas ACE- III scores have greater
variability, with means ranging from the low 80s to the low 90s, and higher standard deviation i.e. 5.814. Independent samples t-tests were conducted to compare the mean scores of the Montreal Cognitive Assessment (MOCA) and the Addenbrooke's Cognitive Examination III (ACE_III)
between the control and experimental groups at baseline, first reassessment, and second reassessment (Table-5). It showed that there was no significant difference between the groups at baseline for both MOCA and ACE III scores (p = .345 & p = .501).). At 1st reassessment, for MoCA, there was no significant difference between the groups (p = .802) whereas for ACE III scores, there was a significant difference between the control and experimental groups (p = .009). At 2nd reassessment, there was a significant difference for both the groups for MoCA (p = .013) and ACE III (p = .006)

Table- 4: Changes in outcome measures across three assessments for both groups

Session	Measure	Group	Mean ± Std. Deviation	Minimum	Maximum
Baseline (Pre-intervention)	MOCA Score	Control (n=57)	26.70 ± 0.981	24	29
	MOCA Score	Experimental (n=60)	26.49 ± 1.393	23	30
	ACE_III Score	Control (n=57)	82.75 ± 5.159	66	91
	ACE_III Score	Experimental (n=60)	81.89 ± 8.707	54	96
1st Reassessment (12 weeks post intervention)	MOCA Score	Control (n=57)	27.68 ± 0.956	24	30
	MOCA Score	Experimental (n=60)	27.63 ± 1.029	25	30
	ACE_III Score	Control (n=57)	86.11 ± 4.579	72	96
	ACE_III Score	Experimental (n=60)	88.63 ± 5.443	70	100
2nd Reassessment (24 weeks post intervention)	MOCA Score	Control (n=57)	27.75 ± 0.912	25	30
	MOCA Score	Experimental (n=60)	28.20 ± 0.942	25	30
	ACE_III Score	Control (n=57)	87.25 ± 5.272	68	98
	ACE_III Score	Experimental (n=60)	90.14 ± 5.728	71	100

Table-5: Independent t test

	Levene's Test for Equality	t-test for Equality of Means

			of Variances								
										95% Confidence Interval of the Difference	
			F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Baseline	MOCA score	Equal variances assumed	3.642	0.059	0.947	120	0.345	0.209	0.221	-0.228	0.647
		Equal variances not assumed			0.969	114.876	0.335	0.209	0.216	-0.219	0.638
	ACE III score	Equal variances assumed	6.674	0.011	0.653	120	0.515	0.862	1.319	-1.750	3.474
		Equal variances not assumed			0.675	106.072	0.501	0.862	1.278	-1.672	3.396
1st reassessment	MOCA score	Equal variances assumed	0.568	0.453	0.251	111	0.802	0.047	0.187	-0.323	0.417
		Equal variances not assumed			0.252	110.654	0.802	0.047	0.187	-0.323	0.417
	ACE III score	Equal variances assumed	1.114	0.293	-2.665	111	0.009	-2.524	0.947	-4.401	-0.648
		Equal variances not assumed			-2.669	108.444	0.009	-2.524	0.946	-4.399	-0.650

2nd reassessment	MOCA score	Equal variances assumed	0.151	0.698	-2.534	111	0.013	-0.442	0.174	-0.788	-0.096
		Equal variances not assumed			-2.533	110.715	0.013	-0.442	0.174	-0.788	-0.096
	ACE III score	Equal variances assumed	0.769	0.382	-2.798	111	0.006	-2.897	1.035	-4.949	-0.846
		Equal variances not assumed			-2.796	109.888	0.006	-2.897	1.036	-4.951	-0.844

One-way ANOVAs were conducted to compare the means of MOCA and ACE-III scores across the three assessment sessions (baseline, first reassessment, and second reassessment) separately for the control and experimental groups (Table-6). In summary, both the control and experimental groups showed statistically significant improvements in their MOCA and ACE-III scores across the three sessions.

Table-6: The ANOVA test to compare the MOCA and ACE-III scores for both groups

Groups of the participants			Sum of Squares	df	Mean Square	F	Sig.
Control group	MOCA score	Between Groups	39.200	2	19.600	21.719	.000
		Within Groups	150.706	167	.902		
		Total	189.906	169			
	ACE III score	Between Groups	620.908	2	310.454	12.343	.000
		Within Groups	4200.480	167	25.153		
		Total	4821.388	169			
Experimental group	MOCA score	Between Groups	92.123	2	46.062	34.693	.000
		Within Groups	232.349	175	1.328		
		Total	324.472	177			
	ACE III score	Between Groups	2378.336	2	1189.168	25.023	.000
		Within Groups	8316.366	175	47.522		
		Total	10694.702	177			

4. DISCUSSION

The present study revealed that, 12 weeks of PCP protocol significantly increased the scores of MoCA and ACE-III as compared to the standard Occupational Therapy program. Increase in the scores of MoCA and ACE-III are associated with improved cognitive performance after receiving multicomponent intervention (PCP protocol) for 12 weeks. It has been proved that physical activity can improve cognition, particularly executive functioning, and memory [20]. Physical exercises have been shown to improve neuroplasticity and cerebral perfusion, contributing to better cognitive performance [21]. Cognitive tasks enhance mental flexibility and neural engagement, while psychosocial activities alleviate stress and promote emotional well-being [22, 23]. These findings support the findings of prior research emphasizing the synergistic effects of multicomponent interventions on cognition [24, 25].

A multicomponent intervention program combining physical, cognitive, and social activities was effective in improving spatial working memory and maintaining physical activity [26].The importance of multicomponent approaches for addressing subjective cognitive decline is well recognized in several reviewed studies. The results indicated a notable decrease in memory complaints reported by the participants [17, 27-30]. However, this does not necessarily imply that these interventions will ultimately reduce the occurrence of subjective memory impairment, which is more associated with psychological aspects [31, 32]. The square-stepping exercise (SSE) represents a unique type of mind–motor training that has been linked to beneficial effects on both global and specific cognitive functioning in elderly individuals. Similar studies have been done in the past on multi-modality approach (consisting of aerobic exercise, resistance training, and stretching) combined with mind–motor trainingyielding positive results [33-34].

In our study, both the groups showed improvements, likely due to regular engagement but the experimental group exhibited superior gains in both MoCA and ACE-III scores. The sustained improvements observed at the 24th week underscore the long-term benefits of multicomponent interventions, even after cessation. These results support the integration of holistic therapeutic practices in addressing SCD and preventing cognitive decline [37, 38].

The key to determining an intervention's level of effectiveness is physical exercise. Boa et al (2018) investigated the effects of multiple-modality exercise with additional mind-motor training (SSE) on cognition and found that it did not yield greater improvements in cognitive function as compared to multiple-modality exercise with additional balance, range of motion and breathing exercises [33]. In contrast to the study by Zuniga et al (2016), that a 12-month regimen of weight training and aerobic activities did not significantly improve subjective memory impairment but considerably increased satisfaction levels [31], we claim that a substantial improvement was observed in overall cognition in our study.

The limitation of our study is only those elderly took part in the research, who consented, and whose mental and physical condition was good enough to be capable of completing the tests and the interviews. Exploration of other variables (e.g., education, socioeconomic status, lifestyle factors, marital status) that may influence cognition was not considered. For future studies it is recommended to conduct longitudinal studies to observe the long-term efficacy of multicomponent intervention and clarity regarding its frequency, intensity, and kind.

5. CONCLUSION

A 12-week PCP protocol significantly improved cognitive outcomes in older adults with SCD. The findings advocate for broader adoption of multicomponent interventions to enhance cognitive health.The findings will benefit both the patients and clinicians for improving cognitive health.

Conflict of interests – The authors declare that they have no conflict of interests.

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Authors' contributions - Conceptualization, M.M, M.B.; methodology, M.M, J.S., and P.K.; writing, M.M original draft preparation, M.M.; writing-review and editing, J.S.; All the authors have read and agreed to the published version of the manuscript.

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