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Title: Nutrition support following the American Dietetic Association (ADA) Medical Nutrition Therapy protocol for radiation oncology patients improves dietary intake compared with standard practice

Abstract

Background A randomized controlled trial previously conducted in radiation oncology patients demonstrated that nutrition intervention (NI) had a beneficial impact on body weight, nutritional status and quality of life compared with standard practice (SP) but did not report on dietary intake data.

Objective To determine the impact of NI compared with SP on dietary intake in outpatients receiving radiotherapy.

Design Prospective, randomized, controlled trial.

Subjects Sixty consecutive radiation oncology outpatients (51M;9F; age 61.9 yr \pm 14).

Setting Australian private radiotherapy facility.

Intervention Patients were randomized to receive either NI (n=29)(nutrition counselling following the ADA Medical Nutrition Therapy (MNT) protocol for radiation oncology) or SP (general nutrition talk and booklet)(n=31).

Main outcome measure Dietary intake (protein, kilocalorie, fiber) assessed at baseline, 4, 8 and 12 weeks after starting radiotherapy.

Statistical analyses Repeated measures ANOVA performed on an intention to treat basis.

Results The NI group had a higher mean total kilocalorie (P=0.029) and protein intake (P<0.001) compared with the SP group. Mean intake per kilogram of body weight for the NI group ranged from 28-31 kcal/kg/day compared with 25-29 kcal/kg/day for the SP group (P=0.022). The NI group had a higher mean protein

intake (1.1-1.3g/kg/day) compared with the SP group (1.0-1.1g/kg/day) (P=0.001).

While the changes in fiber intake between the groups were not significant there was a trend in the anticipated direction (P=0.083).

Conclusions Intensive NI following the ADA MNT protocol results in improved dietary intake compared with SP and appears to beneficially impact on nutrition-related outcomes previously observed in oncology outpatients receiving radiotherapy.

Application The ADA MNT protocol for radiation oncology is a useful guide to the level of nutrition support required.

Title: Nutrition support following the American Dietetic Association (ADA) Medical Nutrition Therapy protocol for radiation oncology patients improves dietary intake compared with standard practice

Introduction

In the current health-care climate there is a need to justify resources and demonstrate the importance of effective nutrition services. Outcomes research, the gathering of information on the effectiveness of standard practice, has emerged as an essential process to determine the value of interventions and services rendered through the health-care system (1-3). Research should be action-orientated and evaluate the outcome of current clinical practice, nutrition interventions or behavior change strategies so that the elements of practice which provide positive outcomes can be determined and those practices that are ineffective can be phased out or discarded (4).

With this in mind, the American Dietetic Association (ADA) and Morrison Health Care worked together to develop protocols, Medical Nutrition Therapy (MNT) across the continuum of care which aims to improve patient outcomes and decrease health-care costs. MNT protocols were developed during a consultative process with experts and incorporate professional knowledge and available research (5). These protocols clearly define the level, content and frequency of nutrition care that is appropriate for particular disease states in typical settings (6). They have the advantage of providing a standard protocol which defines the level and frequency of nutritional care but also allows for individual tailoring to meet specific requirements of patients. There are several MNT protocols for various disease states/conditions including nutritional guidelines for radiation oncology.

It has been suggested that adequate nutrition support during radiotherapy can decrease the impact of side effects, minimize weight loss, improve quality of life (QoL) and help patients to recover from radiotherapy more quickly (7). Although professional experience, pilot and descriptive studies agree with these suggestions, there is little evidence based on clinical research to support them. It is well known that malnutrition occurs frequently in patients with cancer of the head and neck (8) or gastrointestinal area (9) and patients receiving radiotherapy are at further risk due to possible side effects such as mucositis, taste changes, dysphagia, nausea and diarrhoea (10). Malnutrition can lead to negative consequences such as increased risk of infections, treatment toxicity and health-care costs, and decreased response to treatment, QoL and life expectancy (11-13). However, few studies have demonstrated the benefits of dietary counseling following a standard protocol in patients receiving radiotherapy.

A randomized, controlled trial investigating the impact of nutrition intervention (NI) following the ADA MNT radiation oncology protocol versus standard practice (SP)(general nutrition talk and booklet), on nutrition-related outcomes in outpatients receiving radiotherapy to the gastrointestinal or head and neck area was conducted previously by our research group (14). Patients receiving NI experienced significantly less deterioration in weight ($P<0.001$), nutritional status ($P=0.020$) and global QoL ($P=0.009$) compared with those receiving SP during the 12-week trial. Clinically significant differences in fat-free mass were observed between the groups ($P=0.195$). We concluded that NI appeared beneficial in terms of minimizing deterioration in nutrition-related outcomes and that weight-maintenance may be a more appropriate goal of NI in this population (14) The current paper forms part of the same study and reports dietary intake data. The aim of this study was to determine the impact of NI

following the ADA MNT radiation oncology protocol compared with SP on dietary intake in ambulatory oncology patients receiving radiotherapy to the gastrointestinal or head and neck area.

Methods and subjects

This trial was approved by the Queensland University of Technology Human Research Ethics Committee (reference number: 2039H) and The Wesley Hospital Multidisciplinary Ethics committee (reference number: 98/42) and informed consent was obtained from all participants. A prospective, randomized, controlled trial was conducted in outpatients who received at least 20 fractions of radiotherapy to the gastrointestinal or head and neck area at a private Australian radiotherapy facility during a 12-month period. Full methods of the randomized, controlled trial are described elsewhere (14).

Nutrition intervention (NI)

The NI group received regular and intensive nutrition counseling by a dietitian using a standard protocol, the ADA MNT protocol for radiation oncology (5). The MNT protocol provides general guidelines covering the time and frequency of dietetic consultations, the type of data to be collected and NI strategies and also allows individualization of the NI to meet the specific goals of patients. Dietetic consultations were conducted within four days of starting radiotherapy, weekly for six weeks and then every two weeks for the remaining six weeks. Telephone reviews were conducted between the face-to-face nutrition counseling sessions. Nutrition resources such as quick and easy snack ideas and high kilocalorie and protein exchange lists were provided when patients were unable to meet dietary

recommendations (i.e. usually after the first few weeks of radiotherapy when side effects were experienced.) The ADA Oncology Nutrition Practice group educational handouts to help minimize treatment-related side effects (15) were used when the professional field notes recorded that someone had experienced significant side effects that negatively impacted on eating. Individually tailored sample meal plans and recipe suggestions were also provided when required during the face-to-face interviews. High kilocalorie (1kcal/cc) and protein oral liquid nutrition supplements were provided free of charge for up to three months if required. Depending on requirements and current intake, patients were typically recommended to consume two glasses of supplement per day (total of 480ml). A one or two weeks supply of supplement was provided during the counselling session by the dietitian.

Standard practice (SP)

The SP group received the standard practice of the radiotherapy centre (i.e. a general nutrition talk by the nurses as part of the planning stages for radiotherapy, a nutrition and cancer booklet (16) and high kilocalorie and protein supplement samples.) Patients had the option of seeing an outpatient dietitian and received the standard practice of that dietitian which was a maximum of two visits. The NI group received tailored and more intensive and ongoing nutrition support when compared with the SP group who received general advice.

Data collection

Dietary intake

Dietary intake was assessed using a modification of the Burke diet history technique (17) and measured at baseline, 4, 8 and 12 weeks after starting radiotherapy. Subjects

were systematically asked about dietary intake during a typical 24-hour period, then asked to account for variations (e.g. weekends and take away meals), and finally a checklist was used as a cross check on the types and quantities of certain foods consumed during the week. Food models were used to help estimate serving sizes. Each interview lasted 40-60 minutes. Mean protein, kilocalorie and fiber intake were determined using computerised Australian food composition data (Food Works Professional, Version 2, 2000, Xyris Software, Brisbane, Australia). Total kilocalorie requirements were estimated using the Harris Benedict equation (18) and an activity factor of between 1.2-1.5 and a stress factor of 1.2 applied (19). For overweight and obese patients an adjusted body weight was calculated as ideal body weight plus 50% of the difference between ideal and actual body weight as described by Barak et al (19). Underweight patients had an adjusted weight that was equivalent to the lower end of the healthy body mass index (BMI) range. Protein requirements were estimated using 1.2-1.5g/kg/d.

Nutritional status

Weight was measured to the nearest 0.1kg (Tanita Inc., Tokyo, Japan, Model 300GS) and height was measured to the nearest 0.1cm with a stadiometer (Harpenden, Holtain Ltd, Crosswell, Dyfed, UK) following standard procedures (i.e. without shoes, minimal clothing and bringing the stadiometer sliding board onto the vertex with the head in the Frankfurt plane.) A trained professional took single measures of height and weight. Scales were checked to be appropriately calibrated prior to data collection and half-way during the data collection period by Wedderburn Scales (Brisbane, Australia). Patients were requested to eat and drink minimally for 2 hours prior to

assessments. BMI was calculated from current weight and height using the standard formula: $\text{weight}/\text{height}^2$ (kg/m²).

Nutritional status was assessed using the valid and reliable scored Patient Generated-Subjective Global Assessment (PG-SGA) (13,20) which consists of a patient-completed section and a physical examination conducted by the trained health professional (i.e. dietitian.) Each subject was classified as well nourished (PG-SGA A), moderately malnourished or suspected of being malnourished (PG-SGA B), or severely malnourished (PG-SGA C), and a numerical PG-SGA score was calculated. Typical scores range from 0-35, with a higher score reflecting greater deterioration in nutritional status, and scores ≥ 9 indicating a critical need for nutrition intervention and/or symptom management (14,20). The PG-SGA score has been correlated with a number of objective parameters (% weight loss, BMI) and measures of morbidity (survival, length of stay) and has a high degree of inter-rater reproducibility (21).

Quality of life (QoL)

European Organization for the Research and Treatment of Cancer QLQ-C30 (version 3) a validated, cancer-specific QoL tool was used to assess global QoL and was completed as described by the authors (22). This patient-based instrument is comprised of 30 items making up five functional scales (physical, role, cognitive, social, emotional), and three symptom scales (fatigue, pain and nausea/vomiting), global health status and global QoL scales. QLQ-C30 results are linearly converted to a score out of one hundred, with a higher score reflecting a higher QoL.

Statistical analysis

All continuous variables were normally distributed except for percentage weight loss in the past 6 months which was transformed (natural log) to improve distribution. Independent t-tests or Mann Whitney tests where appropriate were used to calculate the mean change in outcomes and compared by group. Paired t-tests were used to assess differences between estimated and actual kilocalorie and protein intakes at baseline. Differences between the NI and SP groups over time were assessed using repeated measures ANOVA on an intention to treat basis (SPSS version 10, SPSS Inc. Chicago, IL, USA). Statistical significance was reported at the conventional $P < 0.05$ level (two-tailed).

The primary outcome on which sample size was calculated was nutritional status as determined by PG-SGA score (mean change 12.7 units with standard deviation of 4.6 units). Assuming a clinically significant difference of 5 units or greater in one group relative to the other, then complete data would be required on 18 subjects in each group to detect this difference with 90% power and the 95% significance level (2-tailed).

Results

Subject characteristics

Sixty of 78 eligible patients consented to the study. Complete data were available on 54 subjects. Four deaths occurred during the study (2 in NI and 2 in SP groups) and 2 patients from the NI group declined to continue the study as one was experiencing deterioration in condition and did not wish to complete the measurements and the other decided to discontinue radiotherapy treatment and the study. There were no significant differences in baseline characteristics (age; gender; BMI; nutritional status;

tumour type; or radiotherapy treatment) between subjects who did or did not agree to take part in the study nor in those who did or did not complete the study. According to the scored PG-SGA, 35% (n=21) were malnourished (PG-SGA B and C) at baseline. The median weight loss of subjects in the previous six months was 2.8% (0-21). The majority of subjects were receiving radiotherapy to the head and neck area (88%, n=53) and the remaining 12% (n=7) of patients were receiving radiotherapy to the gastrointestinal area.

Subject characteristics at baseline are presented in Table 1. There were no significant differences between the NI and SP groups and no differences in the level of symptoms experienced by the groups as indicated by the nutrition impact symptom section of the scored PG-SGA. While there were no significant differences in the number of malnourished patients receiving NI or SP, there were more malnourished patients in the NI group (n=12) compared with SP group (n=9). There were no significant differences between kilocalorie, protein or fiber intakes at baseline between well nourished and malnourished patients receiving NI or SP. Therefore data including both well nourished and malnourished patients are presented.

In the NI group, 16 subjects regularly consumed high kilocalorie and protein oral nutrition supplements (at least two glasses of supplement per day for at least four weeks). No NI subjects received enteral or parenteral nutrition. Five subjects in the SP group received nutrition counseling from an outpatient dietitian: four subjects received one visit; and one subject received two visits. In the SP group, nine subjects were regularly consuming high kilocalorie and protein oral nutrition supplements, one

subject received nasogastric feeding and one subject received a percutaneous gastrostomy.

Dietary intake

There were no significant differences between estimated and actual kilocalorie intake at baseline for either the NI or SP group but the actual protein intakes were less than recommended (Figure 1). The NI group had significantly higher mean kilocalorie ($P=0.029$) and protein intakes ($P<0.001$) compared with those receiving SP during the 12-week study (Table 2). There was a clinically but not statistically significant mean increase in kilocalorie intake over the 12 weeks for those receiving NI ($M=86$ kcal/day, Standard Error of the Mean (SEM) =90) compared with patients receiving SP [$M=-177$ kcal/day, $SEM=112$; $t_{(52)}=-1.79$, $P=0.079$]. There was a significant mean increase in protein intake for NI patients ($M=3.5$ g, $SEM=2.9$) compared with SP patients (-11.8 g, $SEM 3.1$; $t_{(52)} = -3.6$, $P<0.001$). Mean kilocalorie intake per kilogram of body weight was greater for the NI group and ranged from 28-31 kcal/kg/day compared with 25-29 kcal/kg/day for the SP group over the 12-week period ($P=0.022$). Similarly, the NI group had a greater mean protein intake (1.1-1.3g/kg/day) compared with the SP group (1.0-1.1g/kg/day) ($P=0.001$). While the repeated measures changes in fiber intake between the groups were not significant there was a trend in the anticipated direction ($P=0.083$). There was however a significant mean increase in fiber intake over the 12 weeks for the NI group ($M=2.2$ g, $SEM=1.2$) compared with the SP group ($M=-1.5$, $SEM=0.7$; $t_{(52)}=-2.7$, $P=0.014$).

Figure 2 graphs the mean kilocalorie intake and body weight changes over the 12-week study for the NI and SP groups. At most time points the mean body weight parallels the mean kilocalorie intake, except between week 8 and 12.

During treatment more patients in the NI group were assessed as well nourished and less were assessed as malnourished according to PG-SGA global rating compared with the SP group (Table 3). This was statistically significant at 8 weeks ($X^2_{(1)}=5.4$, $P=0.020$) and approached significance at 12 weeks ($X^2_{(1)}=3.4$, $P=0.065$), where the proportion of malnourished patients in the SP group remained greater than pre-treatment levels. The NI group also had a significantly smaller decrease and faster recovery in global QoL ($P=0.009$) and physical function ($P=0.012$) over time compared with the SP group (14).

Discussion

This study demonstrated that NI following the ADA MNT radiation oncology protocol resulted in improved dietary intake and QoL, and less deterioration in nutritional status, when compared with SP in ambulatory oncology patients receiving radiotherapy to the gastrointestinal or head and neck area.

Malnutrition

Before commencing radiotherapy to the gastrointestinal or head and neck area, 35% of patients were classified as being either moderately or severely malnourished according to PG-SGA global classification. Other studies have observed that 50-75% of patients were assessed as malnourished when commencing radiotherapy to the head and neck area (23,24). The reasons for the lower prevalence of malnutrition in the

current study may be due to the fact that it was a more heterogenous population including patients receiving radiotherapy to the gastrointestinal, as well as head and neck area and also to the various definitions of malnutrition used in other studies. However, the fact that 35% of patients were malnourished prior to commencing radiotherapy is of concern, as it is known that patients receiving radiotherapy treatment are at further risk of having their nutritional status compromised due to possible side effects which may affect oral intake (10).

Dietary intake

While both NI and SP groups had comparable kilocalorie and protein intakes at baseline, it is evident from Table and Figure 1 that those receiving NI had an increase in kilocalorie and protein intake during the first four weeks of treatment and then maintained an intake similar to that consumed at baseline over the 12-week study. In contrast, those receiving SP had a steady decrease in kilocalorie intake which only started to increase at week 12 where it was still 177 kcal/day less than at baseline. This change in nutrition intake follows the natural progression in side effects for patients receiving radiotherapy. Polisena (7) states that acute side effects begin around the second or third week of radiotherapy, peak two-thirds of the way through treatment and last two to three weeks after treatment has ended. For a typical six-week course of radiotherapy, one would expect the side effects to be significant between five and eight weeks. In this study, dietary intake was found to be negatively influenced by the side effects that patients experienced. However, those receiving NI had an increase in both kilocalorie and protein intake during the first four weeks (when side effects were minimal) and maintained intake for the remainder of the

study. Intensive and ongoing NI minimised the reduction in dietary intake that generally accompanies radiotherapy.

Kilocalorie intake was not different to individual recommendations (Figure 1) for each group at baseline, although protein intakes were less than the 1.2-1.5g/kg/d recommendations. Ravasco's study in patients receiving radiotherapy to the head and neck found similar results using protein recommendations of 0.8-1g/kg/d (24). In the current study despite the intensity of the NI, the highest protein intake in the NI group was 1.3g/kg/d and this was associated with beneficial outcomes compared with the SP group. This suggests that for some patients attaining a protein intake of 1.5g/kg/d is unrealistic and a more appropriate goal is 1.2g/kg/d or maintenance of baseline protein intake.

It has been suggested that treatment side effects such as dry mouth, early satiety, fatigue, and anorexia are possible to ameliorate with the appropriate dietary intake and individualized suggestions for modifying the diet (28). In a randomized, controlled trial (n=75) conducted in patients receiving radiotherapy to the head and neck area, increases were observed in both kilocalorie ($P \leq 0.05$) and protein intakes ($P \leq 0.006$) in those subjects receiving dietary counseling with regular foods (n=25) and usual diet plus supplements (n=25) compared with the ad lib group (n=25) who experienced a decrease in protein and kilocalorie intakes ($P < 0.01$) (24). Both the study performed by Ravasco et al (24) and the current study showed increased kilocalorie and protein intakes with nutrition intervention compared with SP or an ad lib diet. However in Ravasco's study only those subjects receiving dietary counseling with regular foods had maintained their kilocalorie and protein intakes three months after commencing

radiotherapy and subjects in the other two groups had intakes that returned to or below baseline levels. These differences in results may be due to the different lengths of nutrition intervention: approximately 7 weeks (24) and 12 weeks for the current study (14).

The two patients in the SP group who received enteral nutrition were patients that experienced deterioration in oral intake and hence nutritional status. As baseline characteristics were not significantly different it appears that the decrease in oral intake and decline in nutritional status precipitated the need for enteral nutrition rather than reflecting a higher severity of illness. However, a larger study with a more homogenous population and stratified by tumor staging and/or symptom severity would be required to definitively answer this.

While overall kilocalorie and protein intakes varied between patients receiving NI or SP, this is illustrated more clearly when observing daily kilocalorie and protein intake per kilogram of body weight. These results are comparable with other studies which have shown that patients with cancer require a minimum of 30kcal/kg/day (120kJ/kg/day) to maintain weight (29,30).

How does dietary intake relate to other outcomes previously found?

Subjects receiving NI did significantly better in terms of body weight, nutritional status and QoL compared with those receiving SP and full details are presented elsewhere (14). The mean kilocalorie intake can account for the differences in body weight experienced between the groups (Figure 2). The NI group maintained body weight over 12 weeks (mean change = -0.4kg) compared with those receiving SP who

had a significantly greater deterioration in weight (mean change = -4.7kg) ($P < 0.001$) (14). Those receiving NI had a significantly smaller deterioration in nutritional status as measured by PG-SGA score ($P = 0.02$), global QoL ($P = 0.009$) and physical function ($P = 0.012$) over time compared with the SP group (14). Therefore the differences in kilocalorie and protein intake between the NI and SP groups appear to be responsible for the maintenance in outcomes in the NI group compared with a decline in those receiving SP.

Only two other studies demonstrating an association between dietary intake, nutritional status and QoL in patients receiving radiotherapy could be identified in the literature (24,31). Ravasco et al (31) demonstrated a correlation between an increase in nutrition intake and improvements in nutritional status ($P = 0.007$) and QoL ($P = 0.001$) in 125 patients receiving radiotherapy to the gastrointestinal and head and neck area. It was also found that QoL improved proportionally with increases in kilocalorie and protein intakes ($P < 0.001$) and with improvements in patients' nutritional status ($P < 0.05$) in subjects receiving radiotherapy to the head and neck area who were randomized to receive dietary counseling with regular foods ($n = 25$) (24). A post hoc analysis in 107 weight-losing patients with unresectable pancreatic cancer also demonstrated that weight stabilization was associated with improved survival and quality of life (29).

While several studies have shown that enteral feeding prior to commencement of radiotherapy is beneficial in terms of maintenance of nutritional status and body weight (32-34) until recently there has been little evidence that nutrition counseling is beneficial in patients receiving radiotherapy. The current trial (14) and work by

Ravasco and colleagues (24) are the first studies which demonstrate that nutritional counseling in patients receiving radiotherapy is beneficial in terms of improving outcomes including dietary intake, nutritional status and QoL.

Evidence-based dietetic practice protocols

While MNT protocols are developed with evidence that is at hand, it is important that protocols are evaluated and updated as new evidence emerges. To our knowledge this is the first study in patients receiving radiotherapy to the head and neck or gastrointestinal area that has demonstrated that patients receiving NI following the ADA MNT radiation oncology protocol has resulted in improved dietary intake, body weight, nutritional status and QoL outcomes compared with SP. It is known that weekly dietetic counseling during radiotherapy (24,35) and weekly dietetic counseling during radiotherapy with follow-ups every 2 weeks for 6-weeks following treatment (14) are beneficial in terms of dietary intake, nutritional status and QoL in patients receiving radiotherapy to head and neck and/or gastrointestinal area. In a patient satisfaction survey conducted in 143 patients receiving radiotherapy, MNT provided by a dietitian was perceived as being beneficial and problems that best responded to MNT were loss of appetite or weight loss (36). Therefore reviews with the dietitian weekly or every two weeks during radiotherapy and follow-up demonstrate improved outcomes. Polisena (37) investigated 72 patients undergoing radiotherapy (mixed diagnoses) for the perceived benefits of two MNT visits. While two studies were identified in the literature assessing the perceived benefits of MNT in patients undergoing radiotherapy (36,37), the current trial is the first study that we are aware of that has prospectively assessed the benefits of NI following ADA MNT protocols with SP in this population.

Study strengths and limitations

Many NI studies provide insufficient description of what the dietetic counseling involved, the frequency of contact and follow-up (28). The suggested reasons why the current trial was successful in maintaining outcomes in the NI group compared with the SP group is the intensity and frequency of the nutrition counselling by a dietitian following the ADA MNT protocol. There was also a substantial follow-up period even after completing radiotherapy.

A potential limitation of the study is the accuracy of the dietary intake as assessed by the diet history method. Accuracy is a problem for the diet history as it is for all methods of dietary assessment (41). However, the diet history by focusing on usual intake rather than a few specific days, such as the 24-hour recall or food frequency questionnaire, is a major strength of this form of dietary assessment (42). The diet history may help to overcome some of the difficulty accounting for the day to day variations that may occur with fluctuating symptoms such as pain and nausea (29). Although some recall bias by the subjects may have occurred one would expect that this would happen evenly between the SP and NI groups. There may also be limited generalizability of these findings based on the sample size of 54 subjects.

In conclusion, early and intensive NI following the ADA MNT radiation oncology protocol results in improved mean kilocalorie and protein intake compared with SP. It also appears to be responsible for the beneficial impacts on nutrition-related outcomes such as body weight, nutrition status and QoL previously observed in oncology outpatients receiving radiotherapy to the gastrointestinal or head and neck area. It is

recommended that all patients identified as being malnourished or at risk of malnutrition should receive early and ongoing NI by a dietitian to help maintain kilocalorie and protein intakes during radiotherapy treatment.

Applications

The ADA MNT for radiation oncology patients is a useful guide to the level of nutrition support required. If insufficient dietetic resources are available it is recommended that nutrition screening and triage systems be implemented to ensure those clients in most need of care receive a level which demonstrates outcomes. Further research is required to investigate the cost versus benefits of having a dietetic service to the health care facility. Other outcomes that can be measured to provide useful data include mortality and readmission data. Dietetic practice needs to be evidence based in order to ensure that resources are most effectively utilized and that the patient derives the greatest benefit.

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Table 1: Baseline characteristics for 60 subjects receiving nutrition intervention (NI) and standard practice (SP)

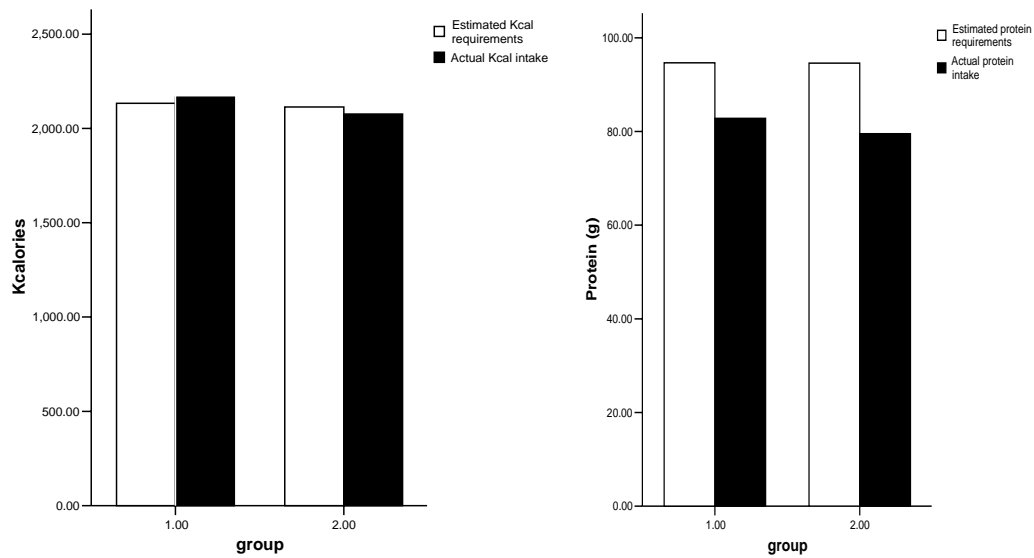
Variable (n)	NI (29)	SP (31)
Gender (M:F)	24:5	27:4
Age (years)	60.6 ± 15.6	63.3 ± 12.5
Weight (kg)	74.8 ± 7.8	77.6 ± 18.2
BMI (kg/m ²)	25.2 ± 4.4	26.4 ± 4.5
PG-SGA* score	7.1 ± 6.1	5.9 ± 4.3
PG-SGA* global rating		
-A (well nourished)	17 (59)	22 (71)
-B (suspected or moderately malnourished)	9 (31)	8 (26)
-C (severely malnourished)	3 (10)	1 (3)
Global QoL score	67.7 ± 18.8	75.3 ± 19.2

Continuous variables presented as mean ± SD. Categorical variables are presented as counts (%).

*PG-SGA = Patient Generated-Subjective Global Assessment (13,20)

No statistically significant differences between groups with P>0.05 for all variables

Figure 1: Actual mean kilocalorie and protein intakes compared with estimated requirements at baseline



Patients' mean actual Kilocalorie intake and recommended intakes were similar with no significant differences between the groups. Actual mean protein intakes were significantly lower than recommendations for both Group 1 ($P=0.022$) and Group 2 ($P=0.002$).

Group 1 = standard practice ($n=31$) and Group 2 = nutrition intervention ($n=29$).

Estimated energy requirements are based on the Harris Benedict equation (18) using adjusted weight for underweight and overweight/obese patients as described by (19)

Estimated protein requirements range from 1.2-1.5g/kg/day.

Table 2: Mean energy, protein and fibre intake for 54 subjects receiving either nutrition intervention (NI) or Standard Practice (SP) while undergoing radiotherapy to the gastrointestinal or head and neck area.

Outcome		Week 0 Mean (SD)	Week 4 Mean (SD)	Week 8 Mean (SD)	Week 12 Mean (SD)	P value[#]
Energy intake (kcal/day)	NI	2104 (509)	2320 (496)	2105 (557)	2190 (427)	0.029*
	SP	2130 (715)	1907 (696)	1801 (593)	1953 (562)	
Energy intake (kcal/kg/day)	NI	27.9 (6.8)	31.2 (8.9)	28.5 (8.4)	29.3 (5.9)	0.022*
	SP	28.5 (9.2)	25.9 (8.3)	25.0 (7.4)	27.8 (8.0)	
Protein intake (g/day)	NI	78.9 (21.1)	92.8 (29.6)	86.3 (25.4)	82.4 (17.2)	<0.0001*
	SP	82.8 (29.6)	72.7 (31.7)	70.3 (28.2)	80.0 (25.3)	
Protein intake (g/kg/day)	NI	1.1 (0.3)	1.3 (0.5)	1.2 (0.4)	1.1 (0.2)	0.001*
	SP	1.1 (0.4)	1.0 (0.4)	1.0 (0.4)	1.0 (0.4)	
Fiber (g/day)	NI	23.7 (7.0)	24.7 (6.5)	24.0 (6.5)	25.8 (5.3)	0.083
	SP	24.3 (6.0)	21.8 (9.2)	22.5 (8.8)	22.8 (6.5)	

[#]Based on repeated measures ANOVA analyses for between-subject effects for the NI and SP groups.

*Statistical significance is reported at P<0.05 two-tailed level.

Figure 2: Mean kilocalorie intake and mean body weight for 54 ambulatory radiation oncology patients receiving either nutrition intervention (NI) or standard practice (SP)

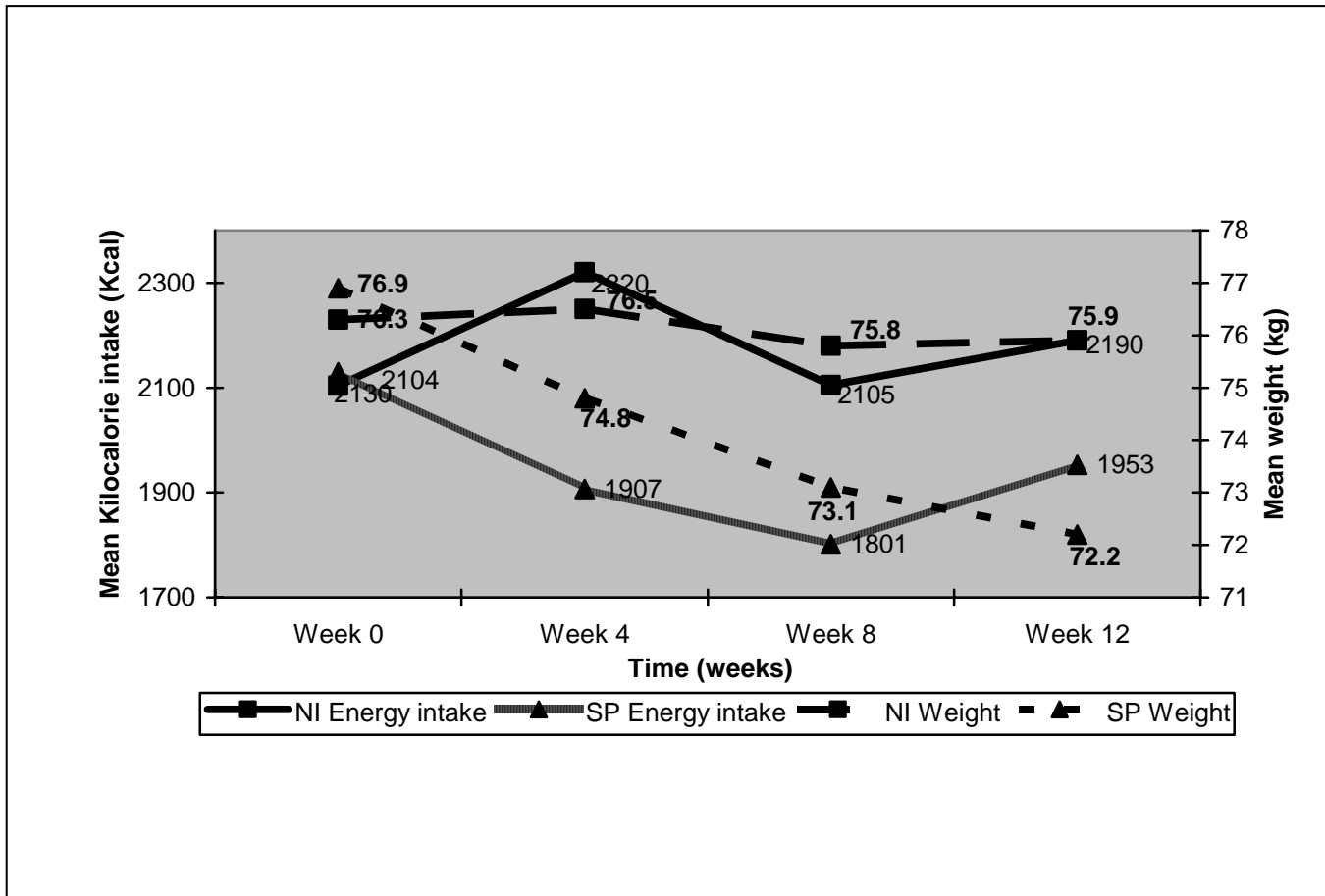


Table 3: Nutritional status as defined by PG-SGA * global rating for oncology outpatients receiving nutritional intervention (NI) or standard practice (SP)

Nutritional status	Week 0 (n=60)		Week 4 (n=57)		Week 8 (n=55)		Week 12 (n=54)	
	NI	SP	NI	SP	NI	SP	NI	SP
Well nourished (PG-SGA A)	17	22	13	9	18	11	19	15
Malnourished (PG-SGA B, C)	12	9	14	21	8	18	6	14
P value [#]	0.316		0.160		0.020		0.065	

*PG-SGA = Patient Generated-Subjective Global Assessment (13,20)

[#]Chi square analysis