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Research Article
Role of Ready to Drink Nutritional Formula (Protison Enriched with ω-3 FA and BCAA) Supplemented by Nasogastric Tube Feeding in Various Cancer Patients: A Clinical Trial

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Abstract

Background and Objective: Cancer patients often encounter various health issues like malnutrition, cachexia and fatigue during or after chemotherapy. Hence, they need balanced nutritional support (nutraceuticals and dietary supplements) to maintain optimal health status. Current clinical trial was designed to examine the impact of balanced nutritional formula-Protison™ cancer nutritional formula (PCNF; enriched with ω-3 FA, fibers, BCAA and micro-nutrients), in various cancer patient by checking calorie intake and overall health status. **Materials and Methods:** Totally 42 cancer patients with poor nutritional status under nasogastric (NG) tube feeding was recruited and administered with the commercial nutritional formula (PCNF; 237 mL/Pack) for 5-6 times/day via bolus NG tube feeding for 12 weeks. **Results:** Subjects administered with PCNF showed a significant increase ($p<0.001$) in calorie intake and increased body weight, BMI. Also, the levels of total proteins, pre-albumin and transferrin were also significantly increased ($p<0.007$) in PCNF supplemented patients. Moreover, PCNF fed cancer subjects showed normal range of various biochemical parameters like glycemic indices, lipid profile and various biochemical markers with improved nutritional status. **Conclusion:** Taking together that PCNF tube-fed cancer patients showed better health status (lower the risk of malnutrition and cachexia) by improving body weight, BMI, protein and pre-albumin without any adverse effects.

Key words: Cancer, cachexia, nutritional status, tube feeding, PCNF

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Hospitalized cancer patients are highly vulnerable to malnutrition (altering nutritional and health status) and its associated complications like anorexia, cachexia and fatigue. Several reports have indicated that cancer-induced malnutrition and cachexia could contribute around 20% of cancer-related death particularly in pancreatic, gastrointestinal, liver, head and neck cancer patients[1,2]. Thus, cancer-induced malnutrition and cachexia is a major contributor to the mortality and morbidity during and before cancer therapy[3]. Hospitalized cancer patients during treatment face several health issues (adverse effects) due to malnutrition (lack essential nutrients), altered metabolic function (increased catabolism and inflammation-infectious complications) and subsequently result in cachexia, weight loss and fatigue. Especially, older hospitalized cancer patients staying in hospitals and care centers (under the bed) are highly vulnerable to malnutrition or undernutrition, cachexia and fatigue. Therefore, cancer patients need balanced nutritional support (therapy) to respond positively for chemotherapy or radiotherapy (tolerance to therapy) and to improve overall health status (increase recovery rate) and thus the quality of life[4]. American Society for Parenteral and Enteral Nutrition (ASPEN), as well as European Society for Clinical Nutrition and Metabolism (ESPEN), also recommended nutrition support (guidelines) for cancer patients receiving cancer therapy with signs of malnutrition as well as elderly who unable to ingest or absorb adequate nutrition to lower the inflammatory and metabolic stress[5,6].

Ample amounts of studies (including ASPEN/ESPEN) have demonstrated that balanced diet formula rich in nutraceuticals like omega 3 fatty acids (ω-3 FA), fibers, protein as well as mineral, vitamins (trace elements) are essential for cancer patients to improve health status and tolerability of chemotherapy as well as to suppress various cancer-associated deleterious conditions such as malnutrition, fatigue, cachexia[1,5,7]. Hence, oncologic nutritionist strongly recommends cancer patients (with cachexia) to consume a diet rich in protein and dietary fibers along with balanced essential micronutrients like vitamins and minerals[3,8]. From the above statement it cleared that nutritional support is a crucial aspect of multi-modal cancer care, by improving the overall health status by suppressing various adverse events as well as enhance treatment regimen for a speedy recovery. Hence, the present multi-centered, clinical trial was framed to evaluate the efficacy of ready to use balanced nutritional formula-PCNF [rich in omega 3 fatty acids (ω-3 FA), dietary fibers, Medium Chained Triglyceride (MTC), Branched Chained Amino Acids (BCAA) and micro-nutrients] in various cancer patient by checking calorie intake and overall health status through assessing various anthropometric and biochemical parameters especially total proteins, pre-albumin and transferrin.

MATERIALS AND METHODS

Sample details (PCNF): Protison-cancer balanced nutritional formula (PCNF) ready to drink formula was provided by SMAD Biotechnology Co., Ltd (Taipei, Taiwan). Each pack of PCNF contains 237 mL (372 kcal) with 21.6 g of protein (23% of calories), 49.5 g of carbohydrates (52% of calories) and 10.4 g of fat (25% of calories). Also, it contains medium-chain triglyceride (MCT), dietary soluble fibers like Fructose-Oligosaccharide (FOS-2%), omega 3 fatty acids (ω-3 FA), Branched Chained Amino Acids (BCAA) as well as many micronutrients (vitamins and minerals). The detailed composition of PCNF ready to drink formula was shown in Table 1.

Subject requirement: This is a multi-centered, clinical trial (hospital, care center, nursing home, old care center) that was carried between March, 2019 to 2020. This trial was approved by the institutional clinical ethical review board (CS17106) and was registered on ClinicalTrial.gov (NCT04643613). All the protocols/procedures conducted in the present study were in accordance with the guidelines put forth by the Good Clinical Practice (GCP) and the Declaration of Helsinki. Totally 60 various hospitalized/care centered cancer patients under nasogastric (NG) tube feeding (due to GI discomfort and for better nutritional utilization) are recruited through flyers and advertisement. An initial assessment was conducted based on various questionnaires (gastric discomfort) as well as based on inclusion and exclusion criteria. The major inclusion criteria were to include only hospitalized cancer patients with risk of malnutrition and underweight (confirmed with BMI, protein and pre-albumin level) and must be under NG tube feeding. The major exclusion criteria were avoiding cancer patients under critical conditions, with cardiac, renal and hepatic disorders. Also, heavy smokers, chronic or chain smokers and pregnant/lactating women were not included. Finally, based on the above-indicated inclusion and exclusion criteria only 42 cancer patients (out of 60 patients) were enrolled for this

Table 1: Major composition of protison™-cancer balanced nutritional formula (PCNF) ready to drink formula (SMAD Biotechnology Co., Ltd)

Nutrients	Per package (237 mL)	Per 100 mL
Energy (kcal)	372	157
Protein (g)	21.6	9.1
Fat (g)	10.4	4.4
Saturated fat (g)	2.8	1.2
Unsaturated fat (g)	4.6	1.9
Medium chain triglyceride (g)	1.9	0.8
Omega-3 fatty acids (mg)	1030	435
Carbohydrates (g)	49.5	20.9
Sugars (g)	7.2	3
Dietary fiber-FOS (g)	3.1	1.3
BCAA (mg)	4000	1688
Glutamine (mg)	4400	1857
Arginine (mg)	580	245
Taurine (mg)	51.5	21.7
Sodium (mg)	244	103
Potassium (mg)	351	148
Calcium (mg)	330	139
Phosphorus (mg)	258	109
Chlorine (mg)	309	130
Iron (mg)	4.04	1.70
Magnesium (mg)	113	47.7
Copper (mg)	0.31	0.13
Zinc (mg)	5.15	2.17
Chromium (mcg)	30.9	13.0
Manganese (mg)	0.72	0.30
Molybdenum (mcg)	30.9	13.0
Selenium (mcg)	23.7	10.0
Vitamin A (mcg-RE)	258	109
Vitamin B2 (mg)	0.52	0.22
Vitamin B6 (mg)	0.54	0.23
Vitamin B12 (mcg)	0.78	0.33
Vitamin C (mg)	41.2	17.4
Vitamin D3 (mcg)	4.64	1.96
Vitamin E (mg-TE)	3.86	1.63
Vitamin K (mcg)	33.9	14.3
Biotin (mcg)	10.3	4.35
Folic acid (mcg)	129	54.4
Pantothenate (mg)	2.06	0.87
Niacin (mg-NE)	5.00	2.11
Iodine (mcg)	45.1	19.0

trial. All the subjects who were ready to involve in this trial were requested to sign a consent. Also, the complete details of this study were explained in detail to each subject and their parents or guardians/caretakers.

Experimental design and sample collection/analysis: All the recruited 42 patients (after a week of assimilation period aged between 50-97) were administered with commercial Protison-cancer balanced nutritional formula (PCNF; 237 mL/Pack) for 5-6 times/day (based on Harris-Benedicts formula calorie need-BMR) via bolus nasogastric tube feeding for 12 weeks (84 days). Since it's a multi-centered trial all the commercial PCNF packages were directly delivered to specific center and the details/indications were explained to doctors, dietitians and nurses as some patients are still under chemotherapy or radiation therapy. The calorie intake (energy) was recorded every day based on how many packages they administered as well as the macronutrient levels (proteins, carbohydrates and fats) were noted. The flowchart of the present trial was shown in Fig. 1.

The complete demographic characters, during baseline, were recorded which includes types of cancer, associated co-morbid conditions, therapeutic types and other basic information. Besides, the basic anthropometric parameters like body weight, height, Body Mass Index (BMI), mid-arm circumference (MAC); mid-arm muscle circumference (MAMC), triceps subcutaneous fat thickness (TSF); Waist Circumference (WC); Hip Circumference (HC) and waist-to-hip ratio (ratio of WC/HC) were calculated using Omron body composition monitor (Kyoto, Japan) and measuring tape. As well as blood pressure [Systolic Blood Pressure (SBP); Diastolic Blood Pressure (DBP)] was noted using the Omron M7 Intelli blood pressure monitor (Kyoto, Japan). Fasting blood samples were collected at baseline (0 weeks) and 12th week and were used to quantify various biochemical parameters including glycemic indices (blood glucose, HbA1c-glycosylated hemoglobin, insulin), lipid profile [total cholesterol (TC), triglyceride (TG), high-density lipoproteins cholesterol (HDL-c), low-density lipoproteins cholesterol (LDL-c)], renal markers [Blood Urea Nitrogen (BUN), creatinine (Cr), urea], hepatic markers [glutamic oxaloacetic acid transaminase (GOT); glutamic pyruvic acid transaminase (GPT)], total bilirubin, cardiac markers [creatine phosphokinase (CPK); lactic acid dehydrogenase (LDH)], protein or nutritional assessment markers [total protein, pre-albumin, transferrin] were analyzed using various commercial diagnostic kits using Shimadzu 7600 fully Automated analyzer system (Shimadzu Corp, Kyoto, USA). After 84 days of intervention with PCNF, only 31 patients completed this trial and the remaining 11 patients were dropped due to transfer to other care centers or hospitals (need extensive care), removed NG tube (no longer required).

Statistical analysis: Values are expressed as the Mean± standard deviation (SD). The Significant difference (p-value) between the baseline and after 12 weeks of intervention (baseline vs week 12) were calculated by paired *t*-test using Statistical Package for Social Sciences (SPSS) version 21 (IBM Inc, NY, USA).

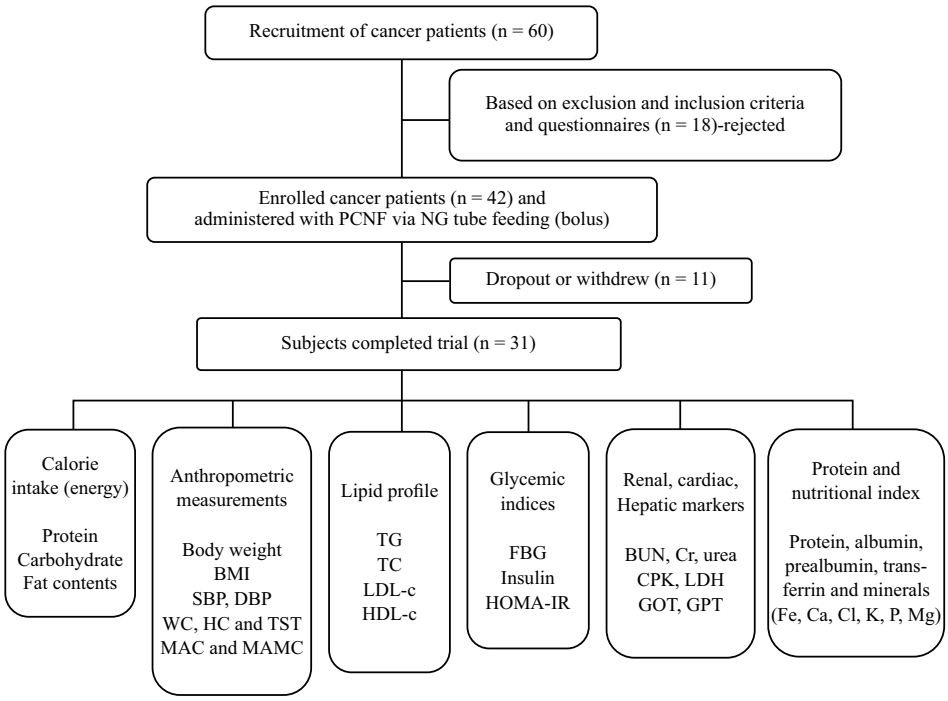

Fig. 1: Flowchart of the present trial

Table 2: Baseline demographical characteristics of subjects

Characteristics	Subject details
Gender	
Male	19
Female	12
Age (year)	70.06±14.78
Height (cm)	159.23±6.28
Weight (kg)	50.03±6.69
BMI (kg m^{-2})	18.73±2.32
Types of cancers	
Tongue cancer	2
Oral cancer	5
Esophageal cancer	4
Laryngeal cancer	2
Colorectal cancer	7
Brain cancer	3
Breast cancer	3
Lung cancer	1
Cervical cancer	1
Prostate cancer	2
Bladder cancer	1
Types of associated chronic diseases (Co-Morbid conditions)	
Diabetes	8
Hypertension	6
Diabetes combined with hypertension	2
Therapeutic type	
Currently under no treatment	5
Surgery+chemotherapy	8
Surgery+radiotherapy+chemotherapy	9
Chemotherapy+radiotherapy	6

Values are expressed as the Mean±standard deviation (SD)

RESULTS

Impact of PCNF on demographical characteristics, calorie intake and macronutrients: The baseline demographical characteristics of subjects including base information are shown in Table 2 especially the gender (male-19; female-12), age (70.06), body weight (50.03), BMI (18.73), types of cancer (mostly GI related cancer), types of associated co-morbid conditions (especially diabetes and hypertension) and cancer therapeutic regimen (surgery, chemotherapy or radiation therapy). The calorie intake (energy consumption) as well as macro-nutrients levels during baseline and 12 weeks after intervention with PCNF was shown in Table 3. The mean value of calorie intake (energy), as well as the protein and carbohydrate contents, were significantly increased ($p<0.001$) after 12 weeks of administration with PCNF via NG tube feeding in different cancer patients. However, the content of fat was moderately decreased upon supplementation with PCNF.

Impact of PCNF on anthropometric parameters: As shown in Table 4 the levels of various anthropometric parameters were considerably altered after 12 weeks of administration with PCNF (baseline vs. 12th week). In particular, the body weight (50.03 vs. 51.24), BMI (18.73 vs. 20.26) were markedly

Table 3: Total calorie intake from baseline to 12th week in cancer subjects

	Baseline	Week 12	p-value
Total energy (kcal/day)	1517.74±131.37	1784.40±106.30	<0.001
Protein (g)	59.77±6.53	102.60±6.11	<0.001
Fat (g)	54.34±9.16	49.57±2.95	0.007
Carbohydrate (g)	197.41±22.69	223.05±13.29	<0.001

Values are expressed as the Mean±standard deviation (SD). p-value: Significant difference between the baseline and after 12 weeks of intervention (baseline vs. week 12)

Table 4: Anthropometric parameters and hemodynamic parameters in cancer subjects

	Baseline	Week 12	p-value
SBP (mmHg)	119.10±18.31	120.77±17.43	0.405
DBP (mmHg)	75.94±19.31	77.97±17.79	0.104
Body weight (kg)	50.03±6.69	51.24±6.94	<0.001
BMI (kg m^{-2})	18.73±2.32	20.26±2.40	<0.001
MAC (cm)	24.47±2.20	24.755±2.81	0.457
MAMC (cm)	20.55±1.72	20.73±2.68	0.633
TSF (mm)	12.48±5.40	12.81±5.29	0.096
Waist circumference (cm)	81.13±9.12	81.66±8.58	0.070
Hip circumference (cm)	86.73±7.82	87.00±7.71	0.361
Waist-to-hip ratio	0.94±0.06	0.96±0.06	0.276

Values are expressed as the Mean±standard deviation (SD). p-value: Significant difference between the baseline and after 12 weeks of intervention (baseline vs. week 12). MAC: Mid-arm circumference, MAMC: Mid-arm muscle circumference, TSF: Triceps subcutaneous fat thickness, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BMI: Body mass index

Table 5: Glycemic indices/markers and lipid profile in cancer subjects

	Parameters	Baseline	Week 12	p-value
Glycemic index	Fasting blood glucose (mg dL^{-1})	108.00±29.37	106.52±22.36	0.658
	HbA1C (glycated hemoglobin %)	5.90±1.00	5.99±1.08	0.193
	Insulin (μU mL^{-1})	7.95±2.40	7.99±2.40	0.701
Lipid profile	Cholesterol (mg dL^{-1})	153.45±40.56	157.00±41.97	0.390
	Triglyceride (mg dL^{-1})	114.19±59.53	117.58±61.26	0.670
	HDL-cholesterol (mg dL^{-1})	44.12±14.62	44.22±15.70	0.950
	LDL-cholesterol (mg dL^{-1})	89.12±34.75	92.89±36.06	0.278

Values are expressed as the Mean±standard deviation (SD). p-value: Significant difference between the baseline and after 12 weeks of intervention (baseline vs. week 12)

improved (p<0.001) in cancer patients who consumed PCNF via NG tube feeding for 12 weeks. Nevertheless, the other anthropometric parameters were also improved but not significant as like body weight or BMI.

Impact of PCNF on various biochemical parameters: The changes in various biochemical parameters like glycemic indices and lipid profile in various cancer subjects was shown in Table 5. Patients Received Nutritional Formula (PCNF) for 12 weeks did not show any significant changes in the levels of glycemic indices like fasting blood glucose, insulin and glycosylated hemoglobin (HbA1c). Likewise, the levels of lipid profile including TC, TG, HDL-c and LDL-c were also not considerably altered after 12 weeks of administration with PCNF as compared to baseline. Overall, all the biochemical parameter levels were under normal range and thus indicating that PCNF had no direct impact on those indices. Thus, PCNF supplementation showed improved nutritional status in cancer patients by improving various anthropometric and biochemical parameters.

Impact of PCNF on various renal, hepatic and cardiac markers and nutritional index: Renal, hepatic and cardiac markers (biochemical markers) and nutritional index in cancer subjects was shown in Table 6. Those subjects who were administered with PCNF for 12 weeks did not show any notable changes in the levels of any renal markers (BUN, Cr, urea), hepatic markers (GOT, GPT) and cardiac markers (LDH, CPK). Whereas, the protein nutritional assessment index like total protein (6.54 vs. 6.88), pre-albumin (19.23 vs. 22.35) and transferrin (212.72 vs. 238.51) were significantly improved (p<0.001) in the cancer patient, who received PCNF as compared to baseline (0 weeks). However, the levels of other minerals (nutritional index) were not considerably changed, upon supplementation with PCNF through NG tube feeding. Nonetheless, all the nutritional index values were moderately improved in PCNF consumed cancer patients.

Table 6: Renal, hepatic and cardiac markers (biochemical markers) and nutritional index in cancer subjects

	Parameters	Baseline	Week 12	p-value
Renal markers	BUN (mg dL^{-1})	15.01±5.97	17.10±7.59	0.021
	Creatinine (mg dL^{-1})	0.80±0.26	0.83±0.32	0.363
	Urea (mg dL^{-1})	5.53±1.49	5.55±1.62	0.920
Hepatic markers	GOT (IU L^{-1})	23.35±11.10	25.45±11.41	0.098
	GPT (IU L^{-1})	17.23±7.93	19.26±11.31	0.182
	Total bilirubin (mg dL^{-1})	0.53±0.38	0.49±0.33	0.450
Cardiac marker	LDH (U L^{-1})	177.42±71.14	188.06±65.01	0.506
	CPK (U L^{-1})	70.97±64.25	67.97±93.52	0.878
Protein assessment	Albumin (g dL^{-1})	3.31±0.64	3.47±0.49	0.116
	Total protein (g dL^{-1})	6.54±0.78	6.88±0.78	0.007
	Prealbumin (g dL^{-1})	19.23±6.78	22.35±7.28	0.007
	Transferrin (mg dL^{-1})	212.72±64.94	238.51±50.66	0.009
Nutrition index (mineral)	Fe (µg dL^{-1})	53.65±28.04	59.61±30.60	0.126
	Ca (mg dL^{-1})	8.93±0.68	9.14±0.84	0.219
	Cl (mmol L^{-1})	100.26±4.98	101.65±4.39	0.051
	K (mmol L^{-1})	4.28±0.60	4.35±0.57	0.574
	P (mg dL^{-1})	3.59±0.69	3.45±0.83	0.401
	Mg (mg dL^{-1})	2.08±0.28	2.11±0.34	0.525

Values are expressed as the Mean±standard deviation (SD). p-value: Significant difference between the baseline and after 12 weeks of intervention (baseline vs. week 12). BUN: Blood urea nitrogen, CPK: Creatine phosphokinase, LDH: Lactic acid dehydrogenase, GOT: Glutamic oxaloacetic acid transaminase, GPT: Glutamic pyruvic acid transaminase

DISCUSSION

To the best of our knowledge, this is the first multi-centered clinical trial conducted with a balanced nutritional formula enriched with nutraceuticals (ω-3 FA), MCT, BCAA, dietary fiber (novel combinational formula) along with other various essential nutrients (vitamins, minerals) in various cancer patients. The specialty of this nutritional formula is the usage of plant source ω-3 FA (linseed/flaxseed), with increased protein, carbohydrate content and low fat (vegan source). Moreover, for the present study, author included only cancer patients under NG feeding (due to some GI-related discomfort) and hence the nutrient intake can be well controlled. The major advantage of NG feeding is to ensure that the patient will get sufficient nutrition (daily calorie requirement) to support chemotherapy as well as to lower adverse effects even though the subject has GI-related discomfort[1].

Initially, the author would like to check the calorie intake and macronutrient consumption rates in cancer patients as malnutrition (related conditions-cachexia) is common for older hospitalized cancer patients. The average value of calorie intake (energy), as well as the protein and carbohydrate consumption rate, were significantly increased after12 weeks of intervention with PCNF via NG tube feeding. The above result showed that this nutritional formula (PCNF) could improve energy levels by improving carbohydrate and protein contents and thus making cancer patients stronger and healthier. Then, the various anthropometric parameters were evaluated to confirm the effect of PCNF on body composition. The mean body weight and BMI levels were significantly increased in cancer patients, after 12 weeks of PCNF administration. Generally, the nutritional status or treatment efficiency of cancer patients is evaluated by checking albumin, pre-albumin, total protein and transferrin[9]. Even in this study, the nutritional index was checked by evaluating the levels of total protein, pre-albumin and transferrin. The levels of total protein, pre-albumin and transferrin were considerably improved upon supplementation with PCNF. Moreover, we conduct the handgrip test (using grip strength dynamometer) to check the overall health status, as it has a strong relation with body weight and muscle strength/anti-cachexia[10]. In study, the values of handgrip were substantially improved in cancer patients supplemented with PCNF for 12 weeks as compared to baseline (21.25 vs. 24.08). Thus, indicating that PCNF improves overall nutritional status and thus improved patient physical strength (muscle strength) by maintaining normal body weight (calorie intake) and BMI. As mentioned previously that PCNF is enriched with ω-3 FA, fibers, MTC, BCAA and micro-nutrients which may holistically (directly or indirectly) contribute to the improvement of the overall health status of cancer patients by lowering protein/ muscle wasting through increasing body composition like body weight, lean body mass.

Omega 3 fatty acids (ω-3 FA) like eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are reported to improve chemotherapy tolerability owing to its various therapeutic properties like antioxidant, anti-inflammatory,

immunomodulatory, anti-cancer (anti-metastasis and anti-proliferative) activities and thus improve overall health status during or after chemotherapy/radiotherapy and surgery by lowering anorexia, cachexia, weight loss[11,12]. Similarly, several randomized trials show that consumption of fish oil rich in ω-3 FA (EPA/DHA) could considerably increase the appetite and thereby improving body weight, lean body mass and thereby improving overall health status as well as lower neuropathy (adverse effects) caused during chemotherapy[13,14]. Another study, conducted by Smith and his co-workers[15] indicated that ω-3 FA (EPA) did not show a direct impact on protein synthesis, but when EPA combined with protein (amino acids) can considerably improve protein synthesis. Even in our trial, our PCNF has a ω-3 FA rich in proteins (23%-BCAA) along with various minerals and thus improves protein synthesis (lower muscle loss) and thus improves overall health and body strength. Moreover, Mantovani and his colleagues[16], proved that consumption of ω-3 FA along with various micronutrients can markedly improve body weight, BMI and overall body strength (lower cachexia) and health status.

Furthermore, PCNF also contain high dietary soluble fibers like fructo-oligosaccharides (FOS), which are reported to help digestion and lower GI-related disorders and can significantly help those cancer patients to recover faster and improve digestion and lower GI-related complications[17]. Since, in this trial, most of the hospitalized cancer patients are old cancer patients (in bed) with GI-related complication this PCNF formula will significantly help in ease digestion and GI-related complications as well as lower fat deposition and improve overall health status via positively regulating altering microbiota. In addition, PCNF contains MCT, which also reported to improve lipid digestion and lower muscle breakdown in GI disorder patients[18]. Also, consumption of MCT rich diet can significantly improve lipid oxidation (thermogenesis) and thus reduce excess fat deposition (indirectly lower inflammatory response) and help in maintaining body composition[19]. Also, Otto and his co-workers[20], concluded that supplementation with a diet rich in ω-3 FA and MCT can delay the growth and development of gastric cancer in mice model. Therefore, the above evidence confirmed that MCT (present on PCNF) could display supportive effect along with other nutrients and thereby improve overall health status in cancer patients.

Also, the presence of other micronutrients (vitamins and minerals) and amino acids (glutamine, arginine and taurine) are reported to enhance protein synthesis and thereby lower muscle protein depletion (tissue repair) and favor cancer treatment[21]. Moreover, glutamine and arginine (immuno-nutrients) are reported to modulate immune system through improving lymphocytes and macrophages (immune cells) production/function via altering inflammatory signaling pathway[22,23]. Especially, the vitamins (A, B, C, D, E, K) and trace elements like selenium, chromium, zinc, copper, iron, potassium and chloride are reported to lower metabolic, oxidative stress and inflammatory response and thereby improving overall health status as well as enhance chemotherapy tolerability[24,25]. The PCNF consumed subjects showed mild improvement in the levels of various nutritional index like vitamins and minerals (but no significant difference). Thus, indicating that presence of various micronutrients might aid the effect of PCNF in cancer patients to maintain overall health status. This trial was associated with few limitations, as we not used control arm for comparison. Since we included only hospitalized elderly cancer patients, they are not recommended to take control nutritional formula. Besides, we have not evaluated the inflammatory and oxidative stress markers to check the in-depth impact of PCNF in cancer patients, which will be rectified in our future studies. This study lacks specificity and sensitivity as we have not focused on a particular cancer type and specific stage.

CONCLUSION

Overall, the supplementation of PCNF (nutritional support) for 12 weeks in various cancer patients can significantly improve health status by improving nutritional status (lower the risk of malnutrition and weight loss) with improved body weight, BMI, protein and pre-albumin without any adverse effects. However, this nutritional support alone is not sufficient to curb the cancer conditions and cancer patients must follow the proper therapeutic regimen recommended by oncologists along with a modified lifestyle (healthy balanced diet) would significantly help to recover from the various deleterious effect of cancer. A large scale and longer trials are needed to support our outcome.

SIGNIFICANCE STATEMENT

This study highlights the importance of novel nutritional formula (PCNF) and how it acts as a supporting tool (nutritional therapy) for improving the overall health status in cancer patients by lowering the risk of malnutrition (weight loss) as well as for speedy recovery. Hence, this PCNF

nutritional formula would be developed as a special formula for NG feeding with GI problems in various cancer patients to increase chemotherapy tolerability (with less adverse effects) and thus improve overall health status.

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