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Address for Editorial Correspondence:
Editor, *Nutrition & Dietetics*
1/8 Phipps Close
Deakin ACT 2600
Australia
Email: ndi.eo@wiley.com

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ORIGINAL RESEARCH

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Implementation of a very low calorie diet program into the pre-operative model of care for obese general elective surgery patients: Outcomes of a feasibility randomised control trial

Greta Hollis AdvAPD, Senior Dietitian[1] |
Robert Franz FRACS, Medical Director[2] |
Judy Bauer PhD, FDAA, Associate Professor[3] |
Jack Bell PhD, AdvAPD, Principal Research Fellow[1,3,4]

[1]The Prince Charles Hospital, Brisbane, Australia

[2]Department of General Surgery, The Prince Charles Hospital, Brisbane, Australia

[3]School of Human Movement and Nutrition Sciences, The University of Queensland, Brisbane, Queensland, Australia

[4]Allied Health Research Collaborative, Metro North Hospital and Health Service, Brisbane, Australia

Correspondence
Greta Hollis, The Prince Charles Hospital, Rode Rd, Chermside, Brisbane, Qld 4032, Australia.
Email: greta.hollis@health.qld.gov.au

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Abstract

Aim: The present article aimed to evaluate the feasibility of implementing a very low calorie diet (VLCD) weight loss program into the pre-operative model of care for elective general surgery patients with obesity.

Methods: A prospective, randomised control trial of adults with obesity awaiting elective general surgery was conducted at an outpatient clinic at a tertiary hospital. Patients were randomised to the intervention group, an 8-week VLCD program incorporating Optifast (Nestle Health, Germany) shakes, or to standard care (generic healthy eating information). Data were collected at baseline, week 8 and at 30 days post-surgery. The primary outcome of the study was feasibility, which was evaluated through demand, practicality, integration and acceptability measures.

Results: Forty-six participants (M 17: F 29, mean age 51.6 (13.1) years) with a mean body mass index $\geq$ 30 kg/m^2 (40.5 kg/m^2 (5.9)) were recruited. Of participants who completed the study there was a higher mean weight loss in the intervention group compared to the control group (−6.5 vs +0.15 kg; $P = <.001$), with no excessive loss of muscle mass (MM), measured by bioelectrical impedance analysis. The reduction in waist circumference was greater for the intervention compared to control group (−6.11 vs +1.36 cm; $P = .003$). Quality of life increased significantly in the intervention group ($P < .001$).

Conclusions: The pre-operative VLCD program produced clinically meaningful rapid weight loss pre-surgery and improved quality of life without an excessive loss of MM.

KEYWORDS

obesity, surgery, VLCD, weight loss

1 | INTRODUCTION

Obesity is a non-communicable disease of the modern era. Trends show global obesity prevalence has increased 3-fold since 1975; estimates suggest over 650 million adults were obese in 2016.[1] The burden of disease attributable to obesity is extensive, with global annual costs associated with the treatment of obesity and related complications estimated to increase from $800 billion to $1.2 trillion by 2025.[1] A study evaluating the economic impact of obesity on patients undergoing non-bariatric surgery found people with obesity had hospital incurred costs 3.7% higher than their non-obese counterparts.[2] Over 5 million Australians are in the obese range (>30 kg/m^2),[3] with estimated costs for obesity of $9.8 billion annually.[4] A 3% to 5% weight loss in people with obesity can provide clinically meaningful health benefits including improvements in quality of life, blood lipid profile, whilst reducing risk of type 2 diabetes and cardiovascular risk factors.[5,6]

Obesity has long been perceived as a risk factor for adverse post-surgical outcomes, with reported complication rates of up to 24.9%.[7-9] People with obesity undergoing general elective surgery are at significantly higher risk of wound infection,[7,8,10-16] intra-operative blood loss[14,15] and increased length of stay.[17] A prospective review of 819 patients undergoing laparoscopic repair of ventral hernias showed patients with a BMI > 40 kg/m^2 had a longer intraoperative time.[18] Conversely, a retrospective analysis of 1721 patients undergoing elective laparoscopic colectomy found no association between obesity and risk of surgical complications.[19] However, there are a number of studies that report the association between pre-operative weight loss and reduction in surgical complications in patients with obesity undergoing bariatric surgery.[8,11,20,21] The inconsistencies in findings highlight a clear gap for further exploration. Obesity is considered a modifiable risk factor for surgical complications, with pre-operative weight loss having the potential to reduce unfavourable surgical outcomes.

Very low calorie diets (VLCDs) are considered the most effective short-term non-surgical weight loss intervention for adults with obesity.[6,22-26] They involve one or more meal replacements each day with foods or formulas that provide energy in the range of 1675 to 3300 kJ/d (400-800 kcal/d).[22] The effectiveness of pre-operative VLCDs has been reported in patients with obesity awaiting general surgery, achieving up to 15% weight loss.[26,27] However, neither study measured the impact of VLCD on muscle mass (MM) stores, patients' quality of life or surgical complications. Adequate lean muscle stores and prevention of pre-operative sarcopenia are essential in enabling the individual to have the energy reserves to respond to the surgical stress state.[27]

The primary aim of the present study was to assess feasibility of pre-operative VLCDs in patients with obesity, with a key focus to evaluate the effect of a VLCD program in achieving pre-surgical weight reduction without excessive loss of lean body mass. Secondary outcome measures were unfavourable surgical outcomes.

2 | METHODS

This prospective randomised control study targeting a convenience sample of 50 patients at a tertiary hospital in Queensland, Australia was conducted between June 2017 and June 2018. The study was approved by The Prince Charles Hospital Human Research Ethics Committee (HREC/16/QPCH/178) and The University of Queensland Research Ethics Committee (clearance number 2016001397) and was registered on the Australian New Zealand Clinical Trials registry as ACTRN12616001569493.

Patients were recruited from a general surgery outpatient clinic and were screened for eligibility by the research dietitian (GH). Inclusion criteria included patients awaiting elective general surgery with a BMI $\geq$ 30 kg/m^2 and aged over 18 years. Patients were excluded if they were pregnant, preparing/undergoing IVF, were intellectually or mentally impaired, had liver failure, portal hypertension, acute cardiovascular disease or type 1 diabetes.

An independent statistician developed randomly generated treatment allocations using the Stata statistical software package (Version 13), which were place within sequentially numbered, opaque sealed envelopes prior to the activation of the trial. Eligible patients were consented by the research dietitian and the envelopes were used to allocate patient into the control or intervention group.

The control group received standard care consisting of generic weight loss tips and healthy information sheets, developed by the hospital's dietetic department. Participants underwent assessment of clinical, anthropometric measurements, body composition analysis using bioelectrical impedance analysis (BIA) and health related quality of life (HRQoL) at baseline, week 8, and on admission to the hospital for the planned surgery.

The dietitian provided the intervention group with an individualised 8-week VLCD program including advice to manage symptoms and promote adherence. The VLCD utilised Optifast (Nestle Health, Germany) meal replacement shakes to restrict intake to 700 to 800 calories/d intake with $\geq$0.75 g/kg adjusted body weight protein. The consumption of 3 to 4 Optifast shakes mixed on water with an additional $\geq$ two cups (non-starch) vegetable/salad, at least 2 L of energy free fluids, and one teaspoon

of vegetable oil were recommended daily for 8 weeks. Oil was recommended to provide sufficient fat intake to stimulate the gallbladder, add flavour to vegetables and to improve adherence.[28] Baseline, week 4 and week 8 appointment times were 45 minutes each, whilst week 2 and week 6 reviews were 30 minutes.

Effectiveness of the intervention was assessed using clinical and anthropometric parameters and body composition at baseline, fortnightly until week 8 and on admission to the hospital for the planned surgery. HRQoL was measured at the same time points as the control group. Adherence to the VLCD program was evaluated using the presence of urinary ketones in ≥50% of fortnightly samples collected by the clinic nurse over the 8-week period.[28] Mild ketosis was expected to occur whilst on the intensive phase of the Optifast program.[28]

The primary outcome was the feasibility of implementing a pre-operative VLCD weight program for obese patients awaiting general elective surgery. Measures of acceptability, demand, practicality and integration were used to evaluate feasibility, detailed in Figure 1.[29] Secondary outcome measures were surgical complications as defined by the Clavien-Dindo classification system.[30]

Weight was measured using the BIA scale (Model Tanita BC420SMA) at fortnightly appointments over the 8-week program (intervention) and at baseline and week 8 (control). For patients in the control group that did not attend the final appointment, weight data were collected from the patients' medical charts if measured within 7 days either side of their scheduled clinic appointment. Likewise, for patients in the intervention group, the most recent weight measure from the study period was used for

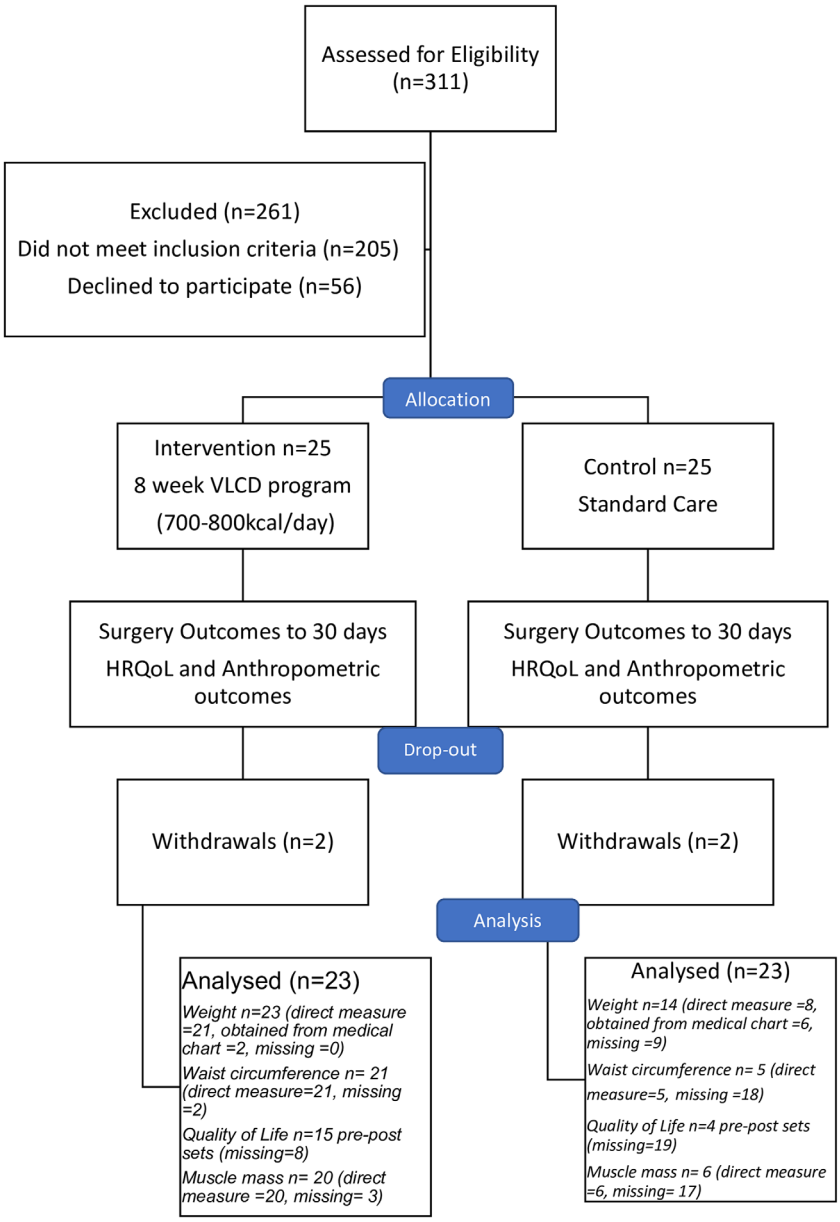

FIGURE 1 CONSORT diagram

analysis. BIA data were collected to measure the impact of the intervention on body composition, specifically, MM and fat mass (FM). MM and FM were expressed in kilograms and change measured from pre-operative baseline values.

Intervention group attendance was defined as complete when a patient attended at least four of the five scheduled appointments or went to surgery before the intervention period was complete; and in the control group

FIGURE 2 Measures of feasibility

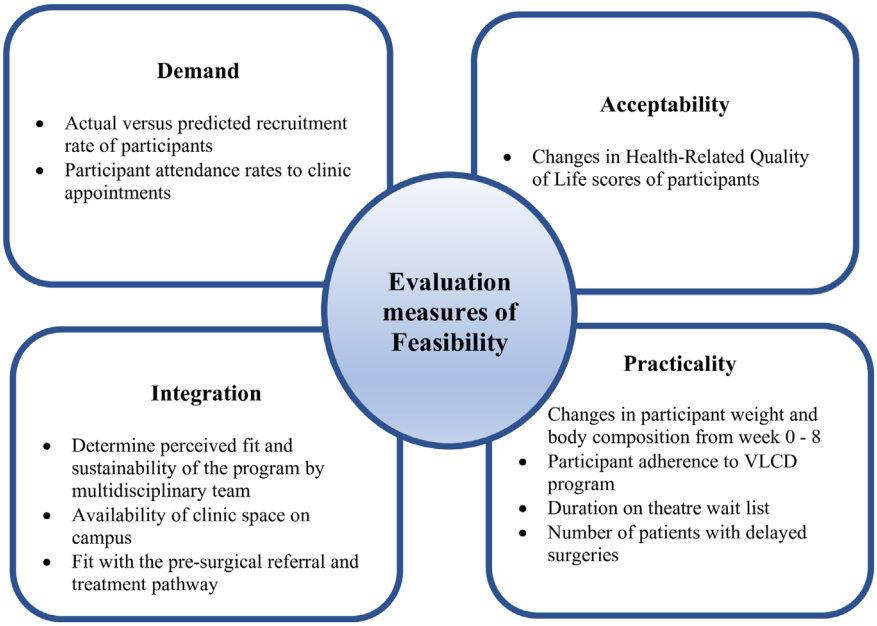

TABLE 1 Clinical and behavioural baseline characteristics of 46 pre-operative elective general surgery patients with obesity in a very low calorie diet 8-week randomised control trial

Characteristic	Intervention group (n = 23)	Control group (n = 23)	Total	*P* value
Mean (SD)[a]				
Age, y[a,b]	48.2 (13.3)	51.8 (12.2)	51.6 (13.1)	.07
Sex[a,b]	n (%)			
Male	9 (39.1)	8 (34.8)	17 (37)	.76
Female	14 (60.8)	15 (65.2)	29 (63)	
Mean (SD)[a]				
Baseline BMI[b,g]	40.3 (6.0)	40.7 (5.9)	40.5 (5.9)	.85
Surgery[c]	n (%)			
Lap cholecystectomy	14 (60.8)	13 (56.5)	27 (58.6)	.39
Umbilical hernia repair	7 (30.4)	4 (17.3)	11 (23.9)	
Ventral hernia repair	1 (4.3)	4 (17.3)	5 (21.7)	
Inguinal hernia repair	1 (4.3)	2 (8.69)	3 (13)	
Mean (SD)[a]				
Health related quality of life[b,d]	60.8 (15.9)[e]	67.1 (23.9)[f]	63.8 (20.1)	.34

[a]SD, standard deviation.
[b]Independent *t* test when normality of data.
[c]Chi square or Fisher's exact test were used as appropriate.
[d]Health related quality of life score as determined by the IWQOL-Lite tool. Raw scores for each scale were computed for each of the five scales only if a minimum of 50% of the items for that scale are answered, and for the total score out of 100, only if 75% of the answers for all items are completed.
[e]n = 21 completed.
[f]n = 19 completed.
[g]BMI, body mass index (kg/m^2).

TABLE 2 Patient-related outcomes for 46 pre-operative elective general surgery patients with obesity in a very low calorie diet 8-week randomised control trial

	Intervention group (n = 23)				Control group (n = 23)				Difference	*P* value
Patient related outcomes	**Baseline**	**Post-intervention**	**Difference**	**Within group *P* value**	**Baseline**	**Post-intervention**	**Difference**	**Within group *P* value**	**Between groups**	**Between groups**
Weight (kg)[b]	118.9	112.4	−6.5 (3.8)	<.001*	116.9	117.0	0.1	.834[b]	6.6	<.001*[c]
Mean (SD)[a]	(17.9)[m]	(18.1)			(13.5)[n]	(14.02)	(−2.6)		(1.2)	
Waist circumference (cm)[b]	124.2	118.1	−6.1	<.001*	128.4	129.8	1.36	.355[b]	7.5	.003*,[c]
Mean (SD)[a]	(13.9)[k]	(14.0)	(4.8)		(10.14)	(10.3)[l]	(2.9)		(2.3)	
Muscle mass (kg)[b,g,h]	64.9	63.3	−1.53	.019*	65.1	65.0	0.1	.72	1.43	.213[c]
Mean (SD)[a]	(12.0)	(11.6)	(2.7)		(9.5)	(10)	(0.6)		(1.1)	
Fat mass (kg)[b,g,i]	49.8	44.4	−5.48	<.001*	47.2	47.0	0.16	.88	−4.2	.002[c]
Mean (SD)[a]	(14.8)	(14.9)	(4.7)		(10.4)	(10.2)			(4.8)	
Quality of life[d,j]	58	85	18	<.001*	74.2	72.4	4.6	.715	17	.009[o]*
Median (range)	(27-81)	(61-98)[e]	(6-41.4)		(12-93)	(50-93.8)[f]	(−14 to 13.85)		(−14 to 41.4)	

[a]SD, standard deviation.
[b]Dependent *t* test.
[c]Independent *t* test.
[d]Wilcoxon signed rank.
[e]n = 15 complete pre-post data sets.
[f]n = 4 complete pre-post data sets.
[g]n = 20 complete pre-post data sets.
[h]Muscle mass as measured by bioelectrical impedance analysis, expressed as kg.
[i]Fat mass as measured by bioelectrical impedance analysis, expressed as kg.
[j]Quality of life score as determined by the IWQOL-Lite tool. Raw scores for each scale were computed for each of the five scales only if a minimum of 50% of the items for that scale are answered, and for the total score out of 100, only if 75% of the answers for all items are completed.
[k]n = 21 complete pre-post data sets.
[l]n = 5 complete pre-post data sets.
[m]23 complete pre-post data sets.
[n]14 complete pre-post data sets.
[o]Mann-Whitney *U* test.
*Statistical significance, defined by *P* value <.05, confidence interval >95%.

if they attended the baseline and week-8 appointment or went to surgery before the 8-week period was complete.

Participants' HRQoL were evaluated using the Impact of Weight on Quality of Life Lite (IWQOL-lite) tool, a validated 31 item self-report instrument specific to effects of obesity on patient's quality of life.[31] Raw scores for each scale were computed for each of the five scales only if a minimum of 50% of the items for that scale were answered, and for the total score only if 75% of the answers for all items were completed. The dietitian (GH) was blinded to HRQoL until the completion of the intervention period for all participants.

Prior to commencing the feasibility study, a power calculation was performed and demonstrated the sample sizes required to detect a significant difference in unfavourable surgical outcomes between the two groups (α .05) with 80% power were n = 141 in each arm (total n = 282). Before undertaking a large randomised control trial, a study of 50 participants was chosen as a convenience sample to test feasibility. Associations between categorical variables of interest and the outcome were analysed using chi square analyses and associations between continuous variables and the outcome were analysed using Student's *t* tests or non-parametric methods as indicated by the distributions of variables of interest. All statistical tests were completed using IBM SPSS (Version 23) and significance were determined by a *P* value <.05.

3 | RESULTS

One hundred and six patients eligible to participate attended the general surgery outpatient clinic between June 2017 and June 2018. Fifty patients agreed to participate in the study (47.2% consent rate). The details of the enrolment process and outcomes are shown in a CONSORT 2010 flow diagram in Figure 2.

On consent, patients were randomised to the intervention group (n = 25) or the control group (n = 25). The final sample was n = 46, as there were four exclusions. Reasons for the two withdrawals from the intervention group as reported by the patients were work commitments and gastrointestinal upset, respectively. The one withdrawal from the control group was due to dissatisfaction with randomisation to the control group, and one further exclusion from the control group as the participant reported using another weight loss program.

Patients in the intervention group and the control group were well matched at baseline, the baseline characteristics of the participants are shown in Table 1.

Over the duration of the study, the consent rate was 4.5 participants per month, which did not differ from the expected rate of 5 (*P* = <.06). The intervention group had a significantly higher appointment attendance rate, 93%, compared to the control group, 39.1% (*P* < .001). Positive urinary ketones were found in 56% of participants in the intervention group. Weight loss above 5% of initial body weight was associated with presence of urinary ketones (*P* = <.02). The duration (days) on the surgical wait list (184.9 vs 156.9; *P* = .53) and number of delayed surgeries due to obesity was higher in the control group compared to the intervention (9 vs 0; *P* = <.001).

From Table 2, participants in the intervention group demonstrated a significantly greater reduction in mean (SD) weight loss (6.6 kg (1.2); *P* < .001), mean (SD) waist circumference (7.5 cm (2.3); *P* = .003) and mean (SD) FM (−5.48 kg (4.8); *P* = <.001), without excessive loss of MM (−1.53 kg (2.7); *P* = .02). There were significant

TABLE 3 Surgical outcomes for pre-operative elective general surgery patients with obesity in a very low calorie diet 8-week randomised control trial*

Group	Intervention group (n = 20)	Control group (n = 14)	Difference	*P* value
Unfavourable surgical outcomes[a,b]	n (%)			
Wound infection	0 (0)	2 (14.2)	2	.16
	Mean (SD)[c]			
Intraoperative time (min)[d]	89.9 (29.3)	107.5 (41.4)	17.6 (12.1)	.16
Hospital length of Stay (d)[d]	1.2 (0.5)	1.36 (0.7)	0.16 (0.2)	.47

[a]Unfavourable post-operative outcomes were collected up until and including 30 days post-surgery. Unfavourable outcomes are defined by Avenell 2010 as the number of trial participants who died plus the number of survivors with complication. Alternatively, where these data were unavailable, a slightly different definition (mortality or survivors with a major complication or two or more minor complications). Complications were defined as per Clavien-Dindo classification.

[b]Chi square or Fisher's exact test were used as appropriate.

[c]SD, standard deviation.

[d]Independent *t* test or Mann-Whitney *U* test as appropriate.

*Who have received surgery.

improvements in HRQoL in the pre- and post-mean (SD) scores of participants within the intervention group (21.2 (11.3); $P < .001$) and when compared to the control group (18.9 (6.4); $P < .003$).

Interim surgical outcomes are reported in Table 3 for 34 (intervention group n = 20 and control group n = 14) study participants. Mean (SD) intra-operative time was 89.9 (29.3) minutes for the intervention group vs 107.5 (41.4) minutes for the control group ($P = .156$); wound infections were recorded for no patients in the intervention group vs 2 in the control group ($P = .162$); hospital length of stay was 1.2 (0.5) days in the intervention group vs 1.36 (0.7) days in the control group ($P = .474$).

4 | DISCUSSION

This randomised control study is the first to demonstrate that VLCDs are effective in inducing significant pre-operative weight loss without excessive loss of MM stores and improving patient quality of life. Results suggest a high level of demand, acceptability, practicality and integration for the pre-operative VLCD program.

The demand for this pre-surgical intervention is demonstrated by a significantly higher clinic appointment attendance rate. The attendance rates are on the higher end of those reported in the literature demonstrating a range of 30% to 97% adherence to pre-surgical VLCDs across programs of 2-12 week duration.[21,32,33] Weight loss above 5% of initial body weight was associated with presence of urinary ketones ($P = <.02$), demonstrating an induced state of ketosis, reflecting high adherence to the VLCD program. Interestingly, patients who had negative urinary ketones still achieved weight loss of up to 5% over the VLCD intervention, suggesting ketosis is not essential for weight loss. Two studies evaluating pre-surgical VLCD adherence in bariatric surgery also found an association between increased weight loss and presence of urinary ketones.[34,35]

The significant improvement in HRQoL of participants receiving the intervention represents participant acceptability of the program. Findings from a two year randomised trial in non-surgical people with obesity showed significant improvements in HRQoL of participants with weight loss of 3.7%.[36] No patients had a negative overall IWQoL score in the present study, suggesting the VLCD intervention did not have a detrimental effect on quality of life.

The practicality of pre-operative VLCDs is demonstrated by the significant lower number of patients on the surgical wait list who had delayed surgeries due to obesity compared to the control group (0 vs 9, $P < .001$). Additionally, the mean duration on the surgical wait list was lower in the intervention group 156.9 vs 184.9 days for the control group ($P = .53$). This is clinically relevant, as they had a lower average wait list time of 156.9 days compared to the 90th percentile waiting time to treatment for Category 3 general surgery at Queensland Health Public Hospitals of 261 days.[37]

The intervention group had a greater weight loss (5.5%) and reduction in FM without excessive loss of MM, compared to the control group. Similar weight loss of between 4% and 15% has been reported in non-bariatric surgery patients using a pre-surgical calorie restricted diet.[21,32,33,38] A high proportion of weight loss (85%) was from FM in participants receiving the VLCD intervention, likewise other studies evaluating low calorie diets on body composition showed 68.9 - 85% of weight loss was from a reduction in FM without excessive loss of muscle mass.[39,40] Using BIA to measure body composition is not without flaw, as results can be influenced by body water distribution and body morphology in individuals with obesity, potentially overestimating body FM.[41]

Whilst it is acknowledged the present study is not powered to detect a significant difference in surgical outcomes, results are suggestive of the utility of pre-surgical VLCDs to induce positive clinical benefits to patient and health outcomes including a reduction in wound infection and shorter intra-operative time. Burnand demonstrated significant reduction in theatre time in a study evaluating the impact of a 2-week VLCD program prior to cholecystectomy, with average weight loss of 3.7%.[21] Furthermore, a randomised multi-centre trial of n = 298 patients by Van Nieuwenhove found that the intervention group (VLCD) had a significant higher weight loss (3.8%), compared to the control group and this was associated with a reduction in the number of overall post-operative complications (18 vs 8 – non-significant).[42]

The present study was not controlled for participants' physical activity level; however, the RCT design may account in part for this limitation. However, these factors do not impact on feasibility outcomes such as demand and integration. Greater weight loss demonstrated in the intervention group compared to the control group may be impacted on by participation confounder, where participation can be seen to have a therapeutic effect on influencing change.[43] However, this may be viewed as an advantage for patient engagement and service with the health system. It is acknowledged that the low attendance rate at the final appointment in the control group is a limitation of the study as a substantial portion of the final data presented for the control group were collected from medical charts or were unavailable.[43] Measuring attrition rates was a key component of the feasibility trial and an advantage of using a pragmatic trial looking at standard of care. The authors concluded that it was not feasible to continue onto a large RCT with such a high

dropout rate in the control group and, therefore, this contributed to the decision to implement pre-operative VLCDs into routine care.

The present study has demonstrated that the use of pre-operative VLCDs in patients with obesity awaiting general surgery is feasible. Results have indicated an improvement in quality of life and achievement of rapid fat loss, without excessive loss of muscle mass in patients undertaking the VLCD. Further research to determine the impact of pre-operative weight loss on unfavourable surgical outcomes and body composition is underway.

CONFLICT OF INTEREST

Greta Hollis is using this trial to contribute toward the completion of a Master of Philosophy at the University of Queensland, Brisbane Australia.

AUTHOR CONTRIBUTIONS

All authors have contributed to trial design and have reviewed and approved the final manuscript. G.H. wrote the first draft of the manuscript and statistical analysis. J.B. and J.B. contributed to manuscript review and assisted with statistical analysis. R.F. contributed to manuscript review. All authors are in agreement with the manuscript and declare that the content has not been published elsewhere.

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ORCID

Greta Hollis https://orcid.org/0000-0002-4492-7970
Judy Bauer https://orcid.org/0000-0002-3830-5147
Jack Bell https://orcid.org/0000-0002-7217-3635

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ORIGINAL RESEARCH

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Secondary-prevention behaviour-change strategy for high-risk patients: Benefits for all classes of body mass index

Keanne Langston BNutrDiet (Hons), APD, Clinical Dietitian[1] | Lynda J. Ross PhD, AdvAPD, Senior Lecturer[1,2,3] | Angela Byrnes BHlthSc (Nutr&Diet), APD, PhD Candidate[1,2] | Robin Hay BHlthSc (Nutr&Diet), APD, Senior Clinical Dietitian[2]

[1]Nutrition & Dietetics, School of Allied Health Sciences, Griffith University, Gold Coast, Queensland, Australia

[2]Nutrition and Dietetics Department, Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia

[3]Menzies Health Institute Queensland, Southport, Queensland, Australia

Correspondence
Ms Keanne Langston, Nutrition & Dietetics, School of Allied Health Sciences, Griffith University, 58 Parklands Drive, Southport, QLD 4215, Australia.
Email: keanne.ln@gmail.com

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Abstract

Aim: Research is needed to support the long-term benefits of lifestyle interventions for management of high-risk patients with different BMI classifications. This prospective multicentre study assessed two-year outcomes of hospital-referred patients (BMI 25-61 kg/m^2) attending a dietitian-led multidisciplinary Healthy Eating and Lifestyle Behaviour-Change Program in group or individual formats in hospital outpatient settings.

Methods: Bodyweight, quality of life (Short Form-12) and intuitive eating (Intuitive Eating Scale) data were collected at pre-intervention, post-intervention and 2 years. Outcomes were reported in BMI classes.

Results: At pre-intervention (n = 493), 11% had pre-obesity, 25% obesity class I, 30% obesity class II and 34% obesity class III. Characteristics of participants with available data at post-intervention (n = 290) and 2 years (n = 178) were comparable ($P > .05$). Significant mean weight loss was seen at post-intervention (-2.0 ± 0.4 kg, $P < .001$, n = 290) and 2 years (-4.3 ± 0.5 kg, $P < .001$, n = 178). All BMI classes had significant weight losses ($P < .05$). Participants with higher obesity (classes II and III) had greater improvements in mental quality of life ($P < .05$) and initial weight reductions ($P < .05$) than those with lower classes. However, those with obesity class I had the greatest long-term weight reductions and significant improvements in physical quality of life at 2 years ($P < .05$). All BMI classes reported similar improvements in intuitive eating. No effect was found for differences in intervention format, duration or setting ($P > .05$).

Conclusions: The results support dietitian-led multidisciplinary lifestyle interventions for multidisciplinary management of high-risk patients of all BMI classes.

KEYWORDS

intuitive eating, lifestyle intervention, obesity, overweight, quality of life, weight control

1 | INTRODUCTION

Pre-obesity and obesity affects more than 60% of the Australian population,[1] persisting as a major health issue worldwide[2] and potentially leading to a plethora of chronic illnesses, increased mortality risk and economic burden.[3] Modest weight loss of 5% bodyweight or more can assist in reducing risk of chronic diseases such as cardiovascular disease and diabetes.[3]

Lifestyle interventions with behaviour-change therapies have been observed to lead to significant weight loss in the mid-term (up to 12 months post-intervention).[4] However, further research is needed to determine maintenance of outcomes over the long-term (up to 2 years). Systematic reviews report on lifestyle interventions conducted in primary care and community centres,[4] comprising group or individual formats of varying durations, and found delivery by a multidisciplinary team may be more effective than individual sessions.[3] Less commonly reported are lifestyle interventions conducted as secondary-prevention strategies for risk-management of patients attending hospital outpatient services,[4] though there is greatest potential for health benefits in patients already accessing the health system. Evaluation of varying formats, durations and settings will inform these services.

Further, guidelines, such as National Institute for Health and Care Excellence (NICE), suggest lifestyle intervention may be more beneficial in those with obesity than pre-obesity.[5] However, a study by Unick et al indicated that intensive lifestyle interventions are effective across all BMI classes, but the study spanned just 6 months and relied on provision of meal replacements.[6] Therefore, it is important to substantiate the appropriateness of lifestyle intervention for all BMI classes in real world settings.

This present study focuses on the Healthy Eating and Lifestyle Program (HELP), conducted in Queensland hospital outpatient settings, for management of weight and related disease risk in hospital-referred patients (BMI $\geq$ 25 kg/m^2). The study aimed to evaluate two-year outcomes in adults with different BMI classes. Secondary aims were to determine whether outcomes differed by intervention format, duration or setting.

2 | METHODS

A prospective multicentre cohort study was conducted to evaluate dietitian-led HELP sessions conducted in hospital outpatient or hospital-outreach settings in Queensland. Patients with BMI $\geq$ 25 kg/m^2 attending in-hospital clinics were identified by health professionals for referral to HELP. Patients attending an initial HELP session between July 2014 and June 2015 participated in the study. A two-year follow-up was conducted by researchers, with a telephone call placed on at least two occasions. Study inclusion criteria were being $\geq$18 years old and having a BMI of $\geq$25 kg/m^2. Exclusion criteria were lack of fluent English; pregnancy; bariatric surgery; or mental health unsuitability to participate, as assessed by a psychologist using the Depression, Anxiety and Stress Scale (DASS-21).[7] Participants could withdraw from the study at any time. Ethical approvals were obtained from the Royal Brisbane and Women's Hospital (RBWH) Human Research Ethics Committee (HREC) for pre- and post-intervention data collection (Ref No: HREC/14/QRBW/289) and 2-year follow-up data collection (Ref. No: HREC/14/QRBW/445). This study was reported against Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.

HELP content (Appendix S1) was developed by a team of dietitians at the Royal Brisbane and Women's Hospital. Dietitians developed this from evidence-based clinical practice guidelines.[3] Ten topics employed several current behaviour-change strategies including: Cognitive Behavioural Therapy; motivational interviewing; Acceptance and Commitment Therapy; intuitive eating; self-monitoring; problem-solving; contingency management; relapse prevention; social support. Implementation was conducted by one dietitian at each centre, with two sessions (topics six and seven) in the programme being co-facilitated by a psychologist where available (group formats only). All dietitians promoted the Australian Dietary Guidelines[8] and a "moving more and sitting less" ethos, supported by physiotherapist-guided exercises where available. Where no physiotherapist was available, topics five and nine were either led by the dietitian or omitted from the programme.

Eleven centres were included in the study—nine outpatient settings and two hospital-outreach community settings. The programme at each site was led by a dietitian each, totalling 11 dietitians throughout Queensland. All 11 dietitians were invited to attend regular monthly teleconference meetings to ensure support and consistency for the state-wide service and data collection. Three centres offered group format only, two offered individual dietetic consultations only, and six centres offered group and individual formats—in addition or as an optional alternative to the group. Group formats were conducted with 10 to 15 participants in two-hour weekly sessions over 6 to 10 weeks intensive phase. Individual consultations were conducted face-to-face, with the number dependent on the dietitian's discretion and participant agreement. After the intensive phase of HELP, participants of some programmes were invited to participate in

a dietitian-led monthly recharge group programme over 12 months, which covered similar programme content to HELP. Participant attendance at Recharge sessions was not recorded. Attendance by participants at other hospital clinics (e.g. for physiotherapy or diabetes management) was independent of HELP participation and unknown to the researchers.

Pre- and post-intervention data were collected by onsite dietitians from patients attending an initial HELP session (pre-intervention) and a final HELP session (post-intervention) between July 2014 and June 2015, inclusive. Data included measured height, bodyweight and waist circumference, using standardised equipment. As per the NICE guidelines, waist circumference was measured only in those with pre-obesity (BMI $< 30\ kg/m^2$) or obesity class I (BMI $< 35\ kg/m^2$).[5] Paper surveys measured quality of life (Short Form-12—SF-12)[9] and intuitive eating (Intuitive Eating Scale—IES).[10] Two-year follow-up was conducted by researchers between July 2016 and June 2017 via telephone, where participants consented to answer verbal questions from SF-12 and IES questionnaires and self-reported their current bodyweight. Previous research supports self-reported weight as a valid measure of actual weight.[11]

The SF-12 comprised 12 questions, assessing eight domains: physical functioning; role-physical; bodily pain; general health; vitality; social functioning; role-emotional; mental health.[8] Scores were combined to give Physical Component Summary-12 (PCS-12) and Mental Component Summary-12 (MCS-12) scores, indicative of physical and mental quality of life, respectively.[9] PCS-12 and MCS-12 scores range from zero (lowest quality of life) to 100 (highest quality of life).[12] SF-12 can detect differences in quality of life associated with BMI, and has been validated in populations with pre-obesity and obesity.[12,13]

IES is a validated tool used previously in similar populations to HELP to measure intuitive eating. It has been suggested that intuitive eating may assist with sustaining of healthy dietary behaviours.[10,14] IES uses 21 statements to assess three subscales: *unconditional permission to eat* (referred to as IES-Unconditional); *eating for physical rather than emotional reasons* (referred to as IES-Physical); *reliance on internal hunger/satiety cues* (referred to as IES-Reliance).[10] Answers are scored on a five-point Likert scale: one = *strongly disagree* (lowest score); two = *disagree*; three = *neutral*; four = *agree*; five = *strongly agree* (highest score), with 13 statements being reverse-scored.[9] IES scores were reported for each subscale and in total, with higher scores representing better intuitive eating.[10]

The data were entered into Statistical Package for Social Sciences (SPSS version 25, New York, United States). Results were expressed as mean ± SD for continuous variables and number frequency (percent) for categorical variables, and 95% confidence intervals were reported. Normality tests were conducted to identify errors and outliers. All outliers were checked for random and systematic errors, which were corrected or ruled out. Genuine outliers were retained and treated the same as other data to avoid statistical bias and undervaluing a heavy-tailed distribution for weight and BMI. The outlier sub-population were contained wholly within the obesity class III category. Descriptive statistics assessed baseline characteristics. Independent *t* tests determined differences between sub-groups. Linear mixed model assessed differences between datasets at different time points. Intention-to-treat analysis was impractical due to missing follow-up data (due to data collection issues, as discussed in the Results section). Therefore, representativeness of datasets at each time point were assessed by comparing baseline characteristics of the total sample to those participants with and without subsequent bodyweight data. To minimise possible type 1 error due to the number of statistical tests conducted, significance was set at $P < .05$.

3 | RESULTS

In total, 493 patients attended an initial HELP session and provided pre-intervention weight data during the data collection period. The mean ± SD age of participants providing age data at pre-intervention (n = 485) was 55.75 ± 13.66 (range: 18-84) years. The mean ± SD baseline (n = 493) BMI of 38.15 ± 7.28 (range: 25-61) kg/m^2 was equivalent to obesity class II (BMI $> 35\ kg/m^2$), reflective of severe disease risk relative to normal bodyweight.[15] Mean ± SD waist circumferences of 124.99 ± 16.27 cm 113.95 ± 14.26 cm for females represented a substantial increase in disease risk when compared to World Health Organisation recommendations of <102 cm for males and <88 cm for females, respectively.[15] Almost all (96%) participants had previously been diagnosed with at least one comorbid condition, including: hypertension, hyperlipidaemia, diabetes, cancer, history of stroke, lung disease, arthritis, chronic kidney disease, depression, anxiety or ischaemic heart disease. Many participants did not report their ethnicity (n = 277 or 56%). Of those who reported ethnicity (n = 216), most were Caucasian (89%, n = 192/216), followed by Aboriginal or Torres Strait Islander (4%, n = 9/216) and Pacific Islander (4%, n = 9/216), with the remainder (3%, n = 6/216) being from other ethnic backgrounds. Most participants were born in Australia or New Zealand (77%). Levels of education and employment

status were unable to be reported with confidence due to substantial missing data.

Table 1 outlines the numbers and proportions of participants who provided a bodyweight at each data collection time point. At pre-intervention, the majority (n = 315/493, 64%) of participants had obesity class II or III. Genuine outliers for weight at pre-intervention (n = 4; 1% of all data; 2% of the obesity class III category) and BMI (n = 7; 1.5% of all data; 4% of the obesity class III category) were part of a heavy-tailed distribution (outlier range: 56.0-58.3 kg/m^2). The numbers of participants who provided a bodyweight at post-intervention and/or at two years post-intervention decreased substantially across time points due to difficulties surrounding data collection. However, the data were considered representative of BMI and gender classifications where the proportions of participants within each BMI classification remained stable over time, as did the proportion of females: n = 349/493 (71%) at pre-intervention; n = 203/290 (70%) at post-intervention; n = 118/178 (66%) at two-year follow-up. Reasons for incomplete data collection included: the participant did not attend the specific HELP session in which data were collected; data were not collected or recorded by the onsite dietitian; the participant did not wish to be contacted by telephone; was unavailable by telephone; did not recall their current bodyweight; contact details were incorrect or out of date; the timeline for the project ended before all participants could be contacted. These findings suggest missing data were random and not due to systematic errors.

Table 2 further demonstrates the representativeness of the available data by providing pre-intervention (baseline) characteristics of the total sample and at each data collection time point. Baseline height, weight and BMI were statistically similar between participants with and without bodyweight data at each time point ($P > .05$), and were similar to those of all participants (n = 493) ($P > .05$). The exception was age, where participants who provided a bodyweight at post-intervention and/or at two-years were significantly older compared to participants without bodyweight data at these time points ($P < .01$). These data contribute to a reasonable assumption that the available data were representative of the total number of patients attending HELP.

Table 3 shows participant outcomes (mean ± SD) at post-intervention and 2 years according to their baseline BMI classifications, based on available data at each time point. Compared to pre-intervention, mean bodyweight was statistically significantly lowered at post-intervention (n = 290, −2.0 kg, −1.9%, $P < .001$) and two-years (n = 178, −4.3 kg, −4.1%, $P < .001$). Similarly, BMI was statistically significantly reduced at post-intervention ($P < .001$) and two-years ($P < .001$). According to baseline BMI classifications, the greatest mean percentage weight loss achieved at post-intervention was by participants with obesity class II (n = 91, −2.2 kg, −2.1%, $P < .001$) and obesity class III (n = 90, −2.5 kg, −2.0%, $P = .007$), followed by obesity class I (n = 79, −1.4 kg, −1.5%, $P = .018$) and pre-obesity (n = 30, −1.0 kg, −1.3%, $P = .086$). Compared to pre-intervention, participants with obesity class I (n = 46, −4.2 kg, −4.6%, $P < .001$) and obesity class II (n = 66, −4.4 kg, −4.2%, $P < .001$) reported the greatest mean percentage weight loss at two-years, followed by pre-obesity (n = 17, −3.3 kg, −4.1%, $P < .001$) and obesity class III (n = 49, −4.4 kg, −3.4%, $P < .001$). Notably, weight loss achieved by participants with lower BMI classes (pre-obesity, obesity class I and II) approached clinical significance, that is, approximately 5% of initial weight, which is associated with lowered disease risk and subsequent health benefits.[3] In relation to programme delivery, long-term weight loss was similar between: settings (hospital vs community,

TABLE 1 Total number and proportions of participants with bodyweight data at each time point by BMI classification

Participants with bodyweight data	Pre-intervention N = 493	Post-intervention n = 290	Two-year n = 178
Proportion of all participants	100%	59%	36%
	n (n/N%)	n (n/N%)	n (n/N%)
Pre-obesity (BMI 25-29.9 kg/m^2)	56 (11%)	30 (10%)	17 (10%)
Obesity class I (BMI 30-34.9 kg/m^2)	122 (25%)	79 (27%)	46 (26%)
Obesity class II (BMI 35-39.9 kg/m^2)	146 (30%)	91 (31%)	66 (37%)
Obesity class III (BMI ≥ 40 kg/m^2)	169 (34%)	90 (31%)	49 (28%)

Note: Data are n (number of participants who provided bodyweight data)/N (total number of participants who attended an initial HELP session and provided a bodyweight) (%).

TABLE 2 Baseline participant characteristics (mean ± SD) and comparisons between datasets at each timepoint

		Post-intervention		Two-year	
	All participants n = 493 Mean ± SD	**Participants with BWT data n = 290 Mean ± SD**	**Participants without BWT data n = 203 Mean ± SD**	**Participants with BWT data n = 178 Mean ± SD**	**Participants without BWT data n = 315 Mean ± SD**
Age (years)	55.75 ± 13.66	57.66 ± 12.60	53.00 ± 14.65[a]	58.21 ± 12.56	54.33 ± 14.08[a]
	n = 485	n = 286	n = 199	n = 178	n = 307
Height (m)	1.66 ± 0.09	1.66 ± 0.09	1.66 ± 0.09	1.67 ± 0.09	1.66 ± 0.09
Pre-BWT (kg)	105.78 ± 22.23	104.90 ± 21.28	107.03 ± 23.52	105.57 ± 21.57	105.89 ± 22.63
Pre-BMI (kg/m^2)	38.15 ± 7.28	37.87 ± 7.17	38.54 ± 7.44	37.66 ± 6.88	38.43 ± 7.50

Abbreviation: BWT, bodyweight.

[a]Independent *t* test, significant difference between groups with and without bodyweight data at a single data collection time point, $P < .01$.

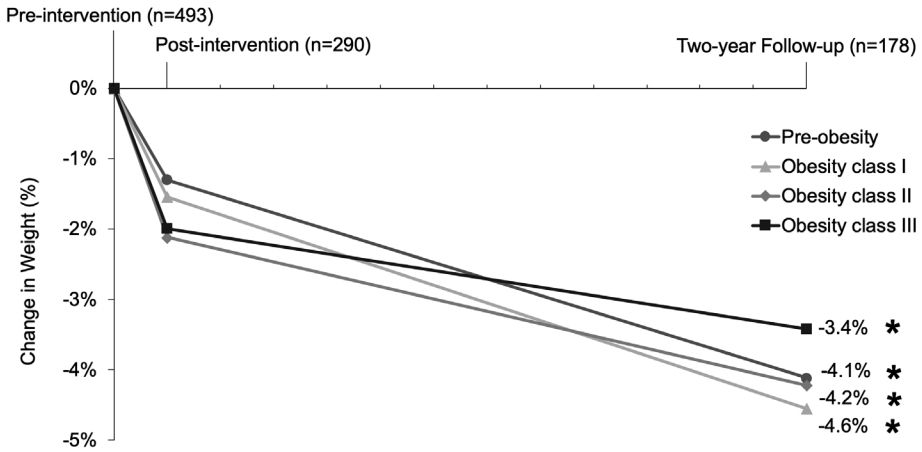

FIGURE 1 Mean percentage weight change over time by BMI class

$P = .141$); formats (group vs individual and mixed, $P = .582$), and duration (6 vs 10 weeks, $P = .734$).

Figure 1 shows mean bodyweight changes for participants at pre-intervention (n = 493), post-intervention (n = 290) and two years post-intervention (n = 178), according to BMI classifications. Significant weight loss was observed for HELP participants at post-intervention (n = 290, −2.0 ± 0.4 kg, $P < .001$) and two-year follow-up (n = 178, −4.3 ± 0.5 kg, $P < .001$). All BMI classes achieved significant weight loss at post-intervention and two years (linear mixed model, $P < .05$), with the exception of those with pre-obesity where weight loss was not significant at post-intervention ($P = .086$), but significant at two-year follow-up ($P < .001$).

Table 3 shows mean scores for physical (PCS-12) and mental (MCS-12) quality of life by BMI classification at each time point. Overall, compared to pre-intervention, PCS-12 and MCS-12 scores improved at post-intervention (PCS-12 + 3.0 ± 1.0, $P = .002$; MCS-12 + 4.3 ± 1.1, $P < .001$) and two-years (PCS-12 + 2.4 ± 0.9, $P = .009$; MCS-12 + 4.3 ± 1.1, $P < .001$). Some BMI-specific differences in response to intervention were: participants with obesity class II and obesity class III had statistically significant improvements in MCS-12 at post-intervention ($P < .05$). At two-year follow-up, those with obesity class I showed statistically significant improvement in PCS-12 scores ($P = .007$), and participants with obesity class I and III showed statistically significant improvement in MCS-12 compared to pre-intervention ($P < .05$).

Table 3 shows mean total intuitive eating (IES) scores by BMI classification at each time point. Compared to pre-intervention, participant IES-Total scores were significantly higher at post-intervention (+0.2 ± 0.3, $P < .001$) and two years (+0.2 ± 0.3, $P < .001$). Similarly, IES-Physical and IES-Reliance scores were higher at post-intervention (+0.5 ± 0.1, $P < .001$; and + 0.3 ± 0.04, $P < .001$, respectively), and two years (+0.4 ± 0.1, $P < .001$; and + 0.2 ± 0.04, $P < .001$, respectively).

TABLE 3 Weight, BMI, quality of life and intuitive eating outcomes (mean ± SD) by BMI classification and timepoint

	Pre-intervention Mean ± SD n = 493	Post-intervention Mean ± SD n = 290	Two-year Mean ± SD n = 178	Change pre-intervention to post-intervention Mean change (95% CI)	*P*	Change pre-intervention to 2-year follow-up Mean change (95% CI)	*P*
BMI (kg/m^2)	38.15 ± 7.28	37.24 ± 6.98	36.12 ± 7.61	−0.67 (−0.96, −0.37)	.000[a]	−1.50 (−1.87, −1.14)	.000[a]
BWT (kg)	105.78 ± 22.23	102.98 ± 20.76	101.16 ± 22.39	−2.00 (−2.74, −1.25)	.000[a]	−4.32 (−5.23, −3.40)	.000[a]
Pre-obesity	79.10 ± 10.38 (n = 56)	79.45 ± 9.09 (n = 30)	74.62 ± 11.50 (n = 17)	−1.03 (−2.22, 0.15)	.086	−3.26 (−4.77, −1.74)	.000[a]
Obesity class I	91.19 ± 8.96 (n = 122)	89.49 ± 8.41 (n = 79)	87.78 ± 10.45 (n = 46)	−1.41 (−2.57, −0.25)	.018[a]	−4.15 (−5.61, −2.69)	.000[a]
Obesity class II	103.21 ± 11.61 (n = 146)	101.71 ± 12.26 (n = 91)	99.81 ± 13.95 (n = 66)	−2.19 (−3.29, −1.09)	.000[a]	−4.36 (−5.62, −3.10)	.000[a]
Obesity class III	127.36 ± 19.29 (n = 169)	123.96 ± 19.07 (n = 90)	124.75 ± 21.16 (n = 49)	−2.54 (−4.38, −0.70)	.007[a]	−4.36 (−6.76, −1.98)	.000[a]
PCS-12	31.78 ± 9.36 (n = 163)	34.47 ± 9.92 (n = 95)	33.89 ± 11.69 (n = 176)	3.03 (1.09, 4.96)	.002[a]	2.43 (0.62, 4.24)	.009[a]
Pre-obesity	33.98 ± 7.26 (n = 13)	38.58 ± 10.56 (n = 8)	35.04 ± 10.78 (n = 17)	—[b]	—	—	—
Obesity class I	32.28 ± 10.61 (n = 32)	34.83 ± 8.77 (n = 22)	36.75 ± 12.78 (n = 45)	3.39 (−0.76, 7.54)	.105	5.60 (1.62, 9.57)	.007[a]
Obesity class II	32.41 ± 9.94 (n = 56)	35.81 ± 10.72 (n = 32)	33.61 ± 11.78 (n = 65)	3.47 (−0.21, 7.16)	.064	2.02 (−1.17, 5.22)	.212
Obesity class III	30.49 ± 8.54 (n = 62)	31.94 ± 9.49 (n = 33)	31.24 ± 10.45 (n = 49)	1.43 (−1.59, 4.46)	.349	0.70 (−2.22, 3.61)	.635
MCS-12	42.47 ± 12.73 (n = 163)	47.61 ± 12.42 (n = 95)	47.64 ± 12.34 (n = 176)	4.25 (2.07, 6.44)	.000[a]	4.60 (2.54, 6.65)	.000[a]
Pre-obesity	48.48 ± 10.52 (n = 13)	48.67 ± 7.93 (n = 8)	47.23 ± 13.14 (n = 17)	—[b]	—	—	—
Obesity class I	45.44 ± 12.66 (n = 32)	48.44 ± 11.17 (n = 22)	49.23 ± 11.83 (n = 45)	2.01 (−2.58, 6.59)	.380	4.36 (0.08, 8.64)	.046[a]
Obesity class II	42.15 ± 13.08 (n = 56)	48.58 ± 13.36 (n = 32)	46.12 ± 12.54 (n = 65)	5.46 (1.43, 9.49)	.009[a]	2.98 (−0.60, 6.57)	.101
Obesity class III	39.96 ± 12.40 (n = 62)	45.85 ± 13.41 (n = 33)	48.28 ± 12.42 (n = 49)	5.54 (1.59, 9.50)	.007[a]	8.05 (4.27, 11.82)	.000[a]

(Continues)

TABLE 3 (Continued)

	Pre-intervention Mean ± SD n = 493	Post-intervention Mean ± SD n = 290	Two-year Mean ± SD n = 178	Change pre-intervention to post-intervention Mean change (95% CI)	*P*	Change pre-intervention to 2-year follow-up Mean change (95% CI)	*P*
IES-Total	3.00 ± 0.46 (n = 353)	3.21 ± 0.40 (n = 192)	3.17 ± 0.45 (n = 175)	0.21 (0.15, 0.27)	.000[a]	0.17 (0.11, 0.23)	.000[a]
Pre-obesity	3.01 ± 0.42 (n = 32)	3.30 ± 0.45 (n = 18)	3.25 ± 0.34 (n = 17)	0.28 (0.09, 0.47)	.004[a]	0.23 (0.03, 0.44)	.025[a]
Obesity class I	3.02 ± 0.45 (n = 88)	3.27 ± 0.36 (n = 51)	3.15 ± 0.41 (n = 44)	0.24 (0.14, 0.34)	.000[a]	0.13 (0.01, 0.25)	.027[a]
Obesity class II	3.01 ± 0.49 (n = 108)	3.20 ± 0.41 (n = 57)	3.24 ± 0.45 (n = 65)	0.19 (0.08, 0.29)	.001[a]	0.23 (0.12, 0.33)	.000[a]
Obesity class III	2.98 ± 0.46 (n = 125)	3.16 ± 0.40 (n = 66)	3.08 ± 0.50 (n = 49)	0.21 (0.98, 0.31)	.000[a]	0.11 (−0.13, 0.31)	.079

Abbreviation: BWT, bodyweight.

Note: Quality of Life: PCS-12, Short Form-12 physical component score and MCS-12, Short Form-12 mental component score; IES-Total, Intuitive Eating Scale total score across three subscales.

[a]Linear mixed model, significantly different from pre-intervention, $P < .05$.

[b]Change in PCS-12 and MCS-12 for those with pre-obesity was unable to be assessed with confidence due to a small sample size.

IES-Unconditional scores, however, were not significantly different at post-intervention or two-year follow-up. IES scores were similar between BMI classes at post-intervention and two years, with all with obesity classes having statistically significant improvements in IES-Total, IES-Physical and IES-Reliance scores, with the only exceptions being IES-Total for obesity class III, and IES-Reliance for pre-obesity, where the improvements were not significant at two-year follow-up only. Participants with obesity class II had significant improvements in IES-Unconditional at two-year follow-up compared to pre-intervention ($+0.1 \pm 0.1$, $P < .05$).

4 | DISCUSSION

This study aimed to evaluate long-term outcomes of hospital-referred high-risk patients attending a lifestyle behaviour-change programme conducted in hospital outpatient settings. The results suggest that an evidence-based approach to dietary behaviour-change is an effective secondary-prevention strategy for promoting quality of life, intuitive eating and weight loss for up to two-years in all BMI classes. Available measured data indicated an average weight loss of 2 kg post-intervention, and patients reported a total average weight loss of 4.3 kg at two years, significant across all BMI classes. Total weight loss was clinically significant and comparable to other lifestyle interventions,[16,17] but the two-year maintenance of weight loss and downward trajectory experienced by some individuals may challenge previous research that most weight is regained within 2 to 5 years.[3,4] However, for patients identified as high-risk, any maintenance of initial weight loss is considered beneficial to future disease risk.

Importantly, participants within all BMI classifications achieved significant weight loss, including those with severe obesity. This finding is in agreement with a previous lifestyle intervention that evaluated outcomes by BMI class.[6] However, that study gave meal replacements to participants with type 2 diabetes mellitus and included a narrow age range—whereas the current study provides evidence of the effectiveness of lifestyle intervention in free-living patients with comorbidities participating in real-life clinical settings. This is an important finding, given the increased disease risk amongst those with obesity.[15]

Weight loss outcomes were consistent across multiple participating sites regardless of format (group or individual), programme duration, setting (hospital or community), or whether the site offered follow-up support. These findings confirm those of previous studies that

programme effectiveness is independent of delivery setting or format,[3,4] but contrasts with previous research that weight loss increases with programme duration.[3] Participants of this study were hospital-referred patients attending other clinics and likely receiving other treatments for comorbidities throughout the study and possibly during the follow-up period. The contribution of these treatments is unknown, and whether participants accessed other weight management interventions and/or support across the two years is also unknown, but is reflective of the "real-world" nature of the study.

Pre-obesity and obesity are associated with poorer quality of life.[3] Baseline physical and mental quality of life of study participants were poorer than reported previously for individuals with pre-obesity and obesity participating in lifestyle interventions[18,19] or in another Queensland study,[13] likely reflecting the high burden of comorbid disease amongst the hospital-referred participants in the current study. However, improvements in post-intervention physical and mental quality of life were greater than those in other lifestyle interventions,[18,19] possibly due to lower baseline levels, early achievement of significant weight loss and/or the high number of behaviour-change strategies and patient-centred care delivered by the multidisciplinary team.[3] Interestingly, improvements in physical quality of life were mainly attributable to those with obesity class I. In contrast, improvements in mental quality of life were mainly attributable to obesity classes I, II and III, perhaps due to poorer baseline mental quality of life. Changes in quality of life for those with pre-obesity were unable to be assessed with confidence due to a small sample size.

Intuitive eating represents eating according to one's physiological cues, rather than emotional or situational cues, and may assist with sustaining healthy eating behaviours.[10,14] No other lifestyle intervention studies have compared long-term intuitive eating outcomes by BMI, where significant improvements were seen across all BMI classes. All obesity classes tended to have improvements in eating for physical rather than emotional reasons and relied on internal hunger/satiety cues. There was no change in the degree to which participants allowed eating of any foods desired (*unconditional permission to eat*), possibly as HELP conveys mixed messages through emphasising an enjoyment of all foods and discouraging dieting, whilst also encouraging a reduction in discretionary intake to more closely align one's diet with the Australian Guide to Healthy Eating.

Whilst loss to follow-up can be considered a substantial study limitation, gaps in data collection were not due to a significant dropout or low motivation to participate in the follow-up study. Losses to follow-up were due to difficulties associated with data collection in a real-life study relying upon busy clinicians at multiple sites, free-living participants attending specific data collection sessions of HELP (initial and final), and a defined timeframe that did not allow all participants to be contacted. However, baseline characteristics across datasets remained similar and were likely representative of the total study population. The authors acknowledge there was no control group for comparison and that detected differences may be affected by regression to the mean.

This study supports dietitian-led lifestyle intervention as a secondary-prevention behaviour-change strategy for high-risk hospital-referred outpatients of all BMI classes. The positive results substantiate the importance of multidisciplinary patient-centred care to enhance intuitive eating and long-term self-management of weight and associated disease risk. Further research is required to confirm the impact on the economic burden of healthcare.

CONFLICT OF INTEREST

R.H. and A.B. are employed by the Royal Brisbane and Women's Hospital; L.J.R. is a visiting research fellow at the Royal Brisbane and Women's Hospital.

AUTHOR CONTRIBUTION

R.H. and L.R. conceived the study; R.H., L.R., A.B. and K.L. were involved in data collection; L.R., A.B. and K.L. were involved in data analysis, interpretation of the data and writing of the paper; and all authors were involved in reviewing the manuscript and had final approval of the submitted and published versions. This content has not been published elsewhere. Griffith University Internal Funding was given for a research assistant.

ORCID

Keanne Langston https://orcid.org/0000-0003-4835-592X
Lynda J. Ross https://orcid.org/0000-0003-2947-4130
Angela Byrnes https://orcid.org/0000-0003-4069-4724

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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ORIGINAL RESEARCH

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Carbohydrate counting accuracy in adults with cystic fibrosis related diabetes

Jenna Stonestreet BHlthSc Nutr Diet (Hons), APD, Senior Dietitian[1] |
Ashmitha AR BHlthSc Nutr Diet (Hons), Dietitian[2] |
Karen Herd BHlthSc Nutr Diet (Hons), APD, Senior Dietitian[1] |
Angela Matson BHlthSc Nutr Diet (Hons), APD, Senior Dietitian[1] |
Jack Bell PhD AdvAPD, Principal Research Fellow[1,3,4]

[1]Department of Nutrition and Dietetics, The Prince Charles Hospital, Brisbane, Queensland, Australia

[2]School of Exercise and Nutrition Sciences, Faculty of Health, Queensland University of Technology, Brisbane, Queensland, Australia

[3]Allied Health Research Collaborative, The Prince Charles Hospital, Brisbane, Queensland, Australia

[4]The University of Queensland, Brisbane, Queensland, Australia

Correspondence
Jenna Stonestreet, Nutrition and Dietetics Department, The Prince Charles Hospital, Rode Road, Chermside, Brisbane 4032, Australia.
Email: jenna.stonestreet@health.qld.gov.au

Abstract

Aim: Poorly controlled Cystic Fibrosis-Related Diabetes (CFRD) is associated with adverse impacts on lung function and nutritional status. Insulin therapy is the only recommended medical treatment. Carbohydrate Counting (CC) is used to guide insulin doses and can assist in achieving optimal postprandial blood glucose levels. This study aimed to determine the prevalence of individuals with CFRD who carbohydrate count, explore barriers to its use and assess the accuracy of CC in hospitalised patients.

Methods: A cross-sectional, mixed-methods, descriptive study recruited individuals with CFRD hospitalised at an Australian tertiary hospital. Consenting patients completed a questionnaire. Patients were asked to estimate the carbohydrate content of their ordered meals provided by hospital foodservices. The study dietitian assessed each meal's estimation against the actual content.

Results: 17 individuals were recruited to this study and five declined. Seven had a fixed insulin regimen, and ten had a flexible insulin regimen and used CC. Patients in the fixed insulin group reported lower levels of confidence in their ability to carbohydrate count ($P < .001$) and placed less importance on CC ($P < .001$). 53% of the fixed insulin group's and 41.7% of the flexible insulin group's estimations of the carbohydrate content of the hospital food items were accurate.

Conclusion: Of those patients recruited to this study, 59% used CC as a tool to guide insulin dosing, and patients estimated accurate carbohydrate values in only 46% of meals. Further research is warranted to investigate the most suitable method to assist accurate carbohydrate content estimations in a hospital setting.

KEYWORDS

carbohydrate counting, cystic fibrosis, diabetes

1 | INTRODUCTION

Cystic fibrosis related diabetes (CFRD) is a form of diabetes unique to individuals with cystic fibrosis (CF) and shares features of both type 1 and type 2 diabetes.[1] Insulin is the only recommended medical treatment.[1] Options for insulin delivery include single or multiple insulin injections, or a continuous subcutaneous insulin infusion (CSII).[1,2]

It is well established that abnormal glucose tolerance in individuals with CF is associated with adverse impacts on lung function and nutritional status, and consequently morbidity and mortality.[3] Insulin therapy in these individuals has been shown to reverse the decline in both lung function and body mass index (BMI).[4-6]

Carbohydrate counting (CC) is a method of calculating the grams of carbohydrate consumed at different meals and snacks to determine the appropriate dose of bolus insulin to achieve optimal glycaemic control. Inaccurate carbohydrate counting and consequent inaccurate insulin dose administration can lead to postprandial hypoglycaemia or postprandial hyperglycaemia. Moran et al proposed that the use of CC to guide insulin doses in individuals with CFRD can assist with achieving postprandial blood glucose levels in the target range.[1] CC education is associated with improvements in the percentage of postprandial blood glucose levels in target range and perceived quality of life (QoL) in individuals with type 1 diabetes, as well as an enhanced flexibility of food choices at mealtimes.[7,8] No such studies have been published for those individuals with CFRD.

Many factors can impact an individual's ability to carbohydrate count including literacy level, motivation and time commitment, but most critical is the impact of other comorbidities. The treatment burden for individuals with CF alone is significant, and a diagnosis of CFRD represents another substantial psychological impact to manage. For this reason, the timing and appropriateness of CC education needs to be tailored to the individual and delivered in a setting of an experienced multidiscplinary CF team.

A meta-analysis reviewing the effects of carbohydrate counting in children, adolescents and adults with type 1 diabetes showed that CC reduced Glycosylated Haemoglobin (Hba1c) levels when compared to other methods, and a significant reduction in Hba1c levels was demonstrated in the adult group.[9] It reports that CC is the preferred method of dosing bolus insulin although high-quality randomised controlled trials are required.[9] Koontz et al developed the PedCarbQuiz (PCQ) to assess carbohydrate counting and the calculation of insulin doses in youth with type 1 Diabetes.[10] This study demonstrated that higher scores on the PCQ were associated with lower Hba1c scores. Another study investigating the effect of CC in adults with type 1 diabetes using a continuous subcutaneous insulin infusion (CSII) showed a reduction in Hba1c and improved QoL using a Diabetes-Specific Quality of Life Questionnaire.[11]

The role of CC in adults with CFRD has been scarcely reported. As the life expectancy of individuals with CF continues to increase and the prevalence of CFRD increases with age,[2] it is prudent to investigate CC and its role in optimising health outcomes in this population. Therefore, this study aims to determine the prevalence of individuals with CFRD who carbohydrate count and to explore barriers to using this diabetic management tool in this patient group. This study also aims to assess the accuracy of CC in hospitalised individuals with CFRD at a tertiary Australian hospital.

2 | METHODS

This cross-sectional, mixed-methods, descriptive study recruited individuals hospitalised at a tertiary, metropolitan hospital in Brisbane, Australia between June and August 2018. Participants were included if they had a diagnosis of CFRD and were on insulin therapy, were aged 18 highest in past years old or above and provided informed consent. Participants were excluded if they had Indeterminate Glucose Tolerance (INDET), Impaired Glucose Tolerance (IGT) or Gestational Diabetes Mellitus (GDM) using insulin therapy or had end-stage lung disease with modified treatment goals. All patients with CF who are admitted to thishospital are seen by the dietitian as part of routine care. CC education by the dietitian is offered in both inpatient and outpatient settings as a nutritional intervention in the management of CFRD.

Once informed consent was obtained, demographic and clinical information was collected from the participant's medical record by the study dietitian including age, gender, pancreatic status, current lung function and highest in past 12 months (FEV_1 and FEV_1% predicted), current HbA1c level and lowest in past 12 months, insulin regimen (including type of insulin and doses) and the prescription of corticosteroids in the past 3 months.

Additional information was also collected via a short questionnaire which included information on the date of CFRD diagnosis and commencement of insulin therapy. Patient perceptions of their own confidence level using CC, importance of CC to improve glycaemic control and reported level of difficulty of CC were collected via a five-point Likert scale. This 5-point Likert scale was collapsed into two groups for each of the questions for data analysis (Table 2). Participants were also asked one open-ended question that assessed their barriers to CC.

Participants were asked to complete the carbohydrate counting assessment component of the study, then to order their meals through the hospital foodservice system as per usual practice. Participants estimated total carbohydrate content (grams) of their ordered breakfast, lunch and dinner meals provided by hospital foodservices, on one day of their choice. If they consumed additional food at these meals, not provided by the hospital foodservice system, it was not to be included in their estimate. Participants documented estimated carbohydrate content on their meal tray ticket at the time of consumption and it was collected by the study dietitian the following day. The study dietitian assessed each meal's estimation against the actual grams of carbohydrates entered into the foodservice system CBORD (CBORD. Foodservice Suite Version 18.10.100, Ithaca, New York). An estimate was considered accurate if it was within 15 g of the actual amount. Participants were given the option to receive feedback on the estimations to guide future insulin doses.

Data were analysed using Statistical Package for Social Scientists (SPSS) version 23.0 database (SPSS, IBM Corp., Armonk, New York). All available data were included in analysis. Continuous variables were explored for normality. Patient characteristics including age, FEV_1%, Hba1c and actual carbohydrate content of meals were presented using descriptive statistics, with means and SDs. Independent *t* tests were used for analysis of unpaired measures. The χ^2 test (or Fishers exact test where appropriate) was used to examine associations between categorical variables. Statistical significance was set at 5% level ($P < .05$).

This research was completed at The Prince Charles Hospital, Brisbane, Australia. Ethical and governance approval for this study was granted by the hospital Human Research Ethics Committee and Governance Unit (HREC/18/QPCH/42). The reporting of this paper also conforms to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.

3 | RESULTS

A total of 22 individuals were identified to be eligible for the study and 17 gave informed consent. Seven study participants identified themselves as having a fixed insulin dose regimen, and 10 study participants identified as having a flexible insulin regimen (basal-bolus regimen) and used CC. Characteristics of the patients included are described in Table 1. There was a trend for a lower lung function (FEV_1%) in the fixed insulin group but this was not significant. There were no statistically significant differences between the two groups in terms of gender ($P = .435$), age ($P = .683$), current FEV_1% ($P = .538$), recent Hba1c ($P = .616$) or duration of CFRD diagnosis ($P = .729$). All participants were pancreatic insufficient. All participants from the flexible insulin dose group and 71.4% from the fixed insulin group reported receiving some form of CC education from a health professional since their diagnosis. The two other participants (28.6%) from the fixed insulin group reported they were unsure if they had received CC education.

Patients in the flexible insulin group reported greater significance in their confidence to carbohydrate count as a strategy to manage their CFRD in comparison to the fixed insulin group which was statistically significant ($P < .001$), as per Table 2. Additionally, patients in the fixed insulin group also reported a statistically significant lower level of importance for CC when compared to the participants in the flexible insulin group ($P < .001$). Interestingly, only 71.4% of the fixed insulin group rated CC as very difficult, difficult or somewhat difficult.

TABLE 1 Patient characteristics

Variables	Fixed insulin dose (n = 7)	Flexible insulin dose (n = 10)	Statistical significance
Gender n (%)			$\chi^2(2) = 1.665$, $P = .435$[a]
Male	3 (42.9%)	6 (60.0%)	
Female	3 (42.9%)	4 (40.0%)	
Intersex	1 (14.2%)	0 (0.0%)	
Mean age—years (SD)	30.6 (8.7)	32.8 (12.1)	$t(15) = -0.416$, $P = .683$
Mean duration of CFRD dx—years (SD)	7.7 (4.3)	6.8 (5.8)	$t(15) = 0.354$, $P = .729$
Mean current FEV_1% (SD)	47.8 (14.9)	54.1 (22.9)	$t(15) = -0.631$, $P = .538$
Mean best FEV_1% (SD)	54.7 (15.1)	64.3 (22.3)	$t(15) = -0.985$, $P = .340$
Mean recent HbA1c (SD)	6.8 (1.3)	7.1 (1.1)	$t(15) = -0.512$, $P = .616$
Mean best HbA1c (SD)	6.3 (1.0)	7.1 (1.1)	$t(15) = -1.513$, $P = .151$

[a]Five cells have expected count less than five.

TABLE 2 Carbohydrate counting and reported level of confidence, importance and difficulty

Variables	Fixed insulin dose (n = 7)	Flexible insulin dose (n = 10)	*P* value
Confidence in CC n (%)[a]			<0.001[d,*]
Not confident	7 (100.0%)	1 (10.0%)	
Confident	0 (0.0%)	9 (90.0%)	
Importance of CC n (%)[b]			<0.001[d,*]
Not important	6 (85.7%)	1 (10.0%)	
Important	1 (14.3%)	9 (90.0%)	
Difficulty in CC n (%)[c]			1.00[d]
Not difficult	2 (28.6%)	2 (20.0%)	
Difficult	5 (71.4%)	8 (80.0%)	

Abbreviation: CC, carbohydrate counting.
[a]Collapsed Likert scale legend—not confident included responses "not confident" and "a little confident"; confident included responses "somewhat confident," "confident" and "very confident." Three cells have expected count less than 5.
[b]Collapsed Likert scale legend—not important included responses "not important" and "a little important"; important included responses "somewhat important," "important" and 'very important." Three cells have expected count less than 5.
[c]Collapsed Likert scale legend—not difficult included responses "not difficult" and "a little difficult"; difficult included responses "somewhat difficult," "difficult" and "very difficult." Two cells have expected count less than 5.
[d]Fishers exact test (two-sided).
*$P < .05$.

TABLE 3 Carbohydrate content estimations of breakfast, lunch and dinner meals

Variables	Fixed insulin dose (n = 5)	Flexible insulin dose (n = 8)	Statistical significance
Breakfast			
Est. CHO within 15 g accuracy n (%)	2 (40.0%)	5 (62.5%)	$\chi^2(1) = 0.627$, $P = .429$[a]
Mean CHO content of meal—g (SD)	46.0 (23.5)	48.8 (15.4)	$t(10) = -0.246$, $P = .811$
Lunch			
Est. CHO within 15 g accuracy n (%)	4 (80.0%)	3 (37.5%)	$\chi^2(1) = 2.236$, $P = .135$[a]
Mean CHO content of meal—g (SD)	54.3 (35.4)	73.6 (23.0)	$t(10) = -1.159$, $P = .273$
Dinner			
Est. CHO within 15 g accuracy n (%)	2 (40.0%)	2 (25.0%)	$\chi^2(1) = 0.325$, $P = .569$[b]
Mean CHO content of meal—g (SD)	68.3 (32.3)	83.3 (30.4)	$t(10) = -0.788$, $P = .449$
Total (B, L, D)			
Est. CHO within 15 g accuracy n (%)	8 (53.0%)	10 (41.7%)	$\chi^2(1) = 0.506$, $P = .477$
Mean CHO content of meal—g (SD)	56.2 (29.5)	68.5 (27.1)	$t(10) = -1.075$, $P = .308$

Abbreviations: CHO, carbohydrate; est, estimated.
[a]Four cells have expected count less than 5.
[b]Three cells have expected count less than 5.

Nonetheless, there were no statistically significant differences of the level of reported difficulty in CC between the two groups ($P = 1.000$).

Thirteen of the 17 participants who initially provided informed consent completed the study component on carbohydrate estimations in the hospital setting. Four participants from the overall study declined to participate in this component. Of this consenting subgroup, there were no statistically significant differences between these two groups in terms of gender, age, FEV_1% or duration of CFRD diagnosis. Fifty-three percent of the meals assessed by the fixed insulin group were considered accurate based on the participant's carbohydrate content estimate being within 15 g of the actual amount, as seen in Table 3. Comparatively, 41.7% of the meals assessed by the flexible insulin group were considered accurate. There were no statistically significant differences in the carbohydrate content estimations or actual carbohydrate

content of ordered meals between the fixed insulin and flexible insulin groups, or between different mealtimes.

Additionally, participants' perceptions of why CC was difficult was collated. Only 15 responded and two participants reported CC as not difficult. The most common theme was the difficulty in application when ingredients were unknown such as when visiting restaurants and hospitals (46.6%). This was followed by CC triggering feelings of anxiety and stress (33.3%), CC being too time-consuming for the individual (13.3%) and the individual reporting having an inadequate knowledge of CC (6.6%).

4 | DISCUSSION

This study demonstrates that less than two-thirds of those with CFRD used carbohydrate counting as a diabetic management tool despite it being the preferred method to guide insulin doses at mealtimes for individuals with CFRD.[1] This is the first study to investigate CC prevalence in individuals with CFRD. It is difficult to compare its prevalence to type 1 diabetes as the literature focuses on the effects of CC on individuals with type 1 diabetes, rather than prevalence.

This uptake is not surprising given the burden of disease on individuals living with CF is significant. They are incumbered by multiple treatment activities such as daily physiotherapy and pancreatic enzyme replacement therapy to digest fat at each meal as well as by symptoms and recurrent pulmonary exacerbations and hospitalisations.[12] This is also coupled with the emotional impact of having CF, often while managing education, employment and family life. An additional diagnosis of CFRD can often be overwhelming, and some individuals are not willing to accept CC in addition to their multiple other treatments. This enforces that CC is only a valuable tool for those wanting to tailor their treatments to suit changes in their diet and lifestyle.

Results from this study also showed that those who do not carbohydrate count (fixed insulin group) were less confident with CC than those who did CC ($P < .001$) and placed less importance on this as a tool to improve glycaemic control ($P < .001$). Again, this supports the notion that in terms of their treatment loads, CC may not be a high priority. However, as the life expectancy of individuals with CF continues to increase, the risk of developing micro- and macrovascular complications associated with poor control of their CFRD may become more of a concern to the individual. One study has shown no difference in the prevalence of peripheral neuropathy, nephropathy, or microvascular complications in patients with CFRD and those with type 1 diabetes.[13] Such a diagnosis in an individual with CFRD can further challenge their overall treatment regimen, and so discussing the importance of CC in relation to their overall diabetic control and goals may assist in reducing the risk of developing these secondary complications longer-term.

BMI is an independent predictor of mortality in CF.[3,4,6] A diet high in energy is recommended to meet the often elevated nutrition requirements associated with infection, malabsorption and inflammation.[1,2] Meeting these higher nutritional requirements can be challenging, and so a diet unrestricted in carbohydrate content for some individuals is important to allow these requirements to be met.[1] The average carbohydrate content of meals in the fixed and flexible insulin groups was 56.2 and 68.5 g, respectively. There were no statistically significant differences in the actual carbohydrate content of ordered meals between the fixed and flexible insulin groups. CC is a means to be able to meet these often elevated nutrition requirements while maintaining optimal glycaemic control, and so further education may be required to ensure the importance of such a method is understood.

Although the fixed insulin group reported a lower level of confidence in their ability to carbohydrate count, both groups reported similar levels of difficulty in doing so. Furthermore, only 53% of the fixed insulin group and 41.7% of the flexible insulin group's estimations of the carbohydrate content of the food items provided were considered accurate. There were no statistically significant differences in the carbohydrate content estimations between the fixed insulin and flexible insulin groups or between different mealtimes. Although there are no studies to compare to for individuals with CFRD, this rate of carbohydrate counting accuracy is not dissimilar to other studies examining adolescents with type 1 diabetes[10,14,15] and adults with type 1 diabetes on a CSII.[16] Again, this supports that self-management of diabetes can be complex and challenging not only in those with CFRD, and finding barriers to CC is imperative to developing appropriate interventions. Participants perceived that not knowing the ingredients of meals such as in restaurants or hospitals as the most common reason as to why CC is difficult. The current hospital's foodservice provision does not offer nutrition profiles alongside the food and drink items being provided.

This study also showed satisfactory HbA1c levels in both the fixed and flexible insulin groups. HbA1c is not recommended for routine screening in CFRD as it may be lower due to increased red blood cell turnover and inflammation,[1,4,17] but it does offer some use in the management of CFRD.[17] Corticosteroid treatment is known to increase blood glucose levels[18] however, no participants were prescribed corticosteroids at the time of recruitment or in the 3 months prior. Based on HbA1c levels, there was no significant difference between those in the fixed or

flexible insulin group. Hba1c levels may not accurately reflect average blood glucose monitoring[17] and so additional research assessing carbohydrate content estimations with postprandial levels is recommended.

The strengths of this study were that it is the first investigating the prevalence and accuracy of CC in individuals with CFRD and it adds to the limited research available on CC and adults with insulin-dependent diabetes. This study also reflected selected meal choices of individuals while hospitalised, mirroring true situations and providing a pragmatic avenue for feedback about carbohydrate content estimation accuracy. Conversely, a limitation is that the meals were not comparable from patient to patient as they reflected the individual's selection for the day and that nutrition profiles are not offered with foodservice delivery. Individuals were also asked to submit their estimation of grams of carbohydrate for the meal in total. Asking for estimations of individual components of meals may have assisted in determining particular food items that individuals were more likely to over or underestimate and influence further educations. Another limitation is the small sample size that may not have been sufficiently powered to detect a statistical significance between the two groups. This group represents 27% of the total number of patients with CFRD attending this hospital's CF service; however, not all individuals with CFRD are admitted to hospital regularly and may have a more stable disease. Lastly, most of the measures were self-reported and were therefore subject to reporting bias.

This study shows that 59% of those patients with CFRD recruited to this study used CC as a tool to guide insulin dosing. 76.5% of participants reported a level of difficulty to its application and this was supported with only 46% of meals having accurate carbohydrate content estimations for food items provided in a hospital setting. Further research is warranted to investigate the most suitable tool for optimal glycaemic control in those with CFRD and a method to assist accurate carbohydrate content estimations in a hospital setting.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

J.S. formulated study aims and design. J.S. and A.A. contributed to data collection and analysis and drafted the manuscript. J.B., A.A., K.H. and A.M. contributed to the study design. J.B. contributed to data analysis. All authors contributed to the critical review of the manuscript. All authors approved the final manuscript and content has not been published elsewhere.

ORCID

Jenna Stonestreet https://orcid.org/0000-0002-6837-2578
Jack Bell https://orcid.org/0000-0002-7217-3635

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ORIGINAL RESEARCH

Sarcopenia, nutritional status and type 2 diabetes mellitus: A cross-sectional study in a group of Mexican women residing in a nursing home

María C. VELÁZQUEZ-ALVA,[1] María E. IRIGOYEN-CAMACHO,[1] Marco A. ZEPEDA-ZEPEDA,[1] Irina LAZAREVICH,[1] Isabel ARRIETA-CRUZ[2] and Carlos D'HYVER[3]

[1]Departamento de Atención a la Salud, Universidad Autónoma Metropolitana-Xochimilco, [2]Departamento de Investigación Básica, Instituto Nacional de Geriatría and [3]Facultad de Medicina, Universidad Nacional Autónoma de México, Ciudad Universitaria, Ciudad de Mexico, Mexico

Abstract

Aim: To evaluate the prevalence of sarcopenia and its association with nutritional status and type 2 diabetes mellitus (T2DM) in older women living in a nursing home.

Methods: This cross-sectional study assessed nutritional status using the Mini Nutritional Assessment (MNA). Sarcopenia was defined according to the European Working Group on Sarcopenia in Older People; hand grip strength and physical performance were determined by dynamometry and gait speed, respectively. Muscle mass was assessed using calf circumference.

Results: The mean age of the 114 participants was 84.1 ± 7.0 years. The prevalence of sarcopenia and T2DM was 30.7% and 10.5%, respectively. The majority (66.7%) had a normal nutritional status, 29.8% were at risk of malnutrition, and 3.5% were undernourished. The prevalence of sarcopenia in participants at risk of malnutrition and those who were undernourished was higher compared with participants with a normal NS ($P < 0.0001$). A statistically significant difference was observed in the Barthel Index (BI) between women with and without sarcopenia ($P = 0.048$). The multivariate logistic regression model, adjusted by age ($p = 0.007$) showed an association between sarcopenia and nutritional status. Women with a poor nutritional status were more likely to have sarcopenia (OR 4.97, $P = 0.003$) whilst those with T2DM showed a higher probability of sarcopenia (OR 5.52, $P = 0.019$) than women without T2DM.

Conclusions: Sarcopenia was highly prevalent in women with a poor nutritional status and T2DM. It is necessary to implement intervention programs to reduce adverse outcomes.

Key words: nursing home, nutritional status, sarcopenia, type 2 diabetes mellitus.

Introduction

Sarcopenia is defined by the European Working Group on Sarcopenia in Older People (EWGSOP) as a syndrome characterised by the progressive and generalised loss of skeletal muscle mass associated with the loss of strength and/or function, with a risk of adverse outcomes.[1] The age-related loss of muscle mass is also associated with an increased risk of developing dependence, physical disability and poor quality of life, as well as a high risk of mortality and health-care costs.[2] The prevalence of sarcopenia varies considerably in the world.[3] A high prevalence of sarcopenia in nursing homes has been identified, and its occurrence is more elevated in women who are over 70 years of age.[4] In Mexico, the prevalence varies across different groups, from 9.9% in independent individuals who are 60 years old and older and have Social Security to 48.5% in community-dwelling adults.[5,6]

On the other hand, both sarcopenia and malnutrition are frequently found in elderly individuals. Vandewoude *et al.* recommended that clinicians identify malnutrition-sarcopenia syndrome in geriatric groups to improve the clinical outcomes.[7]

Likewise, some studies on sarcopenia have considered the association of this condition with nutritional status and activities of daily living (ADL).[8]

M. C. Velázquez-Alva, MD, MSc, Professor
M. E. Irigoyen-Camacho, MPH, PhD, Professor
M. A. Zepeda-Zepeda, BSc, Professor
I. Lazarevich, MD, PhD, Professor
I. Arrieta-Cruz, MD, PhD, Professor
C. D'Hyver, MD, Professor
Correspondence: M. E. Irigoyen-Camacho, Departamento de Atención a la Salud, Universidad Autónoma Metropolitana-Xochimilco, Calzada del Hueso # 1100, Colonia Villa Quietud, Código Postal 04960, Ciudad de Mexico.
Email: meirigo@correo.xoc.uam.mx

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In addition, the elderly are frequently affected by chronic diseases, such as type 2 diabetes mellitus (T2DM). The prevalence of T2DM is increasing worldwide,[9] and its occurrence in 60–65-year-olds is reaching epidemic proportions in developing countries. The prevalence of T2DM has increased significantly among Mexican adults who are 50 years old and older, from 14.6% in 2001 to 19.3% in 2012, with higher rates in women.[10] According to the National Health and Nutrition Survey 2012 in Mexico, the prevalence of T2DM was 19.4% and 26.3% in individuals who are 50–59 and 60–69 years old, respectively.[11] Furthermore, several studies have shown that T2DM patients exhibited a greater loss of muscle mass, strength and functional capacity over time than non-T2DM individuals.[12]

The metabolic consequences of sarcopenia have received less consideration than the functional features, although T2DM is a prominent cause of disability, decreased life expectancy and mortality.[13] Some studies have identified an association between sarcopenia and T2DM in elderly people.[14]

Hyperglycaemic and hyperinsulinaemic status observed in T2DM patients could impair the response of muscle protein synthesis by changes in the S6K1 pathway activation in human muscle, inducing a reduction in the new protein synthesis for the failure of the response to anabolic stimuli.[15]

Currently, there is little evidence of the interrelationship between nutritional status, T2DM and sarcopenia in elderly individuals.[16] The simultaneous effects of these three diseases are particularly devastating, their early identification and timely management in clinical practice could contribute to improving the living conditions of the elderly. This is particularly relevant considering the increasing prevalence of T2DM and the ageing of the global population.

The aim of this study was to evaluate the prevalence of sarcopenia and to study its association with nutritional status and T2DM in a group of old women residing in a nursing home in Mexico City.

Methods

This study utilised a cross-sectional design. The protocol was registered by the Council of the Division of Biological Sciences and Health of Universidad Autónoma Metropolitana -Xochimilco and accepted by the Ethic Committee in Mexico City (Code: DCBS.CD, Approved CD.52.17.).

This study was conducted in a women's exclusive nursing home. In Mexico, women are a vulnerable social group; this is exacerbated by old age. In addition, most of them were widows, and some were neglected by their families. This facility is located in the southern part of the Mexico City and has private and public financing. The study was conducted between May and August 2016.

The inclusion criteria were: women 65 years old and older, capable of providing written informed consent, living for more than 1 year in the nursing home, capable of performing the functional test and able to answer the study questionnaire.

The exclusion criteria were as follows: residents were not eligible for the study as a result of being bed ridden or if they had amputated limbs and/or pretibial oedema (as this condition may cause an overestimation of calf circumference). Those with end-stage palliative diseases, terminal phase, advanced dementia, cancer or another medical condition that would limit data collection or unwilling to participate in the study were also excluded.

The sociodemographic characteristics of the participants, as well as pre-existing medical conditions and anthropometric characteristics, were recorded. The following sociodemographic information were obtained from the participants´ records: age, marital status, level of education, hospital admissions, chronic diseases and falls. In particular, for the identification of patients with diabetes, special attention was paid to the previous physician's diagnosis. For all of the diabetic patients, therapeutic measures were adopted, including control through pharmacotherapy and diet. The participants had medical insurance. The objectives and procedures of this study were explained to the nursing home residents, and all participants signed a written consent form.

Two registered dietitians evaluated the nutritional status and assessed the anthropometry of each participant. The standardisation procedures were performed with a certified dietitian (International Society for the Advancement of Kinanthropometry (ISAK)) using recommended, validated and standardised protocols, as well as calibrated instruments.[17] The results indicated 84% and 89% intra- and inter-examiner agreement, respectively.

The anthropometric evaluation included: height, weight, mid upper-arm circumference (MUAC), arm muscle circumference (AMC), tricipital skinfold (TSF), waist and hip circumference (WC and HC), waist–hip ratio and calf circumference (CC). The body mass index (BMI) was classified according to the World Health Organization (WHO) criteria.[18] In addition, the Lipschitz BMI cut-off values specifically stated for elderly with a BMI below 22 were considered.[19] MUAC was measured at the point of maximum bicep convexity with the limbs completely relaxed.

TSF was measured in mm, including both layers of skin, underlying connective tissue and subcutaneous fat, but not muscle. A Harpenden calliper (Baty International, Burgess Hill, West Sussex, UK) was applied 1 cm below and at a right angle to the pinch. AMC was calculated with the following formula: AMC (cm) = 97 mid arm circumference (cm) - [π x triceps skinfold (cm)].[20]

WC was measured at a mean level between the lowest rib and the iliac crest. HC was measured at the greater trochanters with the legs positioned close together. To measure CC, an inelastic tape was positioned horizontally around the maximum circumference in a plane perpendicular to the long axis of the CC. The cut-off point was 31 cm, which has been recommended in older people by the WHO.[21]

The Mini Nutritional Assessment (MNA) was used to evaluate the nutritional status of the participants. Good nutritional status was defined as an MNA score > 23.5; elderly women with a score of 17–23.5 were considered to have a malnutrition risk, and individuals with a score < 17 were considered malnourished.[22]

Activities of daily living (ADL) were assessed by applying the Barthel Index.[23] This Index is a scale that measures disability or dependence in ADL in geriatric patients (feeding, bathing, dressing, grooming, bowels (incontinency), bladder (incontinency), toilet use, transfers (bed to chair and back), walks with help of one person, stairs (needs help)). This index ranges from 0 to 100. Low scores indicate physical disability.

A geriatric physician performed the procedure to assess sarcopenia. Sarcopenia was defined according to the EWGSOP algorithm.[1] Physical performance was evaluated by measuring the participants' usual gait speed (in meters per second) over a 4-m course. Values less than 0.8 m/s indicate low gait speed. Hand grip strength was measured with dynamometry using a mechanical hand dynamometer (TKK 5001; Takei Scientific Instruments, Tokyo, Japan), and low muscle strength was classified as a hand grip <20 kg.

The diagnosis of sarcopenia requires the assessment of muscle mass, which was performed using CC of the dominant leg (cut-off < 31 cm). CC is considered a surrogate marker of muscle mass for the diagnosis of sarcopenia.[24]

Sample size calculation was performed to find a difference between two sample proportions to compare the proportion of elderly women with sarcopenia in the group with low MNA score (MNA≤23.5) and the proportion of sarcopenia women in the group with good nutritional status. This calculation was based on the information of elderly women in a nursing home in a developing country.[16] For calculating sample size $\alpha = 0.05$, power $(1-\beta) = 0.80$ and null difference in proportions of 0.10 was used. The sample size required was 105 participants.

The characteristics of the participants with and without sarcopenia were compared using one-way analysis of variance, the Kruskal-Wallis test and the Chi-square test. Multiple logistic regression analysis was performed to assess the association between the independent variables of interest and sarcopenia; odds ratios (OR) and 95% confidence intervals (95% CI) were obtained. The Goodness of Fit test for the logistic regression model was evaluated using the Hosmer-Lemeshow test. The significance level was set at $P < 0.05$. The software STATA V14 (STATA Corporation, College Station, TX) was used for statistical analysis.

Results

A total of 137 women agreed to participate and signed the consent letter. Twenty-three (16.8%) were excluded on the following grounds: severe cognitive dysfunction (n = 10), difficulty moving (gait impairment) (n = 8), a previous cerebrovascular event (n = 1) and cancer (n = 4). Therefore, 114 women were selected for analysis.

Among the 114 elderly women who participated in the study, the mean age was 84.0 (± 7.0) years. According to the WHO classification of the BMI, 3.5% (n = 4) of the participants were underweight, 43.0% (n = 49) had a normal weight, 37.7% (n = 43) were overweight, and 15.8% (n = 18) were obese. Of the participants, 15.8% (n = 18) presented a value below 22, indicating underweight according to Lipschitz's[19] cut-off points.

Table 1 presents the sociodemographic, clinical and functional characteristics, as well as chronic diseases, occurring in the nursing home participants. The level of education was high, with 59.7% participants who either completed a college degree or finished high school. Regarding chronic diseases, 53.5% had hypertension, 28.1% had osteoarthritis, and 10.5% had T2DM. According to the MNA, 66.7% (n = 76) had a normal nutritional status, 29.8% (n = 34) had a malnutrition risk, and 3.5% (n = 4) were malnourished. Finally, according to the Barthel index, approximately half of the participants needed help climbing the stairs, and almost 30.0% needed help walking.

Figure 1 depicts the EWGSOP algorithm, which indicates that 35 (30.7%) women presented signs of sarcopenia. Most of the women (107, 93.9%) had a low gait speed (≤0.8 m/s), and 35 (30.7%) of the women had low CC.

Table 2 presents the characteristics of study participants by sarcopenic status. Women with sarcopenia were older than women without this condition ($P < 0.0026$). Regarding the anthropometric results, all the measurements except height were significantly lower in the sarcopenic group. Furthermore, a higher percentage of malnutrition risk or malnutrition categories was observed in the sarcopenic group ($P = 0.0004$). The Barthel index was lower in women with sarcopenia ($P = 0.0488$). In addition, they had a lower gait speed ($P = 0.1197$) and a lower hand grip strength ($P = 0.0022$).

Table 3 presents the results of the multivariate logistic regression model. An association between sarcopenia and malnutrition risk/malnourished individuals was observed. Women with poor nutritional status were more likely to have sarcopenia (OR = 4.07, $P = 0.002$) after adjusting for age. In addition, women with diabetes mellitus had a higher probability of sarcopenia (OR = 5.14, $P = 0.024$) than women without T2DM after adjusting for age. Physical disability (Barthel index) was excluded from the final regression model because it was not statistically significant.

Discussion

The results of this study showed that nutritional status and T2DM were associated with the presence of sarcopenia. In this research, sarcopenia was identified in approximately one-third (30.7%) of the institutionalised very old women who were studied. The EWGSOP group[1] recommends detecting the presence of low skeletal muscle mass, low muscle strength and physical performance evaluation for sarcopenia diagnosis. The measurement of muscle mass could be performed by magnetic resonance image (MRI) and dual energy X-ray absorptiometry (DXA), which are

Table 1 Characteristics of the nursing home participants

Characteristics			
Age (years) (mean(sd))	84.0 (±7.0) (range: 64–99)		
Height (cm) (mean(sd))	153.36 (±6.68) (range: 134.0–172.0)		
Weight (kg) (mean(sd))	61.2 (±12.3) (range: 35.30–95.13)		
Calf circumference (cm) (mean(sd))	32.72 (±3.75) (range: 24.5–42.0)		
Body Mass Index (kg/m^2) (mean(sd))	26.0 (±4.79) (range: 14.88–38.5)		
Characteristic	Category	n	%
Marital status	Married	2	(1.8%)
	Divorced	8	(7.0%)
	Single	18	(15.8%)
	Widowed	86	(75.4%)
Education	Illiterate	1	(0.9%)
	Elementary school	6	(5.2%)
	Middle High school	21	(18.4%)
	Senior High school	31	(27.2%)
	Technical degree	18	(15.8%)
	Bachelor degree	37	(32.5%)
Hospital admission (last year)	None	98	(86.0%)
	1–3 times	14	(12.3%)
	≥4 times	2	(1.7%)
Specific diseases	Hypertension	61	(53.5%)
	Diabetes mellitus	12	(10.5%)
	Cardiovascular disease	27	(23.7%)
	Osteoarthritis	32	(28.1%)
	Thyroid diseases	17	(14.9%)
	Depression	18	(15.8%)
Falls last year	None	78	(68.4%)
	Yes	36	(31.6%)
Smoker	Yes	8	(7.0%)
	No	106	(93.0%)
Alcohol habit	Not drink	22	(21.4%)
	Social drinker	42	(40.7%)
	≥2 drinks everyday	39	(37.9%)
Mini nutritional status (MNA)	Undernourished	4	(3.5%)
	At risk of malnutrition	34	(29.8%)
	Normal	76	(66.7%)
Barthel index (ADL)	Needs help/dependent		
	Feeding	9	(7.9%)
	Bathing	27	(23.7%)
	Dressing	29	(25.4%)
	Grooming	21	(18.4%)
	Bowels (Incontinency)	21	(18.4%)
	Bladder (Incontinency)	34	(29.8%)
	Toilet use	23	(20.2%)
	Transfers (bed to chair and back)	23	(20.2%)
	Walks with help of one person	34	(29.8%)
	Stairs (needs help)	54	(47.4%)
	Score lower than 90 points	60	(52.6%)

considered gold standards. However, Rolland *et al.*[25] reported that CC correlated with appendicular skeletal muscle mass (r = 0.63) and that CC under 31 cm was the best clinical indicator of sarcopenia (sensitivity = 44.3% specificity = 91.4%). In some hospitals, sarcopenia also has been evaluated using other anthropometric characteristics like mid-upper arm muscle circumference (MUAC).[26] It should be noted that CC had an optimal reliability when performed by experienced personnel.[27] The prevalence of sarcopenia found in the present study according to the same EWGSOP criteria (30.7%) was lower than that identified by Arango-Lopera *et al.*[6] in community-dwelling elderly individuals in southern Mexico City (48.5%) and was higher than the rate found in elderly women affiliated with the

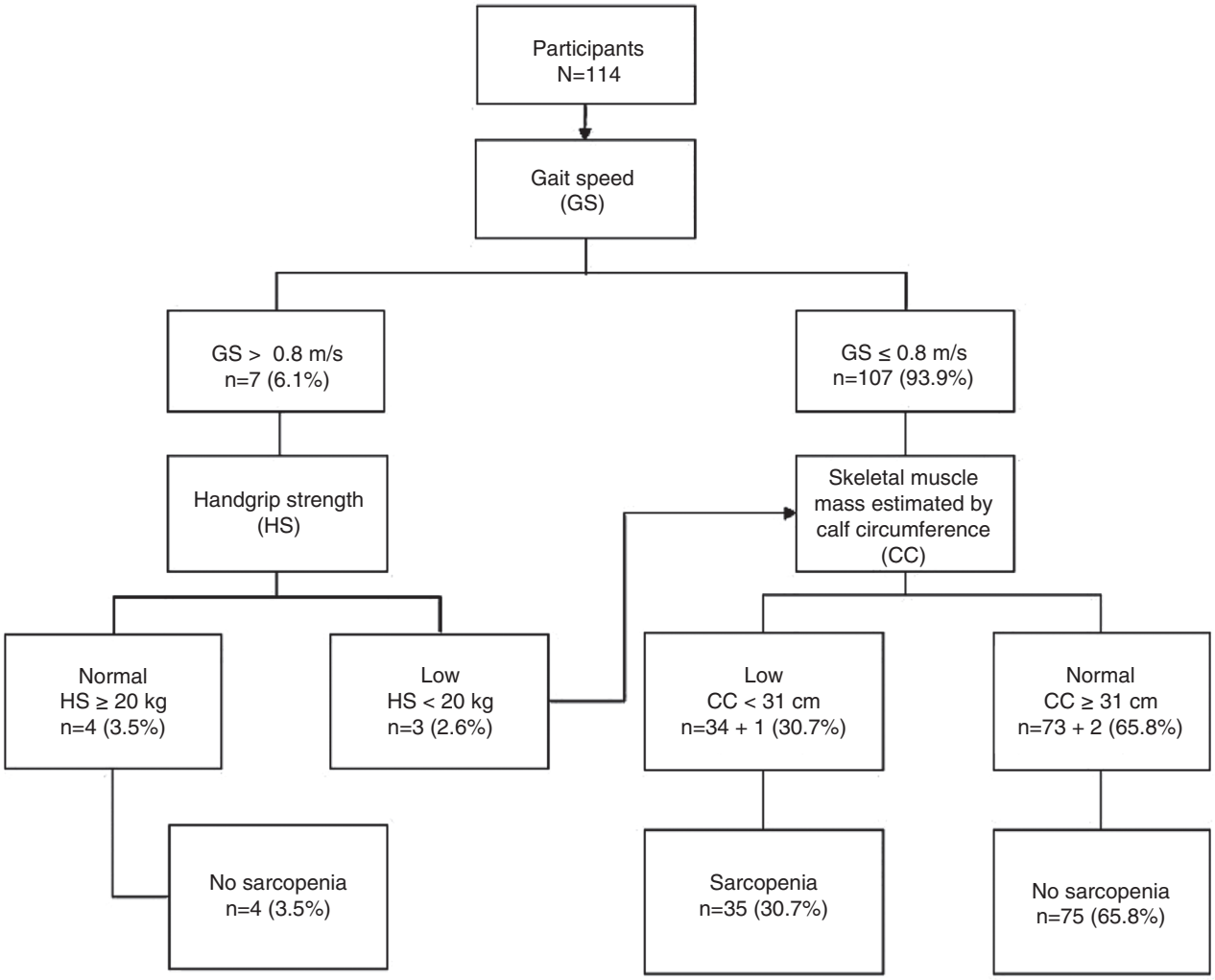

Figure 1 Flowchart when applying the European Working Group on Sarcopenia in Older People algorithm, using calf circumference, on nursing home residents in Mexico City.

Mexican Institute of Social Security at Mexico City in community-dwelling older women residing in Mexico City (9.0%).[5] These differences in sarcopenia prevalence in different groups may be explained by age, characteristics of the population, the functional grade of residents, methods used for identifying skeletal muscle mass and cut-off points used for the diagnosis of sarcopenia.

It has been reported that a high percentage of nursing home residents are at risk of malnutrition because of functional disabilities, which may not be improved over time. As expected, sarcopenic participants in the present study showed lower values in each one of the anthropometric measurements, except in height; similarly, the total score of the MNA was lower in elderly women with sarcopenia compared to women without sarcopenia. In addition, in the women studied who had a malnutrition risk and who were identified as malnourished, the percentage of sarcopenia was higher (57.1% *vs* 22.8%). Similarly, the study by Lardiés *et al*.,[28] which was conducted in older patients living in nursing homes, showed a high prevalence of malnutrition among female nursing home residents (45.4%).

In the multivariate model adjusted in the present study, an association between nutritional status and sarcopenia was identified. Residents with a malnutrition risk or who were malnourished had a higher probability of sarcopenia than well-nourished participants (OR = 4.07, $P = 0.02$).

The association between sarcopenia and malnutrition has been identified as Malnutrition-Sarcopenia Syndrome (MSS),[7] and recently, Hu *et al*.[29] conducted a prospective study in China to identify the prevalence of malnutrition, sarcopenia and MSS in hospitalised older patients, as well as to study the association between MSS and mortality. The authors found an overlap between malnutrition risk/malnourished status and sarcopenia.

The multivariate analysis used in the present study showed that sarcopenia was not associated with the Barthel Index. Similarly, other studies in the elderly groups have failed to find an association between sarcopenia and ADL.[30] In contrast, a study in community-dwelling elders receiving

Table 2 Anthropometric measurements results, MNA, functionality index (Barthel) and comorbidities by sarcopenia status in the study group

Characteristics	*Non-sarcopenic (n = 79)*	*Sarcopenic (n = 35)*	P-*value*
Age (years)	82.8 ± 7.4	87.0 ± 5.0	0.0026
Height (cm)	154.0 ± 7.3	152.0 ± 4.8	0.1475
Weight (kg)	66.3 ± 11.5	51.8 ± 8.1	<0.0001
BMI (kg/m^2)	27.6 ± 4.5	22.4 ± 3.4	<0.0001
Mid-upper arm circumference (cm)	28.6 ± 3.4	24.5 ± 3.1	<0.0001
Mid-upper arm muscle circumference (cm)	20.9 ± 2.6	18.7 ± 2.0	<0.0001
Tricipital skinfold (mm)	24.5 ± 6.8	18.4 ± 6.6	<0.0001
Waist circumference (cm)	98.0 ± 12.3	89.5 ± 10.4	<0.0006
Hip circumference (cm)	108.0 ± 11.2	96.5 ± 9.4	<0.0001
Calf circumference (cm)	34.5 ± 2.9	28.7 ± 1.7	<0.0001
MNA (points)	26.1 ± 3.3	22.2 ± 4.8	<0.0001
Normal nutritional status (n)	61 (77.2%)	15 (42.9%)	0.0004
Risk of undernutrition or undernourished (%)	18 (22.8%)	20 (57.1%)	0.0004
Barthel Index ADL (points)	86.3 ± 21.2	77.1 ± 25.9	0.0488
Hand grip strength (Kg)	15.2 ± 5.5	11.9 ± 4.0	0.0022
Gait speed (m/s)	0.43 ± 0.18	0.40 ± 0.15	0.926
Hypertension n (%)	45 (57.0%)	16 (45.7%)	0.2670
Diabetes mellitus n (%)	6 (7.6%)	6 (17.1%)	0.1392
Cerebrovascular disease n (%)	5 (6.3%)	3 (8.6%)	0.6707

ADL, activities of daily living; BMI, body mass index; MNA, mini nutritional assessment.

geriatric service at a public governmental hospital in Mexico City showed an association between sarcopenia and ADL.[8] It is likely that, in the present study, the conditions in which the elderly women lived did not permit the identification of some of the difficulties that were associated with ADL. These difficulties may be more evident in independent elderly individuals.

In the results of the present study, an association between sarcopenia and T2DM was identified. The findings of this study are consistent with previous studies that reported an association between sarcopenia and T2DM.[31] Kim *et al*.[13] found that diabetic patients had approximately two- to fourfold higher risk of low appendicular skeletal muscle mass than participants without T2DM.

In addition, the Baltimore Longitudinal Study of Aging identified an association between hyperglycaemia and lower muscle strength.[32] The results suggested that this association starts at the initial stages of T2DM, and the later diabetic peripheral neuropathy stages might accelerate the reduction of muscle strength.[33]

Furthermore, in the Health Ageing and Body Composition Study, it was found that T2DM in older adults led to an accelerated loss of leg muscle strength.[34] In T2DM patients, factors such as inflammatory cytokines, comorbidities, inadequate nutrition and low levels of physical activity have been related to muscle loss and a decrease in muscle strength and function.[33] It is likely that a significant decrease in skeletal muscle mass results in the reduced availability of glucose disposal in older adults with sarcopenia, and the muscle plays a major role in glucose regulation.[14]

In geriatric patients with T2DM, it is especially recommended that muscle function be improved to attenuate skeletal muscle loss. This approach is more relevant considering that the number of elderly patients with diabetes is increasing worldwide. A clear relationship exists between insulin, muscle anabolism and protein intake, as shown by the fact that, even though insulin has a stimulatory effect

Table 3 Unadjusted and adjusted odds ratios [95% CI] from the logistic regression models for the association of sarcopenia

	OR[(a)] unadjusted	*[95% CI[(b)]]*	P-*value*	*OR[(a)] adjusted[(e)]*	*[95% CI[(b)]]*	P-*value*
Age (mean SD)	1.11	(1.03, 1.19)	0.005	1.11	(1.02, 1.20)	0.010
MNA[(c)] (Risk/undernutrition)	4.51	(1.92, 10.58)	0.001	4.07	(1.64, 10.01)	0.002
T2DM[(d)] n (%) (Yes)	2.51	(0.75, 8.44)	0.135	5.14	(1.25, 21.21)	0.024
Barthel Index (Dependent)	0.47	(0.21, 1.07)	0.075	—	—	—

[(a)] OR, odd ratio.
[(b)] CI, confidence interval.
[(c)] MNA, mini-nutritional assessment.
[(d)] T2DM, type 2 diabetes mellitus, reference category: Barthel Index: independent, MNA: well nourished, T2DM: non-diabetic.
[(e)] Adjusted OR for age, MNA and T2DM. Hosmer/Lemeshow test Chi/square = 52.3, *P* = 0.274.

on muscle protein synthesis, an adequate availability of amino acids is necessary to increase its synthetic rate.[35] Consequently, good nutrition plays an important role to ensure the healthy nutritional status of the elderly diabetic.

However, adding the resistance exercise could induce the stimulation of muscle protein synthesis, helping the prevention of sarcopenia and improving glucose levels. According to the results of this study, it is advised that a routine screening test for sarcopenia and malnutrition be implemented upon admission to nursing homes, followed by regular assessment of these conditions, particularly in patients with T2DM, to delay the deterioration process.

This study has some strengths, including the use of standardised methods to assess both sarcopenia (EWGSOP) and nutritional status (MNA) and have medical records of each patient. In addition, this study has some limitations, for example, its cross-sectional design does not allow the identification of cause–effect relationships. The sample size was small, which has a negative impact on the reliability of the study; however, it is interesting to study very elderly women surviving diabetes for a long term, identifying the association between sarcopenia and their nutritional status and increasing the awareness of researchers to study this group, which may provide useful information for new generations considering the high rate of diabetes in adults and the ageing of the population. In addition, CC was utilised to estimate skeletal muscle mass, and this estimation could be more accurate using MRI, DXA or bioelectrical impedance analysis; however, the application of more complex techniques may be disruptive or difficult to use in studies of nursing homes residents.

From the clinical perspective, it is important to increase the ability of physicians and the dietitian to identify sarcopenia, specifically in vulnerable groups of elderly living in nursing homes. According to our results and other studies performed in nursing home residents, there is a significant relationship between sarcopenia with nutritional status and T2DM, emphasising the importance of the detection of sarcopenia and implementing programs focused on nutritional interventions and resistance exercise.

In conclusion, sarcopenia was identified in a third of old women residing in a nursing home in Mexico. The results indicated an association between sarcopenia and poor nutritional status, as well as T2DM. Timely recognition of sarcopenia and poor nutritional status in older women with T2DM should be routine clinical practice to optimise adequate interventions and improve the quality of life of nursing home residents.

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Conflict of interest

The authors have no conflict of interest.

Authorship

MCVA and MEIC designed the study; MCVA, MEIC, IAC and CD wrote the manuscript. MEIC, MAZZ and IL performed the statistical analysis; and MCVA, MEIC, MAZZ, IL, IAC and CD participated in the analysis and discussion of the results. All authors read and approved the final version of the manuscript.

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ORIGINAL RESEARCH

Effect of high polyphenol extra virgin olive oil on markers of cardiovascular disease risk in healthy Australian adults (OLIVAUS): A protocol for a double-blind randomised, controlled, cross-over study

Wolfgang MARX [1,2] Elena S. GEORGE,[1,3] Hannah L. MAYR [1,4,5] Colleen J. THOMAS [6] Katerina SARAPIS [1] George MOSCHONIS [1] Greg KENNEDY,[7] Andrew PIPINGAS [7] Jane C. WILLCOX,[1] Luke A. PRENDERGAST [8] and Catherine ITSIOPOULOS [1]

[1]Department of Dietetics, Nutrition and Sport, School of Allied Health, Human Services and Sport, College of Science, Departments of [6]Physiology, Anatomy and Microbiology, School of Life Sciences, College of Science, Health and Engineering and [8]Mathematics and Statistics, School of Engineering and Mathematical Sciences, College of Science, Health and Engineering, La Trobe University and [7]Centre for Human Psychopharmacology, Swinburne University of Technology, Melbourne, [2]Food & Mood Centre, IMPACT SRC, School of Medicine and [3]School of Exercise and Nutrition Sciences, Institute for Physical Activity and Nutrition, Deakin University, Geelong, Victoria and [4]Faculty of Health Sciences and Medicine, Bond University Nutrition and Dietetics Research Group, Gold Coast and [5]Nutrition and Dietetics Department, Princess Alexandra Hospital, Brisbane, Queensland, Australia

Abstract

Background: Previous clinical studies have suggested that high polyphenol extra virgin olive oil (EVOO) provides a superior cardioprotective effect compared to low polyphenol olive oil. However, further studies are required to replicate these results in non-Mediterranean populations.

Aim: To investigate the effect of high polyphenol EVOO versus low polyphenol olive oil with known polyphenol composition on markers of cardiovascular disease risk in a healthy non-Mediterranean cohort.

Methods: In a double-blind randomised cross-over trial, the present study will examine the effect of high polyphenol EVOO versus low polyphenol olive oil in 50 healthy participants. Each intervention phase will be 3 weeks long with a 2-week washout period between each phase. Outcomes to be assessed include HDL cholesterol efflux, oxidised LDL, blood lipids, C-reactive protein, arterial stiffness, blood pressure and cognitive function. Dietary intake, physical activity levels and anthropometry will also be collected.

Discussion: Because of the rigorous trial design, novel and clinically relevant outcomes, the use of a well-characterised EVOO, and, in contrast to the current literature, the non-Mediterranean study population, the present study will provide a significant contribution to the understanding of the clinical importance of polyphenol intake in the Australian sociocultural context.

Key words: biophenol, cognition, Mediterranean diet, olive oil, oxidative stress, polyphenol.

Introduction

The traditional Mediterranean diet, known for its cardioprotective effect, has been shown to improve cardiovascular disease (CVD) risk factors including specific measures of blood lipids (HDL cholesterol (HDL-C), triglycerides), markers of inflammation, blood pressure, fasting blood glucose and risk of diabetes.[1,2] The traditional Mediterranean diet is characterised by an abundance of plant foods (e.g. leafy greens, tomatoes, onions, herbs, wholegrain cereals, legumes and nuts), moderate amounts of fermented dairy foods, seafood, red wine and small quantities of red meat and homemade sweets.[3–5] Of particular relevance to the proposed study, is the large servings of extra virgin olive oil (EVOO; 60–80 mL daily) as the primary source of culinary fat and a unique culinary component of the

W. Marx and E.S. George are co-first authors
W. Marx, PhD, Postdoctoral Research Fellow
E.S. George, PhD, APD, Lecturer
H.L. Mayr, PhD, APD, Research Fellow
C.J. Thomas, PhD, Senior Lecturer
K. Sarapis, MSc, PhD Student
G. Moschonis, PhD, APD, Associate Professor
G. Kennedy, BSc(Hons), PhD Student
A. Pipingas, PhD, Associate Professor
J.C. Willcox, PhD, Research Fellow
L.A. Prendergast, PhD, Associate Professor
C. Itsiopoulos, PhD, APD, Professor
Correspondence: C. Itsiopoulos, School of Allied Health, College of Science, Health and Engineering, La Trobe University, Bundoora, VIC 3086, Australia. Tel.: +61 (0) 3 9479 1721.
Email: c.itsiopoulos@latrobe.edu.au

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Mediterranean dietary pattern. Olive oil contains highly variable concentrations of polyphenols which can be affected by season, olive variety, region and soil, ripeness of the fruit and processing.[6] EVOO is characterised by a low-temperature, mechanical processing technique which preserves the higher polyphenol content in comparison to the refining methods such as deodorisation and chemical processing techniques used to produce refined olive oils, which subsequently have significantly lower polyphenol content.[7,8]

In healthy adults, EVOO has been shown to improve CVD risk factors including blood pressure, low grade inflammation and lipid profile.[9] The cardioprotective properties of EVOO have been primarily attributed to the high monounsaturated fat content; however, EVOO contains an array of unique polyphenols, also referred to as 'biophenols'.[10] These polyphenols have shown improvements in measures of glucose metabolism, lipid peroxidation and cholesterol markers in clinical trials.[11–14] Despite this evidence, the unique, cardioprotective polyphenols in EVOO are not currently recognised by CVD guidelines, possibly because of the need for additional high-level evidence.

To further understand the mechanisms involved in the cardioprotective effect of EVOO-derived polyphenols, further clinical research is needed to: (i) replicate previously reported improvements in routinely measured cardiovascular markers (e.g. HDL/LDL cholesterol, blood pressure) in the Australian population; (ii) determine the feasibility of a provision of 60 mL of EVOO per day in a non-Mediterranean population and (iii) investigate the effect of high polyphenol EVOO on novel CVD risk markers. Increased CVD risk has, in part, been attributed to low plasma levels of (HDL-C).[15] However, emerging evidence suggests that impaired HDL function, rather than low HDL-C, may explain HDL-associated CVD risk.[16] HDL-C efflux, as measure of HDL function, has been identified as a marker that may independently predict risk of CVD.[17]

To improve the existing evidence base in this area, the proposed trial aims to investigate the effect of a high polyphenol EVOO compared to a low polyphenol olive oil on both routinely measured (e.g. blood pressure and cholesterol) and novel markers (e.g. HDL-C efflux) on CVD risk in a healthy Australian cohort.

Furthermore, recently published clinical and animal studies have provided preliminary evidence to suggest that EVOO, as well as other polyphenol-rich interventions, may improve cognitive performance and prevent age- or experimentally induced cognitive impairment.[18,19] Hence, as a secondary outcome, the present study will also investigate the effect of high polyphenol EVOO and low polyphenol olive oil on measures of cognitive performance in this healthy cohort.

Methods

The OLIVAUS study is a double-blind, randomised, controlled cross-over trial that aims to investigate the effect of a 3-week intervention of high polyphenol EVOO compared to a retail-purchased low polyphenol olive oil on CVD risk factors in 50 healthy participants (Figure 1). Compared with a low polyphenol olive oil, we hypothesise that a high polyphenol EVOO intervention will result in improved measures of HDL-C efflux, oxidised LDL and low-grade inflammation in a healthy adult population. The trial protocol (registered 30/04/2018, updated 13/02/2019) has been prospectively registered with the Australia New Zealand Clinical Trials Registry ACTRN12618000706279 and was created in accordance with the SPIRIT statement.[20]

This trial will be conducted in accordance with the Guidelines for Good Clinical Practice and the Declaration of Helsinki and CONSORT reporting guidelines. The trial team has obtained written approval for the protocol and Patient Information and Consent Form from the La Trobe University Human Research Ethics Committee (HEC17-067).

Participants will be recruited in Melbourne, Australia using social media advertisements, and through La Trobe University using email advertisements, mailing lists, word of mouth, and posters on campus and at local medical clinics. Table S1 (Supporting Information) provides the inclusion and exclusion criteria for the present study.

Figure 1 provides a visual representation of the study flow. The participant schedule throughout the trial is shown in Table S2, including data collection time-points. Once enrolled, participants will be asked to undergo an initial washout period where they will be instructed to abstain from consuming all olive oil, olive products, and antioxidant supplements for 2 weeks prior to the scheduled baseline meeting (T1). Participants will be requested to complete a 3-day diet diary including 2 week days and 1 weekend day where they are asked to include details on the foods and beverages consumed including type, brand,

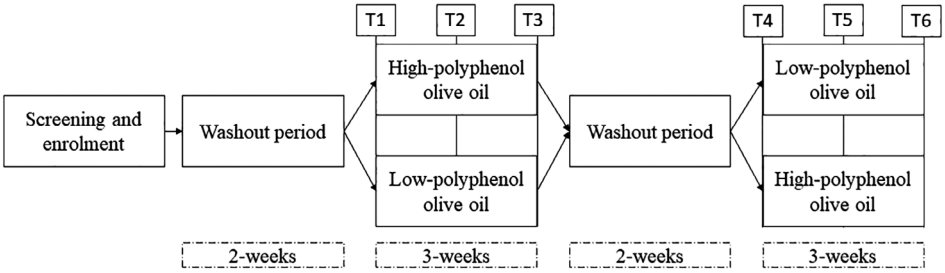

Figure 1 Study flow.

quantity in household measures and cooking methods. Participants will be asked to complete this diet diary in the days preceding the initial appointment and at the conclusion of the intervention phases. Participants will be asked to come to the baseline meeting in a fasted state. At the end of each intervention phase, participants will receive a $25 AUD gift voucher ($50 AUD in total).

The research staff will screen against the eligibility criteria during a face-to-face meeting. Following informed consent, participant numbers will be assigned sequentially and will be block randomised to receive either high polyphenol EVOO or low polyphenol olive oil. The block randomisation sequence will be developed using blocks of 6, by a senior researcher (GM), who will not have any direct involvement in the participant recruitment or data collection phase. After baseline measures are taken, a researcher who is not involved in any participant contact (JCW) will email the allocation for each participant to the team. De-identified bottles of high and low polyphenol olive oil will be randomised and coded prior to the recruitment phase and all staff will be blinded to this randomisation.

Participants will receive a 3-week supply of either the low polyphenol olive oil or high polyphenol EVOO (1.26 L) at the commencement of the first intervention (T1) and the commencement of the second intervention (T4). Participants will be required to consume 60 mL per day for each of the 3-week intervention phases. Measuring cups will be provided for participant use, where appropriate, to demonstrate the required volume. Emphasis on strategies that incorporate olive oil into their habitual diet in a raw, uncooked form will be provided by researchers. This will include dressing salads or vegetables, drizzling the oil on prepared meals such as soups or casseroles, and ensuring leftover amounts are also consumed. Participants will be supplied with the full amount of EVOO and olive oil required per 3-week intervention period.

Total polyphenol and polyphenol subclasses for each olive oil intervention were analysed by Modern Olives Laboratory Services (Lara, Australia), a Commonwealth Government accredited testing agency, using high-performance liquid chromatography. Samples were prepared and blinded for the researcher. Table S3 provides a comparison of the total polyphenol and polyphenol subclasses of each olive oil intervention. All high polyphenol EVOO was sourced from Cobram Estate Pty. Ltd. from the same harvest and lot and stored under the same conditions. An EVOO with a confirmed polyphenol count of approximately 320 ppm will be provided to participants as the high polyphenol EVOO intervention. A low polyphenol olive oil was sourced from a local supermarket where a bulk purchase of the same brand from the same lot number was made. This oil was confirmed to have a polyphenol count of approximately 86 ppm.

At the commencement of the first and second intervention phase meeting (T1 and T4), participants will attend a 1-hour appointment in the morning with research staff at the nutrition clinical rooms, Bundoora campus, La Trobe University. Data collection including 3-day diet diaries, medical history and lifestyle (e.g. physical activity) questionnaires, anthropometry, fasting blood collection, blood pressure, arterial stiffness measures and cognitive performance will take place at each face to face appointment. Basic demographic data will also be collected at baseline including age, gender and ethnicity. These are described in detail below.

The research staff will contact participants by phone or email approximately 1.5 weeks into each intervention phase to discuss progress, adherence to the intervention and to ask participants if they have experienced any adverse events during the study period.

At the end of each intervention phase (T3 and T6) participants will attend a face to face appointment where they will complete all the data collection indicated at the T1 and T3 appointment. In addition, participants will be required to return their olive oil bottles so that research staff can record the weight of any remaining oil as an additional marker of adherence.

For T3 only: Research staff will instruct the participants to undergo a 2-week washout period whereby they cease consumption of all olive oil and olive products during this period, until their next meeting (T4, start of second olive oil phase).

For T6 only: Research staff will assess blinding by asking the participant about the order they think they received the two olive oil interventions and whether there were any differences in taste.

All outcomes described below will be measured pre and post the olive oil intervention phases (T1, T3, T4, T6) as per Table S2. Blood collection will also take place at each pre- and post-time-point. Research staff will confirm that participants have fasted for 8–12 hours. If so, fasting venous blood samples will be obtained, by a researcher trained in venepuncture, from the antecubital vein using standard venous puncture techniques. If blood collection is unsuccessful research staff will arrange for blood collection at a local pathology centre within 48 hours of the scheduled appointment.

HDL-C efflux, the primary outcome, will be analysed using a Cholesterol Efflux Fluorometric Assay Kit (Biovision, Milpitas, California). Participants will be invited to participate in an optional cognitive performance assessment. If they have consented to this aspect of the trial, the participant will conduct the full cognitive assessment at each face to face appointment. The Swinburne University Computerised Cognitive Assessment Battery (SUCCAB) is a validated, computer-based cognitive battery, administered using a 5-button control box.[21] Eight tests of cognitive function will be assessed by both accuracy and response time. These tests include Simple and Choice Reaction Times, Immediate and Delayed Recognition, Congruent and Incongruent Stroop colour-words, Spatial Working Memory and Contextual Memory. This battery has been used in numerous studies to assess the cognitive effects of dietary supplementation and other interventions.[22–24]

Total, HDL and LDL cholesterol, high sensitivity C-reactive protein and triglyceride levels will be measured using standard enzyme assays. Oxidised LDL will also be analysed using a solid phase two-site enzyme immunoassay (ELISA; Mercodia, Uppsala, Sweden).

Cardiovascular function will be assessed using the non-invasive SphygomoCor XCEL system (AtCor Medical, Australia) once the participant has rested for 5 minutes in the supine position. Assessments will include standard brachial blood pressures, aortic (central) blood pressures, pulse wave analysis of peripheral arterial stiffness, and carotid-femoral pulse wave velocity analysis of central arterial stiffness.

Three-day diet diaries will be collected at each face to face appointment. Research staff will conduct a baseline interview with all participants and will confirm that they underwent the required 2-week washout period. The research staff will also review the 3-day dietary intake data to ensure sufficient detail has been recorded for nutrient analysis and to clarify any missing data on responses that look inaccurate. Participants will self-report details regarding their intake of food and liquids over a 3-day period including the quantity (via household measures), type and timing of items consumed. Furthermore, a specific section to capture timing and amount of olive oil will be incorporated. Participant weight, height and waist circumference will be measured using standard techniques, in duplicate by the research staff. If there is >10% variation between the two measures, a third measure will be obtained. The mean of the closest two measures will be used. Self-reported physical activity will be completed prior to the commencement of the trial (T1) and at the end of the trial (T6) via the Active Australia Survey,[25] a validated tool within the Australian population and consists of eight questions to assess the previous 7 days. The questionnaire captures a range of activity types including walking, work in the yard, vigorous physical activity and moderate physical activity. Adverse events will be monitored at all time-points. If a participant experiences significant adverse events, they will be withdrawn from the study. All adverse events will be reported to the trial steering committee, comprised of the Principal Investigator and trial staff. The Human Research Ethics Committee will also be notified, as appropriate. Emergency unblinding will occur for serious adverse events deemed related to the study product. All participant data will be securely stored either in onsite locked cabinets or password protected documents on secured university servers with restricted access to the study team only.

All outcomes will be analysed by using linear mixed-effects (LMEs) models with random intercepts and slopes to account for within-participant correlation over time and varying treatment effect among participants. The effect of intervention order, because of potential carry-over effect, on all outcomes will be tested and adjusted for in the LME model if necessary by including and interaction term between the treatment and period effects. A senior statistician (LAP) will oversee the fitting of the LME models and be responsible for assessing model validity.

Participant 3-day dietary records will be analysed and dietary changes will be used as a covariate. Adjusted results will be calculated using a multiple linear regression model including the stratification factors (e.g. gender, physical activity levels). A sensitivity analysis comparing the LME analyses and pooled estimates from the multiple imputation procedures will be conducted to prevent against bias. All reported *P*-values will be 2-tailed. The levels of statistical significance will be set at $P < 0.05$ and estimates will be accompanied with 95% confidence intervals. All statistical analyses will be conducted using the SPSS statistical software for Windows (version 25); IBM, Armonk, New York. Based on the results of previous research, a sample size of 40 was considered adequate to provide sufficient statistical power to detect a statistically significant 5% difference in HDL-C efflux between the two intervention phases with 80% power and 5% level of significance.[26] To account for a 20% level of potential attrition, this sample size was expanded to 50 participants.

Results

Recruitment commenced in July 2018 and is expected to be completed by late-2019. Currently, a total of n = 21 participants have been enrolled in this trial, leading to an average recruitment rate of 7 per month. Sixty-five per cent of participants are female with a mean age of 37 years. Five of the currently recruited cohorts have completed the intervention with 100% of outcome data collected. Incomplete data have been collected on one participant due to withdrawal from the study because of inability to consume the required amount of olive oil. Ten per cent of participants that have completed the intervention consumed at least 80% of the provided oils. There have been no reported serious adverse events related to the study intervention. Reported adverse events include diarrhoea, bloating, reflux and heartburn.

Discussion

Previous clinical studies have reported that EVOO provides a cardioprotective effect through mediating improvements in cardiovascular risk factors;[1,9] however, few studies have investigated the contribution of the polyphenol component of olive oil to these improvements. The present study will compare the effect of high polyphenol EVOO to low polyphenol olive oil on markers of CVD risk that are related to cholesterol transport and metabolism, LDL oxidation, blood pressure (peripheral and central), arterial stiffness, and inflammation, as well as measures of cognitive function. By implementing a study design that will be able to differentiate between the effect of polyphenols from the other components of olive oil (e.g. monounsaturated fat will remain consistent between study arms), this trial will provide important information regarding the effect of EVOO polyphenols on a range of cardiovascular risk factors and cognition. In contrast to the current literature which has predominantly been conducted within Mediterranean

populations, this will assess the use of high polyphenol EVOO in the Australian western sociocultural context. In addition, previous research has primarily assessed the effect of a Mediterranean diet and EVOO in populations with existing comorbidities such as coronary heart disease, type 2 diabetes, cancer and cognitive decline while the present study aims to recruit healthy participants.[2,27] The present study is one of the first trials to comprehensively assess the polyphenol composition within each of the oils provided to participants. Other studies, even those which compare oils with varying polyphenol content, do not report the composition of the polyphenols contained within.[9] Finally, this study will report HDL efflux, oxidised LDL and other biomarkers of CVD that have not been extensively studied in previous dietary intervention studies. If shown to be beneficial, the present study will provide evidence for a widely accessible, low cost dietary intervention to reduce CVD risk and will significantly contribute to the existing literature on the clinical importance of polyphenol intake.

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Conflict of interest

ESG, CI, CJT and HLM have received food donations for previous trials (Cobram Estate Pty Ltd., Jalna Dairy Foods Pty Ltd., Almond Board of Australia, Simplot Australia Pty Ltd., Birds Eye, HJ Heinz Company Australia, Carmen's Kitchen).

Authorship

All authors contributed to the development of the protocol. WM and ESG lead the development of the manuscript. KS provided data on current trial results. LAP provided statistical support. GK and AP provided the information regarding the cognitive function component. CJT, HLM, CI and JCW all contributed to the manuscript. We declare that the content of this manuscript has not been published elsewhere. We would like to acknowledge the work of Mr Siddharth Shivantha (Honours student) in the early data collection phase of this trial.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1 Study eligibility criteria.
Table S2 Study procedure and time points in the OLIVAUS trial.
Table S3 Polyphenol composition of the HPOO and LPOO provided in the OLIVAUS trial.

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ORIGINAL RESEARCH

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Developing meaningful client-dietitian relationships in the chronic disease context: An exploration of dietitians' perspectives

Annaliese Nagy BNutrDiet Hons APD, PhD Candidate[1] | Anne McMahon PhD APD, Discipline Lead Food and Society[2] | Linda Tapsell PhD FDAA, Senior Professor[1] | Frank Deane PhD, Professor[3]

[1]School of Medicine, University of Wollongong, Wollongong, New South Wales, Australia

[2]School of Health & Society, University of Wollongong, Wollongong, New South Wales, Australia

[3]School of Psychology, University of Wollongong, Wollongong, New South Wales, Australia

Correspondence
Annaliese Nagy, School of Medicine, University of Wollongong, Northfields Avenue, Wollongong, NSW 2522, Australia.
Email: ajn028@uowmail.edu.au

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Abstract

Aim: Meaningful client-dietitian relationships are central to effective dietetic practice. The chronic disease management setting provides an opportunity to examine what is meaningful and how these relationships are constructed, because the dietitian and client generally have multiple interactions over an extended period of time. This study aimed to explore dietitians' perspectives of how they develop meaningful relationships with clients managing lifestyle-related chronic diseases.

Methods: Study design and analysis were guided by Charmaz's constructivist grounded theory. Dietitians working in Australia with clients managing chronic diseases were recruited through initial, snowball and theoretical sampling. Online videoconference and telephone semi-structured interviews were conducted. Recorded interview transcripts were analysed using repeated reviews comprising initial, focused and theoretical coding and memoing.

Results: Twenty-two dietitians were recruited. A conceptual model developed from the data showed the dietitian's role in developing the client-dietitian relationship is complex. Key elements were identified and described as 'Sensing a Professional Chemistry', and the dietitian's skills in 'Balancing Professional and Social Relationships' and 'Managing Tension with Competing Influences'. Influences were categorised as relating to the client and dietitian as individuals (eg, their values), their support network and external contextual factors (eg, working with interpreters).

Conclusion: Developing relationships with clients in the chronic disease context appears complex due to the dietitian's role of managing multiple interrelated elements and influential factors simultaneously. To deepen understanding, research should explore clients' perspectives of relationship development and how knowledge of practitioner-client relationships in other disciplines may be utilised to enhance dietetic service delivery.

KEYWORDS

chronic disease management, client-dietitian relationship, patient-centred care, practitioner-patient relations, qualitative research

1 | INTRODUCTION

Shifts in paradigms on healthcare delivery have recognised the importance of practitioner-client relationships, specifically within patient- and relationship-centred care paradigms.[1,2] This has been acknowledged in dietetic practice. A recent integrative review identified a 'positive dietitian-patient relationship' as a component of patient-centred dietetic care.[3] Practitioner-client relationships appear well-researched in other disciplines, particularly within medicine and psychology.[4-6] Furthermore, research shows the strength of practitioner-client relationships positively influences outcomes, including those related to clients' health.[6]

The importance of client-dietitian relationships has been reiterated throughout research to date.[3,7] This importance is reflected in the Nutrition Care Process, a key model underpinning an approach to current dietetic practice, which articulates the relationship as the 'central component' of this approach.[8] Despite this importance, meaningful explanations of this relationship and how it is developed in dietetics are limited. Qualities of the client-dietitian relationship have been identified in qualitative and quantitative research,[9-11] however what these qualities mean in the dietetic context and how they interact with each other as a process to facilitate relationship development is not clear. Examples of qualities include the dietitian's communication skills and integrity.[9,10] A model of how dietitians can build 'positive relationships' with clients was suggested in a recent integrative review, however this research only briefly described qualities of relationships without in-depth explanation of the interplay between them or meaningful processes underlying them.[3] As a result, our understanding of how dietitians might develop relationships with clients appears superficial. The importance of this relationship drives the need to think more critically about this crucial aspect of practice to gain a deeper, more meaningful and comprehensive understanding of client-dietitian relationship development as an entire process, rather than as individual qualities. Further in-depth qualitative research is needed in order to address this.

An important setting to explore client-dietitian relationship development appears to be within lifestyle-related chronic disease management. These diseases, such as type 2 diabetes, are a global issue, and dietitians play a key role in managing these diseases.[12] In addition, care in chronic disease settings generally occurs over an extended period of time. This sustained care and the global prevalence of chronic disease drives the imperative to further explore how dietitians deliver patient-centred care, specifically through their relationship with clients.

The aim of the research reported here was to explore dietitians' perspectives of how they develop meaningful relationships with clients in the context of lifestyle-related chronic disease management. While appreciating the contribution of the client to the relationship,[13] this research focused on dietitians' perspectives exclusively. The purpose of this was to address the knowledge gap around meaningful processes of relationship development in dietetic chronic disease management from the professional perspective. The research was guided by the question 'How do dietitians perceive their process of developing meaningful relationships with clients managing lifestyle-related chronic diseases?'

2 | METHODS

This study was approved by the University of Wollongong Health and Medical Human Research Ethics Committee (2017/575). All participants gave informed consent prior to participating.

Qualitative research is conducted when a complex and detailed understanding is needed.[14] As this research sought to gain a deeper and more comprehensive understanding of client-dietitian relationship development than what is currently understood, a qualitative approach was utilised. Charmaz's interpretation of grounded theory guided the study design, including sampling and data collection and analysis.[15] Grounded theory is recognised as both a methodology and method, for the purpose of 'generating a theory for a process or an action'.[16] Charmaz assumes a constructivist view, where findings are recognised as a subjective interpretation of the researcher.[15] This approach utilises key interrelated elements, including sampling, coding and memoing, that are conducted simultaneously to generate findings.[15] Methods were reported in accordance with the COREQ checklist for reporting qualitative research.[17]

Sampling occurred in three stages between January and July 2018. Firstly, a purposive approach was taken where initial sampling was used to identify individuals who could provide an understanding of the problem.[15,18] This stage recruited qualified dietitians working in Australia, who were currently managing, or had recent experience managing, adult clients regarding lifestyle-related chronic diseases (overweight and obesity, type 2 diabetes, cardiovascular disease). Dietitians were required to see clients individually within the free-living environment (eg, not in hospital). Participants were recruited through approved advertisements in e-newsletters from the Dietitians Association of Australia (DAA) to its members. Expressions of interest were also collected during a workshop led by authors at the 2018 DAA conference. Workshop attendees were informed of the study and invited to provide their contact details if interested. Dietitians known by the primary researcher (AN) through professional networks were also contacted by email, hence a relationship with some participants existed prior to the study commencing.

The second stage used a snowball sampling technique where participants identified colleagues who might be interested in participating and these were contacted via email.[18] The third stage used theoretical sampling (as a component of grounded theory), to clarify questions generated from data in early interviews.[15] For example, questions arose regarding how perspectives of relationship development may differ in dietitians practising within weight-neutral approaches,[19] so dietitians who met the original inclusion criteria and practised within these approaches were contacted. Dietitians identified by theoretical sampling were recruited through face-to-face contact during a workshop at the DAA conference. Other dietitians were identified by applying relevant search terms to the Google search engine and were contacted through the email address provided. Dietitians who confirmed they met the inclusion criteria were sent an information sheet and consent form to sign and return.

Charmaz's grounded theory methodology[15] recognises the researcher as being actively involved in the research process, therefore AN reflected on her biases as a novice researcher and qualified female dietitian prior to and during the study. Reflections were documented within written memos regarding emerging codes which were embedded within the analysis. This process enabled AN to be aware of preconceptions held and thus facilitated a more critical approach to data analysis, where the emerging analysis was challenged in light of these reflections both throughout coding and in discussions with the research team.

A core component of grounded theory methods is simultaneous data collection and analysis, and this was utilised throughout.[15] Participant demographic information was collected through an online survey.[20] Online videoconference or telephone semi-structured interviews were undertaken by AN to account for distances between geographic locations. Telephone interviews were conducted as per participants' preferences, or when technical problems occurred with the videoconferencing software.[21] The interviewer undertook each interview in a private room at the University of Wollongong with no other persons present. A semi-structured interview guide ensured that key questions were addressed while allowing flexibility in following participants' leads. The interview guide was developed in consultation with authors, and probes were identified from empirical literature.[9,10,22,23] Prior to use, the interview guide was piloted with dietitians at the University of Wollongong, and recommendations were incorporated. Interview questions were open-ended and included asking participants to identify key elements of successful interactions with clients. To support the collection of rich data, participants were provided with the interview questions via email before their interview to ensure ample time to reflect on their responses.

Each participant was interviewed once, with interviews lasting between 27 and 82 minutes. To ensure thorough data collection, interviews were recorded using a digital audio recorder with consent from participants. Field notes were documented by AN during and after each interview, which included details such as how the interview was conducted (including any technical problems). Recordings were transcribed verbatim by AN, during which participants were assigned numerical codes and each transcript was de-identified. Transcripts were checked twice against the recording, once by AN and again by a second researcher AM to ensure accuracy. Participants were invited to check their transcript however only one participant elected to do so.

Analysis was conducted manually and was derived from the data as per grounded theory methods.[15] AN undertook initial coding where each line or segment of data was coded using gerunds (verbs that functions as nouns, such as 'demonstrating empathy').[15] Focused coding was then used to categorise significant and similar initial codes at a more abstract level. Finally, theoretical coding was conducted where comparisons were analysed between focused codes to produce more abstract and advanced theoretical codes. Detailed memos were written throughout this process to document relationships between codes. These memos were used in conjunction with discussions with the research team to construct the final conceptual model.

The constant comparison technique was applied to the interviews as a whole to distinguish similarities and differences between codes, for example how self-disclosure is used, and memos regarding this were documented. This technique was also used once the conceptual model was finalised to ensure the analysis reflected transcripts and memos, and to enhance study rigour.[15] Other memos were kept to document code definitions, possible analytical avenues and further questions of the data. Findings were presented during regular meetings with authors where raw data were discussed, the emerging analysis was critiqued and potential analytical avenues raised. Data collection and analysis ceased when data saturation was reached, that is when no new codes emerged as per grounded theory methods.[15,16] The use of cross comparison techniques, recording detailed analytical memos and discussing the analysis with the research team throughout the study allowed for continuous interrogation of the data and recognition of data saturation.

3 | RESULTS

Interviews were conducted with 22 dietitians (online $n = 14$; telephone $n = 8$). A total of 47 dietitians were contacted or expressed interest in participating. Dietitians declined participation due to time constraints ($n = 4$), health reasons ($n = 1$), or because they did not meet the inclusion criteria

($n = 2$). Some dietitians did not respond to email communication ($n = 18$). The majority of participants identified themselves as female ($n = 19$, 86%), aged between 20 and 39 years ($n = 16$, 72%) and working in New South Wales or Queensland ($n = 14$, 64%) (Table 1).

TABLE 1 Participant demographic characteristics ($n = 22$)

	n (%)
Gender	
Female	19 (86)
Male	3 (14)
Age	
20-29	8 (36)
30-39	8 (36)
40-49	2 (9)
50-59	4 (19)
State or territory	
New South Wales	7 (32)
Queensland	7 (32)
Victoria	3 (14)
Australian Capital Territory	2 (9)
South Australia	2 (9)
Western Australia	1 (4)
Geographic area	
Metropolitan	13 (59)
Regional	5 (23)
Rural or remote	4 (18)
APD status	
Provisional APD	5 (23)
APD	17 (77)
Years of experience	
Private practice	
0–2	7 (32)
3-5	5 (23)
6-10	4 (18)
11-20	4 (18)
Not applicable	2 (9)
Other areas	
0–2	10 (46)
3–5	2 (9)
6–10	3 (14)
11–20	2 (9)
20 or more	3 (14)
Not applicable	1 (4)
Unanswered	1 (4)

Abbreviations: APD, Accredited Practising Dietitian.

A conceptual model of relationship development was developed from the data, consisting of three main categories (Figure 1). Two categories related to the direct interaction between a client and dietitian: 'Sensing a Professional Chemistry' and 'Balancing Professional and Social Relationships'. These categories are shown in blue at the centre of the model, representing this direct interaction. A third category 'Managing Tension with Competing Influences' emerged relating to influences on the direct interaction. This category is shown in orange, with inward-facing arrows representing this influence. The model shows that from the dietitian's perspective, developing relationships with clients managing lifestyle-related chronic diseases appears complex. This complexity relates to the dietitian's role of managing both the direct interaction and influences on it simultaneously.

The first category 'Sensing a Professional Chemistry' reflected an undefinable quality of relationships apparent in dietitians' responses that was suggestive of a connection between people. Having this sense of a professional chemistry seemed to be important in whether dietitians were able to develop a functional relationship with their client in the context of undertaking their professional activities. The importance of this sense of chemistry to the potential for a functional relationship is represented visually in Figure 1, where 'Sensing a Professional Chemistry' is embedded within 'Balancing Professional and Social Relationships' (where 'Balancing Professional and Social Relationships' reflects the functional relationship).

The category 'Sensing a Professional Chemistry' arose from dietitians' descriptions of good relationships, where 'gelling', 'clicking', 'connection', 'subconscious aspect' and 'vibe' were used. Dietitians further explained these terms to some extent, describing them as finding a commonality,

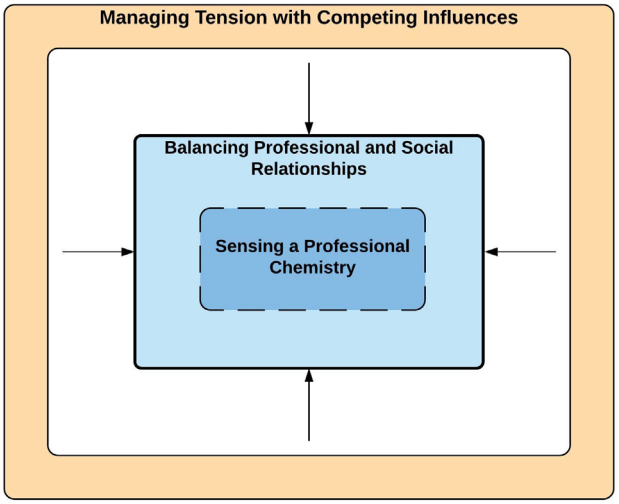

FIGURE 1 Client-dietitian relationship development in lifestyle-related chronic disease management from the dietitian's perspective: A conceptual model

openness, trust and rapport. Dietitians also noted this chemistry may reflect their personalities and the client's motivation. It also appeared that dietitians had some difficulty articulating these terms:

> "*it's one of those things (gelling) that I don't know that I could put words to*" (P20)
> *"it's hard to explain, cause you feel it… you get this feeling they're being open towards you, and that you can be open towards them… and you have that trust"* (P15)

Dietitians' responses also reflected that this sense of chemistry was unmodifiable, that is dietitians expressed they would not be able to 'gel' with a client in the future if they were not able to initially. This quality further contributed to the sense of a professional chemistry in that dietitians perceived it as natural and unable to be forced:

> *"there's some element of subconscious aspect with that… there's lots of people no matter what I do we still just don't connect"* (P3)
> *"there's gonna be people that you just don't gel with, and you're never gonna gel with"* (P20)

The second category 'Balancing Professional and Social Relationships' described the dietitian's skill in balancing two functional relationships within the client-dietitian relationship. 'Professional relationship' referred to a relationship where roles as either professional or client are fulfilled and focused on skills needed in upholding the professional nature of the interaction. 'Social relationship' differed in that it referred to humans interacting without labels of 'dietitian' or 'client', and reflected the importance of ensuring humanity exists within the client-dietitian relationship. Table 2 and Figure 2 provide further explanation of subcategories within this category.

The perceived need to maintain an appropriate balance of professional and social relationships was evident. However, dietitians recognised the difficulty of achieving this in practice, and suggested the appropriate balance depended on each client and dietitian. The need for established indicators and strategies to ensure dietitians address their professional obligations was recognised. Indicators of balance appeared education-based, such as providing new individualised education, or outcome-based, such as tracking clients' progress. The importance of utilising clinical expertise was also a concern:

> "*I don't think there's much point being all 'nicey nicey'… saying 'don't worry you can eat whatever', but also being able to (answer) should I eat butter or margarine, being able to give them a decent answer*" (P6)

An example of a strategy to ensure professional obligations were addressed was to focus on developing the social relationship in the initial stages of engaging with a client. Establishing a social relationship first appeared to ensure the professional relationship had more value and meaning for the client. This appeared particularly important for 'resistive' clients.

> "*it is a priority… I think you have to get that before talking nutrition, cause if (you) go straight into the nutrition and say someone comes to see you… and it's automatically into 'this is how much you need of carbs, fat, protein', there's not gonna be a connection and they're gonna say 'well who are you to say that*?'" (P15)

Although the need to balance professional and social relationships was recognised, the professional relationship appeared to be the foundation of the client-dietitian relationship as the dietetic consultation is a professional service. This is exemplified in a statement by a dietitian who noted that the relationship weakened if the professional attributes of the interaction, such as goal setting, were missing:

> *"It weakened at the end, because we were done with what we set out to do and they were… smashing their goals so to speak"* (P10)

The third category 'Managing Tension with Competing Influences' reflected dietitians' perspectives that developing both professional and social relationships with clients, and achieving an optimal balance between them, can be influenced by factors unrelated to their direct interaction. Dietitians' responses suggested that tension exists between the need to develop and achieve optimal balance between professional and social relationships, and influential factors of that interaction (Figure 1). This category suggests a need for dietitians to be skilled in managing this tension in order to maintain an optimal balance of professional and social relationships with their client and thus uphold an interaction that supports overall relationship development.

Influences were further categorised as being related to clients and dietitians as individuals, their support network and external contextual factors. Factors related to the dietitian and client as individuals were their values, beliefs and opinions and their health. Dietitians' responses suggested that the client's opinion of the dietitian's expertise, the client's value of the dietetic input generally and the client's motivation and belief in their ability to change were influential. The dietitian's value of relationships, their negative

TABLE 2 Description and illustrative quotes of subcategories relating to either professional or social relationships, as part of main category 'Balancing Professional and Social Relationships'

Professional Relationship		
Subcategory	**Description**	**Quotes**
Managing differences	Refers to dietitians managing points of difference between clients and themselves as points of difference were recognised as potential barriers to relationship development. Differences were categorised as misaligned preconceptions and expectations, values and opinions, and gender and cultural differences.	*"it was difficult for me to help her achieve her own goals when I disagreed with them"* (P15) *"and his idea of… I wasn't a good dietitian because I hadn't helped him lose as many kilos as this other dietitian… it was quite a like, not a fraught relationship but we were both coming from very different angles, he was so, so, so weight focused and I was very slowly trying to guide him away from it"* (P16) *"I try to take the gender aspect out of it I guess and just talk about that I've got the knowledge regarding what you're here for and it doesn't matter that I'm a male telling you this… a female (dietitian) would be telling you the same sort of information"* (P22)
Grounding practice for clients	Refers to dietitians modifying their practice to ensure that every aspect of their practice is driven by the client's needs, which includes: • Respecting the client's expertise in their own lives (asking the client for their perspective; giving the client time to express themselves; ensuring the client's perspective is addressed) • Reading the client and recalibrating practice according to the client's needs (acknowledging and responding appropriately to client's emotion; recognising and responding to client's need to have interest shown in them; recognising where continuing to focus on data collection would be detrimental) • Being attune to and interpreting verbal and non-verbal cues from clients • Applying motivational interviewing techniques	*"I sort of start the interview… so my standard is 'now I've received this lovely referral from your doctor and I'm very interested to see what your doctor has to say, but tell me how can I help you today?'… so it's this idea that you acknowledge the human being in front of you, that the doctor's sent something and that's important but what are you hoping to get out of it?"* (P13) *"I guess I showed interest in him you know he has tattoos everywhere so I was like oh wow what's that tattoo on his leg, that I probably did do different behaviour on that front, to build that relationship"* (P9) *"ah body language, you know if they're crossed up or hunched up and hiding behind their hand bag or not making eye contact then there's that barrier that they're not feeling open, so you can pick up on those signals"* (P15)
Establishing reciprocal honesty and openness	Refers to needing honesty and openness within the relationship, and that one person's honesty and openness seems to enable the other to feel they can also be open and honest within the context of the dietetic consult.	*"you just get this feeling like they're being open towards you, and that you can also be open towards them a little bit more as well"* (P15) *"they can tell us what they're eating but if they're not telling us the truth it's really hard for us to help where we can"* (P19) *"if I'm not comfortable with the content, being able to tell the person that I'm not comfortable with the content like, when I try and fluff my way through it, people can generally tell"* (P3)
Communicating with transparency and clarity	Refers to the dietitian being clear in their communication with the client to minimise the potential for misunderstandings that may impede relationship development. This primarily involved providing explanations to clients about the dietitian's role and scope of practice, what they can expect from the consult and the consult process, the dietitian's approach to practice, the rationale for the client receiving dietetic input and stopping consultations once therapeutic benefits cease.	*"if people don't understand why I'm asking questions that are involving them talking more than I need to talk, I explain to them that I really need to know what's happening for you otherwise you're just going to walk out with a plan that could be given to anyone, and that won't be the best thing for you. And they really come around to that"* (P17) *"So in the initial (consultation)… we talk about before we go into anything deeper, we talk about how I work and that it's not the only way to work, this is one of the options that they have and the reasons why I work from that (Health at Every Size approach)"* (P18)
Establishing two-way communication	Refers to establishing communication pathways where dietitians and clients are able to communicate with each	*"I always end my consult with giving my business card and saying if you've got any questions my email's there, send*

(Continues)

TABLE 2 (Continued)

Professional Relationship		
Subcategory	**Description**	**Quotes**
	other equally and feel comfortable in doing so. Importance was placed on enabling clients to feel comfortable instigating communication with the dietitian, as it allows the client to perceive their dietitian as approachable and supportive. The medium of communication (eg, email, telephone, face-to-face) and how dietitians manage that medium also appeared important.	*me an email or admin are always happy to take calls and get them to give them a call back so that approachability really comes through"* (P22) *"Yeah that was definitely the issue, it was the promising something I couldn't deliver and then avoiding the communication of that… because of this desire to be able to do it for them, but not prioritising or having the time to be able to do it so yeah definitely communication was an issue there"* (P24)
Using comfort carefully to enable progression	Refers to the dietitian's skill in utilising comfort appropriately within the consultation to ensure it facilitates relationship development, rather than impedes relationship development. The need for dietitians to create a calm, relaxing and comfortable interaction for both themselves and clients was evident. Managing this balance of comfort was suggested as a skill for dietitians in ensuring clients feel comfortable but also recognising when the client's comfort may be detrimental to their progress. Comfort and discomfort appeared to be drivers of relationship development when utilised appropriately by the dietitian.	*"I think that that's one of the thing(s) that they feel quite comfortable, I mean that's possibly not a great thing, because I think sometimes it's a way to just listen to all their stuff that's going on… they can manipulate, maybe so we do not give it to them for instance?"* (P7) *"people do need to feel like they do not need to change everything and that there are things that they are actually doing quite well, so being comfortable and remembering to give that positive feedback to people I think is quite important"* (P17) *"embracing discomfort is something that we can all do better because by doing so we really can connect with that human in front of us, and it's both embracing our own discomfort as well as the client's discomfort"* (P13)
Building sense of trust	Refers to dietitians building clients' trust in their role delivering a professional service. Building a sense of trust appeared to be determined by multiple factors, such as the ability of the dietitian to fulfill promises made to the client, and as needing to be developed over time.	*"trust is probably 99% of what we do because if they don't trust you… they're not gonna tell you the truth, they'll tell you what they think you want to hear"* (P4) *"because if people don't trust you they won't listen to you and they won't open up to you, so you'll never know, you'll never be able to address the right barriers with them and help them find solutions to those barriers"* (P17) *"I've got a good location, but I guess it (trust) just takes time doesn't it? To build trust, and I don't rush people in their appointments so they're half an hour or an hour so they have time for questions if they've got any"* (P7)
Demonstrating empathy and acknowledgement through listening and understanding	Refers to a process of interaction between the client and dietitian which includes: • Listening to the client using interpreting, clarifying and probing skills, being present and focused and giving the client uninterrupted time to talk • Developing a holistic understanding of the client and their story, perspectives, culture and experiences • Acknowledging client's progress, feelings and experiences throughout the consult • Demonstrating empathy (creating a comfortable and supportive environment; being non-judgemental; conveying a sense of working together, showing understanding of the client's history and integrating understanding verbally throughout consult; using body language)	*"the empathy is a big part to be able to have that relationship because if you just disregard everything then there's that lack of respect isn't there?"* (P10) *"anyone with a chronic disease has been in the health system for a long time and often they've dealt with a lot of challenging situations and without identifying that and acknowledging it, you'll get nowhere"* (P14) *"just asking them you know how does it feel to be in that situation, and just trying to tease out their story more, and also recognising that story throughout the consultation, so even when setting the goals… reiterating look I know that you're going to find this part challenging because in the past this has happened to you here"* (P10) *"I will actually paraphrase back to them emotions and feelings… so that they know I've heard what they've said, in you know I'm busy I don't have time to cook dinner, but then I'll also say something like gosh that sounds really challenging… we're all expected to be on 24/7… we're only human, that sort of thing so that then they feel like I'm hearing them but I'm also actually understanding where they're coming from, from an emotional point of view"* (P20)

(Continues)

TABLE 2 (Continued)

Professional Relationship		
Subcategory	**Description**	**Quotes**
Managing goal-setting process	Refers to the dietitian's skills in managing the goal-setting process to facilitate relationship development, particularly regarding how it impacts the client's perception of the dietitian's value of their opinion. This skill overlaps with the need to respect the client's expertise in their own lives (as part of the skill 'grounding practice in client'). Dietitians appeared to involve clients in the goal-setting process to varying degrees, ranging from dietitian-lead approaches to client-lead approaches. Goals were identified as needing to be specific, long-term and understood by the client.	*"I think it has a big impact (setting goals with clients) because it actually shows that you're listening to them, and you're valuing their opinion and what they think that they can actually achieve"* (P10) *"I always try to encourage them to have participation in setting their goals so that it's something they they're interested in"* (P19) *"Sometimes it's as simple as getting through their diet history and then just saying what do you think about your diet? What do you think you do well? What do you think you'd like to change and what do you think you can change?"(P14)*
Removing judgement and blame	Refers to dietitians removing any judgement or blame they may contribute to the consult. Dietitians perceived clients to appreciate a non-judgemental approach, and that it enabled clients to be more comfortable within the consultation and open to change. Verbal and non-verbal techniques were identified.	*"I guess the way I respond to, you know if we're going through a food diary, how much soft drink do you drink or something and they go oh two litres, I wouldn't respond in a way that's ah, wow that's a lot but sort of pointing out that, that is something that we need to change, so not being judgemental in a way I respond I guess to some element of the food diet history that is out of the ordinary or needs to be changed"* (P22) *"Once a client realises that they're not being judged and their situation's unique… you can take the pressure off that it's not their fault, then they're more open to change"* (P23)
Facilitating focus on positivity	Refers to dietitians facilitating positivity within the consultation to promote relationship development. Strategies included focusing on food in a positive light, such as focusing on foods that the client can eat.	*"Well you want it to be positive for everybody I mean, who wants to sit there and just hand out meal plans and tell people what not to eat all day, like that's pretty awful"* (P6) *"I think what made it successful is that I tend to work more from a, working with where they're at, making it positive about foods that they can have, and why certain foods are better choices, or why certain foods aren't great say in terms of cholesterol, and then turning that into well here's a meal you could make or here's something you could take for lunch that would be a better option, and might help your cholesterol"* (P6) *"so what I'm trying to do especially for the overweight or obese patients… I won't restrict their diet but instead I will encourage them to make some healthy changes for example maybe just to get them to eat more vegetables and drink more water to keep them full, so they don't have to starve themselves and they can build a happy and positive relationship with food"* (P21)
Social Relationship		
Subcategory	**Description**	**Quotes**
Being warm and personable	Refers to dietitians being warm and personable when interacting with clients managing chronic diseases due to clients likely experiencing feelings of confusion and anxiety. Dietitians reflected a need to behave in a way that was more 'human' than 'clinical' and included: • Engaging in casual and non-dietetic related conversation • Remembering and following up on personal details of client's life • Being reassuring	*"the second time they come in you know really trying to remember small things about what they said first consult, so they might have been a bit (stand-offish) because they were having (a) bad day, the car broke down… and if you sort of make little notes about that next time you come in you ask them so how did it go with the car, like little personal details, I think they appreciate that a bit more then they start to open up a little bit to you, so that persistence as well, will help, just that personal touch I think makes a bit of a difference"* (P12)

(Continues)

TABLE 2 (Continued)

Social Relationship		
Subcategory	**Description**	**Quotes**
	• Providing positive feedback • Responding with emotion, such as smiling and laughing when appropriate • Displaying a genuine interest in the client	*"I think in terms of warmth it's showing that you're genuinely interested in the person, explaining to them what you know changing could mean for them so really linking it, not just to like biochemical parameters but really like explaining to them what it could mean for their life and their lifestyle and their future"* (P17)
Duality of developing rapport	Refers to dietitians developing rapport with clients, and that rapport development appears to have a sense of duality. This refers to dietitians' perspectives of rapport development suggesting contrasting qualities, in that it appeared to be both a natural and unnatural skill for dietitians, both easy and difficult with particular clients, and that it should be a focus both during initial stages of interacting and throughout all interactions. This apparent duality suggests that rapport development may depend on the individuals within the interaction.	*"there are people who have a natural tendency towards looking for that rapport building and I know for myself that is very much what I do with everybody, in every social interaction"* (P3) *"Building rapport is also really important and I spend any opportunity I can in the consult to have those human interactions and emotional connections"* (P24) *"with those one(s) I find the thing that really helps with the interaction… is needing to establish rapport early on"* (P12) *"I think rapport building is something that you do every single session even though after a few months you know there's that strong relationship you still want to make sure that you're welcoming her in and really listening to what they want"* (P18)
Connecting through seeing each other as relatable humans	Refers to clients and dietitians seeing each other as relatable humans through identifying similarities in each other. Generally dietitians recognised the importance of relating to each other however some questioned its importance. How dietitians develop a sense of relatability appeared multifactorial and dependent on each client. Factors include: • Seeing each other as human • Showing understanding and acknowledgement • Establishing a shared experience • Ensuring clients feel normal • Using self-disclosure • Verbal and non-verbal language	*"I find especially you know budget related to food, if you can relate to them that 'oh yeah I know, you gotta buy sausages, isn't steak expensive', it is where I mention I do things myself you know 'oh yeah for my family too I'm buying up on mince'"* (P9) *"I'm hoping that I've tried to actually have an angle of what I would call common humanity, where people say things like 'oh you know and then I did this and then I ate another chocolate'… and I'd say 'well yes because that's what human beings do, that makes you a normal human'"* (P20) *"I think being authentic is really important, and say knowing that you're not perfect either and you don't have to resemble the Australian Dietary Guideline(s) every single day is really important"* (P18) *"So if I was seeing a young woman who was dealing with similar issues, cause that's one of the things that I think actually does help me, cause I'm dealing with my own chronic disease, and so I think I can relate a lot to that myself, but if someone was very different and was sort of, again like the classic example, a middle aged white man, I wouldn't be as nearly as open with them as I would be if I had somebody who was really struggling with a lot of issues who was a lot more similar to me"* (P20)

opinions of clients and their belief in their professional ability appeared influential. For example, responses suggested that when dietitians have negative opinions of clients, they perceive practising in a way that facilitates relationship development to be more difficult:

> "*I find it really hard to not have my back up with those people cause they've been quite demanding*" (P9)

Another dietitian recognised qualities of clients that could bring on negative thoughts, such as when the client makes sexist statements. Hence, it appears that dietitians may develop negative opinions towards clients when there is conflict between how the client behaves and the dietitian's values.

Tension between clients' and dietitians' physical and mental health and their ability to form relationships was identified, where poorer health appeared to make

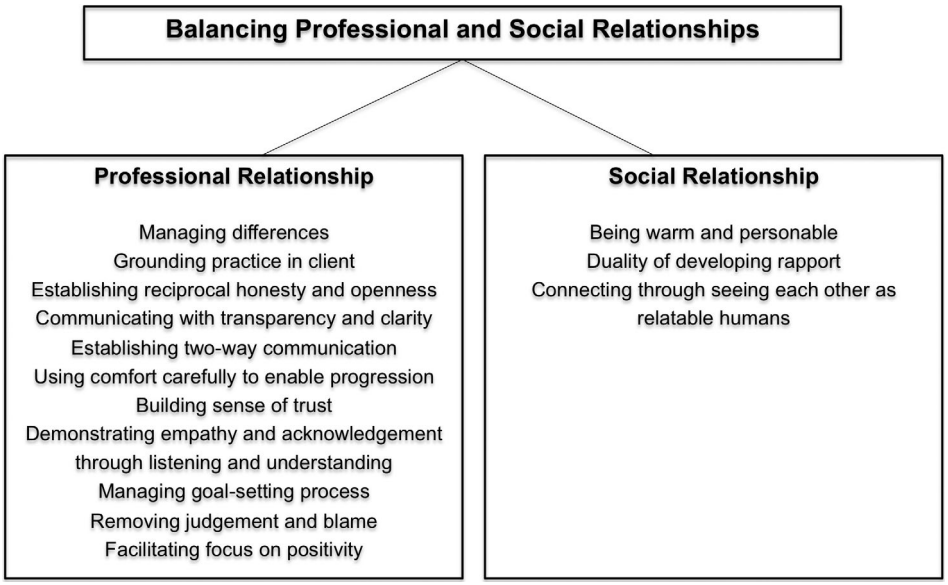

FIGURE 2 Subcategories of main category 'Balancing Professional and Social Relationships'

relationship development more difficult. It was suggested that for clients, this may be due to having lower motivation and attending fewer consultations. Dietitians described 'running with their own agenda' when they felt stressed, tired or sick. The negative impact of poor health on the dietitian's ability to be empathetic, patient and motivating was also identified:

> "*if you're feeling sick or tired… you're like I don't even want to do this job, I hate this job, it's gonna be so hard to overcome that and put a smile on and be really perky and… get people motivated*" (P25)

The need for clients to have a supportive network, including their broader socioeconomic context and their home environment was expressed. Clients of lower socioeconomic status were described as being likely to attend consultations less frequently, impacting contact time and therefore relationship development. Dietitians described situations where the client's support network caused tension between their relationship. For example, the impact of the involvement of a client's family was described:

> "*the conflict between this young man and his family became so significant because he felt they were over-involved in his care… he slipped away in the end*" (P13)

Dietitians' responses also reflected a need to form a relationship with the client's support network, such as their family or friends:

> *"no one is a silo, everyone is part of a network, unless you can engage effectively with the entire network you will never be an effective clinician"* (P14)

In addition, dietitians recognised the influence of their own support network, including working within a supportive multidisciplinary team and having a network to engage in reflective practice with. Dietitians described reflecting formally through regular clinical supervision, whilst others described reflecting informally with fellow colleagues.

> *"that… formal supervision process, particularly for a private practice practitioner, who's isolated is absolutely essential for me, and has made such a difference to my mental health, and my capacity to work more meaningfully with my clients"* (P13)

External contextual influences were unrelated to the client and dietitian, but seemingly needed managing by dietitians to ensure meaningful relationships with clients. These included influences on their contact time, such as their workplace, the physical environment of the consultation, having an interpreter present, the need to complete documentation and sources of conflicting information. For example, dietitians perceived having insufficient time with clients as negatively impacting their relationship, which exposed the issue of who determines how much time dietitians spend with clients. Some dietitians described their time with clients being governed by workplace constraints enforced by the Medicare Chronic Disease Management Plan and expressed their

frustration at this. For example, one dietitian questioned their ability to develop a relationship under the time constraints of Medicare-funded consults:

> *"you're so time limited that I mean what chances (are) there of developing trust and rapport?"* (P9)

Hence consultation time appeared to influence how dietitians address key elements of both professional (trust) and social relationships (rapport) (Figure 2).

4 | DISCUSSION

This study has produced a novel model of relationship development in chronic disease management from the dietitian's perspective, which offers a more in-depth and comprehensive representation than what is currently understood in dietetics. It has done this by building on the knowledge of individual qualities important for client-dietitian relationships within literature,[3,9-11] and by identifying meaningful processes underlying those qualities and how they might interact with each other. Furthermore, this model offers a more comprehensive picture of relationship development by recognising not only the direct interaction between clients and dietitians as important, but also influences on this interaction. As a result, this model demands an additional skillset of dietitians in being able to manage the tension between this direct interaction and factors that may influence it. Thus this study offers a unique insight into the complexity of our role as dietitians in establishing meaningful relationships with clients in a chronic disease context. By exposing this, our findings have also contributed to the evidence describing how dietitians can be patient-centred in their practice and key tenets to be addressed. The need for more in-depth understanding of relationship development in dietetics, and for further professional support in this crucial aspect of practice has been identified.

Research in psychology and medical disciplines has established therapeutic relationships as multidimensional.[5,13] An example from psychology-based research describes therapeutic relationships consisting of personal role investment, interactive coordination, expressive attunement, affective attitude and experiential congruence. These dimensions are each articulated in detail, for example, 'expressive attunement' is described as the quality of communication consisting of expressiveness, empathic understanding and communicative rapport.[13] This example highlights the degree to which therapeutic relationships are understood in this field. The difficulty dietitians had in explaining ambiguous terms they had used, such as 'gelling', were represented within the category 'Sensing a Professional Chemistry'. This may suggest a limited understanding of, or limited language to describe aspects of therapeutic relationships within dietetics in comparison to other disciplines. For example, what does it mean to 'gel' with a client? Thus, it appears there is a need to further explore what this sense of 'professional chemistry' is in dietetics, and how it might compare to dimensions of therapeutic relationships explicitly identified in other disciplines. Interdisciplinary collaboration between dietetics and psychology, for example through education and training, and overt recognition of the psychology existing in this aspect of dietetic practice may benefit dietitians in better understanding therapeutic relationships.

Psychology-based literature also recognises that different types of relationships exist within the therapist-client relationship: the working alliance, transference and countertransference, and the real relationship.[24] This supports our finding that the client-dietitian relationship consists of both professional and social relationships, as the working alliance is based on therapeutic 'work' (professional relationship), whereas the real relationship is recognised as the 'person-to-person, non-work connection' (social relationship).[24] Thus the support of this finding within established psychology-based literature highlights the need to explore if, and how, dietitians are aware of these dimensions of relationships and to further understand how they might co-exist in client-dietitian interactions, particularly in the chronic disease context. A deeper understanding of how to appropriately balance professional and social relationships when interacting with clients may further support dietitians to deliver optimal dietetic care.

The need to balance professional and social relationships within the client-dietitian relationship exposes a potential grey area in the blurring of professional conduct. Dietitians receive payment from clients and hence there is an obligation to deliver a professional service. Therefore, ethical questions can be raised about the responsibility of the dietitian in fulfilling the professional relationship. Key dietetic bodies recognise the ethical obligation of dietitians to deliver a professional service and this was reflected in dietitians' responses where the importance of the professional relationship was expressed.[25,26] This is further supported and discussed in other healthcare disciplines, where for example Zur[27] identified a direct impact of maintaining therapeutic boundaries on the effectiveness of psychotherapy. Therefore, further research is needed in understanding how this is expressed and managed in dietetic practice, particularly within education and training, and how it can be integrated into meaningful relationship development.

The finding that dietitians' values, beliefs and opinions and their health, can influence relationship development reflects the need to consider our own lens as dietitians: who we are, what we bring to the relationship and what impact it

may have. Research suggests dietitians can show weight stigma towards clients,[28,29] whilst a cross-sectional study[30] surveyed dietitians about their management of obesity and found they experienced frustrations with clients' lack of motivation, commitment and compliance. Furthermore, Diversi et al[28] acknowledge the negative impact these emotions may have on client-dietitian relationships. Quantitative research in psychotherapy suggests that therapists are less able to develop strong relationships with clients when they feel burdened in their personal lives.[31] In addition, Vandenberghe and Martins de Silveria[32] describe a type of psychotherapy where therapists engage in mindfulness exercises in preparation for interacting with clients by reflecting on themselves and their past experiences. This literature supports our findings and suggests a need for dietitians to reflect on who they are as a person and how this may impact relationship development, particularly how this might contribute to their sense of a 'professional chemistry' with their client. Thus the need for dietitians to be self-aware and be able to self-manage this for optimal relationship development with clients managing chronic diseases seems important, and further accentuates the importance of dietitians engaging in regular and critical reflective practice. It seems that further emphasis on dietitians' self-awareness and self-management skills is needed within professional development opportunities, and increased professional support in this area of service delivery, to continue advancing dietitians' relationship development skills.

There are strengths and limitations of this study. From the limited data available, the sample appears to reflect the mostly female-dominated dietetic profession in Australia that primarily works in New South Wales, Queensland or Victoria.[33,34] Also, it is likely that dietitians who participated were motivated to share their perspectives due to their own interest in the topic. Hence, this research may offer a 'one-sided' perspective from dietitians who sought to express their views, and that perspectives of dietitians not interviewed may have differed. The reflexive processes employed by the first author meant that their preconceptions of relationship development seen through a dietetic lens, could be challenged by psychology-based perspectives offered by the interdisciplinary research team. Finally, the constructivist approach to this research acknowledges findings as embedded within a specific context, where the researcher's involvement is recognised as part of this context.[15]

In conclusion, developing meaningful client-dietitian relationships in the chronic disease context appears complex for dietitians due to needing to manage multiple interrelated elements and influential factors simultaneously. The appropriate management depends on the dietitian as both a person and professional, and the individual client. Further research is needed to advance the profession's understanding of meaningful relationships, particularly from the client's perspective, and how knowledge of practitioner-client relationships in other health disciplines may be utilised to enhance dietetic service delivery.

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CONFLICT OF INTEREST

The authors wish to declare no conflict of interest.

AUTHOR CONTRIBUTIONS

A.N., A.M. and L.T. contributed to the study conceptualisation and design. A.N. conducted all interviews and transcribed each audio-recorded interview. A.N., A.M., L.T. and F.D. contributed to data analysis. A.N. developed the manuscript for publication, and A.M., L.T. and F.D. critically reviewed the manuscript prior to submission. All authors are in agreement with the manuscript. The authors would like to acknowledge and thank Angela Messina who conducted transcript checks and the dietitians who participated in this study.

ORCID

Annaliese Nagy https://orcid.org/0000-0001-7727-8180

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Food neophobia and its association with food preferences and dietary intake of adults

Alexandra Costa BNutrDiet, Student[1] | **Cláudia Silva PhD, Professor**[1,2] | **Andreia Oliveira PhD, Professor**[1,3]

[1]Faculty of Health Sciences, Fernando Pessoa University, Porto, Portugal

[2]FP ENAS (Unidade de Investigação UFP em Energia, Ambiente e Saúde), CEBIMED (Centro de Estudos em Biomedicina), Rua Carlos da Maia, Porto, Portugal

[3]EPIUnit - Institute of Public Health, University of Porto, Porto, Portugal

Correspondence
Alexandra Costa, Fernando Pessoa University, Faculty of Health Sciences, Porto, Portugal.
Email: 29826@ufp.edu.pt

Abstract

Aim: To assess the association of food neophobia (FN) with food preferences, dietary intake and dietary quality.

Methods: A cross-sectional study was conducted in a non-probabilistic sample of 229 Portuguese adults, aged 18 to 84 years. FN was measured with the FN Scale. Dietary intake over the previous 12 months was assessed by a validated semi-quantitative food frequency questionnaire. We defined a dietary pattern the Healthy Diet Indicator, to summarise the effects of overall dietary intake. Generalised linear models were performed to test associations in multivariate analyses (controlled for sex, age and education).

Results: FN was negatively associated with a general liking for the act of eating ($\hat{\beta} = -2.976, 95\%\text{CI}: -5.324; -0.993$) and with reduced preferences for specific foods (fruit and vegetables, some types of meat and fish and traditional Portuguese dishes with blood). Those with higher FN showed a lower consumption of fruits and vegetables, but a higher consumption of milk and codfish, a popular Portuguese ingredient. However, FN did not affect the macronutrients and energy intake, as well as sodium, added sugars and fibre intake. Adherence to a healthy dietary pattern was not significantly associated with FN.

Conclusions: FN was associated with a decreased consumption and preference for specific foods, but it had no impact on a healthy dietary pattern.

KEYWORDS

adults, diet quality, dietary intake, dietary pattern, food neophobia, food preferences

1 | INTRODUCTION

Food neophobia (FN) is characterised by the tendency to reject new/unfamiliar foods or to experience anxiety and aversion when exposed to unfamiliar foods.[1,2] The food rejection can be explained by fear of its adverse consequences, but also by the dislike of its sensory characteristics, or disgust, due to the idea of the food's nature or origin.[3]

FN is a very complex attitude that varies throughout life. The literature suggests that it reaches a peak between 2 and 6 years old and stabilises in adult life.[4] Beyond age, several factors can affect FN such as cultural and economic aspects, gender and genetics.[5-7] Although there may be a strong genetic influence, FN can be changed.[8] Repeated taste exposures have been found to be effective in increasing acceptance of new/unfamiliar foods.[8-10] The peer-influence can also be important, peer modelling has been shown to increase the acceptance of foods in childhood.[11]

Studies suggest that FN has adverse impacts on food choices affecting the quality and variety of the diet.[3,12] This trait was previously associated with higher consumption of unhealthy foods, a lower consumption of fruit, vegetables

and fish and with poorer overall dietary quality.[5,12-19] Increasingly neophobia is negatively associated with pleasantness of food and with a higher dislike of food overall.[20,21] In relation to the macronutrients and energy intake, the literature shows inconsistent results. In some studies, individuals with a high level of FN had a lower intake of protein,[2,22] while others did not find any associations.[13,23] The association with the total energy intake seems also to be controversial; a few works report a positive association,[22,24] others report a negative or null association.[2,5,14]

The analysis of the relationship between FN, food preferences and intake has been limited to date and most studies were performed in children. Although some previous studies have described some food groups less frequently consumed by more neophobic individuals,[16,19,20,25] it is not completely clear regarding the associations with food preferences, food intake and dietary quality, which have been more scarcely discussed in adults. As food preferences influence food intake, FN may influence food intake partly by its effect on food preferences. So, it would be interesting to explore if the association of FN is the same with both food intake and preferences in the same population. Therefore, the aim of the present study was to assess the association of FN with food preferences, dietary intake and dietary quality.

2 | METHODS

A cross-sectional study was conducted in a non-probabilistic (convenience sample) sample of 229 adults, aged 18 to 84 years. Participants who had demonstrated an interest in being a part of the study were approached. The inclusion criteria were being 18 years or older, Portuguese and able to read, interpret and provide written answers. Participants with an energy intake greater than 5000 kcal/day or smaller than 500 kcal/day[26] were excluded from the dietary intake analysis (n = 5). The study protocol was approved by the Ethics Committee of the University Fernando Pessoa. The present study was performed according to the principles established by the Declaration of Helsinki. Data confidentiality was assured.

Data were collected between October and November 2016 by Nutrition Science students in the northern region of Portugal. Participants with whom students had privileged academic or personal contacts and who had demonstrated an interest in being a part of the study were approached.

Two self-administered questionnaires were used. Before completion, the students explained the nature of the study and subsequently gave them a consent form and the questionnaires which they returned directly to the students when completed. The first questionnaire gathered information about sociodemographic characteristics, drinking habits, food preferences, FN and self-reported body weight and height. The other was a semi-quantitative food frequency questionnaire used to assess dietary intake over the previous 12 months.

Sociodemographic characteristics were used as confounders of the tested associations. A complete number of age and schooling years were reported; age as a continuous variable and education in a closed question with eight categories, grouped into four: elementary school (≤4 years), middle school (5-6 years), high school (7-11 years), and college (>12 years). Income was also reported, by selecting one out of four options (<530€, 530€-1060€,1061€-2000€, >2000€). Self-reported weight and height were used to calculate body mass index (BMI).[27] Regular physical exercise practice was gathered as a dichotomy question.

FN was measured with the FN Scale (FNS).[1] The FNS is an auto-assessment questionnaire which the participants must indicate their agreement to 10 statements about their willingness to try novel foods on a 7-point Likert scale. Five of the statements indicate a low FN; in those questions, the coding was reversed. The final score can range from 10 to 70. A high score represents less willingness to try new or unfamiliar foods (neophobia), while a lower score indicates more willingness to try novel foods (neophiliac).[1,3] For missing values of a single statement in the questionnaire data were recovered by replacement for the median of the total answers (n = 2). This scale has been applied in several different samples.[28-31] We used the Portuguese translation of the FNS.[30] Cronbach's alpha coefficient was calculated, indicating a good internal consistency ($\alpha = 0.80$). As there are no standardised cut-off values for classifying individuals as "food neophobic" or "food neophiliacs," the final score was used as a continuous variable.

A self-administered questionnaire was developed. The questionnaire had 28 items divided into 10 different groups (vegetables, fruits, meat, fish, eggs, seafood, junk food, soup, traditional Portuguese food and spicy food). An additional question was added about the general liking for the act of eating. Foods were chosen to represent major food groups and foods frequently consumed by the Portuguese. Responses of preference were evaluated using a 5-point scale ("like a lot" to "dislike a lot"). Responses were scored 1 to 5.

Dietary intake over the previous 12 months was assessed with a semi-quantitative food frequency questionnaire (FFQ). The questionnaire comprises a list of 86 foods or food groups and a closed section with nine categories of frequency of consumption; three closed sections for the average portion consumed (lower, equal or higher than the mean portion size) and the seasonal variation of consumption. The FFQ was previously validated by comparison with four 7-day food records (each one in a different season of the year) (correlations were moderated to high) and with a sample of subcutaneous adipose tissue (significant correlation with saturated and long-chain n-3 fatty acids).[32,33] Food consumption was converted into total energy and nutritional

intake with the software Food Processor Plus (ESHA Research, Salem-Oregon, 1997), which has been adapted to the traditional Portuguese foods.

To summarise the effects of overall dietary intake, a dietary pattern was defined, by using a hypothesis-oriented approach. The healthy diet indicator (HDI) was calculated by using the dietary guidelines for the prevention of chronic diseases, defined by the World Health Organization (WHO).[34] From the 15 dietary items (intake of nutrients or food components) listed in the WHO guideline, nine were included in the score (saturated fatty acids; polyunsaturated fatty acids; protein; complex carbohydrates; dietary fibre; fruits and vegetables; pulses, nuts and seeds; monosaccharides and disaccharides; and cholesterol) as originally suggested.[35] Alcohol intake was added, using a cut off point based on the recommendations of the American Heart Association (15 g/day of alcohol intake for females and 30 g/day for males).[36] We applied a dichotomized scoring method used in the original HDI study,[35] that is, if a person's intake was within the recommended range according to WHO guidelines this variable was coded as 1; otherwise, it was coded as 0. The HDI was the sum of all these dichotomous variables and had a range of 0 to 10 points, with 10 points indicating full agreement with the dietary guidelines.

After checking the normality of distribution, descriptive and inferential statistics were calculated. Mean (SD) differences were compared through the independent sample *t* test. To examine differences in neophobia level according to dietary intake and food preferences, generalised linear models were used, with the calculation of beta regression coefficients and the respective 95% confidence intervals ($\hat{\beta}$, 95% CI). Three models were tested: 1) crude; 2) adjusted for sociodemographic data, such as sex, age and educational level and a 3) third model with further adjustment for body mass index. The latter adjustment did not modify the associations (results not showed) and thus model 2 was assumed as the final model. An interaction effect of sex was tested in the study associations, but no effect was found (results were not stratified by sex).

Data analyses were performed using SPSS software 23.0. A significance level of 5% was considered in all analyses. The paper is reported following the STROBE statement.

3 | RESULTS

Out of the 229 participants, six were excluded due to missing values in the questionnaires. The final sample included 223 participants whose characteristics are described in Table 1. Of the individuals, 40.4% were male, and their mean age was 37.6 years (SD 17.3). The FN score ranged from 10 to 68 (from a possible range of 10-70). The sample mean score was 37.5 (SD 11.2). No significant differences were found in the mean FN score between sexes. However, those more educated and with higher household income had significantly lower mean FN scores, as well as subjects with under/normal weight.

The association between FN and liking of various foods is shown in Table 2. In multivariate analysis, FN was associated with a lower general liking for the act of eating ($\hat{\beta} = -2.976$, 95% CI: −5.324; −0.993). FN was also inversely associated with the liking of fruit and vegetables, game meat, oily fish, seafood, fish soup and some traditional Portuguese dishes.

The results of the association between FN and dietary and nutritional intake are presented in Table 3. Since the used FFQ has a long list, we only presented in the table the significant associations with FN along with the intake of sugar, sodium, fibre and alcoholic beverages because these

TABLE 1 Study sample characteristics

	n[a] (%)	Food Neophobia Scale (FNS) score (10-70)[b] Mean (SD)	*P*
Total sample	223 (100)	37.5 (11.2)	—
Sex			
Female	133 (59.6)	37.1 (11.1)	—
Male	90 (40.4)	38.1 (11.3)	.539
Education level			
Elementary school	29 (13.0)	43.3 (11.5)	—
Middle school	50 (22.4)	43.8 (10.3)	.561
High school	81 (36.3)	35.0 (11.0)	**.001**
College	63 (28.3)	34.5 (11.2)	**.001**
Household monthly income			
<530€	19 (8.5)	44.2 (12.5)	—
530€-1060€	80 (65.9)	39.0 (10.4)	.062
1061€-2000€	70 (31.4)	37.0 (12.0)	**.025**
>2000€	50 (22.4)	33.4 (9.6)	**.001**
Self-reported body mass index (BMI)[c]			
Underweight	8 (3.6)	31.5 (12.0)	.206
Normal weight	131 (58.7)	36.6 (10.9)	—
Overweight	55 (24.7)	40.1 (11.3)	**.048**
Obese	18 (8.1)	42.5 (10.7)	**.039**
Physical exercise			
Yes	109 (51.1)	36.3 (11.4)	—
No	114 (48.9)	38.7 (10.9)	.106

Note: *P* value is calculated by independent sample *t* test, significant results are in bold type.

[a]N varies between 219 and 223, differences due to missing values.

[b]FNS (variation range in parentheses).

[c]BMI was classified according to the World Health Organization guidelines.[34]

components have a high prevalence of inadequate intake. In addition, we reported the intake of foods from the main food groups (dairy products, cereals and potatoes, legumes, meat, fish and eggs, fruits and vegetables).

No associations were found between FN and the macronutrients and energy intake, nor with sodium, added sugars and fibre. Nonetheless, individuals who consume specific food items seem to have significantly different FN levels. Individuals with higher FN scores consume fewer fruits and vegetables, specific types, such as broccoli, turnip greens, onions, lettuce, tomatoes, tree nuts, cherries and melon. No associations with the intake of meat and fish were found, except for codfish, a traditional product of Portuguese cuisine. The consumption of codfish increases with increasing FN score. The same positive association was found with milk.

TABLE 2 Mean food preferences of the study sample and association with food neophobia in crude and multivariate analyses

	Mean (SD)	Crude $\hat{\beta}$ (95% CI)	Adjusted $\hat{\beta}^{a}$ (95% CI)
General liking for the act of eating	4.4 (0.7)	**−4.065 (−6.266; −1.842)**	**−2.976 (−5.324; −0.993)**
Vegetables	4.0 (1.0)	**−2.367 (−3.758; −0.975)**	**−3.139 (−4.490; −0.788)**
Fruit	4.3 (0.8)	**−2.233 (−4.075; −0.390)**	**−2.550 (−4.282; −0.818)**
Beef	3.9 (1.0)	0.086 (−0.568;2.324)	1.063 (−0.367;2.494)
Pork	3.6 (1.2)	0.996 (−0.295;2.287)	0.739 (−0.549;2.028)
Poultry meat	4.1 (0.9)	−1.393 (−3.052;0.266)	−0.913 (−2.501;0.676)
Game meat	3.1 (1.4)	**−1.864 (−2.943; −0.784)**	**−2.158 (−3.20; −1.114)**
Oily fish	3.9 (1.1)	**−2.086 (−3.393; −0.778)**	**−1.947 (−3.190; −0.703)**
White fish	3.9 (1.1)	−0.144 (−1.527;1.239)	−0.530 (−1.890;0.831)
Seafood	4.0 (1.2)	**−2.036 (−3.274; −0.798)**	**−1.661 (−2.844; −0.478)**
Eggs	4.3 (0.7)	−1.444 (−3.440;0.552)	0.495 (−2.410;1.420)
"Junk" food	3.5 (1.4)	**−1.441 (−2.506; −0.376)**	−0.222 (−1.389;0.944)
Vegetable soup	4.2 (1.0)	−0.498 (−2.041;1.045)	−0.877 (−2.362;0.608)
Fish soup	2.6 (1.5)	**−1.912 (−2.872; −0.952)**	**−1.720 (−2.665; −0.775)**
Chicken broth	3.8 (1.3)	−0.026 (−1.175;1.124)	−0.157 (−1.242;0.927)
Tomato soup	2.5 (1.4)	**−1.274 (−2.308; −0.241)**	**−1.021 (−2.013; −0.300)**
"Caldo Verde" [b]	4.1 (1.1)	−0.043 (−1.388;0.481)	−0.827 (−1.388;1.303)
Seafood cream soup	3.0 (1.4)	**−1.691 (−2.707; −0.675)**	**−1.649 (−2.683; −0.696)**
"Tripas à moda do Porto"	3.2 (1.6)	−0.048 (−1.175;1.124)	−0.756 (−1.664;0.195)
"Papas de Sarrabulho"	2.9 (1.6)	0.086 (−0.829;1.001)	−0.696 (−1.611;0.220)
"Rojões à minhota"	3.8 (1.1)	−0.354 (−1.671;0.932)	−0.756 (−2.006;0.494)
"Cozido à portuguesa"	3.8 (1.2)	0.234 (−1.033;1.502)	−0.804 (−2.045;0.438)
"Arroz de cabidela"	3.3 (1.6)	−0.534 (−1.459;0.392)	**−1.099 (−1.928; −0.216)**
Codfish	4.1 (1.1)	0.197 (−1.191;1.585)	−0.513 (−1.840;0.221)
"Arroz à valenciana"	3.5 (1.2)	−1.274 (−2.36;0.239)	−1.023 (−2.244;0.198)
Roasted lamb	3.4 (1.6)	−0.132 (−1.086;0.822)	−0.383 (−1.300; 0.534)
"Coelho à caçador"	3.0 (1.3)	−0.776 (−1.782;0.231)	**−1.095 (−2.063; −0.126)**
"Francesinha"	4.0 (1.3)	**−2.164 (−3.317; −1.011)**	−1.071 (−2.345;0.203)
Spicy food	3.4 (0.7)	**−1.590 (−2.605; −0.575)**	−0.876 (−1.932;0.179)

Note: SD: 95% CI = 95% Confidence interval. Significant associations are in bold type. N varies between 218 and 223, differences due to missing values.

[a]Model adjusted for sex, age and educational level.

[b]Main ingredients of Portuguese traditional dishes: "Caldo verde": potatoes, onions, kale cabbage, chorizo, olive oil; "Tripas à moda do Porto": white beans, tripe, chorizo, chicken, bacon, cow's foot, pig's ear, pig's foot, carrots, onions and hot boiled rice; "Papas de Sarrabulho": pork blood, chicken, pork, cornflour bread, offals, chorizo; "Rojões à minhota": pork, white wine, tripe, pig blood curd, lard, potatoes; "Cozido à portuguesa": savoy cabbage, carrots, potatoes, beef, chorizo, pig's feet, pig's ear, cow's foot, blood sausage; "Arroz de cabidela": rice, chicken, chicken blood, chorizo, garlic, onions; "Arroz à valenciana": rice, chicken, beef, chorizo, seafood, onions, saffron, peppers. "Coelho à caçador": rabbit, red wine, white wine, tomatoes, onions, potatoes. "Francesinha": bread, cheese, ham, sausage, beef, spicy tomato-based sauce with alcoholic beverages.

TABLE 3 Mean daily intake of nutrients and foods from the food frequency questionnaire (FFQ) and their association with food neophobia in crude and multivariate analyses

	Mean score (SD)	Crude $\hat{\beta}$ (95% CI)	Adjusted $\hat{\beta}^a$ (95% CI)
Energy (kcal/day)	2324.8 (548.3)	0.001 (−0.001;0.002)	0.001 (−0.002;0.002)
Protein (energy%)	19.5 (3.9)	−0.029 (−0.416;0.358)	−0.102 (−0.485;0.264)
Carbohydrates (energy%)	46.0 (6.8)	−0.214 (−0.005;0.432)	0.168 (−0.043;0.376)
Lipids (energy%)	34.5 (5.4)	−0.327 (−0.602; −0.051)	−0.216 (−0.479;0.054)
Fibre (g/day)	27.4 (15.1)	−0.007 (−0.107;0.092)	−0.061 (−0.163;0.032)
Sugar (g/day)	52.8 (15.6)	0.027 (−0.002;0.055)	0.017 (−0.011;0.043)
Sodium (g/day)	3.8 (1.5)	0.001 (−0.001;0.001)	0.001 (−0.001;0.001)
Alcoholic beverages (g/day)	79.4 (139.8)	−0.010 (−0.011;0.010)	−0.011 (−0.220;0.001)
Meat (g/day)	111.5 (60.3)	0.010 (−0.015;0.035)	0.007 (−0.017;0.032)
Milk (g/day)	184.5 (180.7)	**0.014 (0.006;0.022)**	**0.015 (0.007;0.023)**
Yogurts (g/day)	67.8 (71.0)	−0.007 (−0.028;0.014)	0.001 (−0.020;0.020)
Cereals and potatoes (g/day)	292.1 (175.5)	−0.002 (−0.006;0.001)	0.001 (−0.008;0.008)
Legumes (g/day)	76.3 (88.2)	0.008 (−0.009;0.025)	0.001 (−0.017;0.017)
White fish (g/day)	21.0 (19.6)	−0.007 (−0.84;0.069)	−0.027 (−0.103;0.048)
Oily fish (g/day)	19.1 (20.0)	0.003 (−0.072;0.078)	−0.035 (−0.108;0.038)
Codfish (g/day)	21.0 (21.7)	0.113 (0.046;0.181)	**0.099 (0.032;0.165)**
Seafood (g/day)	3.0 (4.9)	0.071 (−0.237;0.380)	0.102 (−0.198;0.402)
Vegetables (g/day)	231.5 (230.2)	−0.003 (−0.009;0.004)	**−0.007 (−0.013; −0.001)**
Fruits (g/day)	299.7 (247.3)	0.000 (−0.006;0.002)	−0.004 (−0.010;0.002)
Broccolis (g/day)	17.8 (23.3)	−0.059 (−0.123;0.005)	**−0.086 (−0.148; −0.024)**
Turnip greens (g/day)	15.1 (28.1)	−0.041 (−0.094;0.013)	**−0.062 (−0.113; −0.010)**
Tomatoes (g/day)	27.8 (35.0)	−0.029 (−0.072;0.014)	**−0.054 (−0.092; −0.008)**
Onions (g/day)	30.0 (34.2)	−0.031 (−0.075;0.012)	**−0.054 (−0.096; −0.012)**
Lettuce (g/day)	6.7 (8.2)	−0.138 (−0.320;0.045)	**−0.190 (−0.363; −0.016)**
Tree nuts (g/day)	13.0 (24.0)	−0.341 (−0.124;0.000)	**−0.239 (−0.728; −0.251)**
Cherries (g/day)	8.9 (22.6)	−0.047 (−0.113;0.019)	**−0.067 (−0.130; −0.004)**
Melon (g/day)	14.23 (30.2)	−0.037 (−0.086;0.013)	**−0.050 (−0.097; −0.003)**

Note: SD 95% CI = 95% Confidence interval. Significant associations are in bold type.
[a]Model adjusted for sex, age and educational level.

We used the HDI to measure overall dietary quality and to assess the influence of FN in a specific dietary pattern. The median of the HDI was five points (from a possible range of 0-10). FN was not significantly associated with the adherence to the HDI ($\beta' = -0.691$; 95% CI: −1.832; 0.499).

4 | DISCUSSION

This study suggests that FN is negatively associated with food preferences of certain foods as well as the general liking for the act of eating and seems to influence the consumption of specific food items. For almost half of the listed food items, we found a negative association of FN with the ratings of liking, including for fruit, vegetables, animal protein-foods and traditional dishes with blood. These conclusions are in concordance with previous results.[16,20,21,25] A study that evaluated the association of FN with food preferences in pre-school children found significant effects on preferences for all food groups, but especially for fruit, vegetables and meats. More neophobic children liked a narrower range of food and disliked more food items.[20] Similar results were observed in adults; individuals with high levels of FN presented a lower level of preferences for a large selection of foods[21] and liked less some types of foods, such as vegetables.[16]

These results suggest that FN, which is defined as the reluctance of unknown food products,[1] negatively affects the general liking of eating, but it is more evident for specific foods. Several traditional Portuguese dishes, such as "Arroz de Cabidela," are prepared with animal's blood, which is

more able to trigger disgust or aversion. These dishes are part of traditional food habits, but the perception of disgust contributes to the rejection. Furthermore, the familiarity of food might be not a cultural, but an individual experience; a food that is well-known in a specific culture is still unfamiliar for a person until he/she tastes it.[16]

Regarding the dietary habits, we did not find any significant association between FN and the intake of total energy and macronutrients, which is supported by some studies.[13,23] However, only a few studies, and most of them focused on children, analysed the effects of FN with these dietary components, and the conclusions have been inconsistent.[2,13,14,22-24] This heterogeneity of results may be due to different population subgroups of the studies. We also did not find any association with the intake of fibre, sodium and added sugars.

However, the FN level seems to affect the consumption of specific food items from various food groups. Most of the significant associations were negative, that is, greater FN precludes lower intake. Our findings parallel the results of other studies that associated FN with lower intake of fruits and vegetables.[14-16,18,19,37] In contrast, a positive association was observed between FN and the consumption of codfish. This fish is a much-liked traditional and typical food in Portugal (in the current study, the mean liking score was among the highest). This result supports the conclusion that product origin seems to be important to people with a higher level of FN.[16]

The selective preferences and consumption of more neophobic individuals may be linked with the concept of "picky eating." Picky eating is characterised by eating from a narrow range of accepted foods, firmness about the preparation and presentation of foods, strong food dislikes and preferences, and unwillingness to try new foods.[38] Picky eating could be viewed as an extreme manifestation of FN.[39] Increased levels of pickiness were associated with higher levels of neophobia.[14,39,40]

Furthermore, to discard the possibility of nil associations due to minimal effects of single foods or nutrients, we tested the effect of FN in a dietary pattern. This offers an advantage over examining of consumption of foods or nutrients alone, as it considers overall food intake, and allows for the identification of patterns rather than single foods or nutrients in isolation. No significant association was found between FN and dietary quality, which contrasts with previous literature,[12,13] but it is not possible to directly compare the results because these studies did not use a dietary pattern to estimate the dietary quality. The HDI is a very strong tool for assessing the quality of diet, but it does not consider dietary variety. This might be a concern because FN could affect the food variety. However, several different foods/nutrients are evaluated and only with a varied diet, it is possible to score high on all these items. Additionally, we cannot discard the possibility of a lack of power to detect such associations.

Some strengths and limitations should be considered. The relatively small sample size and the cross-sectional design may have hampered the detection of some of the associations. There are some trends in the results that might become significant associations in a larger sample. Nonetheless, we had power to find out some of them, and we have tested the association with a global dietary pattern. Moreover, the cross-sectional nature of the present study is not so questionable, because there is plausibility for the neophobia trait appearing before food preferences and intake takes place. One limitation to the generalisation of results from this study (external validity) is the non-probabilistic sampling method. Nevertheless, internal validity was assured as we have used measures that have been previously validated and used with Portuguese adult samples, such as the FNS[1] and the FFQ.[32] Additionally, the FFQ has the advantage of assessing the usual intake, minimising the effect of the day-to-day variation in food choices. An important limitation to point out is that the food preferences questionnaire was not previously validated. This questionnaire was developed because there is no available validated instrument to assess food preferences in Portuguese adults. Moreover, physical activity, weight and height were self-reported which may lead to potential over or underestimations. However, previous studies among young adults have showed a moderate to high agreement between weight and height self-reported and objectively measured.[41,42] Besides that, all these variables were only used for descriptive purposes, not affecting the direction and magnitude of the studied associations.

The findings of this study provide further understandings of the influence of FN on dietary habits of adults. Higher FN was associated with a lower general liking for the act of eating and lower preferences for fruit and vegetables, animal protein-foods, and some traditional dishes. We also found that the FN level decreases the consumption of specific foods, particularly some types of fruit and vegetables. However, FN has no impact on a healthy dietary pattern. Further studies associated with quality, quantity and variety of food products in term of FN are necessary.

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AUTHOR CONTRIBUIONS

All authors contributed to interpretation of results and preparation of the manuscript. A. O. and A. C. were responsible for the analysis of the data, with assistance from C. S. All authors critically revised the manuscript and read and approved the final version.

ORCID

Alexandra Costa https://orcid.org/0000-0002-3773-4302

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LETTER TO THE EDITOR

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What is the nutritional value of food and drinks sold in vending machines at an Australian university? A food environment audit study

To the Editor,

Universities internationally are being called to action to cultivate health promoting environments.[1] The majority of university students engage in unhealthy lifestyle behaviours, for example, 83% consume fewer than five fruit and vegetable serves per day,[2] while the average weight gain in the first year of university is 1.36 kg.[3] There is the potential to improve students' health risk factors by creating university environments that enable students to make health promoting decisions.[1,4] As a basis for health promotion strategies, studies are needed which first assess the state of the environment and may provide a means for monitoring and surveillance.[5-7] The focus of the study reported here was the university food environment. The aim was to determine the nutritional quality of items available in vending machines at an Australian university, to extend the evidence from previous audit studies in this setting.[8,9]

An audit of all vending machines at the three major campuses of the University of Newcastle (UON), New South Wales (NSW), Australia was conducted over two weeks in August to September 2019. The UON is a large urban university with approximately 38 000 students and 3000 permanent staff.[10] Included in this audit were the main Callaghan campus and two of the four additional campuses in NSW. The audit tool was developed for the study based on previous vending machine audits.[8,9] All vending machines were visually inspected, and for each slot in the machine, the name, weight or volume and price of the product were recorded. Any promotions on, inside or around machines were also recorded. The audit tool and procedure were pilot tested on a sample of seven vending machines before the full audit was undertaken. The nutritional quality of all food and beverage items was assessed according to the Australian Government's front-of-pack labelling Health Star Rating (HSR) system.[11] The HSR was selected to align with the NSW Healthy Food Provision Policy, and for comparability with the NSW Ministry of Health Healthy Food and Drink Framework.[12,13] This framework was used as no guideline currently exists in NSW or Australia for food provision specifically for the university setting. The HSR ranges from 0.5 stars (least healthy) to 5 stars (most healthy). The number of stars is calculated based on the nutritional composition of the food or beverage, considering the total energy as well as saturated fat, sodium, sugar, fibre, protein, fruit, vegetable, nut and legume content, and is relative to the food or beverage category. Items with a HSR $\geq$3.5 were classified as healthy and <3.5 as unhealthy, in accordance with the NSW Ministry of Health Healthy Food and Drink Framework.[12] The total number and proportion of healthy and unhealthy foods and beverages available for purchase, and their mean cost, were analysed and are reported as number and percentage or mean and SD. Chi-squared tests were used to compare the difference between the proportion of food and beverages available by the HSR, and a test of proportions was conducted to determine whether the proportion of healthy and unhealthy items available was significantly different to the NSW Healthy Food and Drink Framework (ie, recommend ratio of 75% healthy to 25% unhealthy items).[12] *t*-tests were used to compare the difference in mean cost between healthy and unhealthy food and beverages.

A total of 61 vending machines were recorded across the three campuses. Twenty-six machines contained beverages only (43%), 25 contained foods only (41%) and 10 contained food and beverages (16%). In total, 1973 of 2159 slots contained food or beverage items, with the remaining 186 slots either empty or containing non-food items. Of the 1010 slots containing beverages, 86% were unhealthy (HSR <3.5), and of the 963 slots containing foods, 95% were unhealthy (Table 1). Overall, 90% of the items available were unhealthy, which was significantly higher than the recommended <25% ($P < .001$). The largest proportion of items had a HSR of 0.5 stars (27%), followed by 2 stars (23%). Only 7% of items had a HSR of 5 stars. The proportion of food and beverages available in each HSR category was significantly different ($P < .001$), with the majority of foods rated 0.5 stars and the majority of beverages rated 1.0 stars. The mean cost of

TABLE 1 Proportion of food and beverage items available in vending machines (n = 61) at three campuses of the University of Newcastle, Australia, by Health Star Rating

	Slots (n = 1973)			
	Food (n = 963)		Beverage (n = 1010)	
Health Star Rating	%	n	%	n
Healthy				
5	0.1	1	12.8	129
4.5	0.2	2	0.8	8
4	1.2	12	0.0	0
3.5	3.5	34	0.4	4
Unhealthy				
3	2.6	25	0.0	0
2.5	6.7	65	0.0	0
2	24.7	238	21.3	215
1.5	15.8	152	19.8	200
1	6.5	63	28.5	288
0.5	38.5	371	16.4	166

Notes: The difference in the proportion of food and beverages by Health Star Rating was significantly different ($P < .001$).

unhealthy beverages was significantly higher than healthy beverages (AU$4.08 and AU$3.31, respectively, $P < .001$), while the mean cost of healthy foods was significantly higher than unhealthy foods (AU$3.70 and AU$3.17, respectively, $P < 0.001$). Of the 61 vending machines, 40 (66%) had promotions, all of which were branded vending machines. Of these, 88% and 12% promoted unhealthy and healthy items, respectively.

This audit identified that 90% of food and beverages available in vending machines at a large Australian university were unhealthy. This is consistent with audits conducted at other universities in Australia and the United Kingdom, where the proportion of unhealthy items ranged from 79% to 88%.[8,14] However, there is a major discrepancy when compared with the NSW Ministry of Health Healthy Food and Drink Framework, which recommends that food outlets offer a ratio of 75% healthy to 25% unhealthy items.[12] Further, approximately one-third of items audited were categorised as 0.5 stars, that is, the least healthy rating, while only 7% were classified as 5 stars. Therefore, major changes are needed in order to meet the Healthy Framework for this aspect of the food environment. Interventions aiming to improve the nutritional quality of items available in vending machines in the university setting have demonstrated some success.[15] Strategies to increase the availability and/or lower the cost of healthier items have resulted in increased sales of healthier items.[15] However, these have mainly included short-term intervention trials and on a small subset of vending machines.

This study provides additional evidence to advocate for strategies to improve the nutritional quality of food and beverages in vending machines in the university setting. The findings extend the work of Grech et al,[8] where the authors conducted an audit of a large metropolitan Australian university, by providing evidence from an urban university. To significantly impact the university food environment, there is a need for policy change at the university level that encompasses all aspects of food provision and availability.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

M.J.H., A.J.P. and M.C.W. conceptualised the study design. H.S.N. and C.Y.L completed data collection. H.S.N. and C.Y.L conducted the statistical analysis, with the assistance of M.C.W. and M.J.H. All authors contributed to the interpretation of results. M.C.W. drafted the initial manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication. This research was funded by a University of Newcastle School of Health Sciences Pilot Grant 2019. The authors received no external funding for this study. M.J.H is supported by a University of Newcastle Gladys M Brawn Career Development Fellowship (Teaching Assistance).

Megan C. Whatnall PhD, APD[1,2]
Huey Shyuan Ng BND Hons[1,2]
Chen Yee Liau BND Hons[1,2]
Amanda J. Patterson PhD, APD[1,2]
Melinda J. Hutchesson PhD, APD[1,2]

[1]*School of Health Sciences, Faculty of Health and Medicine, University of Newcastle, Callaghan, New South Wales, Australia*
[2]*Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Callaghan, New South Wales, Australia*

ORCID

Megan C. Whatnall https://orcid.org/0000-0003-4798-4505
Amanda J. Patterson https://orcid.org/0000-0002-1868-7918
Melinda J. Hutchesson https://orcid.org/0000-0002-1851-0661

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