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A PUBLIC HEALTH NUTRITION INTERVENTION TO DELAY THE PROGRESSION OF CACHEXIA TO REFRACTORY CACHEXIA IN INDIAN FEMALE CANCER PATIENTS: A CONCEPTUAL FRAMEWORK

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ABSTRACT

Purpose: the main objective of this article is to review existing nutritional guidelines for cancer cachexia patients and to propose a conceptual framework targeted to improve their nutritional status. This presented framework will depict a public health nutrition intervention to delay the progression of cachexia to refractory cachexia.

Methods: this conceptual framework proposes to recruit 72 female cancer cachexia patients. The implementation phase will be piloted through random distribution of sample patients into

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control group ($n=36$) and intervention group ($n=36$). The latter group will consume a nutrient strengthening natural food ingredient formula (IAtta) which will be provided daily for six months while the control group will receive only dietary counselling. Patients in both groups will be encouraged to adopt the physical activity recommendations. Nutritional investigations (FFQ, 24-hr dietary recall, PG-SGA questionnaire), anthropometric measurements (BMI, MUAC and SFT), physical activity level using Indian Migration Study-Physical Activity Questionnaire (IMS-PAQ), quality of life using EORTC QLQ-30 questionnaire and biochemical investigations (haemoglobin, serum C-reactive protein and serum albumin) will be determined at zero, three and six month of intervention (pilot and scale-up stages).

Findings: it is hypothesised that such nutrient-strengthened IAtta formula shall help improve outcomes in cancer patients of intervention group, with respect to quality of life, weight loss prevention and effective response to medical treatment.

Value: IAtta formula could help to combat malnutrition among cancer cachexia patients and improve their nutritional status. IAtta could form a significant part of the palliative care and nutritional guidelines in health services of the developing world.

Keywords: Public health nutrition intervention; cancer cachexia; Tailored Food Recipes (TFR) and quality of life.

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1 INTRODUCTION

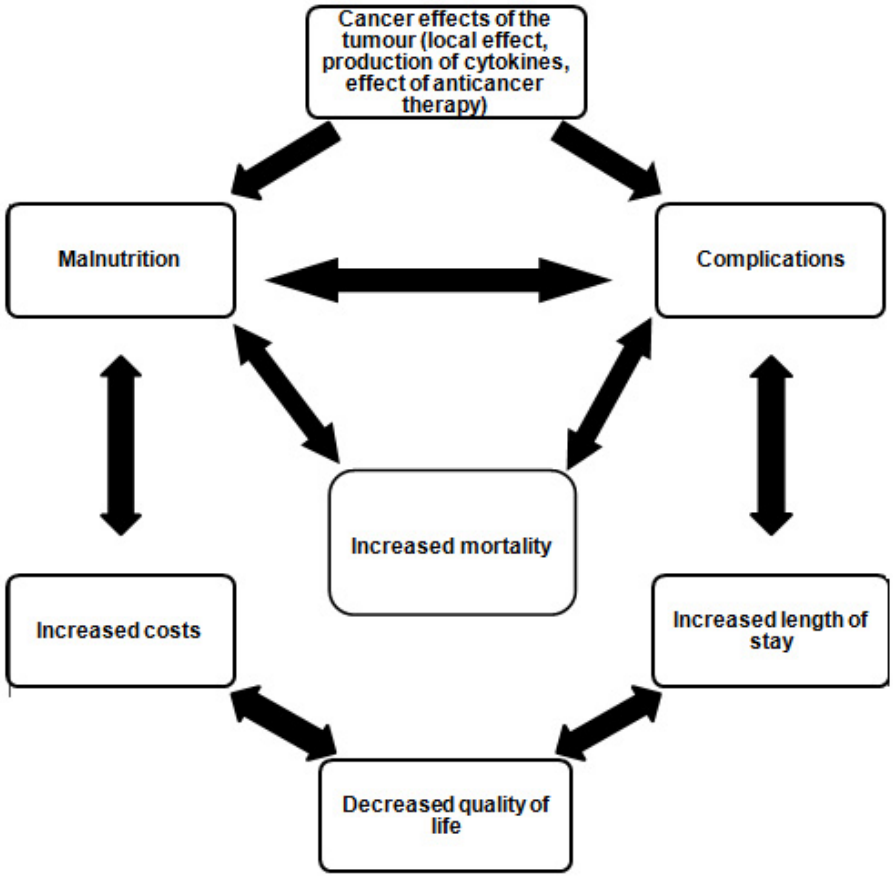
Palliative care is necessary for patients suffering from life threatening incurable diseases such as AIDS, cancer, end stage renal disease and end stage chronic illnesses. In the Indian health care system, palliative care is a developing area and is not well represented in the health sector. Numbers of palliative care centres are increasing and assistance from trained hospital staff is available, but there is still a vast gap in accessibility which requires attention (Maroju et al., 2011, p.134).

1.1 Prevalence of cancer

International Agency for Research on Cancer (GLOBOCAN project, 2012) reported approximately 14.1 million new cancer cases and 8.2 million cancer deaths worldwide. Out of these there were 1015,000 cancer cases and 683,000 cancer deaths in India (Ferlay et al., 2012). According to the National Cancer Care programme in India, at any given point of time the prevalence of cancer is about 2.5 million patients (Government of India Ministry of Health and Family Welfare, n.d.). The World Health Organisation estimates one million new cancer patients yearly in India with approximately 750,000 of them requiring palliative care (Maroju et al., 2011, p.134). The National Cancer Registry revealed that the Delhi female population had the highest cancer incidence rate (113.9/100,000) when adjusted for minimum age (Indian Council of Medical Research, n.d.).

1.2 Malnutrition, cancer and clinical outcome

As cancer develops, a patients' nutritional status is progressively affected. The multiple metabolic changes and nutritional depletion may impact body composition, functional status, psychological status and response to cancer treatment (Doyle and Shaw, 2011, p.11). Inadequate food intake due to anorexia, depression, nutrient malabsorption and metabolism, cancer therapy, etc., leads to malnutrition in cancer patients. Patients losing weight have higher post-operative complications, lengthier hospital stays, reduced response to cancer therapy and low quality of life (Bruera, 1997; Henry, 2011, p.46) (Figure 1). Neglect of malnourished patients and inappropriate nutritional care may lead to a cachectic state (Braun and Marks, 2010). The prevalence of malnutrition is upto 81% among palliative care



Source: Henry (2011, p.65).

Figure 1 Flowchart showing mutual relationships between malnutrition, cancer and clinical outcome

cancer patients (Kumar et al., 2010; Paccagnella et al., 2011).

1.3 Cancer cachexia: prevalence and stages

The word Cachexia is derived from the Greek words kakos meaning bad and hexis meaning state of being or condition, and is a common feature of severe diseases such as acquired immunodeficiency syndrome, cancer and congestive heart failure (Argiles et al., 2004). Cancer cachexia has been documented as a recurrent problem and a major reason of morbidity and mortality amongst cancer patients, accounting for two million deaths yearly worldwide (Muscaritoli et al., 2006; Rubin, 2003). Some tumour sites are widely associated with cachexia (like pancreatic, gastric, head and neck) but the same tumour site may exhibit cachexia of varying degree or be absent in different patients. Nearly 50% of cancer patients progress to cachexic stage (Tisdale, 2009). Therefore cancer cachexia can be described as

> "a multifactorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. Its pathophysiology is characterised by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism" (Fearon et al., 2011, p.490).

There are three stages of cancer cachexia: pre-cachexia, cachexia and refractory cachexia. In the pre-cachexia stage patients experience less than 5% pre-treatment weight loss whilstonce patients enter refractory cachexia stage the survival period is approximately three months only (Fearon et al., 2011).

1.4 Nutritional recommendations for cancer patients

Research has shown that weight maintenance can be attained at 34 kcal/kg body weight/d (Lundholm et al., 2004), another intervention study has documented that weight stabilisation can be achieved with an energy intake of 28.7 kcal/kg body weight/d and protein intake of 1.4 g/kg body weight/d (Bauer and Capra, 2005). Increased calorie intake by Oral Nutritional Supplements (ONS) or enteral feeds in patients undergoing oncological treatment has resulted in decreased incidence of complications (Bozzetti and Mori, 2009).

Nutritional guidelines and recommendation for cancer and malnourished patients have been drafted by the European Society for Parenteral and Enteral Nutrition (ESPEN) (Arends et al., 2006; Bozzetti et al., 2009); National Institute for Health and Care Excellence (NICE) (National Collaborating Centre for Acute Care, 2006); American Society for Parenteral and Enteral Nutrition (ASPEN) Clinical guidelines in adult anticancer treatment (August et al., 2009); European Palliative Care Research Collaborative (EPCRC) (Radbruch et al., 2010) and World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) guidelines (Choi et al., 2013). Currently there are no nutritional recommendations for Indian cancer cachexia patients. The above-mentioned guidelines are suitable for patients on enteral and parenteral feeds. There are no specific guidelines for free living cachexia patients who can eat normal food as well as whose gastrointestinal tract functioning is not compromised.

Interventions with energy and protein dense ONS drinks enriched with omega-3 fatty acids and micro nutrients amongst advanced cancer patients have resulted in weight gain, increased lean body mass and better quality of life as illustrated in Table 1. Furthermore, nutritional supplements containing protein, fat, carbohydrates, vitamins and minerals can provide a convenient and practical way of delivering adequate nutritional support to cancer patients.

1.5 Physical activity amongst cancer patients

Previously cancer patients on palliative care were advised rest by recommending physical inactivity to reduce energy expenditure (Oechsle et al., 2011). According to the Clinical Practice Guidelines on Cancer Cachexia in Advanced Cancer Patients by the EPCRC 2010, physical activity is strongly recommended in the management of cancer related cachexia. It may help to boost the immune function and suppress inflammatory responses (Ardies, 2002). This could also aid in slowing down decreased physical function and improve quality of life (Radbruch et al., 2010). Lowe et al. (2012) reported a positive association between physical activity and quality of life among 50 advanced cancer patients attending an outpatient palliative care clinic in Canada. Palliative chemotherapy patients have also demonstrated better quality of life, with physical activity levels of 9 hr or more per week (Oechsle et al., 2011). A systematic review by Cramp and Byron-Daniel (2012) has reported physical activity in the form of walking and cycling could help reduce cancer-related fatigue in patients undergoing treatment for cancer.

The main aim of this article is to review existing literature on nutritional guidelines for cancer patients and propose a conceptual framework targeted to improve their palliative care outcomes. This presented framework will depict a public health nutrition intervention to delay the progression of cachexia to refractory cachexia. The basis of this nutritional intervention is to develop a Tailored Food Recipe (TFR). This TFR consists of a blend of locally available, affordable, culturally acceptable and commonly consumed foods. In the TFR, foods will be mixed appropriately to enhance the 'nutrient strengths' of each ingredient of the recipe in order to improve its nutritive value without fortification" (Amlogu et al., 2012; Amuna et al., 2004). 'IAtta' is the developed TFR for this proposed intervention, it includes roasted horse gram, roasted barley flour, roasted soybean flour, amaranth spinosus and flax seeds in dry powder form. It is envisaged that this formula will enhance the nutritional status (the response to medical therapy) of cancer cachexia patients and perhaps delay the onset of refractory cachexia.

2 METHODS

The study will be undertaken at a health setting for cancer care in India. Adult female advanced cancer patients will be recruited for the study. Patients with weight loss of more than 5% from pretreatment weight or body mass index less

Table 1 Literature review of ONS intervention studies in cancer patients during the last five years (2007–2013)

Author	*Intervention*	*Variables*	*Outcome*	*Limitations/Comments*
Yeh et al. (2013)	*SG*: Ethanwell/ Ethanzyme-ONS enriched with omega-3 fatty acids, micronutrients and probiotics. Group 1 with BMI<19 kg/m^2 (n=12). Group 3 with BMI<19 kg/m^2 (n=18). *CG*: oral nutritional formula Isocal Nestle. Group 2 with BMI>19 kg/m^2 (n=20). Group 4 with BMI>19 kg/m^2 (n=18). Intervention for three months	Body weight, BMI, serum albumin and prealbumin	SG group with BMI<19 kg/m^2 significantly improved body weight and maintained higher serum albumin and pre albumin compared to CG (P<0.05).	The nutritional intervention is a synthetic ONS and the sample size for participating malnourished patients was small (n=30) in order to validate results. *In our proposed study, nutritional formula is made up of 100% natural ingredients and therefore bioavailability will be higher than the synthetic nutritional supplements. Also according to the protocol, 72 malnourished patients will be recruited therefore a significant difference in the research variables among randomised groups is expected.
Meij van der et al. (2012) and Meij van der et al. (2010)	*SG*: Prosure ONS energy and protein dense with EPA and DHA (n=20) *CG*: Ensure without EPA and DHA Intervention five weeks (n=20) Period of intervention five weeks	BMI, FFM, MUAC, C Reactive Protein, Serum albumin, leucocytes, serum TNF, serum IL-6. EORTC-QLQC-30 and physical activity.	SG had better weight and FFM maintenance than CG (P<0.05). SG had a greater MUAC than CG but not significant. C-reactive protein, serum albumin, serum TNF, serum IL-6 levels were not different in both the group during intervention. SG tended to have higher level of physical activity after five weeks (P=0.05) compared to the CG. Quality of life parameters were noted to be significantly higher (P=0.04) in SG compared to CG	The study participants were a mixture of BMI<18 kg/m^2 and>18 kg/m^2 , therefore the results may not hold true for cachexia patients (as their BMI<20 kg/m^2)
Baldwin et al. (2011)	*G1*: no intervention (n=96). *G2*: dietary advice (n=90) *G3*: nutritional supplement Scandi shake or Calshake (n=86) *G4*: dietary advice plus supplement (n=86) Intervention period One Year	Weight, Hand grip strength, EORTC C30 for QoL.	Significant weight gain (P=0.002) from baseline to 12 weeks, independent of nutritional intervention and group allocated. QoL & Hand grip strength no significant difference between group.	The nutritional supplement contains synthetic processed ingredients. Though the sample size was large (n=358), compliance to the nutritional supplement among study participants was low. Therefore, the intervention failed to show a significant increase in weight among the intervention group. *Compliance in the proposed study should be high as patients visit the clinic every fortnight to collect pain management drugs and hence the study outcomes for intervention group will be significantly different from the control group.

Table 1 *Continued...*

Table 1 Literature review of ONS intervention studies in cancer patients during the last five years (2007–2013)

Author	*Intervention*	*Variables*	*Outcome*	*Limitations/Comments*
Weed et al. (2011)	Prosure – EPA-containing ONS Intervention for average 11 ± 0.85 days. (n = 38)	Body weight, lean body mass.	At the time of discharge patient showed significant ($P<0.01$) increase in lean body mass.	The nutritional supplement contains synthetic processed ingredients. The study was an open label, single arm and non-randomised. The sample size was small ($n=38$). *The proposed study will randomise patients into two groups that is, one receiving only dietary counselling while the other group will receive nutritional supplement. Therefore the results will have a higher validity
Trabal et al. (2010)	*SG*: Prosure ONS energy and protein dense with EPA and DHA and dietary counselling ($n=5$). *CG*: Dietary counselling ($n=6$). Period of intervention 12 weeks	Weight, serum protein, QoL by EORTC QLQ-C30	SG reported statistically significant ($P=0.045$) weight gain compared to CG. No significant change in plasma protein and QoL parameters.	The study patients' baseline BMI was above 20 kg/m^2, therefore the results may not hold true in cachexia patients. The sample size of the study is small ($n=11$) to validate the result. Also the intervention period was only 12 weeks.
Read et al. (2007)	Nutritional counselling and EPA enriched ONS Intervention for nine weeks. 23 patients at start and only 15 patients at the end of intervention	Weight, Lean body mass, C-Reactive Protein, IL-6, PG-SGA score, SGA score, QoL, dietary intake.	Significant ($P=0.03$) 2.5 kg weight gain at three weeks, lean body mass and QoL levels were maintained. Significant correlation between plasma IL-6 ($P=0.03$) and IL-10 ($P=0.003$) concentrations and survival. Also between IL-12 and toxicity ($P=0.023$).	The nutritional supplement contains synthetic processed ingredients. The mean BMI of the recruited patients was 28 ± 6.4 kg/m^2 therefore these results may not hold true in cancer cachexia patients (as their BMI<20 kg/m^2)

Note: (SG=Supplementation group, CG=Control Group, EPA=Eicosapentaenoic acid, DHA=Docosahexaenoic acid, BMI: Body mass index, MUAC=Mid-upper arm circumference, SFT=Skin fold thickness, FFM=Fat free mass, TNF=Tumour necrosis factor, IL-6=Interleukin-6, EORTC-QLQC30=European Organisation for Research and Treatment of Cancer-Quality of Life, QoL=Quality of Life, PG-SGA: Patient Generated –Subjective Global Assessment, SGA=Subjective Global Assessment).

than 20 Kg/m^2 along with haemoglobin level less than 12 g/dl and energy intake of less than 1500 kcal/d will be considered eligible for participation. Patients with gastrointestinal tract disorders and with life expectancy of less than three months will be excluded from participation. A patient information sheet will be distributed amongst eligible patients, the information will also be explained to them verbally in person and then consent will be asked. This study is approved by University of Westminster Ethics Committee, London, UK (App. No. 12_13_11).

2.1 Study design

It is envisaged that the study would recruit 72 eligible patients attending a health centre for treatment at the main hospital. Patients will be randomly distributed into intervention group and control group equally. Intervention group patients ($n=36$) will receive nutritional and physical activity counselling along with optimised TFR for everyday consumption. Control group patients ($n=36$) will receive only nutritional and physical activity counselling. Patients will collect packs for

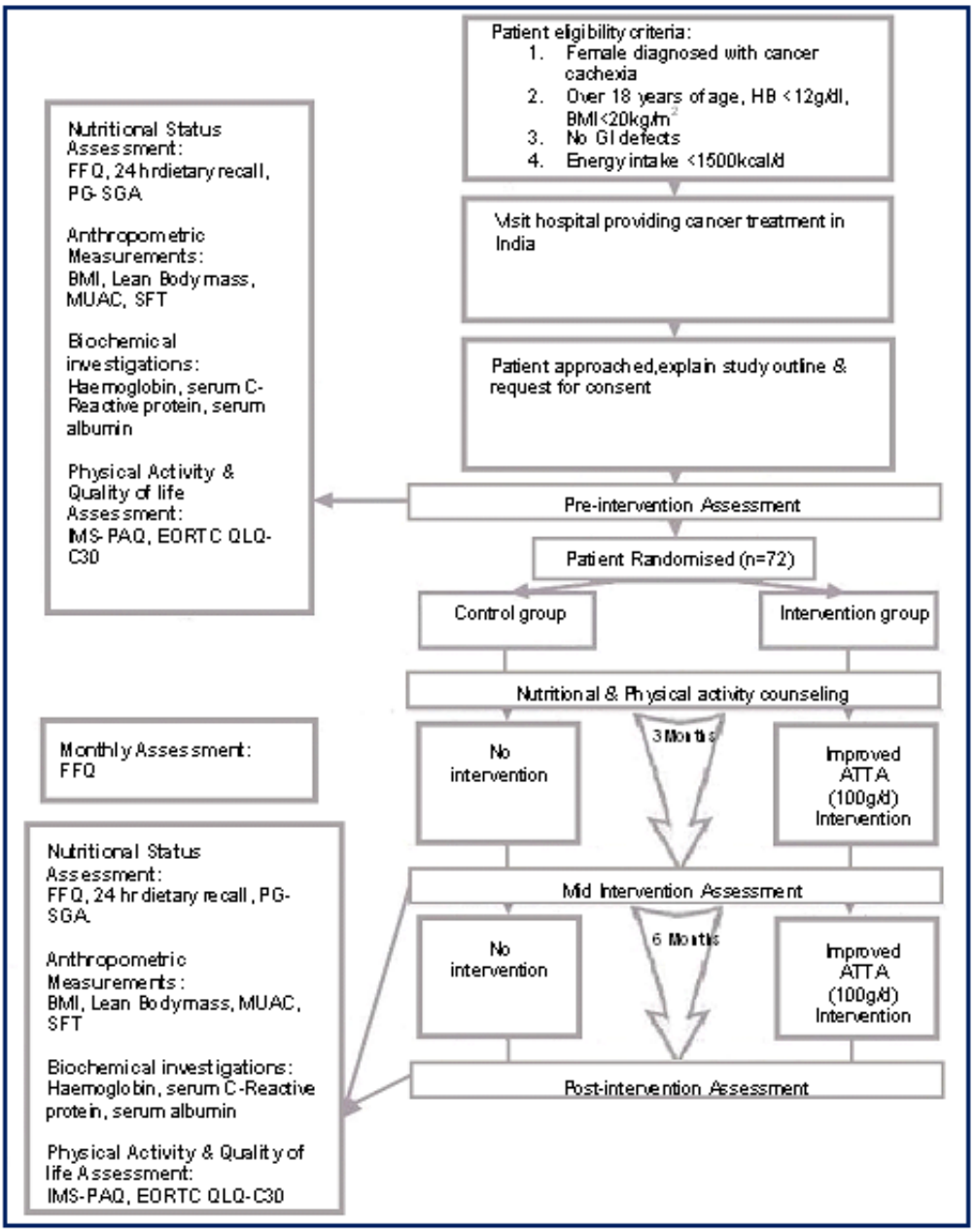


Figure 2 Design of Pilot Study (this would be replicated for the scale-up intervention)

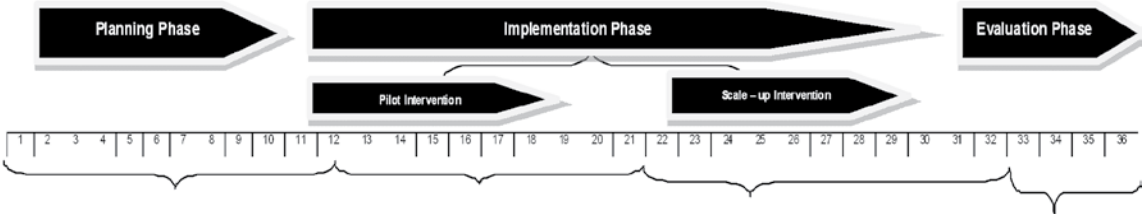


Figure 3 Conceptual framework of the study

daily consumption on their routine visit to the hospital. Nutritional, biochemical, quality of life and anthropometric estimation will be assessed at baseline, after three and six months of intervention for all patients (Figure 2). The sample size for the pilot study was calculated considering the baseline weight in the two groups as similar. After six months of intervention we expect a difference of approximately 10 Kgs of weight between the intervention group and control group. The conceptual framework of the study is depicted as Figure 3. On completion and evaluation of this pilot study, the sample size for the large-scale intervention study will be planned and commenced consequently.

2.2 Research variables and data analysis

The nutritional investigations will include Food Frequency Questionnaire (FFQ), 24-hr dietary recall, PG-SGA. Indian Migration Study-Physical Activity Questionnaire (IMS-PAQ) will help to assess the physical activity level. Quality of life assessment will involve using EORTC-QLQ-C30 questionnaire. Anthropometric measurements taken will be weight, height, BMI, MUAC, four site SFT measurement (i.e. triceps, biceps, sub scapular and supra iliac). Harpenden Skinfold Caliper will be used to measure SFT and lean body mass will be assessed by Tanita segmental composition scale. Biochemical investigations would determine the haemoglobin (Hb) level, serum C-reactive protein and serum albumin.

All the above-mentioned variables will be assessed at zero, three and six months of intervention for all patients in the pilot as well as the large scale intervention study.

Data collected from the questionnaires will be collated and analysed statistically using SPSS (version 20.0) software. Statistical analyses will be carried out dependent on the nature of the distribution (normal or otherwise) of the data obtained and suitable parametric/non-parametric tests will be subsequently conducted. These tests may include analysis of variance, student *t*-test, Mann-Whitney *U*-test and two-by-two factorial analysis. The Friedman Test will be carried out in order to compare body weight of patients at various time intervals. Statistical analyses will determine whether the variation in body weight of those patients receiving dietary intervention was significantly different ($p \leqslant 0.05$) to the body weight of control group patients.

3 EXPECTED RESULTS AND CONCLUSION

The results of this study will help derive nutritional requirements and a better understanding of the dietary pattern of Indian free-living cancer cachexia patients. Consumption of nutrient-strengthened IAtta formula daily shall help improve outcomes in cancer patients, with respect to quality of life, weight loss prevention and effective response to medical treatment. IAtta could form a significant part of the palliative care and nutritional guidelines in health services of the developing world.

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BIOGRAPHICAL NOTES

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Dr. Jane Naufahu is a Graduated from the University of Westminster with a first class Honours degree in Nutrition and Exercise Science and thereafter undertook a PhD which focused on the role of circulating Melanin Concentrating Hormone (MCH) in humans. She teaches on a range of nutrition, performance and physiology related modules at Undergraduate and Postgraduate level as well as providing Nutritional and Fitness Consultancy services to paying clients for the University's Health Screening Service. Her research interests centre on the roles of nutrition and exercise in metabolic disease. She joined the Department of Human and Health Sciences at the University of Westminster as a Lecturer in Human Nutrition and Performance in 2010 and is a Fellow of the Higher Education Academy.

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