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## CHAPTER 5

### SUMMARY AND CONCLUSIONS

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The current projections have considered dementia as an epidemic challenge blasting for low-middle income countries especially India. Undeniably, India today stands third among the ten countries being home to over a million demented people. For curbing of the burgeoning menace of cognitive impairment, the scientific bodies have geared up with identifying of the novel therapeutic targets or neuro-protective nutraceuticals and efficiently managing MCI by thwarting its further progression to severe disorders. Vitamin B12 (methylcobalamin) injectable doses and flaxseeds are holding up to be immensely promising and potentially beneficial for overall health systems. In purview of the recent evidences gathered, vitamin B12 and flaxseeds control the blood pressure, weight, blood lipids and may act for up-scaling the geriatric cognition levels. Hence, the present study was undertaken as, “**Vitamin B12 and Omega-3 fatty acid Interventions for Cognition in Elderly- a V.O.I.C.E. Trial**”. The study trial was then divided into three phases with the following objectives-

PHASE I- Baseline assessment of diet, nutrition and health status of cognitively impaired elderly with MCI.

PHASE II- Food product development using omega-3 fatty acid and sensory trials.

PHASE III- Intervention and impact evaluation of the MCI elderly group with Omega -3 fatty acids and Vitamin B<sub>12</sub> supplementation.

The results and the major highlights of all the phases under study trial have been summarized as follows:

#### 5.1 PHASE I

This formative study phase was conducted for enrolment of 120 subjects (60 -85 yrs) from the University Health Centre of The Maharaja Sayajirao University of Baroda (govt.) and Shri Vallabhacharyajee hospitals by purposive sampling. Pertinent data was obtained through the patient medical records, neuropsychological test battery

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screening, one-to-one interviews, and direct measurements. Bio-physical measurement included monitoring of blood pressure, biochemical parameters like serum vitamin B12, haematological profile, glycemic, lipemic and only in the case of patients for flaxseeds administration –the kidney plus liver function tests were performed from the blood samples of the patients.

## **Salient features of the Phase I**

### ***5.1.1 Cognitive assessment of MCI patients (N=120) based on neurological scoring***

- ACE test on baseline sample (N=402) categorised 51% in the normal range and 49% as cognitively impaired with almost half of the males (46.6%) and females (50.9%) have cognitive impairment.
- 58% were mild cognitively impaired comprising 38% males and 39% females, 16% moderately and 3% severely impaired by MMSE.
- 44% were mild cognitively impaired consisting of 51% males and 39% females by YFPIT.
- 57% had sub-normal nutritional status being in at risk of malnutrition category with 58% females and 56% males.
- Almost half (49%) of 402 baseline subjects were diagnosed with MCI.
- Significant negative impact on nutritional status through increasing age marked between old-old and young-old patients with MNA ( $p < 0.01$ ).

### ***5.1.2 Baseline information and medical history of MCI patients***

- Socio-demographic data found that majority (94%) of MCI patients were Hindus with 73% in young –old and 27% in old-old categories. Males accounted to be 44% and females to be 56%. Maximum subjects fulfilled the literacy levels (91%), stayed in joint families (51%) and had a monthly income  $>10000$  (96%). Most (68%) of them had caretakers.
- With regard to the history of associated health problems majority (76%) of the patients had anaemia. More than 55% had obesity, hypertension and insomnia. One-fourth (34%) patients had balance problems. About 28% had diabetes and 24% had anorexia complaints whereas 21% were dyslipidemic. Nearly 16% of the subjects had the prevalence of depression.

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- Under the medical history, 47% of the patients were on anti-hypertensive medicines. Around 22% patients pursued on oral hypoglycaemic drug- metformin whereas 6% found to be taking cholesterol-lowering medications were enrolled only in the Group 1 of serum vitamin B12 supplementation.

### ***5.1.3 Physical activity pattern and anthropometric profile of MCI patients***

- GRPAH questionnaire developed by the WHO for assessment of physical activity pattern showed that more than half (57%) of the subjects had a low activity level pattern (minutes  $\leq$ 200). Approximately, 36% had moderate activity level whereas only 7% had high physical activity level. More females (65.6%) were in the low activity level as compared to 47% males. In addition to this, more number of old-old group were more sedentary than the young-olds.
- According to the Asia Pacific BMI classification, 40% subjects were stage I obese, 22% being normal and 19% of subjects were suffering from stage II obesity.
- Gender-wise comparison revealed that almost equal males (39.6%) and females (40.2%) were under stage I obesity and 19.1% males had twice more of stage II obesity than 9.4% females.

### ***5.1.4 Bio-physical and biochemical profile of MCI patients***

- According to JNC VII (2003) classification, 45% patients were stage I hypertensive and 37% were pre-hypertensive.
- The mean serum vitamin B12 levels were observed as 186 pg/ml. 82% had poor control of serum vitamin B12.
- The mean fasting blood sugar of the patients was 98.08 mg/dl and the mean glycated hemoglobin was 6.1.
- According to the criteria of ADA (2007), 29% had a poor control of diabetes.
- The serum lipid outcome highlighted that the mean total cholesterol was 195 mg/dl.
- According to the ADA (2016) recommendations, 50% of the patients had good control on total cholesterol levels whereas 43% and 7% had borderline and poor levels.
- About 62% of the patients had good control over LDL levels.

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- 58% of the patients displayed good control on triglycerides (TG) with their mean TG values <150 mg/dl whereas only 8% patients had TG levels  $\geq$  200 mg/dl.
  - In the case of HDL majority (50%) showed a borderline control.
  - About 55% patients showed poor control for TC/HDL ratio. The mean TC/HDL ratio of males was 7.7 and females 4.64 showing an abnormal TC/HDL ratio i.e. >6.4 and >5.6 respectively.

#### ***5.1.4 Dietary profile of MCI patients***

- The general food habits depicted that 76% patients were vegetarians followed by 14% ovo-lacto vegetarians and 10% non-vegetarians.
- 24-hr dietary recall method indicated that the mean energy intake was 4% higher and 5.3% lower than the RDA for females and males respectively.
- Protein intake was 14.8-17.6% higher in both the genders and the fat intake was 230% and 277% higher in males and females respectively.
- The patients had insufficient Vitamin B12 intake being greatly lower by 72% and 68% and the ALA (omega-3) consumed from the diet was also highly poor by 86.3% and 87.5% than the RDA in the case of females and males respectively.
- Iron intake was 37% and 21% lower than the RDA in males and females respectively and almost all the micronutrients were in the normal range except calcium, vitamin A, niacin and riboflavin.
- 88% of the patients consumed milk in the form of tea on a frequent basis. Only 21% were consuming green leafy vegetables and 52% taking fruits frequently.
- Approximately, 58% of the patients consumed milk frequently and 43% were infrequent. For 70% of patients, fenugreek seeds were the only frequent source of omega-3 in the diet.

#### ***5.1.6 Association between neurological test scores and other parameters***

- The Pearson's correlation revealed significant ( $p<0.01$ ) negative correlation between the ACE ( $p<0.01$ ), MNA ( $p<0.01$ ) and MMSE ( $p<0.05$ ) scores with the age.

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- Significant positive correlation was found amongst MNA ( $p<0.001$ ) and ACE ( $p<0.05$ ) scores with BMI. MNA significantly ( $p<0.001$ ) correlated with the WC and HC.
  - ACE ( $p<0.01$ ), MMSE ( $p<0.05$ ) and MNA ( $p<0.05$ ) were significantly correlated with serum Vitamin B12 levels. Total serum cholesterol significantly positively correlated with MNA ( $p<0.05$ ). Significant positive association examined between HDL levels and ACE ( $p<0.05$ ). MMSE ( $p<0.05$ ) and MNA ( $p<0.01$ ) significantly positively correlated with hemoglobin. RBC count significantly positively correlated with MNA ( $p<0.01$ ). MCV depicted positive correlation with ACE and MMSE ( $p<0.05$ ). MCH also positively correlated with ACE score ( $p<0.05$ ).

#### ***5.1.7 Relation between serum vitamin B12 levels and omega- 3 intake with other parameters***

- BMI significantly inversely correlated with serum vitamin B12 levels ( $p<0.001$ ). DBP negatively correlated with both omega-3 intake and serum vitamin B12 ( $p<0.05$ ). Omega-3 intake significantly positively associated with hemoglobin ( $p<0.05$ ). Serum vitamin B12 and RBC were significantly positively correlated ( $p<0.05$ ). Similarly, HDL significantly positively correlated with serum vitamin B12 ( $p<0.001$ ) and TG were negatively correlated with serum vitamin B12 ( $p<0.05$ ).

***Hence, the conclusions drawn from this study phase of the trial highlight that 49% baseline subjects were diagnosed with MCI. Patients had poor control of serum vitamin B12. Majority had good diabetes control, half had good lipemic control with remaining half having borderline HDL, poor TC/HDL ratio and high prevalence of hypertension. Patients consumed inadequate diet having grossly deficient vitamin B12 and ALA with higher fat intake. Serum vitamin B12 levels remarkably diminished with lower ACE, MMSE and MNA scores whereas total cholesterol reduced with respect to MNA and HDL levels with ACE. As a result, supplementation with vitamin B12 and flaxseeds may enhance cognitive health of elderly and could possibly work towards lipemic profile, glycemic response and hypertension of patients.***

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## 5.2 PHASE II

Under this section of the second phase, four products selected for flaxseed substitution were *khichdi*, *porridge*, *laddoo* and *mukhwaas* and thereafter subjected to organoleptic assessment using the 9-point Hedonic scale and the Composite scoring test. These food items are consumed on regular basis in the Gujarat region and so were deemed as potentially vital for flaxseed substitution. The key ingredients for *khichdi*, *porridge* and *laddoo* (rice, green gram, wheat gruel, sugar, milk and jaggery) were incorporated with flaxseeds at the three (10g, 15g and 20g) varying levels respectively.

### Salient features of the Phase II

The first phase of the research work was carried out to assess the proximate, fatty acid analysis of raw versus roasted flaxseeds and organoleptic attributes of roasted flaxseeds substituted Indian food items popularly consumed. The method of substitution was employed to find the prospect of incorporating roasted flaxseeds in the food products. The food products for incorporating varying levels of flaxseeds included *khichdi*, *porridge*, *globs* and *mukhwaas*. The base ingredients of *khichdi*, *porridge* and *globs* were substituted with roasted flaxseeds at three different levels i.e. 10g, 15g and 20g, whereas *mukhwaas* had only 20g of roasted flaxseeds. Thirty semi-trained and 100 untrained panellists evaluated the food products using the 9- point hedonic scale and composite scoring test. The food products were so selected for substitution with roasted flaxseeds as they were part of regular consumption in our study region of Gujarat.

#### 5.2.1 Proximate and Fatty acid analysis of raw versus roasted flaxseeds

- Proximate analysis of the raw flaxseeds revealed energy to be 540 (Kcal/100g), protein 26 (g/100g), fat 33 (g/100g), carbohydrate 35 (g/100g), fiber 4.1 (g/100g), ash 2.7 (g/100g) and moisture 3.9 (g/100g).
- The alpha-linoleic acid (ALA) area % in raw flaxseeds from the fatty acid analysis was 37%.

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- Roasted flaxseeds revealed energy to be 546 (Kcal/100g), protein 26 (g/100g), fat 33 (g/100g), carbohydrate 36 (g/100g), fiber 4.2 (g/100g), ash 2.8 (g/100g) and moisture 2.1 (g/100g).
  - Alpha–linoleic acid (ALA) area % in roasted flaxseeds from the fatty acid analysis was 56%.

### **5.2.2 Organoleptic properties of flaxseeds substituted food products**

- The attributes of *khichdi* namely, taste, absence of defects and overall acceptability were largely affected according to 66% of semi-trained panelists by the composite scoring test. In addition, hedonic scores of 60% semi-trained and 53% untrained panelists favored towards variant with 10g of flaxseeds substitution.
- The attributes of *porridge* namely, taste, absence of defects, suitability of serving, overall acceptability and total score were largely affected according to 57% of semi-trained panelists by the composite scoring test. In addition, hedonic scores of 67% semi-trained panel of judges rated porridge with 20g of roasted flaxseeds substitution to be superior most.
- All of the attributes differed insignificantly for *globs* up to 20g of roasted flaxseeds substitution as per the composite scoring test, representing that the *globs* were well accepted at all the three levels of roasted flaxseeds substitution. Almost 50% semi-trained judges' panel rated *globs* to be equally superior for up to a level of 20g flaxseeds substitution.
- A significant difference was obtained from the composite scoring results of *mukhwaas* having 20 g flaxseeds in the maximum of the organoleptic attributes viz. texture, absence of defects, overall acceptability and total score indicative of its suitability as a preferred food product. Furthermore, the hedonic acceptability scores of 70% semi-trained and 83% untrained panelists too confirmed the 20 g flaxseeds *mukhwaas* to be the end determination point for intervention in comparison to rest of the other developed food formulations. Hence, the flaxseed *mukhwaas* was finally considered for intervention to MCI patients on account of these test results been obtained by both the semi-trained as well as untrained panel members.

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*Thus, it can be concluded that roasting profoundly enhanced the ALA content to 56% as compared to 37% of the raw form. Roasted flaxseeds incorporated porridge and globs were the highest acceptable products at all the three levels whereas mukhwaas at the 20 g levels according to both composite scoring and hedonic rating scale. On the other hand, khichdi showed higher acceptability with the 10g flaxseeds levels. Hence, these food formulations can be regularly consumed for their beneficial effects.*

### **5.3 PHASE III**

In this last phase, 120 elderly willingly consenting for the trial were conveniently enrolled under two subgroups namely, B<sub>12</sub> intervention (n=60) and the other group with B<sub>12</sub> plus omega-3 fatty acid (flaxseeds) (n=60) respectively for 6 months period on a dose dependent basis. Herein this phase clinic-biochemical parameters were examined for cognitive function tests, blood pressure, nutritional status, serum vitamin B<sub>12</sub>, FBS, HbA1c, lipemic response, atherogenic indices, complete haematological profile while kidney and liver function tests were done particularly for those supplemented with flaxseeds for a thorough check of any detrimental health effect post flaxseed supplementation in the MCI patients.

#### **Salient features of the Phase III**

##### **5.3.1 *Anthropometric, Biophysical and Dietary profile of the patients before and after the supplementation trial.***

- An insignificant difference in anthropometric measurements was found between both the experimental Group 1 and Group 2. Significant reduction (p<0.001) in BMI, waist circumference, hip circumference, systolic and diastolic blood pressure was observed within the experimental groups. Though, WHR remained insignificantly different.

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- The BMI reduction of Group 1 patients came to be 3.4% in males and 3.6% for females like-wise for Group 2 in 3.9% males and 3.1% females. Waist circumference reduced by 2.\*% in males and 2.2% in females of Group 1 whereas in Group 2 reduced by 3.0% in males and 3.1% in females. Significant positive shift of the supplementation was encountered from the improved systolic blood pressure of Group 1 being reduced by 8.7% in males ( $p<0.001$ ), 7.6% in females ( $p<0.001$ ), 8.3% for young-old ( $p<0.001$ ) and 7.8% for old-old ( $p<0.05$ ) and for Group 2 lowered by 6.0% in males ( $p<0.001$ ), 6.4% in females ( $p<0.001$ ), 5.5% for young-old ( $p<0.001$ ) and 8.2% for old-old ( $p<0.01$ ).
  - Patients of both groups increased to normal levels of blood pressure by 15% and 18.3%. Positive reduction marked for both group patients from Stage1 and Stage 2 leading to increase in pre-hypertensive category from hypertension stages I and II.
  - Energy, protein, iron, vitamin B12, zinc, phosphorus and folic acid increased in both the groups. A significant increase in the fat and ALA (omega-3) from the baseline values was observed only for the Group 2 ( $p<0.001$ ).

### ***5.3.2 Serum vitamin B12, CBC, Glycemic, lipemic and atherogenic indices of the patients before and after the supplementation trial.***

- Post supplementation, significantly remarkable rise in serum vitamin B12 was apparent to be 370% and 276% in Group 2 and Group 1 patients ( $p<0.001$ ). Significantly, the CBC profile in Group 2 and 1 improved for hemoglobin by 12.2% and 10.9% ( $p<0.001$ ), RBC by 22.3% and 19.8% ( $p<0.001$ ), WBC by 10.7% and 10.9% ( $p<0.001$ ), MCV by 4.2% and 3.1% ( $p<0.05$ ). The noteworthy features were significant increases ( $p<0.001$ ) in values of serum vitamin B12 of Group 1 males, females, young-old and old-old sub-groups by 308%, 249%, 255% and 339%, hemoglobin by 9.8%, 12.1%, 9.6% and 14.6%, PCV by 10.6%, 17.2%, 13.8% and 14.3% while MCV although being insignificant reached upwards by 2.3%, 3.2%, 3.6% ( $p<0.05$ ) and 1.9%.
- Significant increases of serum vitamin B12 in Group 2 males, females, young-old and old-old sub-groups were 390%, 345%, 397% and 310%, for hemoglobin 10.6%, 13.3%, 11.9% and 13.0%, PCV 13.0%, 15.3%, 14.5% and 13.9%

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- ( $p < 0.001$ ) while MCV only in case of females was significantly increased to 5.2% ( $p < 0.05$ ).
- Glycemic response significantly reduced by 2.6% and 13.9% for the FBS ( $p < 0.001$ ) and HbA1c of group 2 by 20.3% ( $p < 0.001$ ) and there was a slight increase of HbA1c by 3.7% in case of Group 1.
  - Significant reduction in FBS values of the total patients ( $p < 0.05$ ) in females ( $p < 0.01$ ), young –old ( $p < 0.05$ ) and HbA1c to be slightly significantly increased ( $p < 0.05$ ) in females belonging to the Group 1. The significant reduction in both FBS ( $p < 0.001$ ) and HbA1c ( $p < 0.001$ ) values with respect to each of the males, females, young-old and old-old patients in the Group 2.
  - A significant reduction in TC, TG, LDL and VLDL values by 18.9%, 23.4%, 20.2% and 33.9% examined in Group 2 ( $p < 0.001$ ). An increasing trend was significantly noticeable in TC ( $p < 0.05$ ), LDL ( $p < 0.001$ ) and VLDL ( $p < 0.05$ ) values by 2.9%, 7.4% and 6.3% for Group 1. Furthermore, a significant increase in the HDL values by 19.3% and 6.7% for both the Group 2 and Group 1 was detected ( $p < 0.001$ ).
  - The flaxseeds plus B12 supplementation caused the HDL to be significantly increased by 21.5% in males, 17.9% in females, 18.6% in young-old and 21.1% in old-old ( $p < 0.001$ ). Significant lowering in the values by 19.6%, 18.5%, 18.6% and 19.6% of TC, 23.9% ( $p < 0.01$ ), 23.1%, 21.2% and 29.1% ( $p < 0.01$ ) for TG, 21.2%, 19.5%, 20.6% and 19.04% ( $p < 0.01$ ) for LDL, 33.0%, 34.5%, 33.5% and 35.2% for VLDL in males, females, young-old and old-old respectively ( $p < 0.001$ ).
  - Significant reduction in the TC/HDL, LDL/HDL, TG/HDL and Atherogenic Index of the Group 2 by 33.3%, 33.9%, 37.3% and 41.2% ( $p < 0.001$ ). In Group 1 patients too, a significant lowering ( $p < 0.01$ ) of TG/HDL by 10.4% succeeded by insignificant decline of the TC/HDL by 3.4%, Atherogenic Index by 4.5% and very minute increase of 0.3% in LDL/HDL was detected. In addition to these changes, a sharp drop off in the Atherogenic Coefficient to 2.48 value of Group 2 patients was noticeable in comparison to the value 3 of Group 1.
  - The Group 1 values in females and young-old were significantly lessened in TC/HDL by 7.1% and 5.8% ( $p < 0.05$ ), TG/HDL by 15.9% and 12.8% ( $p < 0.01$ ) and
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Atherogenic Index by 9.40% and 7.65% ( $p<0.05$ ). Moreover, LDL/HDL values for these insignificantly went down by 3.22% and 1.64%.

- Group 2 values in case of males, females, young-old and old-old significantly lessened in TC/HDL by 35.3%, 31.8%, 32.5% and 35.4% , LDL/HDL by 36.1%, 32.3%, 33.7% and 34.3% ,TG/HDL by 39.3%, 36.0%, 35.0% and 43.0%, and atherogenic index by 43.5%, 39.6%, 40.3% and 43.4% ( $p<0.001$ ).

### ***5.3.3 Neuropsychological test battery of the MCI patients conducted pre and post supplementation.***

- The vitamin B12 supplementation brought forth a significant improvement in the MMSE scores of Group 1 patients with total patient score rise of 9.6% ( $p<0.001$ ). The gender-wise division was also significant showing increase in scores by 6.8% and 12.5% in males and females whereas 10.2% and 8.2% for young-old and old-old categories ( $p<0.001$ ).
- ACE scores too significantly escalated to 12.7% in Group 1 patients ( $p<0.001$ ). Cross comparative analysis also depicted a significant increase in the scores by 10.6% and 14.9% in males and females whereas 14.4% and 8.2% for young-old and old-old ( $p<0.001$ ).
- Significant ( $p<0.001$ ) percent change in the MNA score of Group 1 patients. A 7.2% increase was significantly ( $p<0.001$ ) observed in total patients with 5.4% ( $p<0.01$ ) and 8.8% ( $p<0.001$ ) for males and females. Significant increase of 6.4% ( $p<0.001$ ) and 9.3% ( $p<0.01$ ) was noted in the case of young-old and old-old groups.
- Overall significant ( $p<0.001$ ) change of 17.1% in the MMSE score of MCI patients belonging to the experimental Group 2 observed positive shift towards normal cognition ability after having received this twofold supplementation. MMSE scores took an overall significant ( $p<0.001$ ) net raise of 14.4 % for males and 18.8 % for females. Similarly, young –old patients had 15.8% increased MMSE score whereas old-old demonstrated 20.8% increase.
- Group 2 MCI patients had the significant improvement of 20.1% in the total ACE score after flaxseeds plus vitamin B12 supplementation ( $p<0.001$ ).

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- The trend from these gender and age stratifications was depictive of a significant ( $p<0.001$ ) positive shift towards healthy cognition levels resultant from the Group 2 supplementation programme. Moreover, the ACE scores rose to 20.3 % for males and 19.3 % increase for females. Correspondingly, the patients in the age range of 60-69 yrs had a 17.6% increased ACE score while for 70-85 yrs it was an increase by 27.5%.
  - The overall 12.4% significant rise in the MNA scores of total subjects with 12.3% in males and 11.6 % in females was noticed ( $p<0.001$ ). The 11.8% and 14.3% increase was observed for both the age groups.
  - The improvement of patients rose to normal cognition by 65% of total patients in Group 2 using MMSE. Further, 67% of the males, 64% in females, 66% young-old and 62% old-old shifted to normality. 42% of total patients in Group 1 improved to normal side. Similarly, 35% males, 48% females, 32% young-old and 69% old-old progressed to normal cognitive status. The MMSE scores of patients represented that the number of 44 in Group 2 and 27 from Group 1 progressed towards the normal category from the MCI state.
  - The improvement of MCI patients raised to normal cognition levels by 45% in Group 2 with males being 50%, females 42%, young-old 45% and old-old to 44% using ACE. Likewise, the number changed to 23% in Group 1 where 28% males, 19% females, 22% young-old and 25% in old-old reversed to normal condition. As symbolized from the ACE scores, Group 2 had 27 MCI patients reverted to normal condition and 14 patients in the case of the Group 1.
  - Normal condition of MCI patients increasing to 60% in Group 2 with males being 58%, females 61%, young-old 64% and old-old to 50% using the YFPIT. In the same manner, 38% normal increase in Group 1 along with 35% males, 42% females, 41% young-old and 31% old-old moved to normal status. A number of 39 patients in Group 2 and 28 patients in Group 1 progressed to normal condition according to YGPIT.
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- An increase of 45% was observed in the normal nutritional status of Group 1 patients with a reduction in at risk of malnutrition and malnourished categories amounting to 51.7% and 3.3% using the MNA scores. Further 11 males, 16 females, 21 young-old and 6 old-old regained towards normal status.
  - An increase of 53% was brought in the normal nutritional status of Group 2 patients alongside a reduction in at risk of malnutrition and malnourished categories to be 46.7% and 0% using the MNA scores. Moreover, 11 males, 21 females, 25 young-old and 7 old-old patients recovered back their normal status.

#### ***5.3.4 Relationship between the neuropsychological test battery, serum Vitamin B12, glycemic response and serum lipid parameters of the MCI patients.***

- Serum vitamin B12 was significantly ( $p < 0.05$ ) and inversely associated with FBS whereas change in serum B12 with HbA<sub>1c</sub>, dietary omega-3 levels with the changes of FBS and HbA<sub>1c</sub> proved to be inversely associated with insignificance.

#### ***5.3.5 Associations between serum vitamin B12, cell blood counts and lipemic responses with the anthropometric, biophysical, biochemical and dietary parameters.***

- Change in serum vitamin B12 demonstrated a significant positive correlation with the change in hip circumference (HC) ( $p < 0.05$ ). Dietary omega-3 was significantly positively correlated to the change in the waist circumference (WC) ( $p < 0.05$ ). However, serum vitamin B12 insignificantly positively correlated to BMI as well as SBP and insignificantly negatively correlated with WC, WHR and DBP. Omega-3 too showed an insignificant positive correlation for BMI, HC, WHR, DBP and insignificant negative correlation with SBP.
- The Omega-3 levels significantly ( $p < 0.05$ ) positively correlated to the ACE and MMSE neurological scores and insignificantly positively correlated to the MNA score. Serum vitamin B12 was established to correlate insignificantly and positively to all of the ACE, MMSE and MNA scores.

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*As observed from the above findings, it can be concluded that vitamin B12 and roasted flaxseeds remarkably stood out as an adjunct therapy towards MCI management. Post 6 months the dual supplementation programme brought forth enhanced cognitive improvement with escalated serum vitamin B12 levels and regulation of anthropometry, glycemic, lipemic, hypertensive profiles. Thus, flaxseeds formulated mukhwaas along with vitamin B12 injectable doses used in this study ought to be encouraged as maintenance therapy for attenuating cognitive decline in MCI.*

## MAJOR CONCLUSIONS

- ACE assessment found 49%, MMSE 39%, YFPIT 44% to be having MCI whereas MNA depicted majority (57%) in at risk of malnutrition in baseline subjects. This comprehensive test battery usage was elemental in fulfilling our primary objective detecting cognitive and nutritional status in of MCI patients.
- Fatty acid estimation ascertained that roasted flaxseeds had higher (56%) ALA content than of raw. Sensory acceptability trials of roasted flaxseeds *mukhwaas* portrayed great likeability among all variants. Meanwhile, *porridge* and *globs* too emerged to be well accepted at higher (15g and 20g) substitution levels. Herein, post attainment of the second objective we can stress that 20g roasted flaxseeds being co-preventative can be safely included as part of daily geriatric diet for advancing their nutrition and in turn cognition status simultaneously.
- Alternate hypothesis was accepted in this study trial with accomplishment of final study objective indicator of overall improvement highlighted in the scores viz. ACE, MMSE, MNA, ALA, vitamin B12, glycemic, CBC, lipemic, atherogenic, SBP and BMI profiles thus proving potency of flaxseeds plus vitamin B12 supplementation.