

Title: Exploring Relationships with Food after Dietary Intervention in Patients with Colorectal Cancer: A Qualitative Analysis from the Protein Recommendations to Increase Muscle (PRIME) trial

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Abstract: **PURPOSE:** Patients with cancer often experience nutritional challenges and are vulnerable to muscle mass loss. While substantial research is directed towards understanding how nutritional interventions affect clinical outcomes, insights into patients' personal experiences during these trials remain limited. This qualitative study aimed to gain a deeper understanding of how participation in the Protein Recommendations to Increase Muscle (PRIME) trial affected patients' relationships with food. **METHODS:** A subset of patients who completed a minimum of one follow-up visit in the PRIME trial participated in a semi-structured interview about their experience implementing dietary modifications to increase protein intake. Data from 26 patients with a recent diagnosis of stage II-IV colorectal cancer (non-cachectic) were included. Interviews were audio recorded, transcribed verbatim, and qualitative content analysis was applied. **RESULTS:** Most patients were male (65.4%) with stage II or III (69.2%) colorectal cancer and were a mean age of 57 ± 10 years. Five key themes emerged to provide a deeper understanding of patients' relationship with food after the PRIME trial: (1) new positive perspectives on nutrition and coping with a cancer diagnosis; (2) embracing a comprehensive approach to food and nutrition; (3) facilitators promoting adherence to the intervention; (4) barriers challenging adherence to the intervention; and (5) shaping future dietary intake. **CONCLUSION:** This qualitative study explored the emotional and psychological effects of a clinical nutrition trial on patients, focusing on their relationship with food. It underscored the trial's comprehensive intervention and its enduring influence on patients, extending beyond the immediate intervention phase. The role of current perspectives, motivation, and knowledge acquisition on ability to adhere to dietary changes to increase protein intake were emphasized by patients and are key considerations for both clinicians and researchers.

Trial Registration: ClinicalTrials.gov Identifier: NCT02788955; registration posted on 2016-06-02.

Keywords: qualitative, cancer, behavioral intervention, nutrition

1 Introduction:

2 Patients with cancer are nutritionally vulnerable and at risk of low muscle mass, a
3 primary problem that independently predicts poor prognosis [1, 2]. Anti-cancer treatments may
4 be less effective without optimal nutrition; yet, oncologists often do not prioritize nutrition,
5 mainly due to time constraints [3] and focus on acute clinical care, necessitating advocacy for
6 nutrition-related care from patients and/or their support (e.g., family, friends) [4]. Additionally,
7 there is insufficient registered dietitian availability to accommodate all patients undergoing
8 chemotherapy in the outpatient setting [5].

9 A cancer diagnosis may motivate changes in dietary intake [6]. Patients alter their diet
10 post-diagnosis but may not consider the corresponding impact on muscle health [6, 7].
11 Commonly observed dietary changes such as restricting and/or eliminating animal products (e.g.,
12 red and processed meats) [8], dairy, etc. can decrease overall protein intake, do not align with
13 oncology nutrition guidelines [9], and can negatively impact muscle health [10]. We previously
14 showed that patients with colorectal cancer had varied degrees of post-diagnosis dietary changes
15 that stemmed from biological and physiological factors (e.g., age, sex, cancer type) and external
16 factors (e.g., education, socioeconomic status, etc.) [7]. Prior to a consultation with a study
17 dietitian and initiating a nutrition intervention, patients expressed that nutrition-related decisions
18 provided a sense of control over physical ramifications of a cancer diagnosis [7].

19 Oncology nutrition guidelines are generally inaccessible and impractical for patients to
20 implement given that they are intended for use by healthcare professionals. To optimize patient
21 outcomes, practice guidelines should be implemented by a multidisciplinary care team that
22 includes dietitian support [11]. Guidelines are mostly based on traditional nutrition research that
23 has employed randomized controlled trials to investigate effects of specific nutrients or

compounds on definite oncology outcomes (e.g., survival) in well controlled settings [9]. Similarly, clinical trials that investigate nutrition-focused behaviour change interventions face barriers such as inability to use a placebo or a control group, need for an active control group (e.g., minimum standard of care), and inability to blind participants to the intervention [12]. Feasible, accessible, evidence-based nutrition guidelines are needed to implement best practice standards that optimize the nutritional status of patients with cancer [12].

A review of ongoing clinical trials investigating nutrition interventions to prevent or treat low muscle mass or function highlighted numerous works underway in the realm of oncology [13]. The Protein Recommendations to Increase Muscle (PRIME) trial is one example. PRIME sought to assess the feasibility of a 1 g/kg/day vs 2 g/kg/day protein-containing diet intervention on muscle mass for 12 weeks during chemotherapy treatment for stages II-IV colorectal cancer. Nutrition research that relies on behaviour change and adherence to an intervention, such as the PRIME trial, face additional hurdles in oncology due to factors such as low recruitment rates [14] and high rates of treatment discontinuation [12]. Beyond challenges to researchers, the impacts of such trials on patients themselves are critical and warrant thorough consideration in nutrition research.

Qualitative studies provide insights into patient-centered impacts of clinical nutrition studies beyond health outcomes, enabling an in-depth examination of the emotional and psychological effects of behavior change interventions. Accordingly, this qualitative study aimed to deepen our understanding of how participation in the PRIME trial affected patients' relationships with food, including thoughts about food, dietary changes and corresponding facilitators and barriers, and the potential impact on long-term dietary habits.

Methods:

Study design and ethics

The PRIME trial was conducted from August 2016 until April 2022. As part of the trial, patients completed a 3-day weighed dietary intake record at baseline to assess usual dietary intake, were randomized to the 1 or 2 g/kg/day diet group, and met with a registered dietitian from the study team for a ~45 minute nutrition consultation [15]. The goal of the consultation was to support the patient with making dietary changes to meet their individualized protein intake based on body weight and trial randomization. Patients were provided publicly available, evidence-based protein-focused educational resources based on individual needs, and dietary record tracking sheets for use throughout the intervention. A research coordinator trained in dietary assessment methods followed up with patients weekly by telephone which included a 24-hour diet recall and support, as needed, to achieve the target protein intake. If patients were struggling to attain their individualized protein target, additional resources such as protein powder were offered. Patients completed another 3-day food record at week 6 and 12, and met with the study dietitian at week 6. Pre-cooked meat portions were initially offered to select patients who were unable to acquire or prepare these foods. Complete trial details are described in full elsewhere [15].

The trial, including the post-treatment interviews described here, was approved by the Health Research Ethics Board of Alberta - Cancer Committee (HREBA.CC-15-0193) and complied with standards on the use of human participants in research. All patients provided written informed consent prior to participation. Reporting was guided by the Standards for Reporting Qualitative Research [16].

Participants

Patients who were participating in the PRIME trial and completed an optional interview on drivers of dietary choices at study baseline [7] were invited to complete this follow up interview to learn about their experiences in the trial. Inclusion/exclusion criteria for the PRIME trial are described elsewhere [15]. Briefly, patients were 18-85 years of age, had been diagnosed within the previous 7 months with stage II-IV colorectal cancer, and were receiving chemotherapy.

Demographic and clinical details including age, sex, presence of an ostomy, and stage of disease were derived from electronic health records. Race and ethnicity, marital status, household income, and education were self-reported using a questionnaire. Body mass index was calculated from height and weight measured during the baseline trial assessment.

Qualitative data collection

A semi-structured interview guide (Table 1) was developed by the researchers to gain a deeper understanding of patients' perceptions and experiences of participating in the PRIME trial. Interviews were conducted by the same female research coordinator (CFT) during the patient's final trial visit (week 6 or week 12) at the Human Nutrition Research Unit at the University of Alberta [17]. Interviews were audio-recorded and transcribed verbatim by a professional transcriptionist. Patients did not have the opportunity to review transcripts. Field notes were taken by the interviewer, who also contributed to and reviewed the final data analysis.

Qualitative data analysis

Interview transcripts were analyzed inductively using qualitative content analysis. In this study, qualitative content analysis referred to "a research method for the subjective interpretation of the content of the text data through the systematic classification process of coding and identifying themes or patterns" (p.1278) [18]. Despite our inductive approach, because

interviews were systematically conducted following an interview guide, the results presented below can be linked to various questions presented in Table 1.

Two members of the research team (KLF and MQ) led the data analysis and brought the emerging codes and themes to other members of the research team for review, discussion, and verification. Interviewer's notes with observations about interview context and patients' engagement were used to complement interview data, enhancing data validity and the overall rigour of the study.

Results:

In total, 26 patients completed the interview (n=22 after 12 weeks and n=4 after 6 weeks of PRIME trial participation). Patient characteristics are described in Table 2. Protein powder was provided to 69% (n=18) of patients after baseline and 31% (n=8) after week 6 to supplement intake. Pre-cooked meat portions were provided to 23% (n=6) of patients after baseline and 12% (n=3) after week 6. Five key themes emerged that provide a deeper understanding of how participation in the PRIME trial affected patients' relationship with food: (1) new positive perspectives on nutrition and coping with a cancer diagnosis; (2) embracing a comprehensive approach to food and nutrition; (3) facilitators promoting adherence to the intervention; (4) barriers challenging adherence to the intervention; and (5) shaping future dietary intake, Fig. 1A. Illustrative quotes are shown in Fig. 1B.

Theme 1: New positive perspectives on nutrition and coping with a cancer diagnosis

Participating in the PRIME trial positively impacted patients, including their perspectives on nutrition, and their ability to cope with the reality of a cancer diagnosis and treatment (e.g., side effects). Supports provided throughout the trial (e.g., nutrition counselling from a registered dietitian, weekly phone call from a member of the trial team, etc.) were compared to a "life

coach” (P122; male; 2g/kg) and were described as features that positively impacted their experience after a cancer diagnosis. Many patients acknowledged that this support increased motivation and accountability, and helped them cope. One patient expressed that they felt more prepared to implement changes that would positively impact their diet and “that’s because of the study” (P119; male; 2g/kg). Others emphasized that the trial motivated them to consider and prioritize nutrition.

Access to resources beyond standard of care such as regular nutrition counselling, education, and access to experts in the field was noted by patients and viewed as supportive for coping with change in health. Contributing to the advancement of science, as part of trial participation, was motivating amid the challenges related to cancer prognosis and treatment side effects. P112 (female; 2 g/kg) said: *“If it wasn’t for this program, when I was sick, nauseated, I wouldn’t have been eating at all. Seriously. I would have not put a piece of meat or anything into my mouth.”* Amid positive feedback, patients also noted the commitment and dedication required to complete the trial, as expressed by P119 (male; 2g/kg): *“I’ve never been involved with something like that, so I enjoyed it. It was more work, but I knew that, I agreed to that, and so that wasn’t a problem for me. It’s not easy though...”*

Theme 2: Embracing a comprehensive approach to food and nutrition

This theme encapsulated changes in perception of foods as well as dietary changes that patients made during the PRIME trial. Following guidance from a dietitian, the aim was to increase protein intake to meet individualized intervention goals based on body weight and trial randomization. Strategies that increased protein intake had positive impacts on their perception of overall diet quality (Fig. 2). P112 (female; 2 g/kg) said *“I think I’m more cautious about eating more healthier, especially with regards to the protein.”*

The most described dietary changes were increasing portions of meat, introducing milk and alternatives or increasing the number of servings consumed, using protein powder, and having frequent meals and snacks throughout the day (Fig. 2). Patients' perception of foods evolved to include a more comprehensive understanding of the nutritional content of food groups (e.g., protein in milk and alternatives). Patients described incorporating new foods or food groups, particularly dairy foods. P105 (female; 2 g/kg) explained that the conscious effort to think about protein led to increased consumption of dairy: *"Thinking about eating more protein, you know, cottage cheese, yogurt. I didn't eat yogurt much at all before, or cottage cheese..."* Others expressed how they started enjoying foods that they weren't previously consuming. P101 (male; 1 g/kg) said *"Milk. I was not used to drinking a lot of milk before"* while P107 (male; 2 g/kg) explained *"I enjoy other foods like yogurt. I never did eat yogurt before"*. Frequency of meals and taking the time to prepare and eat a meal also became front-of-mind for patients.

Theme 3: Facilitators promoting adherence to the intervention

Dietary changes made in attempt to adhere to the trial intervention were facilitated by strategies that fit with personal schedules, helped manage side effects of cancer treatment, and utilized resources from the trial (e.g., dietitian consults, food records, weekly check-ins), patients' community, and family (Fig. 3). Nutrition counselling with a registered dietitian, weighed food records collected prior to each trial assessment visit, weekly phone calls from the trial team, a modified copy of the *Choose Your Foods for Weight Management* book developed by the Academy of Nutrition and Dietetics [19], and provision of protein powder and frozen pre-packaged meat were factors that helped patients increase their protein intake and adhere to the intervention. As P124 (male; 2 g/kg) noted: *"Nothing really hindered [following study recommendations] because a lot of the protein was already precooked and readymade, so that*

was a big advantage for me”. These resources contributed to patients’ accountability and strengthened their commitment to the trial. Factors external to the trial also facilitated patients’ efforts to adhere to the intervention. Common support systems were communities (e.g., faith groups), spouses, and friends who were instrumental for finding protein-rich foods, meal preparation, and encouragement.

Theme 4: Barriers challenging adherence to the intervention

In contrast to patients’ positive perceptions of the trial and facilitators that supported adherence to the intervention, there were barriers that impacted protein intake. This theme included challenges posed by treatment side effects, trial requirements and practical aspects of patients’ routines (Fig. 4). For some patients, treatment side effects were profound, caused nutrition-impact symptoms, and barriers to dietary intake (e.g., nausea, lack of appetite, cold sensitivity, changes in taste and smell, and gum sensitivity). These side effects often overlapped with effects from recent surgeries that resulted in significant changes to their gastrointestinal tract (e.g., ostomies).

The trial intervention (i.e., individual protein target) was based on patients’ actual body weight. For some, this resulted in a large quantity of protein and thus a high volume of food, as explained by P122 (male; 2g/kg): *“The volume of food, it’s higher, because of trying to get all the protein in. I’m finding I’m eliminating some carbs and some vegetables so there’s enough room for the protein.”* For some patients, the increase in protein intake triggered concerns about caloric intake and the potential for weight gain, despite the intervention being eucaloric and based on individualized energy needs (i.e., measured by indirect calorimetry).

Another barrier for patients was keeping up with trial requirements. These included achieving the prescribed quantity of dietary protein, recording consumption of food and

beverages during the 3-day weighed dietary record periods, and responding to weekly 24-hour diet recall questions. For others, barriers to adhering to the trial intervention centered around the feasibility of integrating the intervention into daily routine. For example, patients were challenged with aspects related to food preparation, choosing foods away from home and simply being busy. P120 (female; 2 g/kg) said: *“I think part of it with the chemo, being tired...I just want to go to bed, I don’t want to eat... I’d rather have a muffin than something with more protein”*. For some patients, these challenges were barriers to adhering to the intervention and/or completing trial requirements (e.g., dietary records, weekly 24-hour diet recalls). Notably, these challenges were not unique to patients randomized to the 2g/kg group.

Theme 5: Shaping future dietary intake

This theme captured how patients anticipated the learnings and experiences gained through the PRIME trial would continue to shape their health beyond the trial period. Patients described key takeaways from their participation in the PRIME trial and articulated that the rich learning about nutrition would inform their diets, food decisions, and overall health moving forward. They emphasized the nutrition knowledge gained from the study dietitian and most patients expressed that they were determined to sustain some, or all, of the dietary changes that they had implemented during the trial. P102 (male; 2 g/kg) said *“All of the information that you provide me for the last 12 weeks, I want to follow it myself. I think they are really helpful...and make me healthier.”* P126 (male; 2g/kg) explained that: *“The awareness of how much protein goes into my body...that’s part of the study I’m definitely going to be taking with me. That’s going to stay with me for a long time.”*

Patients perceived their dietary changes as positive during and after chemotherapy and expressed a keen desire to sustain the trial diet and newly acquired nutrition knowledge,

regardless of diet group allocation. Trial participation also expanded patients' thoughts on health to include the importance of nutrition. P123 (male; 1 g/kg) said: *"I think I'm just going to continue on. The higher protein for sure, especially to get through the rest of my chemo. I still have six more to go so – I'm only halfway."* Not all patients planned to continue the intervention post-trial. Some were interested in weight loss while others simply felt that the effort it took to implement dietary changes considering a recent cancer diagnosis was overwhelming, even with supports received, and suggested that implementation strategies be considered in the context of patients' new reality:

"I would encourage you to look closely at the challenges people experienced. If there's any weak point it would be in people's ability to implement, not in anything else, because you're offering lots of support here. It would be nice if we could ... really control the environment, but that's not going to happen." P126 (male; 2 g/kg)

Discussion:

This study highlights, from the perspective of patients with colorectal cancer, the role of a nutrition-focused behavior modification intervention on relationships with food. Themes that emerged included: new positive perspectives on nutrition and coping with a cancer diagnosis; embracing a comprehensive approach to food and nutrition; facilitators promoting adherence to the intervention; barriers challenging adherence to the intervention; and shaping future dietary intake. These findings contribute to the paucity of research investigating oncology patients' perspectives of clinical trials, particularly of nutrition intervention trials and their impact on diet. Furthermore, it demonstrates the utility of qualitative analyses to elucidate a deeper understanding of the impacts of an intervention, beyond primary, secondary, and exploratory clinical outcomes. Patients' experiences and perceptions of participating in research have been

230 explored in other conditions [20], cancer types [21, 22], and study types [23]. To our knowledge,
231 this is the first study to gain a deeper understanding of patients experiences and perceptions
232 participating in a nutrition intervention trial which aimed to support muscle health in cancer.
233 Overall, patients expressed positive engagement with the trial, were motivated to participate in
234 research, and suggested that acquired knowledge would have lasting impacts beyond the acute
235 intervention phase.

236 Data reported herein provide insight into dietary changes implemented by patients
237 participating in a trial assessing two levels of protein intake, and facilitators and barriers to
238 implementing these changes. The PRIME trial dietitian worked with patients to personalize diet
239 modifications that would attain their protein goal based on body weight and trial randomization
240 (i.e., 1 vs 2 g/kg/day protein intake) [15]. Nutrition education combined with a food-first
241 approach were used to support patients with implementing dietary changes, as needed [15].
242 Commonly reported dietary strategies to augment protein intake that emerged from the
243 interviews were increasing portions of meat products, intake of dairy products, and frequency of
244 meals/snacks. Most patients with cancer do not meet the minimum recommended protein intake
245 (i.e., 1 g/kg/day) [9, 24, 25] and many make dietary changes that decrease overall protein intake
246 such as reducing or eliminating animal products [6]. The latter is an important source of protein
247 to support muscle health in cancer and should not be eliminated from the diet solely based on a
248 cancer diagnosis [10]. Our findings underscore the role of trial participation on the evolution of
249 patients' nutrition knowledge and shaping their perception of the importance of nutrition, which
250 are known factors that affect post-diagnosis dietary decisions [6].

251 Psychosocial determinants such as motivation and support systems emerged as focal
252 factors underpinning adherence to the intervention. These align with findings in the oncology

population that suggest external factors (e.g., social networks) influence dietary decisions [6, 7]. We previously showed that patients with colorectal cancer alter their diet based on personal perspectives and beliefs, including the extent to which these changes provide a sense of control over their health [7]. Themes delineated herein highlight the role of patient perspectives and beliefs when implementing dietary recommendations. For example, one patient reported reducing their carbohydrate and vegetable intake as they increased their protein intake during the intervention. Given the extensive involvement of the trial team, there was opportunity to provide nutrition education and individualized support to improve dietary choices. However, such level of support is not accessible to most patients with cancer [5] and highlights the potential for unintended nutritional consequences (e.g., inadequate intake to support muscle health) from self-guided dietary decision making [6, 10].

Oral nutritional supplements are a recommended nutrition intervention when intake is insufficient [9]. These products, and protein powders, are commercially available to patients without a prescription but should be coupled with nutrition counselling to ensure appropriate use. Similar to the PRIME trial [15], other studies investigating muscle mass in patients with colorectal cancer have used nutritional supplements as the primary method for improving dietary intake [26]. The PRIME trial adopted an individualized approach to supplementation whereby patients who encountered challenges with the trial intervention were offered a step-wise approach to supplementation using protein powder, and in few cases pre-cooked, pre-packaged meat products [15]. Oral nutritional supplements are often warranted in cancer, especially when nutritional impact symptoms (e.g., nausea, cold sensitivity, taste alterations, etc.) negatively impact food intake [9] and were viewed by some patients as crucial for augmenting protein intake. Nutritional supplements tailored to the nutritional needs of patients with cancer and

acceptable for those experiencing nutritional impact symptoms are warranted to foster optimal nutritional intake.

Supplements and other measures to support protein intake during the PRIME trial were administered based on individual intake assessed by weighed 3-day food records at 6- and 12-weeks [15]. Although the individualized approach to nutritional support was motivating for patients, the burden of dietary record keeping was noted. Advances in technology such as mobile applications for dietary assessment that use images and artificial intelligence to track dietary intake [27] may decrease patient burden and should be assessed for accuracy in nutritionally vulnerable populations. Patient experiences in the PRIME trial and facilitators and barriers to intervention adherence are key factors that can foster acceptability of the intervention and decrease patient burden, and thus should be considered by researchers when designing behavior change nutrition intervention trials.

Beyond barriers that patients experienced, this qualitative study provided a deeper understanding of challenges encountered by researchers, such as the need for an active control group. Patients in the active control group (i.e., 1 g/kg/day) described efforts to increase their protein intake and acknowledged their newly acquired nutrition knowledge. The inherent limitations of an active control group and inability to blind patients to group randomization are realities of clinical nutrition trials focused on behaviour modification [12]. The magnitude of dietary changes made by patients in the PRIME trial, regardless of intervention group, is accentuated in the context of significant patient and methodological barriers that were faced. For example, engagement with trial staff and support from a nutrition professional far exceeded standard of care [5] yet patients struggled to adapt to oncology nutrition guidelines (e.g., increase

protein intake [9]). Adaptive and pragmatic trial designs are viable options capable of mitigating a range of methodological and patient barriers encountered in nutrition intervention trials [12].

Limitations: Data presented herein are derived from interviews with patients who completed a minimum of one follow-up visit in the PRIME trial and are representative of patients included in the larger trial. Given that interviews were conducted at week 6 and 12, these data do not encompass reflections from patients who withdrew from the trial prior to the 6-week visit. Additionally, interviews were conducted in two distinct settings: face-to-face or while patients were completing an energy expenditure assessment inside a whole-room indirect calorimeter [28]. For the latter, there was a physical separation (i.e., a window) between the patient and the interviewer which may have hindered effective communication. The patient and interviewer could see each other through the window and communicated verbally using a telephone.

This qualitative study unpacked perceived benefits and practical challenges of participating in a trial investigating the impact of different doses of protein on muscle health in patients with colorectal cancer and gained a deeper understanding of the influence of trial participation on patients' relationship with food. This work exemplifies the ability for nutrition intervention trials to impact patients beyond quantitatively measured clinical outcome variables. Patients' perspectives, motivation, and knowledge was discussed in the context of dietary changes related to the trial intervention, particularly those that augment protein intake. It is imperative that clinicians and researchers understand and appreciate the human implications inherent to clinical nutrition trials in the oncology setting.

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Competing interests: Financial interests: K.L.F has received speaking honoraria from Abbott Nutrition. M.Q. owns Quali Q Inc. and provided support for data analysis related to this work.

408 M.B.S has received honoraria from Nutricia, Fresenius Kabi, and Mylan. N.E.P.D. has received
409 honoraria and/or paid consultancy from Abbott Nutrition. C.M.P. reports receiving honoraria
410 and/or paid consultancy from Abbott Nutrition, Nutricia, Nestle Health Science, and Pfizer.
411 C.F.T, W.V.W., M.S., and H.V. declare that they have no financial interests.

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413 Author contributions: CMP conceptualized the study. CMP, HV and CFT designed the study.
414 CFT and HV collected the data. KLF and MQ analyzed the data and wrote the first draft with
415 contributions from CMP. All authors critically interpreted, reviewed and edited the manuscript.

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417 Ethics approval: This study was performed in line with the principles of the Declaration of
418 Helsinki. Approval was granted by the Health Research Ethics Board of Alberta - Cancer
419 Committee (HREBA.CC-15-0193).

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421 Consent to participate: Written informed consent was obtained from all individual participants
422 included in the study.

Table 1. Semi-structured interview guide questions for patients with stage II-IV colorectal cancer participating in a dietary intervention trial. Probing questions (indicated in brackets) were used as needed.

1.	How has participating in the study changed the way you think about food? [How are the study food recommendations different than how you used to eat?]
2.	What we know doesn't always translate to how we act. How would you describe the extent you've applied your new nutrition-related knowledge? [Are the study recommendations easy for you to follow?] [Are there any tips or tricks that you use to help yourself follow the study recommendations?]
3.	Could you describe what helped/hindered you from following the nutritional recommendations you were given for the study? [What made the nutritional recommendations difficult for you to follow?] [What made the nutritional recommendations easy for you to follow?]
4.	How was your enjoyment of food affected by the nutritional recommendations? [Are there other factors, other than the recommendations, that have affected your enjoyment of food?]

427 **Table 2.** Baseline characteristics of 26 patients who completed an interview after participating in
428 a dietary intervention trial.

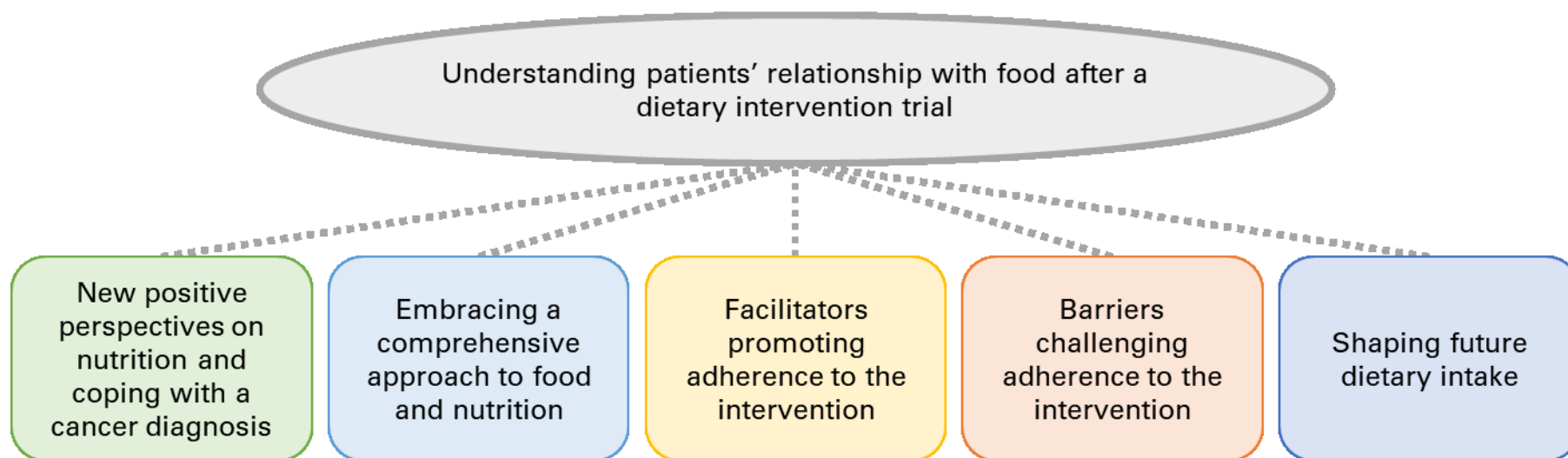
Patient characteristic	
Age, years (mean \pm SD)	57 \pm 10
Sex, n (%)	
Female	9 (34.6)
Male	17 (65.4)
BMI, kg/m ² (mean \pm SD)	26.6 \pm 5.2
Stage of disease ¹ , n (%)	
II	4 (15.4)
III	14 (53.8)
IV	8 (30.8)
Ostomy, n (%)	
Yes	9 (34.6)
No	17 (65.4)
Race and ethnicity, n (%)	
Filipino	2 (7.7)
Indigenous	3 (11.5)
Latin American	2 (7.7)
South Asian	1 (3.8)
White	18 (69.2)
Marital status, n (%)	
Common-law	4 (15.4)
Divorced	2 (7.7)

Married	16 (61.5)
Single (never married)	3 (11.5)
Widowed	1 (3.8)
Household income ² , n (%)	
< \$20,000	1 (3.8)
\$20,000 - \$39,999	3 (11.5)
\$40,000 - \$69,999	7 (26.9)
\$70,000 - \$99,999	4 (15.4)
≥\$100,000	10 (38.5)
Prefer not to say	1 (3.8)
Highest level of education completed, n (%)	
Completed high school	8 (30.8)
Completed trade school/community college	7 (26.9)
Completed university undergraduate degree	8 (30.8)
Completed post-graduate degree	3 (11.5)

¹Stage of disease grouped as per tumor, node, metastasis (TNM) staging [29]. ²Annual household income in Canadian dollars before taxes.

Figures:

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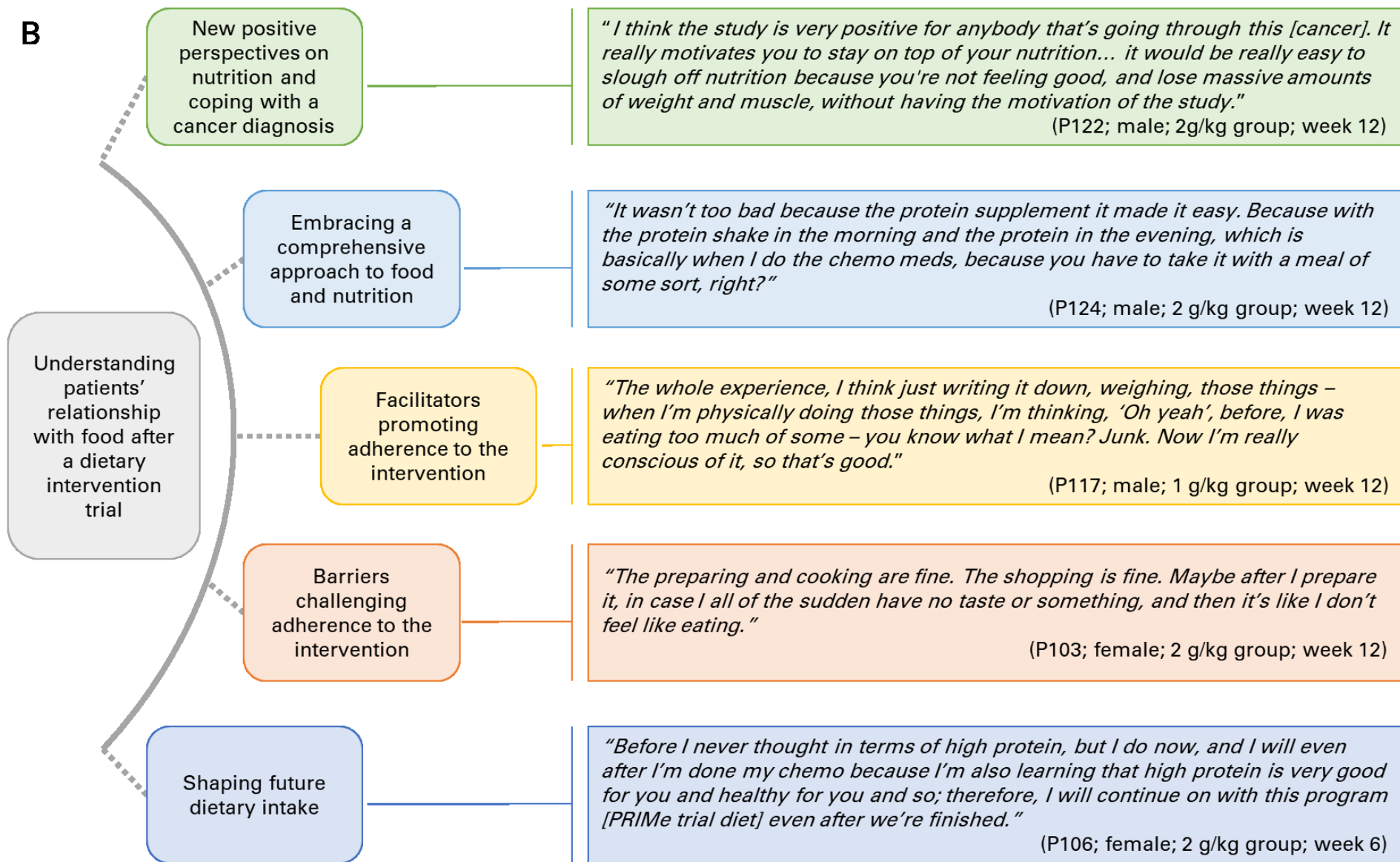


Fig. 1 (A) Summary of the five main themes that informed patients' relationship with food after participating in the PRIME dietary intervention trial and **(B)** respective quotes to illustrate the meaning of each theme

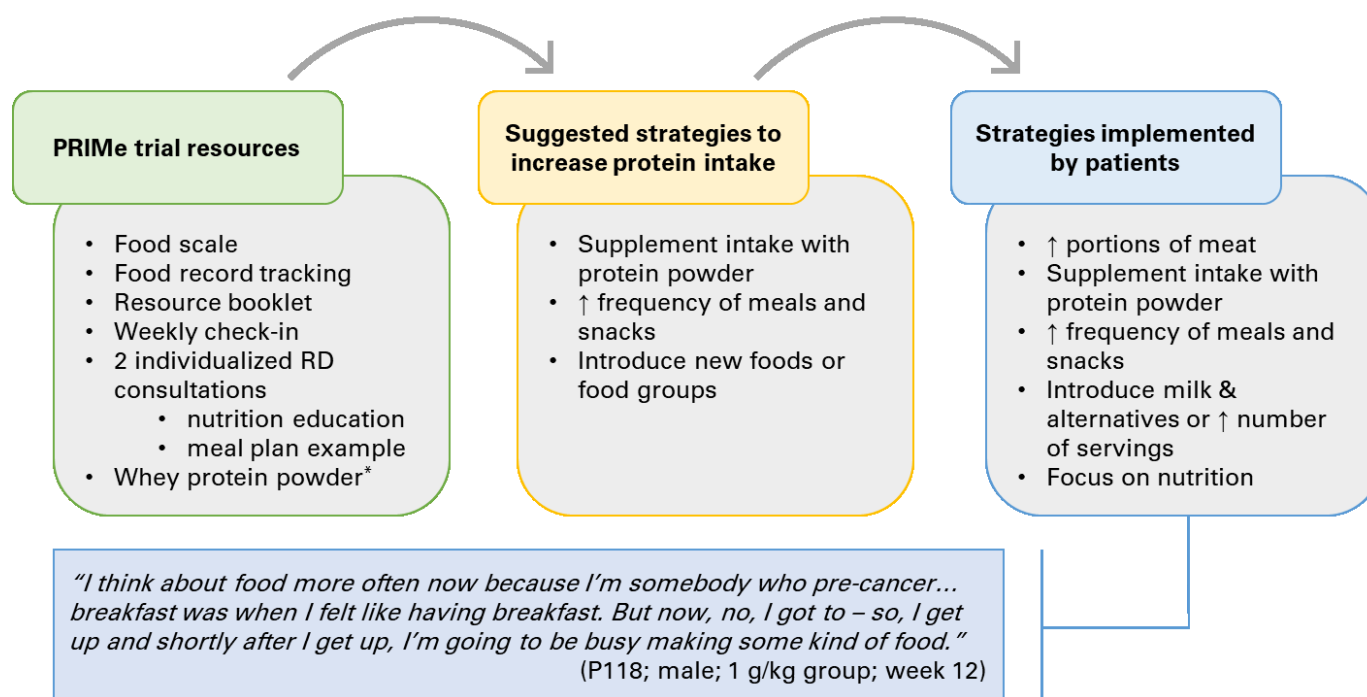


Fig. 2 Summary of resources provided to patients during the PRIME trial; strategies commonly suggested by the dietitian to increase protein intake, and summary of strategies implemented most often by patients PRIME: Protein Recommendations to Increase Muscle; RD: registered dietitian; ↑: increase; * at study start, select patients who could not acquire or prepare meat products were provided pre-cooked portions

Facilitators promoting adherence to the intervention	
PRIME trial resources	External resources
<p>Dietitian consults</p> <p><i>"Also, when you have to fess up about all the garbage you've been eating to a dietitian on a weekly basis [laughs] you feel like man, what am I doing"</i></p> <p>(P126; male; 2 g/kg group; week 12)</p>	<p>Community</p> <p><i>"I have my treatments on a Saturday, so every time I have my treatment on a Saturday, that evening, a member of our church brings over supper for me, so that I don't have to prepare supper that evening"</i></p> <p>(P106; female; 2 g/kg group; week 6)</p>
<p>Food records</p> <p><i>"Writing things down has made things a little bit, kind of having that accountability and thinking about the foods a little bit more"</i></p> <p>(P106; female; 2 g/kg group; week 6)</p>	
<p>Weekly check-in</p> <p><i>"checking up on me" and "encouraging me to keep going"</i></p> <p>(P105; female; 2 g/kg group; week 12)</p>	<p>Spouse</p> <p><i>"There were some extra things, my wife did most of the grocery shopping and still does — she would look for high protein things for me. So, maybe we didn't always have shrimp before, but we always would after"</i></p> <p>(P119; male; 2g/kg group; week 12)</p>

Fig. 3 Summary of facilitators promoting adherence to the intervention. Factors associated with PRIME trial resources are shown in green speech boxes; factors associated with external resources are shown in yellow thought bubbles

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Barriers impacting adherence to trial intervention		
Treatment side-effects (e.g., nausea, vomiting, cold-sensitivity, etc.)	Personal circumstances (e.g., interruption or changes to routine)	Trial requirements (e.g., visits, dietary intake records, dietary change)
<p><i>"I try to apply them [trial recommendations] as best as possible. I was surprised that I was not able to always eat the protein... because initially the amount of protein I needed to eat, I'd go, great, that's my favourite diet. But at times, my stomach just could not handle it."</i> (P122; male; 2g/kg group; week 12)</p> <p><i>"Those barbequed ribs, just that one time, it hit me, and that was, like, burning, rotting, fish. Oh, I thought I was gonna puke."</i> (P109; female; 1 g/kg group; week 12)</p>	<p><i>"I guess more so when I have busier days, when I have other plans and appointments to attend, and things like that. It makes it [adhering to the trial intervention] harder."</i> (P121; female; 1 g/kg group; week 12)</p>	<p><i>"I think the hardest part of the recording would've been...I think the food diaries and the weekly interviews... I'd probably be better at it if I wasn't chemo brained - trying to recall exactly what you had to eat the day before."</i> (P126; male; 2 g/kg group; week 12)</p>

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Fig. 4 Commonly described barriers to adhering to the intervention

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