Nutrition And Food Science Journal

SCIENTIFIC LITERATURE

Research Article

Impact of Whey Protein Supplements and Reasons for Consumption in Older People who are Malnourished or at Risk of Malnutrition: A Breakfast Pilot Study

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ARTICLE INFO

Received Date: February 10, 2022
Accepted Date: March 08, 2022
Published Date: March 11, 2022

KEYWORDS

Ageing
Dietary protein
Essential amino acids
Leucine
Malnutrition

Citation for this article: Bell D, Gardoni A, Dawson B, Sutton E, Gillespie C, D'Souza M and O'Leary F. Impact of Whey Protein Supplements and Reasons for Consumption in Older People who are Malnourished or at Risk of Malnutrition: A Breakfast Pilot Study. Nutrition And Food Science Journal. 2022; 5(1):130

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ABSTRACT

Background: Inadequate dietary protein intake is common in older people and increases the risk of sarcopenia. Research suggests that breakfast is a key target meal for protein fortification. **Objectives:** To examine the effect of whey protein isolate fortified breakfast items on protein, essential amino acid and energy intake and explore reasons for consumption in older adults who are malnourished or at risk. **Design:** Non-randomised study. Setting: Aged care wards at a rehabilitation hospital. **Participants:** Older adults at risk of malnutrition.

Intervention: Two drinks fortified with whey protein isolate (WPI) (20g) were provided at breakfast for three days.

Measurements: Nutritional status assessment using the Subjective Global Assessment and demographic, social and medical information was determined. Dietary intake was assessed using the plate waste method. Questionnaires capturing perceived facilitators and barriers to consumption of WPI fortified items were administered.

Results: A total of 219 patients were screened and 69 patients included; 28 in the intervention group. Compliance with WPI fortified breakfast items was 83%, and 92% chose to continue fortification after the study, largely attributed to product enjoyment and positive perceptions regarding health benefits of nutritional supplements. Much of essential amino acid intake in the fortified group was derived from consumption of WPI breakfast items (65%). Overall, there was a significantly higher short term intake of protein, essential amino acids and leucine ($p < 0.001$) in the supplemented group at breakfast. Energy intake at breakfast did not differ between the groups.

Conclusions: Fortification of breakfast items with WPI may represent a feasible nutrition support option to enhance essential amino acid and leucine intake in older malnourished adults. Further studies are needed to examine the longer term effects on appetite and patient acceptance.

INTRODUCTION

Sarcopenia, the age-related loss of muscle mass, strength and function has profound implications for the elderly including decline in mobility, independence and an increased risk of poor quality of life and mortality [1,2]. Inadequate dietary protein intake is common in older people, and increases the risk of sarcopenia [3].

Sufficient dietary protein and essential amino acids (EEA) are essential to stimulate muscle protein synthesis (MPS) [4,5] for the prevention of sarcopenia. In older adults MPS is impaired due to age-related anabolic resistance, with a reduction in MPS after protein and EAA intake, resulting in a greater net muscle protein breakdown (MPB) [6]. To stimulate MPS, research suggests older people require approximately 2.5 g to 2.8 g of leucine [2], or 25-30g of high quality protein per meal [2]. A recent meta-analysis found that EAA supplementation was the most effective oral nutritional supplement (ONS) for older undernourished people in improving muscular strength and physical function [7].

Classically, protein enriched ONS are offered in health care settings to older adults at risk of protein malnutrition, but compliance varies [8]. These products are typically sweet flavoured milk or cordial-based beverages and may contrast with the dietary preferences or habits of older adults. Other challenges associated with ONS provision in aged care and inpatient facilities include taste fatigue, distrust of new products and gastrointestinal side effects [8,9]. Food-based fortification is an alternative to ONS supplementation and has yielded positive results [9], increasing the total amount of protein and energy consumed by older adults who are malnourished or at risk of malnutrition [10,11].

Research suggests that breakfast is a key target for protein fortification as the elderly consume as little as 8 g of total protein and limited EAAs at this meal [12-14], well below the suggested amounts required for stimulation of MPS [2]. Whey protein isolate (WPI) provides an easily digestible source of EAA and leucine (3 g per 25 g) [15-17], nutrients associated with increases in muscle anabolism [15,18] that can be added to familiar foods. In comparison, conventional ONS, commonly used to manage malnutrition, typically contain less protein (15-20% of energy, 9-18 g), sourced from casein [19], which is digested more slowly and contains fewer EAAs [20].

Currently, WPI products are available in clinical settings as a protein supplement, however, patient compliance and the impact of WPI on protein and EAA intake in older hospitalised adults has not been explored.

Our aim was to explore consumption of WPI fortified breakfast items, the factors that influence the acceptance of these products and to determine the effect of WPI fortification on energy, protein, EAA and leucine intake at the breakfast meal in geriatric hospitalised patients who are malnourished or at risk of malnutrition.

METHODS

This was an exploratory non-randomised study.

Participants: The study included medically stable inpatients aged 65 years and older, conducted across four aged care and rehabilitation wards at a subacute rehabilitation facility (Balmain Hospital, New South Wales, Sydney). Recruitment involved screening electronic medical records (eMR) and CBORD (Version 12.15.100); a food service management IT system.

We excluded inpatients aged <65 years, acutely unwell, with diagnosed dementia or delirium (Mini-mental State Examination (MMSE) <24, Rowland Universal Dementia Assessment (RUDAS) <22), with inadequate spoken English or without family member consent, nil by mouth, on potassium and/or protein restricted, thickened fluid, Halal or dairy- or soy-avoidant diets.

Consenting patients were screened for malnutrition risk, using the Malnutrition Screening Tool (MST) [21], shown to have high sensitivity (81%) and specificity (68%) [22]. Patients with a MST score ≥2 were further assessed using The Subjective Global Assessment (SGA), a validated tool to determine nutritional status category [23,24]. Participants at risk of malnutrition based on the MST were allocated to the supplement group and those well-nourished formed the comparison group.

Demographic, social and medical information was collected from the eMR, including, current ONS. The MDCalc [25] was used to calculate a Charlson Comorbidity Index (CCI) for each participant [26].

Intervention: All patients at nutritional risk formed the supplement group and were asked to consume their choice of two, 150 ml milk and/or juice drinks supplemented with 10g of WPI supplement (Beneprotein, Nestle) to each drink, i.e. 20g per breakfast for three consecutive days (Supplementary Material). Each 20g of Beneprotein contained 17.2 g of protein, 8.8 g EAA and 2.2 g leucine.

Participants who were not at risk of malnutrition according to the MST formed the non-supplement group and received usual

care including their choice of standard breakfast drink(s), of milk or juice or both but without WPI supplementation.

Outcomes: Dietary intake data was collected by researchers at breakfast for three days over a seven-week period (August – October, 2018). The percentage of food and drink consumed was estimated on a five-point scale (0%, 25%, 50%, 75% and 100%) based on the assessment of plate waste [27-29]. For inter-rater reliability, researchers independently estimated food item percentage waste on the breakfast tray. Protein (g) and energy (kJ) of each food were calculated using CBORD food values, obtained from NUTTAB (2010) and manufacturers (nutrition information panel of food packages). EAA (g) and leucine (g) were calculated using the United States Department of Agriculture Food Composition Database [30]. Supplement group participants completed one of two short questionnaires to select reasons for consumption of the WPI fortified items. The questionnaires were based on the validated My Meal Intake Tool [31].

Ethical approval was provided by the Sydney Local Health District Human Research Ethics Committee and written consent obtained.

Statistics: Data was assessed for normality using the Kolmogorov-Smirnoff test and visual estimation with median and IQR reported for skewed data and mean and standard deviation (SD) for symmetric data. The weighted Cohen's kappa statistic was used for inter-rater reliability. Fishers exact and chi-square testing were used for categorical variables. For continuous variables, Mann-Whitney U test was used for skewed data and if not skewed, data was compared using independent samples t-tests. Generalised linear regression was used to examine associations between nutrient intakes and were adjusted by age, gender and BMI as these are the main confounding variables in published literature. As this was an exploratory study no sample size calculation was made. All tests were two sided and statistical significance was accepted at the level of $P < 0.05$. This data was analysed using IBM SPSS Statistics (Version 24).

RESULTS

Two hundred and nineteen participants were screened for eligibility, 121 were excluded, 69 provided consent and two from each group dropped out prior to the study commencing. Sixty-five participants (supplement group n=28; non-supplement group n=37) were included in the final analysis. (Supplementary Material). Characteristics of included subjects can be found in Table 1.

Table 1: Baseline characteristics of analysed study population (n= 65).

Patient variable	Supplemented group (n= 28)	Non-supplemented group (n= 37)	P value ŧ
Age group (years) (n, %)			0.868
65-70	3 (11%)	5 (14%)	
71-75	8 (29%)	6 (16%)	
76-80	6 (21%)	8 (22%)	
81-85	4 (14%)	6 (16%)	
86-100	7 (25%)	12 (33%)	
Sex (female) (n, %)	20 (71%)	24 (65%)	0.764
Length of hospital stay (days) (n, %)			0.909
0-14	18 (64%)	22 (59%)	
14-28	7 (25%)	11 (30%)	
>28	3 (11%)	4 (10%)	
Charlson Comorbidity Index Score (mean ± SD)	5 ±1	5 ±1	1.000
BMI (kg/m^2) (n, %)			0.008
≤ 22.9 (underweight)	13 (46%)	5 (14%)	
23-29.9 (normal)	8 (29%)	12 (32%)	
≥ 30 (overweight)	7 (25%)	20 (54%)	
MST score (n, %)			-
No nutritional risk	0	37 (100%)	
At nutritional risk	28 (100%)	-	
SGA score (n, %)			-
A	2 (7%)	-	
B	24 (86%)	-	
C	2 (7%)	-	
Patient diet code (n, %)			0.224
Full	12 (43%)	20 (54%)	
Texture Modified	7 (25%	9 (24%)	
Diabetic	6 (21%)	8 (22%)	
Other	3 (11%)	0	
Number with prescribed oral nutritional supplement(s) (n, %)	6 (21%)	1 (3%)	0.045

BMI: Body Mass Index; MST: Malnutrition Screening Tool; SGA: Subjective Global Assessment; Texture Modified Diets included soft dental diet, puree diet, soft dysphasia diet and cut up diet; Other Diets included no fish, fluid restriction 1200ml and low fat.

ŧ Chi-square tests were used for categorical variables; Independent Samples T-tests for continuous variables.

Forty-nine breakfast trays, including 219 food or beverage items, were analysed for inter-rater reliability with very strong agreement found (Cohen's k= 0.949, 95% CI 0.926-0.972, $P < 0.001$).

Protein, EAA and leucine intakes were all higher in the supplemented compared to the non-supplemented group. There was no significant difference in the mean intake of energy between the groups (Table 2).

Generalised linear regression indicated an association between energy intake and age (β 318, 95% CI 16 to 621, P = 0.039) with the youngest group having higher energy intake than the oldest group. No evidence of associations were found between age and protein, EAA or leucine intake. Associations were also found between gender and energy intake (β -388, 95% CI -649 to -126, P = 0.004), protein intake (β -5.58, 95% CI -8.97 to -2.20, P = 0.001), EAA intake (β -2.27, 95% CI -3.90 to -0.638, P = 0.006) and leucine intake (β -0.511, 95% CI -0.843 to -0.179, P = 0.003) indicating females consumed less than males. The mean (SD) energy intake for males was 2240 (517 kJ) and females 1780 (575 kJ); protein intake for males 25.3 (10.6 g) and females 19.7 (9.9 g); EAA intake for males 11.1 (5.7 g) and females 8.96 (5.2 g); leucine intake for males 2.4 (1.2g) and females 1.9 (1.1 g).

Table 2: Dietary intake of supplemented and non-supplemented groups.

Dietary intake	Supplemented group mean ± SD (n= 28)	Non-supplemented group mean ± SD (n= 37)	Mean difference (95%CI)	P value ŧ
Energy (kJ)	2052 ± 668	1824 ± 472	-228.0 (-54.5,510.5)	0.112
Protein (g)	30 ± 9.0	15 ± 5.5	15.0 (11.4,18.6)	**< 0.001**
Essential amino acids (g)	14.5 ± 4.4	5.9 ± 2.2	8.6 (6.9,10.3)	**< 0.001**
Leucine (g)	3.1 ± 0.9	1.3 ± 0.5	1.8 (1.4,2.1)	**< 0.001**

ŧ Independent Samples T-tests.

Median consumption of the prescribed two WPI fortified products was 83% (IQR 67%, 100%). WPI fortified items provided 65% (9.7 g, p< 0.001) of total EAA and 65% of total leucine intake (2.2 g, P=0.001) at breakfast. Ninety-two percent of participants opted to continue WPI fortification beyond the study period.

Reasons for consumption or non-consumption of the WPI fortified beverages included perceived health benefits and the belief that nutritional supplements are important (Table 3). Comments such as 'They are there to help' and '(drinking the WPI items) is going to improve your health' reflected this. Almost a third of responses (28%) reflected that the WPI items were enjoyed, with participants commenting 'I really enjoyed the drinks, very satisfying'. Some participants (15%) felt compelled to consume the drinks as part of the study. The most frequently reported barriers to consumption were feeling too full and not usually consuming drinks at breakfast.

Table 3: Questionnaire responses reflecting reasons for consumption (100%) or non-consumption (<100%) of WPI (20g) fortified breakfast drinks across three days (n = 28).

***Reasons for consumption* (*n* = 136)[1]**	***Frequency n* (%)**
I believed the drinks would benefit my health	44 (32%)
I believe nutritional supplements are important	43 (32%)
I was already having a protein supplement at home or in hospital	3 (2%)
I thought I had to drink the milk/juice drink as part of the research study	20 (15%)
My family member/carer/friend encouraged me to have the drinks	9 (7%)
I enjoyed the drinks	38 (28%)
No specific reason	12 (9%)
Other[2]	11 (8%)
***Reasons for non-consumption* (*n* = 61)[1]**	*Frequency n* (%)
I had nausea/vomiting/pain/tired	3 (5%)
I was feeling too full	13 (21%)
I did not like the smell	1 (2%)
I did not like the taste	5 (8%)
I normally do not have drinks at breakfast	11 (18%)
I was not interested in drinking this today/ I am sick of having it	7 (12%)
I was not thirsty/hungry	1 (2%)
I did not have enough time to finish my breakfast	1 (2%)
No specific reason	10 (16%)
Other[2]	9 (15%)

[1]n includes all responses made over a three-day period for each participant (n = 24). Participants could select multiple responses each day.

[2] The other response reflects occasions in which participants made written or verbal responses separate to their selection of pre-formed reasons.

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DISCUSSION

This study found that WPI fortification at breakfast may represent a feasible nutrition support option for elderly sub-acute patients at risk of malnutrition and contributes to a significantly higher intake of protein, EAA and leucine, relative to those who consumed a standard breakfast. The non-malnourished elderly who did not receive WPI fortification failed to meet the 25-30g protein and 2.5g leucine target from consumption at breakfast, a mechanism proposed to mitigate effects of muscle wasting. This study suggests that WPI fortification at breakfast may be appropriate for subacute elderly patients at risk of inadequate protein intake [4], especially if a usual breakfast protein source e.g. eggs are not available.

We found no difference in energy intake between the groups, but as we only assessed intake at breakfast we were unable to determine the effect on food intake and appetite over subsequent meals and days. Research suggests that higher protein intake has less effect on satiety in older compared to younger adults [32] and some studies show additional protein does not significantly impact appetite [33] and food intake at a subsequent meal [34], however protein form may be an important consideration [35]. If energy intake is inadequate, additional nutrition interventions may be required.

Supplement acceptance rates were high. A recent systematic review found lower compliance to ONS, with 67% of hospitalised patients complying with ONS recommendations and adherence as low as 37% in one study of the elderly [8]. Over the short three-day period we observed low rates of fortification discontinuation which contrasts the literature which found noncompliance with ONS as high as 65% and 74% in community-dwelling geriatrics, at one month and three months post-discharge [36].

Reasons for compliance varied. Enjoyment of the fortified beverages may have facilitated consumption of the fortified items which supports the elderly's preference for 'real food' [37]. As previously found, the ease of consumption of the fortified items appeared to influence adherence which may be a result of well-established eating routines in the elderly [38] and their willingness to consume protein fortified items that they consider to be appropriate for consumption with a meal [39].

Limitations include the small sample size and inability to randomise patients and due to this the results could be related to differences in health and demographics between the two patient groups rather than the effect of the intervention. We were unable to collect baseline dietary intake and the intake of energy, protein and leucine was estimated at breakfast only limiting conclusions about energy intake later in the day. No appetite ratings were taken. The study was short and provided a snapshot of intake and although WPI fortification appears to be feasible longer studies are needed to assess the effect on appetite and compliance.

In conclusion the study suggests the use of a WPI supplement may enhance protein, EAA and leucine intake at breakfast in patients who are at risk of malnutrition or malnourished. The delivery of WPI in liquids that are familiar and enjoyed by older adults as part of their usual diet, coupled with fostering positive perceptions about the health benefits of EAA fortification may promote adherence. Future investigations are required to examine the long term acceptability with a focus on compliance with WPI fortification in hospitalised as well as community-dwelling elderly who remain at nutritional risk.

ACKNOWLEDGEMENTS

The authors would like to thanks the patients involved in the study and Food Service Staff of Balmain Hospital who helped facilitate the project.

AUTHORSHIP

FO, ES, BD and CG were involved in the concept and design of the research DB and AG undertook participant recruitment, data collection, analysis and drafting the manuscript as part of the University of Sydney's Master's in Nutrition and Dietetic Program.

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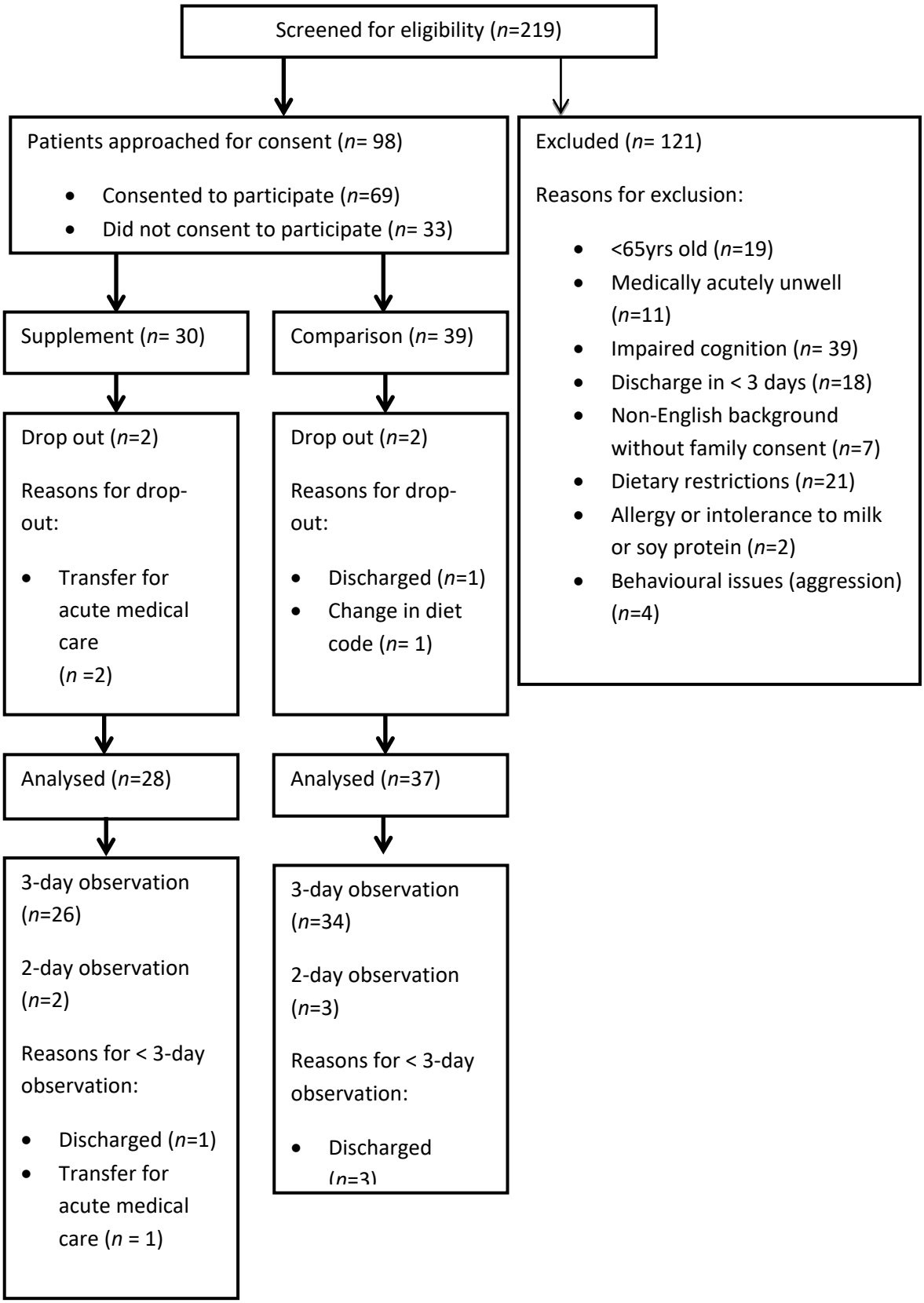

Supplementary Figure 1 Flow diagram of patient recruitment.

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Supplementary Table 1: Nutritional composition of standard and supplemented breakfast drinks.

	Energy (kJ)	Protein (g)	Total EAA(g)	Leucine (g)
Standard Breakfast Drinks				
Cow's milk, full cream (150ml)	416	5.0	2.2	0.45
Cow's milk, skim (150ml)	225	5.4	2.3	0.48
Orange juice (110 ml)	187	0.7	0.07	0.01
Apple juice (110 ml)	206	0	0	0
Whey Protein Isolate Fortified Drinks [$]				
Cow's milk, full cream + Beneprotein (150ml)	566	13.6	6.7	1.44
Cow's milk, skim + Beneprotein (150ml)	375	14.0	6.8	1.47
Orange juice + Beneprotein (150ml)	337	9.3	4.6	1.00
Apple juice + Beneprotein (150ml)	356	8.6	4.5	0.99
Beneprotein (10g WPI)	150	8.6	4.8	1.1

[$ $]Each WPI drink contains 10g of Nestle Beneprotein