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EDITORIAL

Disease-related malnutrition in the twenty-first century: From best evidence to best practice

> 'How will history judge the 21st century? If things go on as they are, the verdict will be dismay and condemnation, that wealthy societies and established social protection systems could allow the tragedy of malnutrition to occur in such a large segment of the population. This is just not tolerable……'
>
> El Read, former member of the European Parliament[1] (Sept 14, 2005)

Malnutrition is a syndrome that results from the intake of nutrients that do not conform to physiological requirements. Malnutrition indiscriminately affects individuals across various stages in life, right from infants and children to adolescents and older adults, and includes under- and over-nutrition. Whilst under-nutrition was once associated with developing countries and over-nutrition with developed countries, many parts of the world experience a dual burden.

Three landmark papers on malnutrition published in the twentieth century include:

- '*Human starvation and its consequences*' by Ancel Keys (1946), that demonstrated when deprived of adequate nutrition, healthy volunteers developed severe physiological and psychological disorders, which improved with the reintroduction of adequate feeding[2];
- '*The skeleton in the hospital closet*' by Charles Butterworth (1974), that was the first to highlight that, despite a noticeable prevalence, hospital-based medical teams failed to identify malnutrition in patients[3];
- '*What supports nutritional support*' by Ronald Koretz (1984), that highlighted the knowledge deficit in making evidence-based decisions regarding when acute care patients should be offered nutrition support.[4]

These works led to the inception of a huge body of clinical research into malnutrition. Depending on the method of assessment, malnutrition is prevalent in approximately 20–50% of adult acute care patients[5], 20–70% of nursing home residents[6] and 5–30% of community-dwelling adults.[7] Research has provided compelling evidence associating malnutrition with frequent readmissions to hospitals; prolonged length of hospital stay; increased risk of infections, falls and pressure ulcers; delayed convalescence; increased health-care costs; and mortality.[8,9] Nutrition screening and assessment tools have been developed and validated to identify and diagnose malnutrition across the continuum of care,[9] with research informing the development of nutrition support and care strategies to manage malnutrition.[9] Working parties and task forces from around the world have compiled, collated and summarised evidence into guidelines to inform best practice amongst clinical staff for the management of malnutrition, which have been endorsed by dietetic associations and societies.[9–13]

The basic premise of evidence-based practice guidelines is to improve and ensure best practice for patient care. Guidelines emerging from clinical research are usually accepted by practitioners at an academic level.[14] Therefore, it is logical that practice would align with evidence-based guidelines. On the contrary, substantive data reflect that practice diverges from evidence-based guidelines.[15–17] So, where lies the problem?

When evidence does not translate into best practice: the case of malnutrition screening and diagnosis

Nutrition screening, as defined by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), is the 'process to identify an individual who is malnourished or who is at risk for malnutrition to determine if a detailed nutrition assessment is indicated'.[18] Therefore, nutrition screening is an important 'trigger' to the nutrition care process, which begins with nutrition assessment and diagnosis of malnutrition.[19] Nutrition assessment is a systematic process of defining nutritional status using information, including medical and nutritional histories, anthropometric measurements, biochemical assays and a physical examination (to determine loss of subcutaneous fat and/or muscle mass), to make a malnutrition diagnosis.[9] Nutrition screening should be simple and quick to perform and can be completed by anyone, including health-care/non-technical staff members, friends/family members or patients themselves, whereas nutrition assessment is a comprehensive, in-depth process and must be completed by a trained dietitian/clinician.[9]

Nutrition screening also identifies patients who are obese but have protein-energy malnutrition and/or ongoing poor dietary intake and require nutritional intervention.[20] Nutrition screening tools perform well in predicting health-related outcomes in adult hospital patients.[21] In the absence of nutrition screening, more than half of the hospital patients at risk of malnutrition are not identified and are unlikely to receive appropriate and timely nutrition support.[22] Unless identified, malnutrition will go undiagnosed, undocumented and therefore untreated.[15] Within the last decade, large multicentre studies in different parts of the world have reported nutrition screening practices in acute care hospitals, indicating that the translation of nutrition

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screening into practice has been less than ideal.[15–17] The literature cites several barriers at the organisational, health-care personnel and patient level that prevent the integration of nutrition screening into routine practice (Figure 1). Although identifying and diagnosing malnutrition will not directly improve patient outcomes, resultant appropriate nutritional intervention is likely to commence, which is likely to have a positive influence on health-related outcomes.[9,17,27,28] Recent reports from multicentre studies reflect disparity in malnutrition diagnosis in medical charts and malnutrition prevalence. Potential reasons to explain this deficit are that there is a lack of understanding regarding malnutrition amongst health-care staff members; malnutrition is not routinely identified, diagnosed and/or documented in medical charts; and malnutrition is perceived as an outcome rather than a medical condition by health-care staff members.[29–32]

When evidence translates into best practice: the case of falls and pressure injury prevention programs

Pressure injuries and falls are a frequent occurrence in the acute care setting and are associated with prolonged hospital stay, reduced quality of life and increased health-care costs.[33,34] Two recent reviews assessed the multi-component strategies in falls and pressure ulcers prevention programs and found that multi-component initiatives have high-level evidence for reducing the risk of in-hospital falls by 30% and moderate-level evidence for reducing pressure injury rates and improving processes of care.[33,35] The reviews also highlighted that the key components for the successful implementation of the guidelines included leadership support, involvement and guidance by a multi-disciplinary committee, engaging front-line staff during intervention design, pilot testing the intervention, ongoing audits and staff education.[33,35]

Pressure injuries, falls and malnutrition have several similarities: (i) they are common whilst largely preventable in the hospital setting; (ii) they are associated with adverse health-related outcomes and increased cost of care; (iii) early screening and management demonstrates improved outcomes and cost savings; (iv) and they have evidence-based guidelines to inform management. One potential difference between the three is that evidence-based guidelines for prevention of falls and pressure injuries have better compliance within the hospital setting than do those for malnutrition management.

Translating evidence into practice

Evidence-based guidelines are 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'.[36] The benefits of using guidelines to inform practice include improved effectiveness and efficiency of health care, avoiding inappropriate variations in practice, improved patient outcomes and increased job satisfaction.[37] Four stages are involved in the evidence-to-practice process for clinicians: to be aware of, agree with, adopt and adhere to the evidence.[14] However, a steady decline or loss of information is observed at each stage of the process,[14] leading to a delay of up to 17 years for scientific evidence to translate into clinical practice.[38] Research indicates that up to 40% of patients do not receive evidence-based care, with as much

Organisational context:

- Not mandatory and/or supported by ward managers
- Staff shortage
- Responsibility not clearly defined

Professional context:

- Inadequate:
  - time due to competing priorities
  - resources (instruments such as weighing scales, height measures)
  - training and education regarding the use of tools
- Perception that tool is 'too difficult' or 'complicated' to use
- Confusion between screening and assessment
- Preference for other parameters to determine nutritional status:
  - Visual assessment of physical appearance
  - Clinical judgment
  - Biochemical markers (serum albumin)
- Accepting malnutrition as an inevitable outcome of old age and/or disease
- Prioritising medical treatment over nutritional support

Patient context:

- Accepting malnutrition as an inevitable outcome of old age and/or disease
- Prioritising medical treatment over nutritional support

Figure 1 Expressed barriers to nutrition screening.[16,23–26]

as 25% of the care provided being unnecessary or potentially harmful.[39,40]

Organisational culture, or 'how things are done here', is defined by leadership support, communication, teamwork and conflict resolution.[41] Existing malnutrition management guidelines focus on practice recommendations for individual health-care providers and do not take into consideration the organisational culture where individual health-care providers work. The successful implementation of evidence-based guidelines for pressure injury and falls prevention were attributable to a positive and supportive organisational culture[33,35] and could explain the disparity in their uptake *versus* malnutrition management guidelines.

The responsibility of malnutrition management across the continuum of care should move beyond the role of dietitians and be integrated into team effort. A more supportive leadership is required at an inter-professional level in addition to increased delivery of integrated care (through the development and implementation of nutrition care protocols) and improved quality management through continuous quality improvement initiatives.[41] In countries such as the United Kingdom, the Netherlands and United States, it is mandatory for hospitals to screen patients for malnutrition risk at the time of hospital admission and participate in audits to determine compliance with nutrition screening recommendations for satisfactory hospital accreditation.[22] In Australia, only those hospitals that use the Australian Council of Healthcare Standards (ACHS) for accreditation must have a nutrition policy that includes malnutrition risk screening on admission and at regular intervals during hospital stay.[42]

Conclusion

Disease-related malnutrition will continue to adversely affect our patients—the most important benefactors of the health-care system. The twentieth century made remarkable strides in providing a framework for an evidence-based approach to manage malnutrition. In the twenty-first century, we must imbibe lessons from guidelines that have successfully translated into practice, receive the required leadership support and acknowledge and use the accumulated experience of inter-professional team members to vigorously translate evidence-based guidelines for malnutrition management into practice. If not now, then when?

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Ekta Agarwal, PhD, APD, RD
Assistant Professor, [1]Master of Nutrition and Dietetic Practice Program, Bond University, Gold Coast and [2]Honorary Research Fellow, Department of Nutrition and Dietetics, The Princess Alexandra Hospital, Brisbane, Queensland, Australia

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ORIGINAL RESEARCH

Feasibility of home-based dietetic intervention to improve the nutritional status of older adults post-hospital discharge

Aliza Haslinda HAMIRUDIN,[1,2] Karen WALTON,[1,2] Karen CHARLTON,[1,2] Amanda CARRIE,[3] Linda TAPSELL,[1,2] Marianna MILOSAVLJEVIC,[2,3] Glen PANG[4] and Jan POTTER[2,3]

[1]School of Medicine, Faculty of Science, Medicine and Health University of Wollongong, [2]Illawarra Health and Medical Research Institute, Wollongong and [3]Illawarra Shoalhaven Local Health District, New South Wales Health, Wollongong and [4]Agency for Clinical Innovation, New South Wales Health, Sydney, New South Wales, Australia

Abstract

Aim: To determine if a model of home-based dietetic care improves dietary intake and weight status in a specific group of older adults post-hospitalisation.

Methods: The Department of Veterans' Affairs clients aged 65 years and over were recruited from hospitals in a regional area of New South Wales, Australia (n = 32 men, n = 36 women). Nutritional status was assessed at home at baseline (within two weeks post-discharge) and three months post-discharge using a diet history, a food frequency checklist and Mini Nutritional Assessment (MNA). Personalised dietary advice was provided by a single dietitian according to participants' nutritional status.

Results: Mean body weight improved significantly ($P = 0.048$), as well as mean MNA score (21.9 ± 3.5 *vs* 25.2 ± 3.1) ($P < 0.001$). Mean energy, protein and micronutrient intakes were adequate at baseline and three months, except for vitamin D. At three months, the underweight group (body mass index (BMI) < 23 kg/m^2) had significantly higher mean protein intake per body weight (1.7 ± 0.4 g/kg) compared to those who were a desirable weight (BMI 23–27 kg/m^2) (1.4 ± 0.3 g/kg) or overweight (BMI>27 kg/m^2) (1.1 ± 0.3 g/kg) peers ($P < 0.001$). There was significant improvement in energy intake contributed from oral nutrition supplements ($+95.5 \pm 388.2$ kJ/day) and milk ($+259.6 \pm 659.8$ kJ/day).

Conclusions: Dietetic intervention improved nutritional status 3 months after hospital discharge in older adults living in the community.

Key words: malnutrition, nutrition assessment, nutrition intervention, nutritional status, older adult.

Introduction

Malnutrition is common in hospitalised patients around the world, especially among older adults. It is estimated that in the Australian hospital setting, approximately 85% of patients aged 65 years and older who are admitted to acute or rehabilitation hospitals are either malnourished or are at risk of malnutrition,[1,2] according to the Mini Nutritional Assessment criteria.[3] Globally, the prevalence in these settings is reported to be 86%.[4]

Deterioration of nutritional status during hospital admission has been demonstrated in older adults, regardless of their nutritional status upon admission.[5] The majority of malnourished patients are discharged home, and they experience a greater mortality rate over 12–18 months, as compared to their well-nourished counterparts, even taking into account underlying illness and age.[1,6] Over the longer term, mortality rates at 10 years of follow-up have been reported to be twofold higher in older women identified to be 'at risk of malnutrition' compared to those that were well-nourished.[7] A compromised nutritional status, without adequate support at home is associated with a downward spiral in health that often results in an increased risk of readmission to hospital[8] and a longer length of hospital stay,[1] resulting in overall higher health care costs.[9] Estimates from the UK indicate that malnutrition-related costs are £19.6 billion each year.[10] Malnourished patients make up approximately

A.H. Hamirudin, MSc (Nutr), PhD candidate
K. Walton, PhD, AdvAPD, Associate Professor
K. Charlton, PhD, AdvAPD, RPHNutr Associate Professor
A. Carrie, MSc (Nutr Diet), APD, Dietitian
L. Tapsell, PhD, FDAA, Senior Professor
M. Milosavljevic, DBA, APD, Manager of Research
G. Pang, MNutrDiet, APD, Aged Health Network Manager
J. Potter, MBBS, MRCP, CCST, FRCP, FRACP, Clinical Professor, University of Wollongong; Illawarra Shoalhaven Local Health District Medical Director of Aged Care, Rehabilitation and Palliative Care
Correspondence: K. Walton, School of Medicine, Faculty of Science, Medicine and Health, University of Wollongong, Wollongong, NSW 2522, Australia. Tel.: +61 2 4221 5197, Fax: +61 2 4221 3151., Email: kwalton@uow.edu.au

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30% of hospital admissions and 35% of aged care admissions, followed by 15% of outpatient clinic presentations and 10% of general practitioner visits.[10]

For optimal outcomes, nutrition intervention strategies in high-risk groups should be seamless between hospital and home.[11] There is a growing body of evidence that home-based dietetic intervention is effective in improving dietary intake, nutritional status and quality of life.[12,13] However, in practice, such patients often fall between the cracks during their period of convalescence, a time that may be critical to the prevention of further nutritional decline. Models of care that facilitate smooth transition from hospital to home or residential aged care through improved communication between health service providers, community-based services and family are required. Even in older adults who have access to regular services such as home nursing, malnutrition remains a significant issue.[14] This may be the case, for example, with clients of the Department of Veterans' Affairs (DVA).

In Australia, DVA clients have different access to services than other groups of older adults.[15] A DVA health card provides unique and specific access to various health-care services for DVA clients,[16] whilst the remaining older adults in the community have access to health services through Medicare or private health insurance.[17] Similarly, DVA in Canada and the United States also provide exclusive services for veterans through specific schemes.[18–20] Despite having better access to care, it remains to be seen whether additional benefits would be obtained from a home-based dietetic intervention.

This study aimed to determine if a model of home-based dietetic care improves nutritional status and weight in a sample of DVA clients over a three-month period following hospital discharge. A secondary aim was to identify how changes in food choices over time influenced nutrient intake. Further insights into dietary practices and the influence of additional types of nutrition support were simultaneously evaluated.

Methods

This study was conducted within a regional area of New South Wales, Australia. Eligible participants were those that were clients of the DVA, aged 65 years and older, living in a community, non-institutionalised and had been admitted to hospitals within the Illawarra Shoalhaven Local Health District between December 2010 and December 2011. Exclusion criteria included being discharged to high-level nursing home care, being enterally fed or being terminally ill. Patients' nutritional status was routinely assessed in the ward using the 18-item Mini Nutritional Assessment (MNA). The MNA has been specifically developed to identify older adults' nutritional risk status and is a validated tool for this age group.[21] Nutritional status was categorised according to three cut-offs for total score, <17: malnourished; 17–23.5: 'at risk of malnutrition'; and 24–30: well-nourished. Prospective participants were provided with a copy of a participant information sheet and consent form by ward dietitians and given time to make an informed decision regarding participation.

Nutrition assessment and intervention for this study started post-hospital discharge. Consenting participants were visited at home by a single dietitian within two weeks of discharge from hospital. A diet history was performed and a food frequency checklist completed. Nutritional status was assessed using the MNA. This was repeated at three months post-discharge by the same dietitian to minimise risk of inter-observer bias, unless participants had been readmitted to hospital, withdrew or were deceased. The key nutrition intervention approach used to enhance patients' nutritional status in this model of care was personalised dietetic advice from the dietitian. Other strategies included individualised prescription of oral nutrition supplements (ONS) and/or referral to a Meals on Wheels (MOW) service. Patients were referred to various community services if appropriate, as per usual practice.

A body mass index (BMI) below 23 kg/m^2 indicates higher risk of mortality in older adults.[22] In this study, underweight was defined as BMI < 23 kg/m^2; desirable weight status was considered to be a BMI of 23–27 kg/m^2; whilst overweight was categorised as BMI > 27 kg/m^2.

Dietary intake data were analysed for nutrient assessment using the computerised dietary assessment package FoodWorks 2009 (Xyris Software, version 6.0) using the AUSNUT 2007 database. Adequacy of dietary intakes was assessed against the age- and gender-appropriate estimated average requirement (EAR) or adequate intake, where appropriate.[23] The contribution of MOW towards patients' dietary intake was also evaluated. Protein foods were categorised based on AUSNUT 2007 codes.

Differences in weight, BMI, dietary intake of macronutrients and micronutrients, risk of malnutrition, protein food group and Meals on Wheels (MOW) contributions were compared using paired t-tests for normally distributed data and the Wilcoxon signed-rank tests for non-parametric data. A two-way analysis of variance (ANOVA) was used to examine the impact of BMI and gender on daily protein intake, expressed per kilogram of body weight (g/kg). Missing information and data of participants who did not complete follow-up at three months were excluded from analysis. Significant differences were defined as $P < 0.05$. Analyses were performed using IBM SPSS statistics software version 19 (SPSS Inc., Chicago, IL, USA).

Ethics approval was granted by the University of Wollongong/South Eastern Illawarra Area Health Service Human Research Ethics Committee (HE10/413).

Results

A convenience sample of 79 participants was recruited, of whom 68 (86.1%) were available at three months, with seven having withdrawn from the study and four deceased. According to the MNA classification, those who did not complete the three-month assessment were either 'at risk' (n = 8) or 'malnourished' (n = 3) at baseline.

The mean age was 85.5 ± 5.8 years, with men being significantly older than women (87.1 (6.3) *vs* 84.0 (5.1) years) ($P = 0.028$). Mean body weight increased from 67.1 ± 13.5 kg to 68.0 ± 13.7 kg ($P = 0.048$), while mean MNA scores improved significantly from being in the 'at risk of malnutrition' category (21.9 ± 3.5) to the 'well-nourished' category (25.2 ± 3.1) ($P < 0.001$) (Table 1). The total percentage of participants who were identified as 'at risk' and malnourished was 61.8% at baseline and reduced to 23.5% at the three-month follow-up. No significant change was detected for BMI at three months. When analysed by gender, MNA scores showed significant improvements for both genders ($P < 0.001$), but changes in weight and BMI were no longer significant.

At three months, a significant difference was identified for mean MNA scores (SD) among the underweight (23.7 ± 3.7), desirable weight (26.5 ± 2.1) and the overweight group (25.8 ± 2.6) ($P = 0.004$). All BMI groups had a mean MNA score in the well-nourished category (score ≥ 24), except for the underweight group.

No significant changes were detected in intake of energy and macronutrient distribution after three months (Table 2). Mean energy, protein and micronutrient intakes were adequate at both time points, with no change over time, except for vitamin D, which remained below the EAR despite a significant increase at three months (Table 2). At baseline, energy intake was below EAR among 18.8% (n = 6) men and 30.6% (n = 11) women participants, while none of the participants had protein intakes (in g/day) lower than EAR. Vitamin D intake was below the EAR for all participants at baseline except for two female participants. Improvement in vitamin D intake was related to vitamin D supplementation rather than dietary sources.

Table 1 Anthropometric data and MNA score of study participants

	Baseline		*3 months*		
	Mean	*SD*	*Mean*	*SD*	P *value*
All participants (n = 68)					
Weight (kg)[a]	67.1	13.5	68.0	13.7	0.048*[12(c)]
BMI (kg/m^2)[a]	24.3	4.2	24.7	4.5	0.088[12(c)]
MNA score	21.9	3.5	25.2	3.1	0.000*[12(c)]
Men (n = 32)					
Weight (kg)	71.8	14.0	72.7	13.9	0.167[13(d)]
BMI (kg/m^2)	24.0	4.3	24.3	4.3	0.281[13(d)]
MNA score	21.5	3.3	25.5	3.0	0.000*[12(c)]
Women (n = 36)					
Weight (kg)[b]	62.7	11.6	63.8	12.3	0.074[12(c)]
BMI (kg/m^2)[b]	24.6	4.2	25.1	4.6	0.065[12(c)]
MNA score[b]	22.3	3.6	25.0	3.3	0.000*[12(c)]

BMI, body mass index; MNA, Mini Nutritional Assessment.
[a]n = 67 because of unavailable data on weight.
[b]n = 35 because of unavailable data on weight.
[c]Paired t-test.
[d]Wilcoxon signed rank test.
*$P < 0.05$.

At three months, a two-way ANOVA showed that those who were in the underweight group (BMI < 23 kg/m^2) (n = 26, 38.8%) had significantly higher mean protein intake per body weight (g/kg) (1.7 ± 0.4 g/kg) compared to desirable weight (n = 25, 37.3%) (BMI 23–27 kg/m^2) (1.4 ± 0.3 g/kg) and overweight participants (n = 16, 23.9%) (BMI > 27 kg/m^2) (1.1 ± 0.3 g/kg) ($P < 0.001$).

There was significant improvement in energy intake contributed from ONS (+95.5 ± 388.2 kJ/day) and milk (+259.6 ± 659.8 kJ/day) (Table 3), but there were no changes in other protein sources. The preferred food sources of protein were fish, beef and milk. A total of seven participants (10.3%) were receiving MOW at both time points, with five participants using an MOW service at both occasions, while two participants had discontinued at three months; another two participants were new MOW clients at three months, and the use of ONS increased from 11.8% (n = 8) at baseline to 14.7% (n = 10).

Discussion

An in-home, post-discharge nutrition intervention that included dietetic home visits resulted in improvements in the nutritional status of older DVA clients after three months, although these patients already have unique access to a range of clinical and social services. The model of home-based dietetic care was based on a previous hospital-to-home six-month programme that was conducted in the same health district.[24] The Comprehensive Ongoing Management of Malnutrition using Individualised Therapy (COMMIT) Program demonstrated that extended community care can reduce the length of future hospital stays and improve patient satisfaction.[24] Our findings are consistent with those from a Danish study that provided a similar intervention[13] and another study that provided dietetic home visits with tailored individual dietary advice over a period of six months after hospital discharge.[25] The latter study highlighted the effectiveness of dietetic home visits compared to usual care that included inpatient dietetic intervention before discharge. Nutritional intervention should be a primary goal for the management of malnutrition.[26] Early attention to improving dietary intake when patients go home to convalesce may prevent further decline in their already compromised nutritional status.[27]

A high-protein, high-energy diet is fundamental to improve the nutritional status of malnourished older adults post-hospitalisation. Surprisingly, although 61.8% of participants were classified as malnourished or at risk after hospital discharge, mean dietary energy intakes in this study exceeded the age-appropriate recommended intakes of approximately 7400 and 8300 kJ/day for women and men, respectively, based on a physical activity level of 1.6.[23] Energy intakes above the EAR have also been reported in the Australian Longitudinal Study of Ageing, which included 1000 community-dwelling adults aged 70 years and older.[28] That study also demonstrated that dietary intakes by Australian older adults met most macronutrients and micronutrients requirements,[28] which is consistent

Table 2 Mean energy, macro- and micronutrients intake of participants

	All participants (n = 68)			*Men (n = 32)*				*Women (n = 36)*			
Nutrients	*Baseline*	*3 months*	P *value*	*Baseline*	*3 months*	*EAR (>70)*	P *value*	*Baseline*	*3 months*	*EAR (>70)*	P *value*
Energy (kJ)	9366 ± 2069	9627 ± 2389	0.358[b]	10222.8 ± 1896.0	10588.4 ± 2265.0	8300	0.837[c]	8605.2 ± 1935.5	8773.0 ± 2188.7	7400	0.665[b]
Protein (g)	95.2 ± 22.4	97.1 ± 23.7	0.472[b]	103.9 ± 20.7	108.0 ± 22.0	65	0.317[b]	87.5 ± 21.2	87.3 ± 20.9	46	0.943[b]
Protein (g/kg body wt)[a]	1.5 ± 0.4	1.5 ± 0.4	0.991[b]	1.5 ± 0.4	1.5 ± 0.4	0.86 g/kg	0.531[b]	1.4 ± 0.5	1.4 ± 0.4	0.75 g/kg	0.948[c]
Protein (% E)	17.5 ± 2.8	17.4 ± 2.8	0.822[b]	17.5 ± 2.7	17.6 ± 2.8	—	0.818[b]	17.4 ± 2.9	17.1 ± 2.8	—	0.526[b]
Carbohydrate (% E)	47.2 ± 6.2	46.6 ± 6.8	0.567[b]	46.6 ± 7.2	46.0 ± 4.7	—	0.616[b]	47.7 ± 5.3	47.2 ± 8.3	—	0.738[b]
Total fat (% E)	32.6 ± 5.2	33.7 ± 6.1	0.130[b]	32.2 ± 5.6	33.2 ± 4.9	—	0.275[b]	32.9 ± 4.9	34.1 ± 7.0	—	0.287[b]
Alcohol (% E)	1.2 ± 3.3	0.9 ± 1.6	0.422[b]	2.1 ± 4.4	1.6 ± 2.1	—	0.765[c]	0.4 ± 1.5	0.3 ± 0.7	—	0.889[c]
Water (g)	2560.8 ± 658.2	2530.1 ± 635.9	0.693[b]	2664.6 ± 798.5	2729.1 ± 746.0	3.4 L (AI)	0.576[b]	2468.4 ± 495.9	2353.3 ± 461.4	2.8 L (AI)	0.280[b]
Dietary-fibre (g)	31.0 ± 11.2	29.3 ± 9.2	0.197[b]	33.8 ± 12.2	32.2 ± 9.5	30 (AI)	0.513[b]	28.6 ± 9.7	26.7 ± 8.2	25 (AI)	0.178[b]
Thiamine (mg)	1.9 ± 0.9	1.8 ± 0.9	0.253[c]	2.0 ± 1.0	2.0 ± 1.1	1.0	0.667[c]	1.9 ± 0.9	1.7 ± 0.7	0.9	0.246[b]
Riboflavin (mg)	3.0 ± 1.1	3.1 ± 1.4	0.845[c]	3.1 ± 1.1	3.3 ± 1.7	1.3	0.852[c]	2.9 ± 1.1	2.8 ± 1.1	1.1	0.807[b]
Vitamin C (mg)	145.8 ± 98.2	161.1 ± 163.3	0.525[c]	147.8 ± 81.1	172.9 ± 172.8	30	0.985[c]	144.0 ± 112.5	150.7 ± 156.1	30	0.354[c]
Vitamin D (ug)	6.4 ± 10.5	11.8 ± 23.8	0.001*[c]	5.0 ± 1.7	13.2 ± 28.9	15 (AI)	0.004[c]*	7.6 ± 14.3	10.5 ± 18.5	15 (AI)	0.071[c]
Folate (ug)	582.8 ± 289.9	570.0 ± 292.8	0.153[c]	567.4 ± 254.6	612.6 ± 337.4	320	0.881[c]	596.4 ± 321.0	532.0 ± 245.3	320	0.076[c]
Magnesium (mg)	403.0 ± 122.4	395.5 ± 104.9	0.638[b]	437.1 ± 143.1	413.5 ± 99.9	350	0.525[c]	372.7 ± 92.5	379.5 ± 107.9	265	0.700[b]
Calcium (mg)	1174.0 ± 385.4	1246.8 ± 473.4	0.169[b]	1203.2 ± 346.4	1290.8 ± 442.3	1100	0.260[b]	1148.0 ± 420.2	1207.7 ± 502.4	1100	0.418[b]
Iron (mg)	13.9 ± 4.8	13.9 ± 4.5	0.755[c]	15.4 ± 5.6	15.4 ± 4.9	6.0	0.943[b]	12.6 ± 3.6	12.5 ± 3.8	5.0	0.960[b]

AI, adequate intake; EAR, estimated average requirement.
[a]n = 67 because of unavailable data on weight.
[b]Paired t-test.
[c]Wilcoxon signed-rank test.
*$P < 0.05$.

Table 3 Main dietary sources contributing to total dietary protein intake, according to food groups and MOW contributions

	Energy (kJ/day)			*Protein*				
				Baseline		*3 months*		
Food sources	*Baseline*	*3 months*	P *value*	*gram per day (% total protein per day)*	*Protein exchange*	*gram per day (% total protein per day)*	*Protein exchange*	P *value*
Oral nutrition supplement[a]	57.3 ± 374.5	152.8 ± 564.8	0.042[b]*	6.2 ± 10.7 (5%)	—	16.9 ± 7.7 (23%)	—	0.02[b]*
Egg	186.6 ± 279.0	219.2 ± 286.3	0.658[b]	3.9 ± 6.4 (4.1%)	0.6	4.5 ± 6.6 (4.6%)	0.6	0.629[b]
Fish	295.2 ± 450.5	320.9 ± 434.6	0.361[b]	10.0 ± 12.2 (10.5%)	1.4	10.9 ± 12.0 (11.2%)	1.6	0.516[b]
Beef	230.7 ± 188.6	194.2 ± 138.2	0.115[b]	8.8 ± 6.9 (9.2%)	1.3	7.3 ± 5.0 (7.5%)	1.1	0.109[b]
Lamb	194.2 ± 123.7	173.3 ± 129.9	0.279[b]	5.4 ± 3.2 (5.7%)	0.8	4.7 ± 3.6 (4.8%)	0.7	0.422[b]
Pork	169.6 ± 113.4	136.8 ± 88.0	0.508[b]	5.7 ± 3.5 (6.0%)	0.8	5.1 ± 2.8 (5.3%)	0.7	0.575[b]
Milk	818.5 ± 490.2	1078.1 ± 715.2	0.004[b]*	12.8 ± 7.9 (13.4%)	1.6	14.8 ± 9.2 (15.2%)	1.9	0.024[b]*
MOW	1187.4 ± 596.8	1166.7 ± 523.3	0.924[c]	18.6 ± 6.1 (19.5%)	2.7	18.8 ± 7.7 (19.4%)	2.7	0.978[c]

1 exchange for egg, fish, beef, lamb, pork and MOW = 7 g protein, 1 exchange for milk = 8 g protein
[a]Oral nutrition supplement brands: Ensure®, Sustagen®
[b]Wilcoxon signed-rank test.
[c]Paired t-test.
*$P < 0.05$.

with our findings, except for vitamin D. Inadequate vitamin D intake in older adults has also been reported by others.[29,30] Vitamin D supplementation is considered an intervention strategy to improve older adults' vitamin D intake as lower intake contributes to loss of muscle mass and an increased risk of falls.[31]

Adequate protein intake in older adults is particularly important during the recovery process after episodes of illness in order to prevent further loss of muscle mass and to improve functionality.[32] Dietary protein intakes were more than adequate in our sample; however, participants who were underweight at follow-up had improved intakes of protein per kilogram body weight. This demonstrates that our nutritional intervention strategy achieved appropriate protein intake in those most in need. The recommended level for protein intake of 0.8 g/kg/day, regardless of age, has been questioned.[21,33] Recent consensus guidelines on protein intake in old age recommended by the PROT-AGE study group indicate an average daily intake in the range of at least 1.0–1.2 g protein/kg/day for maintenance and/or regain lean body mass, and 2.0 g/kg/day for overtly malnourished older adults.[34] For those with chronic illness, the recommended protein intake is up to 1.5 g/kg/day or equivalent to 15–20% of total energy intake (% E).[33,34] A study of older women has demonstrated that a protein intake of between 1.2 and 1.76 g/kg/day resulted in less health issues than in women with intakes of <0.8 g/kg/day.[35]

Healthy body weight through desirable BMI status is an indicator for positive health outcomes of adults. This was confirmed in a recent meta-analysis that demonstrated an increased mortality risk in older adults with a BMI < 23 kg/m^2, but not in the overweight group.[22] However, the use of BMI in older adults as the only indicator of nutrition risk should be used with caution as overweight older adults were also at risk of malnutrition according to MNA classification, as reported by others.[36] Preventing weight loss through the provision of additional energy and protein using ONS is an effective strategy in older adults who have difficulties in achieving adequate food intake.[37] Our study participants had an increased intake of high-protein beverages as demonstrated by significant changes in the intake of milk and ONS. This may reflect the convenience of using these ready-to-consume beverages, rather than having to prepare meals themselves. A USA study identified that 81% of older adults have difficulties in meal preparation post-hospital discharge and that 40% of this group experienced a poor or fair appetite.[38] According to recorded baseline diet histories, participants in our study had already started consuming ONS prior to the first home visit by the dietitian. A meta-analysis has shown that oral nutrition supplementation helps malnourished older adults gain weight in hospital and institutional care, but not in the community setting.[39] However, the impact of its continued use between hospital and home in the early discharge period is unclear in the meta-analysis. A home-based trial that prescribed a daily intake of 500 kcal/day of high-energy and high-protein ONS for two months post-hospitalisation identified weight increment and

improved MNA scores among the at risk group,[40] whilst another home-based study also reported significant weight gain post-intervention.[13]

Another strategy to enhance dietary intake is referral to the MOW home meal delivery service. MOW services have been shown to be effective in improving older adults' nutritional status, and offering a good alternative for older adults who have limited ability to cook and prepare meals.[41] Charlton *et al.*[42] reported increased energy and protein intakes as well as an improved MNA score with MOW clients after four weeks of receiving nutrient-dense snacks provided through the existing service. In the present study, meals provided by the MOW service made a significant contribution (approximately 20%) to total dietary protein intake among clients. The focus on DVA clients to a certain extent provides a case study of a defined group but also limits the generalisability of the findings because of the non-representative nature of the group. DVA clients enjoy extensive governmental support with access to various medical and allied health services as well as other exclusive support services.[15] Similarly, in the United States, extensive support for veterans is available through Home Based Primary Care (HBPC), a preventive scheme to support DVA clients to live independently at home whilst reducing their risk of hospital admission.[18]

Other study limitations include the small sample size and a relatively short period of low-intensity intervention. The lack of a control group and the non-randomised nature of the intervention are considered major limitations. While the pre–post study design limits scientific quality, we consider it to be unethical to have a control group of at risk or malnourished people who did not receive active interventions. All participants received tailored interventions to meet their needs, but the study is considered largely descriptive and exploratory, although it is feasible for this age group. We have demonstrated that this model of care is potentially beneficial to older patients who are discharged home from hospital, but further evaluation is required to evaluate patient acceptability of the home-based intervention.

Costing of the ambulatory model of care piloted in the current study was not undertaken; however, on average, discharged patients received 4 hours of dietetic care. Nevertheless, in addition to the usual range of services that can be accessed, the provision of home-based individualised dietetic care resulted in an improved nutritional status after three months. This suggests that non-DVA clients may get greater benefits from this kind of service, but further investigation is warranted. Previous findings from the same region highlighted the fact that most older inpatients who were identified as malnourished or at risk of malnutrition are discharged home.[43] This makes a strong case for the need for nutrition intervention in the community.[43] A strength of the study is that all measurements and individualised dietary interventions were performed by a single dietitian, thereby limiting inter-observer bias. Further qualitative evaluations are also needed to identify factors that influence older adults' food choices and eating behaviours in the period post-hospital discharge.

An individualised home-based dietetic service improved the MNA score and body weight of a group of older people discharged from hospital, with evidence of adequate energy and nutrient intake, except for vitamin D. This model of care warrants further demonstration of its effectiveness.

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Conflict of interest

The authors declare that they have no conflicts of interest.

Authorship

AHH drafted and revised the manuscript, designed, analysed and interpreted the data. AC collected the data and critically reviewed the manuscript, KC, KW, LT, MM, GP and JP conceptualised and designed the study; and critically reviewed the manuscript. All authors approved the final version of manuscript submitted for publication.

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ORIGINAL RESEARCH

Does eating environment have an impact on the protein and energy intake in the hospitalised elderly?

Karon MARKOVSKI, Aranka NENOV, Aurora OTTAWAY and Elizabeth SKINNER
Western Health Hospital, Melbourne, Victoria, Australia

Abstract
Aim: This pilot study aimed to examine the difference in energy and protein intake of the midday meal in two different eating environments—the communal dining room and patient bedside—and to obtain feedback on patient preference at each location.
Methods: Elderly patients in two rehabilitation wards were observed consuming the midday meal on two consecutive days: day 1 in the dining room and day 2 at the bedside. The patients' intake was recorded by a visual 5-point assessment scale and analysed for protein and energy content using the hospital food services nutrient analysis of the menu. Patients were also surveyed on preference of eating environment through a written survey.
Results: This study found that patients consumed 20% more energy and protein when dining in a communal environment ($P = 0.006$ and 0.01, respectively). Patients with a body mass index of less than 22 ($P = 0.01$ and 0.01, respectively) and those with significant cognitive impairment ($P = 0.001$ and 0.007, respectively) ate 30% more protein and energy in the dining room, and those identified at risk of malnutrition (Malnutrition Screening Tool (MST) ≥ 2) ate 42% more energy and 27% more protein in the dining room, although this was not statistically significant ($P = 0.05$ and 0.16). A total of 86% of surveyed patients favoured eating their midday meal in the dining room.
Conclusions: This study supports the contention that a dining room environment can increase food intake, increase patients' opportunities to enjoy the social aspect of meal times, and potentially lead to weight gain and reduced malnutrition risk in the rehabilitation setting.

Key words: communal dining, malnutrition, mealtime environment.

Introduction

Hospitalised elderly are known to be at high risk of malnutrition and its associated negative health outcomes such as increased morbidity and mortality, reduced functional capacity, greater lengths of stay, and increased costs to the hospital.[1] The Australian Commission on Safety and Quality in Health Care (ACSQHC) have introduced criteria 1.5.7, which requires that the organisation ensures the nutritional needs of consumers are met. Recent Australian studies have indicated that the prevalence of malnutrition is likely to be up to 50% in the rehabilitation setting.[1] Various nutritional models of care have been implemented in an effort to address inpatient malnutrition. These include protected mealtimes,[2] feeding assistance,[2] and the 'red tray' initiative,[2] where patients at risk of malnutrition are provided meals on red trays which act as a visual indicator to staff that these patients require additional support and assistance to complete their meals.[2] Communal dining is also recognised as a nutritional model of care, and studies have demonstrated that an improvement in eating environment by changing the surrounds and facilitating a social dining experience may positively impact the amount of food consumed.[2–7]

The Western Health Care Service has implemented an inpatient malnutrition strategy that incorporates a combination of nutrition screening, assessment, and treatment of those at high risk of malnutrition. It also includes complimentary nutrition models of care, such as communal dining in geriatric rehabilitation wards and a staggered roll-out of volunteer meal assistance, to facilitate increased oral intake of patients with or at risk of malnutrition across the service.

Specifically in 2010, Western Health introduced the 'Dining With Friends' programme, a supportive communal dining environment in the aged care, subacute setting as part of a broader initiative focusing on patient-centred care (Best Care for Older People Everywhere, BCOP).[8] The 'Dining with Friends' programme commenced in a subacute ward at Williamstown Hospital three days/week and was later initiated in 2011 in a subacute ward at the Footscray Hospital.

Although some literature has demonstrated the influence of the eating environment on energy intake in the

A. Nenov, PGDip. Dietetics APD, Senior Dietitian
K. Markovski, PGDip Dietetics APD, Dietitian
A. Ottaway, MSc Dietetics, APD, Dietitian
E. Skinner, PhD, APAM, Physiotherapist
Correspondence: A. Ottaway, Western Health Hospital, Gordon Street, Footscray, VIC 3011, Australia. Tel.: +03 8345 6670, Email: aurora.ottaway@wh.org.au

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hospitalised elderly,[2–7] no studies have successfully demonstrated an increased oral intake of both energy and protein in the dining room compared to the bedside.

Therefore, the aims of this pilot study were to investigate the effect of the 'Dining with Friends' programme on energy and protein intake in hospitalised elderly patients, identify whether patient groups at risk of malnutrition could benefit from a communal dining environment, and identify patients' preferred environment for meal consumption.

Methods

This study was conducted and reported according to the STROBE checklist.[9] The study was a prospective observational pilot study conducted in the subacute setting across two sites of Western Health Care Service (Footscray and Williamstown campuses). Data pertaining to food intake and patient satisfaction with the dining environment were collected with verbal consent over a three-month period (July–October 2012) on the consumption of the midday meal over two consecutive days, day 1 in the dining room, and day 2 at the bedside. The dietitian approached patients who were deemed to have capacity in the dining room. The purpose of the study was explained, and that the survey was voluntary and would not interfere with their treatment. The study was approved by the Western Health Research Ethics Committee as a low risk study (HREC/12/WH/87). A total of 34 patients were identified and audited. Data was collected on 54 separate midday meals.

Allied health and nursing staff identified patients suitable for attendance in the dining room within 48 hours of admission based on the following criteria; the patient must have been motivated to participate in the group, been behaviourally and socially appropriate in a group setting, been medically stable and requiring limited supervision, set up and assistance. The exclusion criterion included if the patient required physical assistance to feed, was disruptive or aggressive or displayed other antisocial behaviour, was medically unstable or had infection control precautions.

On three days of the week, eligible patients were encouraged to attend a supervised dining room to consume their midday meal. The number of patients in the dining room at any one time varied from two to six, with the supervision of one to two staff members.

Demographic data including age, gender, length of stay, diet type, risk of malnutrition (assessed by completing the Malnutrition Screening Tool (MST)),[2,8] body mass index (BMI) and cognition (assessed by completing the Mini-Mental State Examination—scored out of 30, (MMSE)) were collected from the medical records. Information related to the patient's self-rated appetite (poor/moderate/good), whether feeding assistance was required (nil, set up and full feeding) and patients preference of eating location (dining room *vs* bedside) was collected in person by the dietitian.

Patients who scored an MST score ≥ 2[10] were considered to be at risk of malnutrition; those with a BMI <22[11] were categorised as underweight; and those who scored an MMSE <25[12] were categorised as having a significant degree of cognitive impairment.

The meal tray tickets were used as a reference to compare foods ordered to that consumed. To determine the proportion of meals consumed, a 5-point food consumption scale was used (0, ¼, ½, ¾ and all). Every food item on the tray was estimated for proportion consumed. The protein (g) and energy (kJ) values of each food item consumed were then calculated using the Western Health Care Service hospital food services nutrient analysis of the menu.

The sample size was determined as a sample of convenience in the absence of previous research on which to base a sample size. As per published guidance on the conduct of pilot studies, no specific sample size is required, and only sufficient numbers to ascertain the feasibility and effect sizes to inform future research are required.[13,14]

The sample of convenience comprised all relevant patients during the study period.

The normality of distributions was tested using the Kolmogorov–Smirnov test. Descriptive data are presented as either frequency (count) data or mean (standard deviation) where applicable. Within-group statistical analyses were conducted using paired *t*-tests, and between-group analyses were conducted using independent *t*-tests, with two-tailed $P < 0.05$ accepted as statistical significance. Between-group analyses were conducted on patients by risk group for malnutrition, including MST > 2; BMI < 22; MMSE ≤ 25; and those with a self-described poor appetite.

Data analysis was performed using PASW Statistics 20.0.0 (SPSS Inc., Chicago, IL, USA).

Results

The majority of the cohort were in rehabilitation for 1–2 weeks and had cognitive impairment (Table 1). The mean (SD) age of the patients audited was 79 (12) years; 73% were female; 45% were screened at-risk of malnutrition (MST > 2); and 24% reported a poor appetite (Table 1).

The intake of energy and protein increased by 20% when patients consumed their midday meal in the dining room compared to the bedside, and this was statistically significant ($P = 0.006$ and 0.001, respectively; see Table 2). The majority of patients identified the dining room as their preferred eating site (68%), and all groups identified at risk of malnutrition consumed more energy and protein in the dining room (Figures 1 and 2).

Patients with an MST >2 consumed 42% more energy and 27% more protein in the dining room (Table 2), although this was not statistically significant ($P = 0.05$ and 0.16, respectively). The intake of energy and protein increased by 30% when patients who were underweight (BMI < 22) ate in the dining room (Table 2), and this was statistically significant ($P = 0.01$ and 0.01, respectively). The intake of energy and protein increased by 30% when patients identified with significant cognitive impairment (MMSE ≤ 25) ate in the dining room (Table 2), and these changes were statistically significant ($P = 0.001$ and 0.007,

Table 1 Demographic data (mean (SD) unless otherwise specified)

Variable	*Patients (n = 34)*
Age	79.1 (11.8) years
Gender (n, %)	Female 25 (74)
	Male 9 (26)
BMI	25.7 (7.1)
Type of diet, n (%)	
High energy high protein (HEHP)	10 (29)
Diabetic	8 (24)
Full ward diet	9 (27)
Diabetic HEHP	2 (6)
Low-salt	1 (3)
Soft	1 (3)
Diabetic renal	1 (3)
Diabetic soft	1 (3)
Light ward diet	1 (3)
MST, n (%)	
0	15 (44)
1	4 (12)
2	8 (24)
3	7 (21)
Appetite, n (%)	
Poor	8 (24)
Moderate	13 (38)
Good	13 (38)
Cognitive impairment (MMSE), n (%)	
≤25	21 (62)
≥25	3 (9)
Missing	10 (29)
Length of stay, n (%)	
0–7 days	15 (44)
7–14 days	12 (35)
2–4 weeks	3 (9)
1–2 months	2 (6)
>2 months	2 (6)
Required assistance? n (%)	
No	21 (62)
Set up only	13 (38)
Assistance provided? n (%)	
No	19 (56)
Set up only	3 (9)
Yes	12 (35)
Preference of eating location n (%)	
Dining room	23 (68)
Bedside	7 (21)
Both	1 (3)
Either	1 (3)
Unsure	1 (3)

BMI, body mass index; HEHP, high energy high protein; MMSE = Mini-Mental State Examination; MST, Malnutrition Screening Tool.

respectively). Patients reporting a poor appetite consumed 25% more energy and 31% more protein in the dining room (Table 2), and although there was a trend, these changes were not statistically significant ($P = 0.29$ and 0.07, respectively).

Discussion

The results of this study show that the patients observed consumed more energy and protein in the dining room compared to the bedside. This was both statistically and clinically significant and was consistent with other research that has demonstrated that energy intakes are higher when patients eat in the dining room of acute medical wards[3]. These favourable results may be because of a number of factors. These include the socialisation that was facilitated in the dining room or the normalisation of the eating experience. The high ratio of staff supervision may have also played a role—with staff sitting in the group able to provide encouragement around nourishing meal choices and timely meal assistance that may have been lacking at the bedside.

These results help to illustrate the positive impact of the communal dining programme on food enjoyment and intake, which when incorporated into a standard nutrition programme can potentially lead to weight gain and improvements in nutritional status. It is also possible that improved food intake, weight gain and improvement in nutritional status may lead to other positive benefits such as improved physical functioning, reduced functional decline and reduced incidence of pressure injury.

A recent Australian study also reported that where a dining room was available, it was very popular, especially for patients who were mobile, although they did not conduct statistical analyses on energy intake differences based on location[7]. Combined with the high percentage of patients favoring the dining room in this study, and the positive impact eating in the dining room had on patient nutritional intake - it raises the question of whether communal dining programs should be actively pursued in this patient population - particularly given the increased incidence of malnutrition in this population group.

It is worth noting, however, the results of a qualitative study published in 2014 that found that while some patients in geriatric rehabilitation preferred eating in the dining room, others preferred eating at the bedside[4]. Some of the reasons for this included the participants having a perceived increased control over their personal time when eating at the bedside or a feeling of poor quality of interaction when eating in the dining room.[4] Interestingly, those who reported enjoying the dining room valued the social aspect of eating in a pleasant environment, with the participants staying at the bedside reporting to feel lonely at times.[4] Given the improved energy and protein intake seen in this study when patients ate in the dining room, it might be important to engage patients choosing to eat at their bedsides in strategies to improve their participation in the dining room. Alternatively, it would be interesting to evaluate whether energy consumption was higher at the bedside in those who prefer eating at their bedside (i.e. is energy intake determined by whether people feel comfortable and relaxed when and where they are eating?).

The results of this study demonstrating that patients at highest risk of malnutrition (low BMI and those with cognitive impairment) consumed more energy and protein in the

Table 2 Mean energy and protein intake by location, MST > 2, BMI < 22, MMSE ≤ 25 and poor appetite

	Dining room (mean ± SD)	*Bedside (mean ± SD)*	*Mean difference (95% CI)*	P-*value*
Whole cohort (n = 34)				
Energy (kJ)	2158.3 (813.0)	1723.1 (872.8)	435.2 (136.4, 734.0)	0.006
Protein(g)	28.2 (13.3)	22.5 (14.3)	5.7 (1.3, 10.2)	0.01
MST > 2 (n = 7)				
Energy (kJ)	2295.0 (827.1)	1331.0 (830.3)	964 (–22.3, 1950.3)	0.05
Protein (g)	27.3 (11.8)	19.9 (14.1)	7.4 (–3.7, 18.4)	0.16
BMI < 22 (n = 14)				
Energy (kJ)	2136.6 (794.3)	1479.4 (767.9)	657.2 (165.9, 1148.4)	0.01
Protein (g)	27.2 (12.32)	19.0 (12.7)	8.2 (2.3, 14.2)	0.01
MMSE ≤ 25 (n = 21)				
Energy (kJ)	2213.2 (866.5)	1508.1 (889.8)	705.1 (313.6, 1096.6)	0.001
Protein (g)	28.4 (14.2)	19.9 (13.9)	8.6 (2.6, 14.5)	0.007
Poor appetite (n = 8)				
Energy (kJ)	1732.8 (887.8)	1290.1 (1077.0)	442.7 (–465.0, 1350.2)	0.29
Protein (g)	24.0 (14.7)	16.6 (14.3)	7.4 (–0.7, 15.5)	0.07

BMI, body mass index; MMSE = Mini-Mental State Examination; MST, Malnutrition Screening Tool.

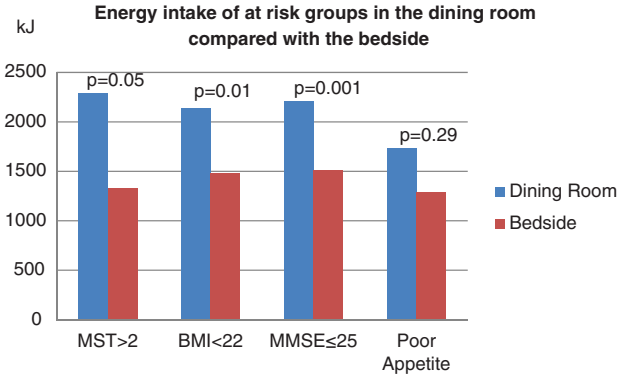

Figure 1 Energy intake of at-risk groups in the dining room compared with the bedside. BMI, body mass index; MMSE, Mini-Mental State Examination; MST, Malnutrition Screening Tool.

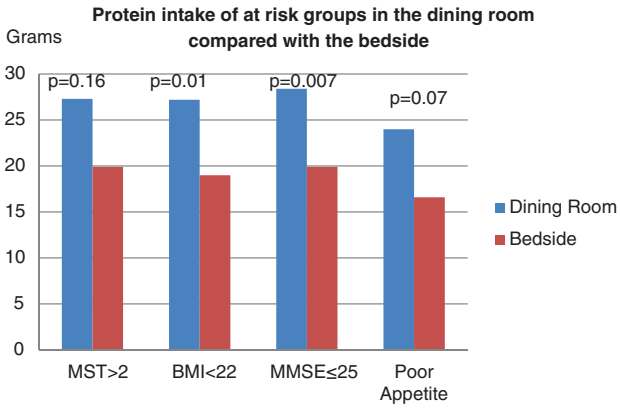

Figure 2 Protein intake of at-risk groups in the dining room compared with the bedside. BMI, body mass index; MMSE, Mini-Mental State Examination; MST, Malnutrition Screening Tool.

dining room are also consistent with results of a study conducted in 2007 in residential care facilities that demonstrated the effect of eating environment (in that study bulk, cafeteria-style food delivery *vs* tray delivery) on energy consumption in patients with lower BMI and cognitive impairment.[5] This supports the hypothesis that this style of programme is a valuable component of a health service's overall malnutrition strategy.

Although this study did not monitor clinical signs of nutritional status, such as anthropometry or biochemical markers of nutrition, it is interesting to note the results of a systematic review and meta-analysis published in 2013, which found a positive association between participating in a communal dining programme and weight gain in residential aged care facilities—although this was not statistically significant.[15] Future studies should aim to investigate the effects of communal dining on additional potential benefits already described, such as improved nutritional status, physical function and reduced pressure injuries.

This study had some important limitations. The study sample was selected from the population with stringent inclusion and exclusion criteria, which although providing a homogenous study sample, may limit external generalisability of the results. Other limitations included the variation in midday meals provided from day to day (both main meals and desserts will differ on consecutive days from the kitchen, and patients may alter meal selection from the menu, e.g. cooked meal one day, sandwiches the next); hence, the two meals patients were observed consuming were not identical and may have had different nutritional compositions. Also, although data was collected on appetite at the meal times, there were no questions around the patients' perception of the tastiness of the meal, which may have also affected meal intake from day to day. Three data collectors were involved in the study; interrater reliability was not tested, and therefore, some interrater discrepancies may have occurred. The observations and data analysis

were not blinded, and given the short period of data collection, only a small number of participants were recruited into this study, limiting the statistical power. This was particularly the case for the subgroup analyses, and the results should be interpreted with caution. The results presented in this study provide a basis for future power calculations.

Future studies could aim to control for these factors in a randomised clinical trial and include evaluation of patient and health service outcomes, such as clinical and biochemical signs of malnutrition, patient weight throughout admission, hospital readmission rates, patient quality of life and cost-effectiveness.

This pilot study supports using a supervised dining room in geriatric rehabilitation settings to increase the intake of energy and protein, particularly for patients who are underweight or who have significant cognitive impairment. Encouraging patients to attend a supervised dining room can potentially lead to weight gain and improvements in patient nutritional status, facilitate achievement of rehabilitation goals and shorten length of stay; however, further studies are warranted to explore this link further.

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Conflict of interest

There are no conflicts of interest in the publication of this study.

Authorship

AN, KM and AO were responsible for data collection. ES was responsible for statistical analysis. All authors contributed equally to the writing of this manuscript.

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ORIGINAL RESEARCH

Nutritional status, management and clinical outcomes in patients with esophageal and gastro-oesophageal cancers: A descriptive study

May MAK,[1] Katherine BELL,[1] Weng NG[2,4,5] and Mark LEE[3,4]

[1]Dietetics Department, Liverpool Hospital, Departments of [2]Medical Oncology, [3]Radiation Oncology, Liverpool Cancer Therapy Centre, [4]Faculty of Medicine, University of New South Wales, Sydney and [5]School of Medicine, University of Western Sydney, Liverpool, New South Wales, Australia

Abstract

Aim: The aims of this study were to investigate the nutritional management practice and nutritional status of patients with oesophageal and gastro-oesophageal cancers, and to propose strategies for improving their nutritional and clinical outcomes.

Methods: All patients diagnosed with oesophageal and gastro-oesophageal cancers and treated with chemotherapy and/or radiotherapy at the Liverpool Cancer Therapy Centre (between August 2010 and February 2014) were included in this retrospective study. Patient and tumour characteristics, nutritional status and management were compared to clinical outcomes.

Results: A total of 69 patients met the inclusion criteria. The median weight loss prior to treatment commencement was 10.5% (Interquartile Range (IQR) = 6.6–15.4). A decline in nutritional status continued throughout the treatment course. The median percentage of weight loss during treatment was 3.53% (IQR = 0.00–6.84). Seven and 19 patients required nutrition intervention using a feeding tube or stent insertion to manage dysphagia, respectively. In patients treated with a curative intent, radiotherapy was completed in 100% of those with a nasogastric tube insertion as compared to 80% who had a stent insertion. There was a higher percentage of patients from culturally and linguistically diverse (CALD) background, experiencing significant weight loss when compared with their non-CALD counterparts ($P = 0.04$).

Conclusions: Patients with oesophageal and gastro-oesophageal cancers commonly present with significant weight loss and this continues during the course of their anti-cancer treatment. A standardised protocol of nutrition management for these cancer patients is recommended, focusing on assisting patients from CALD backgrounds.

Key words: dysphagia management, malnutrition, oesophageal cancer, weight loss.

Introduction

There are more than 450 000 newly diagnosed cases of oesophageal and gastro-oesophageal cancers world-wide each year.[1] In Australia, oesophageal and gastro-oesophageal cancers represent 1.2% of all new cancer diagnosis, and this has risen from 801 to 1424 per 100 000 persons from 1990 to 2010.[2] The long-term survival is poor, with less than 20% of patients surviving beyond 5 years.[3]

M. Mak, MHSM, MND, APD, Deputy Manager/Clinical Dietitian
K. Bell, MND, APD, Senior Oncology Dietitian
W. Ng, PhD, MBBS, FRACP, Medical Oncologist
M. Lee, MSc, MBBS, FRANZCR, Radiation Oncologist
Correspondence: M. Mak, Dietetics Department, Liverpool Hospital, Level 1, Don Everett Building, Liverpool Hospital, Liverpool, Sydney, NSW 2170, Australia., Email: may.mak@sswahs.nsw.gov.au

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Patients with oesophageal and gastro-oesophageal cancers commonly present with weight loss, malnutrition and dysphagia caused by the obstructing tumour.[4–6] Malnutrition occurs in 60–85% of oesophageal cancer patients and has one of the highest reported prevalences when compared with other tumour groups.[6] Patients with these malignancies have the highest median percentage of body weight loss as compared with other cancer subsites.[7] A review of weight changes in 205 patients who had oesophagectomies, found that although more than half of the patients were obese or overweight at diagnosis, 74% had lost weight and 34% of them had lost more than 10% of their weight in 6 months.[8] Whilst obesity and being overweight are associated with an increased risk of surgical complications, significant weight loss appears to be linked with poorer compliance to chemotherapy and radiation treatments.[9]

The mechanism of malnutrition is multifactorial. First, the psychological aspects of the disease can result in depression, anxiety and fear, and these contributes to decreased nutritional intake. Second, the mechanical obstruction

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caused by the tumour can result in dysphagia and food avoidance. Third, the tumour releases factors and cytokines, which result in metabolic complications; this process is known as cancer cachexia, which often causes loss of skeletal and visceral muscle mass. Last, the treatment itself results in various toxicities, which further compromise the patients' nutritional status.[6] The inability to eat adequately prior to treatment coupled with the toxicities of chemotherapy and radiotherapy (e.g. nausea, altered taste, acute inflammation and oedema in the oesophageal mucosa) place the patient at high risk of continual and worsening malnutrition, which in turn can decrease the effectiveness of treatments, limit treatment options and impair quality of life.[4] The common nutritional management strategies for oesophageal dysphagia includes the insertion of feeding tubes or oesophageal stents.[9–11] Oesophageal stents are made of either metal or plastic. The unexpanded stent is positioned under the fluoroscopic guidance at approximately 3 cm above the tumour. Once the stent is expanded, patients often experience immediate improvement in dysphagia.[10]

The aims of this study were to investigate the nutritional management practice and clinical outcomes in patients with oesophageal and gastro-oesophageal cancers.

Methods

This retrospective audit was conducted in the Liverpool Cancer Therapy centre. We included patients who were 18 years and older with a diagnosis of oesophageal and gastro-oesophageal junction cancer and had received chemotherapy and/or radiotherapy treatment between August 2010 and February 2014.

Data were collected using our electronic medical records, MOSAIQ Oncology Information System (ELEKTA/IMPAC Medical Systems, INC, Sunnyvale, CA, USA). Variables collected included patient characteristics (gender, age, language used at home and family support), cancer risk factors (including history of tobacco and alcohol use), tumour characteristics (histology, grade and stage), treatment plan and management strategies for dysphagia (i.e. insertion of enteral feeding tube or stent insertion), nutrition parameters (nutritional status, body mass index (BMI), weight changes during treatment, long-term weight changes and frequency of dietitian review during treatment) and clinical outcomes (hospital admission rate and completion rate of radiotherapy).

Nutritional status was assessed by the treating dietitians using the Patient-Generated Subjective Global Assessment (PG-SGA) and was recorded in the electronic medical record prospectively. The scored PG-SGA is a validated nutritional assessment adapted from SGA. History of weight loss, intake, nutritional-related symptoms, functional capacity and physical examination were the parameters used for the assessment.[12] A global rating of well-nourished, suspected or moderately malnourished or severely malnourished were assigned to the patients.

The study protocol was approved by the South Western Sydney Human Research and Ethics Committee. Statistical analysis was carried out using IBM SPSS Version 22 (SPSS Inc., Chicago, IL, USA). Pearson's chi-square and Fisher's exact test were used to analyse the association between categorical variables. Independent sample t-test and Mann–Whitney U-test were used to compare group differences for continuous variables. Results were considered statistically significant if two sided $P < 0.05$. We analysed patient and tumour characteristics as well as their treatments to assess for factors that were associated with significant weight loss. In order to adjust the treatment period difference, percentage of weight loss per month was used as a parameter. Weight loss of more than 5% per month was considered as significant weight loss.

Results

Sixty-nine patients were identified as meeting the selection criteria. Patient demographics and tumour characteristics have been summarised in Table 1.

Our study population was younger (median age of 68 years old) than the New South Wales (NSW) population (median age of 72 years old for male and 75 years old for female).[13] The gender distribution in our study population (male = 73.9%) was similar to that of the NSW population (male = 75.6%). Fifteen percent of the subjects were from a culturally and linguistically diverse (CALD) background, which was similar to NSW statistics (12%).[13] In this study, over 50% had a history of smoking and 75% consumed alcohol. Approximately 20% of our study population did not have any family support which was defined as those without home care including cooking, shopping or financial.

There was an equal number of patients diagnosed with adenocarcinoma and squamous cell carcinoma. Patients treated with a palliative intent were older than those receiving curative treatment ($P = 0.01$). One-third of the patients were diagnosed with advanced disease (Stage IV). All of them were treated with palliative intent. Forty percent of the study population received treatment with a curative intent. Radiotherapy was a common cancer treatment modality for both curative and palliative patients. Chemotherapy and surgery were significantly used more in patients with curative intent than their palliative counterparts ($P = 0.00$ for chemotherapy, $P = 0.01$ for surgery). Enteral feeding tube and stent insertions were used in both curative and palliative patients.

The nutritional status at diagnosis, weight changes during treatment and clinical outcomes of the study population have been summarised in Table 2.

At the initial assessment, the study population had a median BMI of 25.7 kg/m. The study population had a lower percentage of overweight and obese than the NSW population (45% *vs* 61%).[14] Despite nearly half of the patients being overweight or obese, 80% of the study population was assessed as malnourished (SGA-B or C) on presentation. The prevalence of malnutrition was significantly higher in patients receiving palliative treatment (96%) as compared with curative treatment (63%) ($P < 0.01$). The

Table 1 Demographics of patients, tumour characteristics and treatment received

Characteristics	*Total* 69	*Curative* 28 (40.6%)	*Palliative* 41 (59.4%)	P-*value*
Male, no. (%)	51 (73.9%)	21 (75.0%)	30 (73.1%)	0.87
Median age (IQR), years	68 (60.5–79.5)	63 (55.3–70.0)	72 (62.0–81.0)	0.00*
Alcohol user,[(a)] no. (%)	33 (52.4%)	15 (55.5%)	18 (50%)	0.42
Smoker,[(a)] no. (%)	48 (76.2%)	19 (70.4%)	29 (80.6%)	0.29
Nil family support, no. (%)	11 (17.5%)	8 (29.6%)	3 (8.3%)	0.03*
CALD background, no. (%)	10 (14.5%)	4 (14.3%)	6 (14.6%)	1.00
Tumour site (top three)				
Lower third	36 (52.2%)	17 (60.7%)	19 (46.3%)	
Thoracic	15 (21.7%)	6 (21.4%)	9 (22.0%)	
Middle third	9 (13%)	3 (10.7%)	6 (14.6%)	0.61
Staging[(b)]				
I	6 (8.7%)	4 (14.3%)	2 (4.9%)	
II	15 (21.7%)	11 (39.3%)	4 (9.8%)	
III	22 (31.9%)	13 (46.4%)	9 (22%)	
IV	23 (33.3%)		23 (56.1%)	
UNK	3 (4.3%)		3 (7.3%)	0.00*
Histology				
Adenocarcinoma	33 (47.8%)	15 (50%)	18 (43.9%)	
Squamous cell carcinoma	33 (47.8%)	13 (50%)	20 (48.8%)	
Others	3 (4.4%)	0	2 (4.9%)	0.26
Radiotherapy, no. (%)	57 (82.6%)	25 (89.3%)	32 (78.0%)	0.34
Chemotherapy, no. (%)	32 (46.4%)	24 (85.7%)	8 (19.5%)	0.00*
Surgery, no. (%)	13 (18.8%)	10 (35.7%)	3 (7.3%)	0.01*
Neoadjuvant, no. (%)	6 (8.7%)	6 (21.4%)	0	0.00*
Dysphagia management, no. (%)				
Feeding tube	7 (10.1%)	3 (1.70%)	4 (8.3%)	
Oesophageal stent	19 (27.5%)	5 (17.9%)	14 (34.1%)	

CALD, culturally and linguistically diverse.
[(a)] Alcohol user and smoker: missing data = 6.
[(b)] Staging: missing data = 17.
*Statistical significance was set at $P < 0.05$.

Table 2 Nutritional status, nutritional outcome and clinical outcome

Characteristics	*Total*	*Curative*	*Palliative*	P-*value*
Median BMI (IQR), kg/m^2	25.70 (20.17–28.53)	27.24 (20.42–31.55)	23.78 (19.80–27.91)	0.11
Overweight/obese, no. (%)	25 (45.5%)	14 (53.8%)	11 (37.9%)	0.05
Malnourished (SGA-B or C), no. (%)	40 (80%)	16 (63%)	24 (96%)	0.00*
Median loss prior to treatment (IQR), %	10.50% (6.55–15.35)	10.25% (8.29–14.55)	10.9% (6.00–16.0)	0.94
Median weight loss during treatment (IQR), %	3.53% (0.00–6.84)	4.64% (2.29–8.65)	3.01% (0.00–5.04)	0.05
Median weight loss per month during treatment (IQR), %	2.72% (0.00–5.26)	3.14% (1.74–5.77)	1.10% (0.0–4.22)	0. 18
Seen by dietitian, no. (%)	56 (81.2%)	27 (90%)	29 (74.4%)	0.13
Median number of dietitian review (IQR)	3 (1–6)	5 (2–8)	2 (1–5)	0.01*
Completed radiotherapy, no. (%)	51 (89%)	23 (92.0%)	27 (87.1%)	0.41
Feeding tube	7 (100%)	3 (100%)	3 (100%)	
Stent	13 (72.2%)	4 (80%)	9 (69.2%)	0.06
Hospital admission, no. (%)	13 (18.8%)	8 (28.6%)	5 (12.2%)	
Feeding tube	3 (42.9%)	1 (33.3%)	2 (50%)	
Stent	5 (26.3%)	4 (80%)	1 (7.1%)	
Median survival estimate, months (IQR)	9.0 (5.73–12.28)	28 (8.29–47.71)	5 (3.08–6.92)	0.00*

BMI, body mass index; SGA, Subjective Global Assessment.
*$P < 0.005$.

median weight change prior to treatment was 10.5% (IQR = 6.6–15.4%).

A mean weight loss of 3.53% (IQR = 0.0–6.84) was observed during treatment. During treatment, 90% and 74% of the curative and palliatively treated patients were seen by a dietitian. Patients treated curatively received more dietitian reviews than those treated palliatively ($P = 0.13$).

Nearly 90% of the patients completed their radiotherapy regimen and there were no differences between the groups treated with curative and palliative treatment intent. Nearly one-fifth of the patients were admitted to hospital during the treatment period. Curative treatment was associated with a higher hospital admission rate than their palliative counterparts (29% *vs* 12%, $P = 0.08$). All patients with a feeding tube inserted completed their radiotherapy regimen; on the other hand, only three quarters of the patients with a stent insertion completed treatment. Eighty percent of the curative patients with a stent insertion were admitted to the hospital. This was higher than those with a feeding tube insertion (33%). Patients treated curatively had a longer survival than those treated palliatively (median survival 28 months, IQR = 8.29–47.71 *vs* 5 months, IQR = 3.08–6.97) ($P < 0.01$). Figure 1 shows the Kaplan–Meier survival curve for palliatively and curatively treated patients.

Characteristics that may contribute to weight loss are summarised in Table 3. More than 30% of the patients had significant weight loss. The only characteristic correlating with significant weight loss was CALD background. More than half of the CALD background patients had significant weight loss; whereas, only around 20% of the non-CALD background patients lost more than 5% per month ($P = 0.04$).

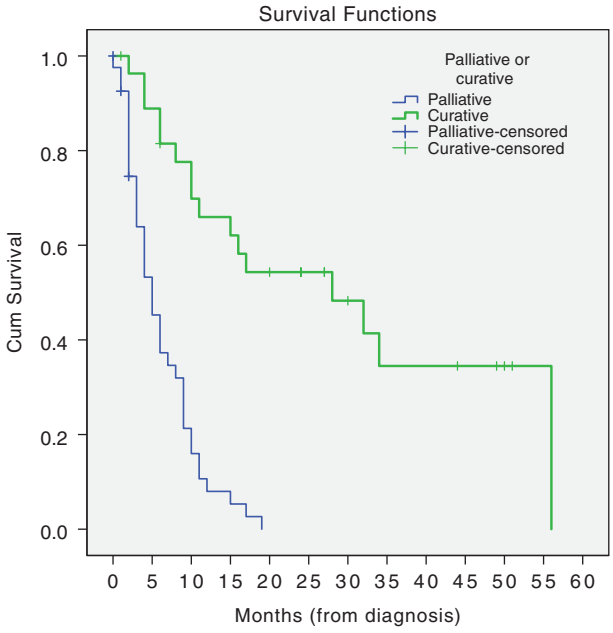

Figure 1 Survival curve of patients categorised by curative and palliative intent.

As there was a statistically significant difference between the survival for patients treated with a curative and palliative intent, palliative patients were excluded when assessing the impact of weight loss on survival. Patients with more than 5% weight loss per month were considered as having significant weight loss. For those with significant weight loss, their median survival estimate was 11 months (IQR = 4.8–17.2), in contrast, to a median survival estimate of 32 months (IQR = 11.7–52.3) for those without significant weight loss. This difference was not statistically significant ($P = 0.65$). The Kaplan–Meier survival curve is illustrated in Figure 2.

Discussion

Patients with oesophageal cancer are at high nutritional risk. They commonly present with weight loss and malnutrition.[5,6] Therefore, this study aims to investigate the nutritional management and outcome of patients with oesophageal cancer. The results of this retrospective audit showed that a significant proportion of patients with both palliative and curative treatment intent lost a substantial amount of weight prior to treatment. The decline of nutritional status continued throughout the treatment as with a median weight loss of 3.5% in our patients.

Weight loss at presentation has been shown to be an independent prognostic factor for poor treatment outcome for patients with gastrointestinal malignancies.[15,16] One study showed that patients with 10% or more weight loss at presentation were significantly more likely to be referred to a dietitian ($P < 0.01$).[17] In this present audit, there was

Table 3 Factors that contribute to significant weight loss (≥5% per month)

Characteristics	*Yes*	*No*	P-*value*
Male	11 (25.6%)	4 (30.8%)	0.73
Age 65 and above	5 (17.9%)	10 (35.7%)	0.13
CALD	5 (55.6%)	10 (21.3%)	0.04*
Smoker	13 (31.7%)	2 (15.4%)	0.35
Alcohol use	10 (37.1%)	5 (19.2%)	0.19
Nil family support	3 (33.3%)	11 (24.4%)	0.55
Advanced disease (stage IV)	2 (25%)	10 (29.4%)	0.98
Radiotherapy	15 (31.9%)	0	0.09
Chemotherapy	8 (25.8%)	7 (28%)	0.85
Surgery	2 (16.7%)	13 (29.5%)	0.48
Neoadjuvant	1 (16.7%)	14 (28%)	1.00
Overweight or obese	7 (30.4%)	6 (23.1%)	0.54
Significant weight loss prior to treatment (>5%)	12 (30%)	2 (33.3%)	1.00
Feeding tube insertion (yes) *versus* stent insertion (no)	2 (33.3%)	6 (46.2%)	1.00

CALD, culturally and linguistically diverse.
*Statistical significance was set at $P < 0.05$.

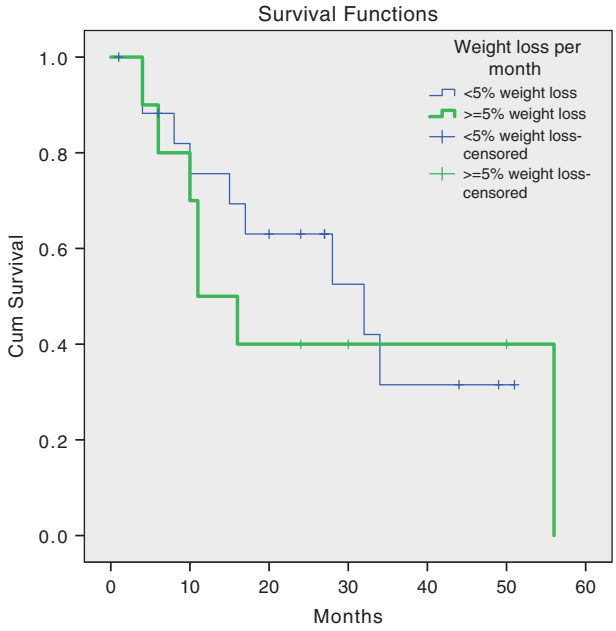

Figure 2 Survival curve of patients with weight loss of more than and less than 5% per month.

no standardised dietitian referral process. For example, despite oesophageal cancer patients being at high nutritional risk, 10% of the curatively treated patients had not been seen by a dietitian during treatment. This indicates the need to implement a better referral system.

In addition to the referral process, the present study also suggests that management for weight loss could be improved. Despite curatively treated patients receiving more dietitian reviews compared with their palliative counterparts, they continued to have a higher percentage of weight loss than those with palliative intent. This highlights the need for intensive nutritional intervention processes to be developed and used to improve the outcomes of patients with oesophageal cancer. Benefits of a dietitian-delivered intensive nutritional support programme has been demonstrated in a study of patients receiving neoadjuvant therapy prior to oesphagectomy.[18] In that study, the treatment group received weekly review by dietitians. Nutritional goals on weight, energy and protein intake were set for each patient. If the patient was not able to meet their nutritional goal orally, tube feeding was implemented. Subsequently, the treatment group had better nutritional and clinical outcomes than the control group. These included a relative preoperative weight gain of 4.8% ($P < 0.005$), less severe complications (odd ratio = 0.23, $P = 0.05$) and shorter median length of stay ($P = 0.04$). This approach is also supported by a literature review.[15] Patients receiving nutritional support had significantly greater radiotherapy completion rates (92% *vs* 50%), fewer hospital admissions (46% *vs* 75%) and shorter hospital length of stay (3.2 days *vs* 13.5 days). The review suggested that all gastrointestinal cancer patients undergoing radiotherapy and chemotherapy should receive intensive dietary advice and oral nutrition supplements. For those patients who are severely malnourished or not responding to dietary counselling, artificial nutrition, such as enteral feeding, should be proposed. Evidence-based practice guidelines developed by the European Society for Clinical Nutrition and Metabolism supports these recommendations.[19]

The beneficial impacts of following a medical nutrition therapy protocol for patients undergoing radiotherapy were demonstrated in other studies.[20,21] In one study, the American Dietetics Association Medical Nutrition Therapy protocol was followed for the treatment group. The protocol standardised the frequency of dietitian reviews and the education resources used. All patients in the treatment group were also recommended to consume two serves of oral nutritional supplement per day. The study found that the treatment group had a better dietary intake, body weight, nutritional status and quality of life outcome compared with the control.[20]

In another experimental study, a nutrition pathway was developed for patients with oesophageal cancer undergoing chemoradiation.[21] Management was based on the nutritional risk identified at the initial assessment. Patients in the treatment group with severe nutrition risks, including those with severe dysphagia, unintentional weight loss of more than 10% and low BMI, would proceed with a prophylactic gastrostomy insertion. In addition, patients who failed to stabilise his/her weight during treatment or with a weight loss of more than 10%, a nasogastric tube was inserted to provide nutrition support. Enteral nutrition, both via a nasogastric tube or gastrostomy tube, was started earlier in the treatment group than the control group (–0.31 weeks *vs* 3.6 weeks, $P < 0.01$). There was also a higher percentage of severely malnourished patients who received enteral nutrition in the treatment group than the control group (100% *vs* 38%, $P < 0.01$). The treatment group had better nutritional and clinical outcomes, including less weight loss (4.2% *vs* 8.9%, $P = 0.03$) and higher radiotherapy completion rate (92% *vs* 50%, $P < 0.01$) than the control group. Enteral nutrition was also recommended in other tumour groups, such as head and neck cancers. One study suggested that enteral tube feeding should be used for patients not meeting 50% of their nutritional requirements for more than five days.[22]

In addition to the nutritional management, an inconsistent dysphagia management was also observed in our patients. In the past, oesophageal stents were mainly used for dysphagia as palliative management. However, it has also recently been used in the management of oesophageal cancer patients treated with curative intent.[10] In our study, no difference in treatment intent was observed between the two methods. Because of the small numbers of patients with feeding tube or stent insertion, it was difficult to draw conclusions regarding the optimal method of managing dysphagia. However, all the patients having nasogastric enteral feeding successfully completed radiotherapy compared with 80% of those with stent insertion. There was also a higher percentage of curative patients with a stent insertion admitted to the hospital than those with a feeding tube

insertion. This result could be explained by the complications or side effects resulting from stents. Although stents were considered as a safe and effective palliative intervention for dysphagia with rapid resolution of symptoms, several complications associated with stent insertion were observed. This included stent migration, incomplete expansion of the stent and tumour ingrowth or overgrowth and pain. In addition, stents that cross the gastro-oesophageal junction can result in increased rates of gastro-oesophageal reflux symptoms.[23] Rates of major complications and mortality associated with stents vary widely from 0% to 26% and 0% to 16%, respectively.[10] Although there was temporary relief of symptoms, the benefit of stent insertion on nutritional status remains inconclusive.[24]

The results of this study demonstrate a positive clinical outcome among the group of patients managed with feeding tube insertion as compared with those with a stent inserted. Placement of a feeding tube, in the form of nasogastric tube, jejunostomy and percutaneous endoscopic gastrostomy, for these patients had been commonly used to maintain adequate nutrition intake during neoadjuvant chemoradiation.[15] Therefore, a feeding tube should be routinely considered for malnourished patients undergoing curative chemotherapy or radiation therapy.

Our study supports the need to implement a standardised protocol or pathway on nutritional management for oesophageal cancer patients undergoing oncologic treatment. The pathway should include frequency of dietitian reviews and appropriate nutritional interventions for low, moderate and high nutritional risk groups. A clear indication and timing of prophylactic gastrostomy and nasogastric feeding tube insertion should be listed.

The present study identified patients from CALD backgrounds as being susceptible to significant weight loss. It is unclear as to the reason for these patients' poor nutritional outcome. At present, there is limited literature on nutritional outcomes for cancer patients from CALD backgrounds. Various studies have proposed that patients from CALD backgrounds have a different attitude and understanding of health when compared with their non-CALD counterparts.[25–27] This difference might lead to poorer compliance with the dietitian recommendations.

In a study conducted among a group of Chinese-Australians with advanced cancer, participants had a strong belief of the illness-combat nature of certain culture-specific food and Chinese herbal medicines.[25] This might explain the challenges faced by some CALD communities in complying with the medical nutritional therapy and support.

The attitude and understandings of health and wellbeing have a strong socio-cultural influence.[26] Cultural and religious beliefs and language barriers might have significant impact on the levels of understanding of the treatment plan and compliance. This is supported by other studies.[22,26] One study suggested that a patient's ability to understand the nature of the illness, the importance of the treatment and the consequences of choices might contribute to non-compliance with the recommendation.[22] Another study found that the Chinese, Vietnamese and Arabic-speaking communities in Sydney, Australia, had limited awareness of signs and symptoms of lung cancer. Their cultural perceptions about cancer and level of trust in general practitioners had a significant impact on their willingness in seeking medical advice.[27]

In addition to cultural belief, the cost of health care and waiting time to receive treatment are the biggest barriers for the CALD population.[28] This might also impact on their access to traditional medical treatment.

Given the poorer nutritional outcomes in patients from CALD backgrounds, our study supports the importance of implementing specific strategies for this group of patients. Strategies suggested in the literature include greater access to interpreter services, culturally appropriate communication and education and having supportive environment.[28,29] The education materials and recommendations, especially for food items, should be culturally relevant.

Another potential factor contributing to poor nutritional outcomes is socioeconomic status, which was not assessed in this audit. Based on the NSW data, the incidence rate of oesophageal cancer was significantly higher in the most disadvantage group.[13] Possible reasons may include associations with poorer uptake of a healthy lifestyle, higher obesity rate and higher alcohol consumption. Socioeconomic status was also a major contributing factor of non-compliance to medical treatment.[29] Our study population is from an area with a relative socioeconomic disadvantage (SEIFA) score compared with Greater Sydney, NSW and Australia. Therefore, it is important to investigate whether the low socioeconomic status also contributes to a poorer nutritional and clinical outcome in future research.

One of the main limitations of the present study was the sample size. Our centres see about 24 cases of oesophageal cancer per year. Because of the retrospective nature of this study and the small sample size, the statistical analysis was under-powered. The present study also assumed that the oesophageal cancer group was relatively homogeneous group. However, there were therapeutic differences depending on the location and stage of the tumour. The diversity in tumour-related and therapeutic factors, such as tumour size, and involvement of lymph nodes, might mask the impact of relevant factors for subpopulations.

In conclusion, our study found that patients with oesophageal cancer lost significant amounts of weight prior to and during treatment. There were inconsistencies in the practice of dietetic referrals and management of nutrition. These results support the use of a standardised protocol for nutrition management of patients with oesophageal cancer. This should include criteria for dietitian referral, frequency of nutritional review and indications for feeding tube insertion. Based on the recommendations from other studies, enteral tube feeding should be used when the patient is unable to consume 50% of their caloric requirement for more than five days. Weight loss of more than 10% prior to treatment should also be considered as a criteria for feeding tube insertion. Research should focus on identifying barriers and strategies for patients from CALD backgrounds and lower socioeconomic background in adhering to nutritional management.

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This study has not received any funding.

Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

MM designed the study protocol, conducted audit, collected data, analysed data, interpreted the data and wrote the manuscript. KB designed the study protocol, critically reviewed the manuscript and approved the final manuscript. WN provided medical advice on study design and data analysis, critically reviewed the manuscript and approved the final manuscript. ML provided medical advice on study design and data analysis, critically reviewed the manuscript and approved the final manuscript.

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ORIGINAL RESEARCH

Dietetic and educational interventions improve clinical outcomes of diabetic and obese clients with mental impairment

Kerri HUNT[1] and Kathy STILLER[2]

[1]Supported Residential Facilities Health Access Team, Sefton Park Primary Health Care Services, Central Adelaide Local Health Network and [2]Central Adelaide Local Health Network, Royal Adelaide Hospital, Adelaide, South Australia, Australia

Abstract

Aim: The aim of this study was to evaluate the effect of dietetic and educational interventions provided to clients with type 2 diabetes (with or without obesity) or obesity-only residing in supported residential facilities and characterised by mental impairment.

Methods: A retrospective audit involving the retrieval of information from medical records and databases was undertaken to evaluate the effect of dietetic and educational interventions. Clinical outcomes were weight, body mass index and glycosylated haemoglobin (HbA1c) levels.

Results: A total of 91 clients were included, 47 with type 2 diabetes (with or without obesity) and 44 with obesity-only. All but one had schizophrenia, an intellectual disability or another psychological condition. After interventions, the diabetic subgroup demonstrated significant decreases in weight (mean [SD] initial = 101.5 [20.7], final = 97.8 [20.6] kg, $P = 0.001$) and body mass index (mean [SD] initial = 35.8 [8.1], final = 34.4 [7.8] kg/m^2, $P = 0.001$) and a non-significant decrease in HbA1c over time. The obesity-only subgroup showed no significant change in outcomes. Factors significantly negatively impacting at least one outcome included the presence of schizophrenia ($P \leq 0.017$) and refusal of intervention(s) ($P \leq 0.048$), whereas a significant positive impact was seen for a greater total number of visits to a dietitian or diabetes educator ($P \leq 0.024$).

Conclusions: These results provide evidence to support the effectiveness of dietetic and educational interventions for this vulnerable client group.

Key words: body mass index, body weight, haemoglobin A: glycosylated, nutritionists, primary health care, quality improvement.

Introduction

Diabetes is reaching epidemic proportions in Australia, with 1 in 20 adults having diabetes.[1,2] In 2012, diabetes was an underlying or associated cause of death for 1 in 10, or 15 095 deaths in Australia.[2] The cost associated with diabetes is substantial, with almost $1507 million spent on diabetes in Australia in 2008–2009 and an additional $153 million spent on government programs, subsidies and research.[3] Excess weight, especially obesity, is a major risk factor for conditions including type 2 diabetes and cardiovascular disease.[4] The number of overweight and obese people is rising in Australia, with almost two-thirds of adults classified as being overweight or obese.[1,4] Being overweight or obese is the second highest contributor to the burden of disease in Australia.[4] Similar findings are seen worldwide.[5,6]

The management of type 2 diabetes is centred on lifestyle modification, including a healthy diet, regular exercise, weight management and monitoring of blood glucose levels and, if required, medications to improve glycaemic control and manage cardiovascular risk.[7] Lifestyle modification is also vital in the management of people who are overweight or obese, with more intensive interventions, such as very low energy diets, medication and bariatric surgery, available for selected patients with severe obesity.[8] There is strong evidence to support the effectiveness of dietetic and diabetes educational interventions in the management of people with type 2 diabetes and/or obesity.[9–11] Overall, these interventions aim to reduce complications and morbidity associated with type 2 diabetes and obesity by promoting healthy eating, optimising glycaemic control and achieving a healthy body weight.[9–11]

K. Hunt, BSc, BND, Dietitian
K. Stiller, B App Sc (Physio) PhD, Allied Health Research Coordinator
Correspondence: K. Hunt, Supported Residential Facilities, Health Access Team, Primary Health Care Services, Central Adelaide Local Health Network, Northwood Plaza, Shop 5, 221 Main North Road, Sefton Park, Adelaide, SA 5082, Australia.
Email: Kerri.Hunt@sa.gov.au

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Compared to the general population, the incidences of overweight, obesity and diabetes are higher in people with mental illness or intellectual disability.[12–17] However, successfully implementing lifestyle interventions to improve health-related outcomes in this vulnerable population is challenging because of clients' difficulties in engaging, learning and adopting new behaviours, low socioeconomic status, poor insight into their health-care needs, poor health literacy and the stigma associated with mental illness.[12,15–18]

For some years, our team, the Supported Residential Facility (SRF) Health Access Team (HAT), has provided nursing and allied health services to people residing in SRFs. These facilities are privately owned and operated (i.e. non-government) and provide basic accommodation, meals and assistance with medication administration (using a medicine pack) for vulnerable people who are unable to live independently, most of whom have a mental illness or intellectual disability. SRFs, unlike aged care facilities, are not rigorously regulated, and residents are expected to manage their own health care with limited assistance. Many residents in SRFs spend a high proportion of their disability pension on accommodation fees, leaving little money to support a healthy lifestyle. Thus, SRF residents are a particularly vulnerable client group despite living in supported care. Anecdotal data from our clientele revealed that almost two-thirds of residents were overweight or obese, with a 25% rate of diabetes, considerably higher than the diabetes rate seen in the general Australian population. To date, there has been no formal review of the outcomes achieved from the nursing and allied health interventions provided to people living in the SRFs we service. This is an important oversight given the increasingly strained health-care resources and the need to demonstrate the effectiveness of health-care interventions. The aim of the current study was to evaluate the effect of dietetic and educational interventions provided to two high-volume client groups within our service, namely, type 2 diabetes (with or without obesity) or obesity-only, on clinical outcomes.

Methods

A retrospective medical record audit was undertaken for services provided by the SRF HAT based at Sefton Park Primary Health Care Service between January 2012 and September 2015. The study design was based on Cusack *et al.*[19] and Stoneman *et al.*[20] who retrospectively audited the effect of interventions for people with type 2 diabetes. The study was approved as a quality assurance activity by the Royal Adelaide Hospital Research Ethics Committee.

Inclusion criteria were residents with a diagnosis of type 2 diabetes (with or without obesity; diagnosis based on fasting blood glucose ≥ 7.0 mmol/L, 2-hour post-prandial oral glucose tolerance test ≥ 11.0 mmol/L or glycosylated haemoglobin [HbA1c] ≥ 6.5% [48 mmol/mol] on two separate occasions)[21] or obesity-only (i.e. body mass index [BMI] > 30 kg/m^2) who had received a health assessment and at least one subsequent allied health intervention from the dietitian or diabetes educator from the SRF HAT. Residents who refused assessment or all interventions were excluded.

There are two SRF catchment areas in Adelaide that are privately run and provide, in a group setting, supported accommodation predominantly for people with a mental illness or intellectual disability. In northern Adelaide, the SRF HAT is based at Sefton Park Primary Health Care Service. The team comprises a manager, two registered nurses and one dietitian and provides services to 12 SRFs housing approximately 475 residents. Residents with type 2 diabetes and/or obesity are referred to the HAT's dietitian and receive a nutritional assessment and management plan followed by ongoing review and advice, with duration and frequency based on individual requirements. The overall aim of dietetic interventions is to promote healthy eating, for clients with type 2 diabetes to improve glycaemic control and for clients with obesity to reduce body weight or prevent/minimise further weight gain. Clients with diabetes are also referred to a diabetes educator. All assessments, dietitian interventions and some (but not all) diabetes educational interventions are provided to clients at their residential address.

Since 2012, the SRF HAT have recorded basic demographic data, clinical outcomes and interventional data for each resident within each client's medical records or databases. A data collection spreadsheet was specifically developed for this audit where outcomes retrieved from medical records or databases were collated and recorded by one of the investigators (KH). Clinical data retrieved included weight and BMI to measure the degree of obesity and HbA1c levels to measure glycaemic control for clients with diabetes. For the purposes of this study, only clinical data from the initial assessment and most recent intervention were recorded as interim data were inconsistently measured and reported. Interventional data retrieved included the number of services provided by the dietitian and diabetes educator and duration of visits.

Outcome data were retrieved from clients' medical records or databases, collated, de-identified and transcribed into an Excel file and imported into the SPSS for analyses. Data have been presented for the overall sample, participants with type 2 diabetes (with or without obesity) and obesity-only. Data were reported as mean (SD) or median (interquartile range [IQR]) for normally and non-normally distributed data, respectively. Clinical outcomes were compared from initial to final measurement using paired samples t-tests. Independent samples t-tests were used to compare clinical outcomes (i.e. change in weight, BMI and HbA1c) according to variables that had the potential to influence outcomes.[19] These variables were the presence of schizophrenia, intellectual disability, other psychological conditions and whether intervention(s) had been refused (categorised as yes/no) and age, number of visits and intensity of visits (duration of visits divided by total number of visits) dichotomised into two groups based on median values (<median; ≥ median). P values < 0.05 were considered significant.

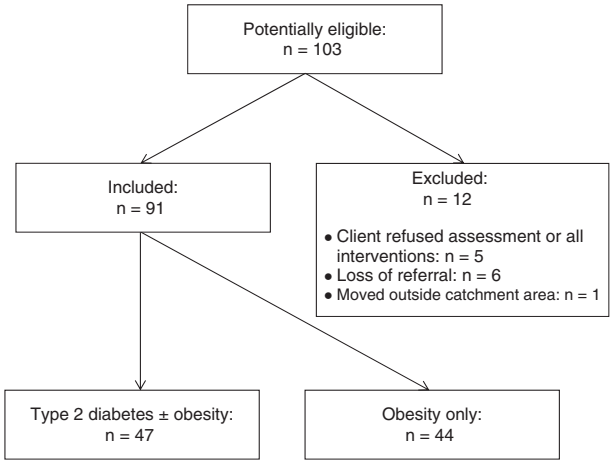

Figure 1 Recruitment to the study.

Results

A total of 103 residents were eligible for participation; 12 were excluded, and thus, data from 91 participants were analysed (see Figure 1). A total of 47 participants (51.6%) had type 2 diabetes, with 39 of these 47 (83.0%) also classified as obese. Eighty-three participants (91.2%) were obese, with 44 of these 83 (53.0%) not having a diagnosis of diabetes. Baseline characteristics of the 91 participants are shown in Table 1. A history of schizophrenia, intellectual disability or other psychological conditions was common, with only one participant having none of these conditions. For the 47 participants with diabetes, this was managed with diet only for six (12.8%), oral hypoglycaemic medications for 40 (85.1%), six (12.8%) required insulin, and two (4.3%) required other injectable medications.

Clinical outcomes are summarised in Table 2. For the entire sample of 91 participants, the median (IQR) time from initial to final weight assessment was 23.00 (19.00) months. Small decreases in weight and BMI were seen over time (Table 2), which was significant for BMI ($P = 0.04$) but not weight ($P = 0.08$). A comparison of the two subgroups (i.e. diabetes [with or without obesity] vs obesity-only) revealed significant differences, both in favour of the diabetes subgroup (mean [SD] change in weight = −4.0 [7.8] vs 0.5 [10.7] kg, $P = 0.03$; mean [SD] change in BMI = −1.5 [2.8] vs 0.0 [3.8] kg/m^2, $P = 0.03$).

For the diabetic (with or without obesity) subgroup, the median (IQR) time from initial to final weight assessment was 24.50 (17.75) months and was 27.50 (22.50) months for HbA1c. A decrease over time was seen for weight, BMI and HbA1c (Table 2), which was significant for weight and BMI ($P = 0.001$) but not HbA1c ($P = 0.07$).

For the obesity-only subgroup, the median (IQR) time from initial to final weight assessment was 22.00 (18.50) months. A slight increase in weight and BMI was seen over time (Table 2), neither of which were significant ($P = 0.77$ and 0.94, respectively).

The median (IQR) total number of visits to a dietitian and/or diabetic educator for the entire sample was 4.00 (4.00), spread over 16.00 (22.00) months (Table 2). Approximately one-third of participants refused at least one intervention.

As summarised in Table 3, the presence of schizophrenia significantly affected some clinical outcomes, with worse outcomes (i.e. lower reduction in weight and BMI) seen for those with schizophrenia compared to those without for the entire sample and diabetic (with or without obesity) subgroup (all $P \leq 0.017$). Refusal of intervention(s) from the dietitian and/or diabetes educator had a significant negative impact on weight change for the entire sample ($P = 0.048$) and Hb1Ac levels for the diabetic (with or without obesity) subgroup ($P = 0.025$). A higher total number of visits to a dietitian and/or diabetes educator was associated with a significantly greater reduction in weight and BMI for the entire sample ($P = 0.021$ and 0.024, respectively).

Table 1 Baseline characteristics of participants

Characteristic	*Overall sample (n = 91)*	*Type 2 diabetes +/- obesity (n = 47)*	*Obesity only (n = 44)*
Gender, n (%)			
Males	51 (56.0)	26 (55.3)	25 (56.8)
Females	40 (44.0)	21 (44.7)	19 (43.2)
Age (years), mean (SD)	54.3 (10.0)	56.6 (10.1)	51.8 (9.4)
Past medical history, n (%)			
Hypertension	27 (29.7)	17 (36.2)	10 (22.7)
Cardiovascular disease	14 (15.4)	10 (21.3)	4 (9.1)
Lipid disorder	29 (31.9)	23 (48.9)	6 (13.6)
Respiratory disease	24 (26.4)	11 (23.4)	13 (29.5)
Renal disease	4 (4.4)	4 (8.5)	0 (0.0)
Other physical	62 (68.1)	31 (66.0)	31 (70.5)
Schizophrenia	56 (61.5)	30 (63.8)	26 (59.1)
Intellectual disability	44 (48.4)	23 (48.9)	21 (47.7)
Other psychological	45 (49.5)	22 (46.8)	23 (52.3)

n, number; SD, standard deviation.

Table 2 Clinical and interventional outcomes

Outcomes	*Overall sample* (*n = 91*)	*Type 2 diabetes +/- obesity* (*n = 47*)	*Obesity only* (*n = 44*)
Clinical outcomes			
Weight (kg), mean (SD)			
Initial	105.6 (22.5)	101.5 (20.7)	110.1 (23.8)
Final	104.0 (23.1)[(b)]	97.8 (20.6)[(b)*]	110.5 (24.0)
BMI (kg/m^2), mean (SD)			
Initial	37.5 (8.7)	35.8 (8.1)	39.3 (9.0)
Final	36.8 (8.3)[(b)*]	34.4 (7.8)[(b)*]	39.3 (8.2)
HbA1c, %, mean (SD)			
Initial	N/A	7.1 (1.3)[(b)]	N/A
Final	N/A	6.6 (1.3)[(c)]	N/A
Interventional outcomes			
Visits, median (IQR)			
Total number	4.00 (4.00)	5.00 (5.00)	3.00 (2.75)
With dietitian	4.00 (4.00)	4.00 (5.00)	3.00 (2.75)
With diabetes educator	1.00 (2.00)	1.00 (2.00)	N/A
Duration (months)	16.00 (22.00)	19.00 (21.00)	15.50 (21.25)
Intensity[(a)(a)]	3.27 (3.33)	3.00 (2.73)	3.96 (3.29)
Refused interventions, n (%)	25 (27.5)	11 (23.4)	14 (31.8)

[(a)] Intensity = duration of visits divided by total number of visits.
[(b)] Data missing from 1 participant.
[(c)] Data missing from 5 participants.
*$P < 0.05$ (paired t tests comparing initial to final data).
BMI, body mass index; HbA1c, glycosylated haemoglobin; IQR, interquartile range; kg, kilograms; m, metres; n, number; N/A, not applicable; SD, standard deviation.

Discussion

This study evaluated the effectiveness of dietetic and educational interventions provided to two high-volume groups, namely type 2 diabetes (with or without obesity) or obesity-only, for clients living in an SRF and characterised by mental impairment, a particularly vulnerable group. Clients with type 2 diabetes (with or without obesity) had significantly better clinical outcomes than those with obesity-only, with significant reductions seen in weight and BMI and a reduction in HbA1c. The absence of a diagnosis of schizophrenia, fewer refused interventions, and a greater number of visits were associated with better clinical outcomes.

The outcomes for our diabetic (with or without obesity) subgroup compare favourably with previous research. For example, our sample demonstrated a mean change in HbA1c levels (%) of -0.5, compared to -0.26 (dietitian only) and -0.32 (dietitian and diabetes educator) reported by Wilson *et al.*[22] in a retrospective audit of 7490 American Indians with type 2 diabetes. Reasons for our favourable findings include that our measurement interval was considerably longer (median 27.50 months vs ~ 132 days) and that our sample had better glycaemic control at initial assessment (mean HbA1c 7.1 vs 8.0%) than that of Wilson *et al.*[22] Our results were also favourable compared to those of Cusack *et al.*[19] who, in a retrospective audit of 64 patients with type 2 diabetes attending a rural dietetic practice, found no significant change in BMI or HbA1c (clinic attendance time = median 32.5 months), whereas we found a significant decrease in BMI (over a median of 24.50 months). The reasons for this difference in results between the two studies are not clear. Stoneman *et al.* retrospectively audited 348 Aboriginal and Torres Strait Islander patients with type 2 diabetes, finding that 26% met their target HbA1c levels of ≤ 7%.[20] For our 47 clients with diabetes, considerably more achieved this target at the initial (n = 29 [61.7%]) and final measurement (n = 31, 66.0%]) times, most likely reflecting that our client sample did not comprise Aboriginal and Torres Strait Islanders. Using a target HbA1c level of ≤ 6%, our results change to 10 (21.3%) initially and 18 (38.3%) at the final measurement, more clearly illustrating the improved outcomes for this subgroup. In keeping with Cusack *et al.*,[19] we found that older participants had better outcomes than younger participants, although this did not achieve significance in our study. The association we demonstrated between better outcomes and the total number/intensity of visits, which was significant for some measures, supports the results of Cusack *et al.*,[19] who found a greater reduction in HbA1c in those attending clinics more frequently. Our finding of an association between the presence of schizophrenia and worse clinical outcomes most likely reflects the adverse effects of antipsychotic medication (e.g. weight gain, higher glucose and lipid levels, higher blood pressure), genetic vulnerabilities, psychosocial and socioeconomic risk factors and an unhealthy lifestyle.[15,17]

Table 3 Comparison of clinical outcomes according to descriptive and interventional variables

Variables	*Overall sample (n = 91)*[a]		*Type 2 diabetes +/- obesity (n = 47)*[a],[b]		*Obesity only (n = 44)*	
Variables based on categorical data	Yes	No	Yes	No	Yes	No
Intellectual disability	n = 44	n = 46	n = 23	n = 23	n = 21	n = 23
Change in weight (kg)	−0.7 (9.4)	−2.9 (9.7)	−4.2 (8.0)	−3.7 (7.8)	3.2 (9.5)	−2.0 (11.4)
Change in BMI (kg/m^2)	−0.5 (3.4)	−1.0 (3.5)	−1.7 (3.1)	−1.3 (2.5)	0.9 (3.1)	−0.7 (4.2)
Change in HbA1c	N/A	N/A	−0.3 (2.0)	−1.3 (2.3)	N/A	N/A
Schizophrenia	n = 55	n = 35	n = 29	n = 17	n = 26	n = 18
Change in weight (kg)	0.3 (9.0)	−5.0 (9.7)*	−1.4 (6.5)	−8.4 (8.0)*	2.1 (10.9)	−1.8 (10.2)
Change in BMI (kg/m^2)	−0.1 (3.1)	−1.8 (3.6)*	−0.6 (2.3)	−3.1 (3.0)*	0.5 (3.9)	−0.6 (3.7)
Change in HbA1c	N/A	N/A	−0.6 (2.2)	−1.1 (2.2)	N/A	N/A
Other psychological problem	n = 45	n = 45	n = 22	n = 24	n = 23	n = 21
Change in weight (kg)	−1.6 (10.4)	−2.0 (8.7)	−4.1 (7.9)	−3.8 (7.9)	0.9 (11.9)	0.0 (9.4)
Change in BMI (kg/m^2)	−0.5 (3.6)	−1.0 (3.2)	−1.3 (2.7)	−1.6 (3.0)	0.3 (4.3)	−0.2 (3.3)
Change in HbA1c	N/A	N/A	−0.8 (1.8)	−0.8 (2.5)	N/A	N/A
Refused intervention(s)	n = 25	n = 65	n = 11	n = 35	n = 14	n = 30
Change in weight (kg)	1.4 (9.1)	−3.0 (9.5)*	−2.6 (6.6)	−4.4 (8.2)	4.5 (9.7)	−1.4 (10.8)
Change in BMI (kg/m^2)	0.3 (3.1)	−1.1 (3.5)	−1.1 (2.6)	−1.6 (2.9)	1.3 (3.1)	−0.5 (4.0)
Change in HbA1c	N/A	N/A	0.6 (1.6)	−1.2 (2.2)*	N/A	N/A
Variables based on median values						
Age (years)	Younger (<54) n = 45	Older (≥54) n = 45	Younger (<55) n = 23	Older (≥55) n = 23	Younger (<53) n = 20	Older (≥53) n = 24
Change in weight (kg)	−0.5 (10.3)	−3.1 (8.6)	−2.7 (9.3)	−5.2 (5.9)	2.8 (11.0)	−1.5 (10.3)
Change in BMI (kg/m^2)	−0.3 (3.5)	−1.2 (3.3)	−1.0 (3.3)	−2.0 (2.3)	0.8 (3.7)	−0.6 (3.9)
Change in HbA1c	N/A	N/A	−0.4 (2.3)	−1.1 (2.1)	N/A	N/A
Number of visits	Low (< 4.00) n = 36	High (≥ 4.00) n = 54	Low (< 5.00) n = 14	High (≥ 5.00) n = 32	Low (< 3.00) n = 17	High (≥ 3.00) n = 27
Change in weight (kg)	1.0 (7.2)	−3.7 (10.5)*	−3.8 (8.4)	−4.1 (7.7)	1.7 (7.8)	−0.3 (12.3)
Change in BMI (kg/m^2)	0.2 (2.7)	−1.4 (3.7)*	−1.4 (2.9)	−1.5 (2.8)	0.5 (2.9)	−0.2 (4.3)
Change in HbA1c	N/A	N/A	−0.8 (2.0)	−0.8 (2.3)	N/A	N/A
Intensity of visits	Low (< 3.27) n = 44	High (≥ 3.27) n = 46	Low (< 3.00) n = 22	High (≥ 3.00) n = 24	Low (< 3.96) n = 22	High (≥ 3.96) n = 22
Change in weight (kg)	−1.2 (7.3)	−2.4 (11.3)	−3.3 (5.7)	−4.6 (9.4)	1.0 (8.6)	−0.1 (12.6)
Change in BMI (kg/m^2)	−0.5 (2.6)	−1.0 (4.1)	−1.3 (2.0)	−1.7 (3.4)	0.3 (2.8)	−0.2 (4.6)
Change in HbA1c	N/A	N/A	−1.1 (2.7)	−0.5 (1.6)	N/A	N/A

[a] Change in weight and BMI data missing from 1 participant.
[b] Change in HbA1c data missing from 3 participants.
* Represents data that were significantly different ($P < 0.05$), using independent samples t-tests, comparing yes versus no or < median versus ≥ median values.
BMI, body mass index; HbA1c, glycosylated haemoglobin; IQR, interquartile range; kg, kilograms; m, metres; n, number; N/A, not applicable; SD, standard deviation.

For our obesity-only subgroup, the increases in weight and BMI were small and not significant. It is possible, but cannot be proven, that their rate of weight gain may have reduced with our interventions, which could arguably be seen as an acceptable outcome for this client group. It is also possible that additional measurements at an earlier stage (e.g. at 12 months rather than 22 months) may have detected changes in weight. In contrast to our findings, Daumit *et al.*, in a randomised controlled trial involving 291 overweight or obese adults recruited from community psychiatric rehabilitation outpatient programs, found that their interventions significantly reduced weight.[18] This difference in results may reflect the far greater number of visits (median of 3 visits over 15 months [our data] vs 77 visits over 18 months) and inclusion of group exercise sessions by Daumit *et al.*[18] Given the poorer outcomes for our obesity-only subgroup compared to the subgroup with type 2 diabetes (with or without obesity), consideration will be given to adding group weight-management and exercise sessions to the services provided to these clients. Additionally, unlike our clients with diabetes (with or without obesity) who receive ongoing monitoring of their food intake by SRF staff and carers, the level of monitoring to improve compliance with nutritional advice is comparatively low for those clients with obesity only. Therefore, in light of our findings, increased levels of monitoring of food intake by SRF staff and carers will be encouraged for those clients with obesity only.

The main limitation of our study was its retrospective nature and relatively small and single-site sample. Whilst

we found improvements in some clinical outcomes after dietetic and educational interventions, causality cannot be assumed. A prospective randomised controlled trial would have enabled cause and effect to be more clearly investigated, although the ethics of a randomised controlled trial would be questionable in such a vulnerable population. Other limitations were our focus on a few clinical outcomes rather than non-clinical outcomes (e.g. nutritional knowledge, changes in dietary intake), non-standardised and relatively infrequent measurement times and the low number and intensity of interventions for some clients, which was below recommended guidelines.[9]

Despite these limitations, the current study provides evidence of the effectiveness of the dietetic and educational interventions provided by the SRF HAT to clients with type 2 diabetes (with or without obesity) or obesity-only, particularly the former. We believe that these findings are particularly noteworthy given the complex nature of this vulnerable client group, with their preponderance of mental illness or intellectual disability and where health-care addressing physical needs is often compromised. This evidence will be used to support ongoing funding for our services to SRFs.

In conclusion, interventions provided by a dietitian or diabetes educator significantly decreased the weight and BMI and improved glycaemic control of participants with type 2 diabetes (with or without obesity) living in SRFs characterised by mental illness or intellectual disability. The absence of schizophrenia, fewer refused interventions, and a greater total number of visits to a dietitian or diabetes educator were associated with improved clinical outcomes. These results provide evidence to support the effectiveness of interventions provided by dietitians or diabetes educators in a primary health-care setting for a vulnerable client group.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

KH and KS have contributed to all phases of this study and are in agreement with the content of the manuscript. This manuscript has not been published or submitted for publication elsewhere.

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ORIGINAL RESEARCH

Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus

Kate ODGERS-JEWELL,[1] Elisabeth ISENRING,[1] Rae THOMAS[1,2] and Dianne P. REIDLINGER[1]

[1]Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Queensland, Australia, and [2]Centre for Research in Evidence-Based Practice (CREBP), Bond University, Gold Coast, Queensland, Australia

Abstract

Aim: The present study developed and evaluated a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus.

Methods: Two frameworks, the Medical Research Council (MRC) framework for developing and evaluating complex interventions and the RE-AIM framework were followed. Data to develop the intervention were sourced from scoping of the literature and formative evaluation. Program evaluation comprised analysis of primary recruitment of participants through general practitioners, baseline and end-point measures of anthropometry, four validated questionnaires, contemporaneous facilitator notes and telephone interviews with participants.

Results: A total of 16 participants enrolled in the intervention. Post-intervention results were obtained from 13 participants, with an estimated mean change from baseline in weight of −0.72 kg (95%CI −1.44 to −0.01), body mass index of −0.25 kg/m^2 (95%CI −0.49 to −0.01) and waist circumference of −1.04 cm (95%CI −4.52 to 2.44). The group education program was acceptable to participants. The results suggest that recruitment through general practitioners is ineffective, and alternative recruitment strategies are required.

Conclusions: This patient-centred, patient-directed, group-based intervention for the management of type 2 diabetes mellitus was both feasible and acceptable to patients. Health professionals should consider the combined use of the MRC and RE-AIM frameworks in the development of interventions to ensure a rigorous design process and to enable the evaluation of all phases of the intervention, which will facilitate translation to other settings. Further research with a larger sample trialling additional recruitment strategies, evaluating further measures of effectiveness and utilising lengthier follow-up periods is required.

Key words: chronic disease management, feasibility study, MRC framework, process evaluation, RE-AIM, type 2 diabetes.

Introduction

Diabetes is the fastest growing disease nationally and internationally, with one Australian being diagnosed every eight minutes.[1] Each year, approximately one million Australians are diagnosed with diabetes, 85% with type 2 diabetes mellitus (T2DM).[2] Patient education, the cornerstone of chronic disease self-management, is essential in achieving improved outcomes and has been acknowledged as an integral and vital component of successful T2DM care.[3–6] The main goal of diabetes patient education is to promote and support positive self-management behaviours in order to optimise metabolic control, improve quality of life (QOL), prevent acute and chronic complications and reduce morbidity and mortality.[6,7]

Group-based education for patients with T2DM has the potential to be a more cost-effective and efficient intervention than individual education because of the reduced time and funding required to educate numerous patients in one session.[5,8] Group-based education allows time for the provision of more detailed information, decreases time demands on health workers, allows the easy incorporation of families and carers and facilitates patient discussions and support from others in a similar situation.[9,10] Research assessing the effectiveness of group-based education compared with usual care for the management of T2DM has found that the benefits in patient outcomes include significant improvements in glycaemic control, fasting blood glucose, diabetes knowledge, self-management skills,

K. Odgers-Jewell, MND (Hons), APD, PhD Candidate
E. Isenring, PhD, AdvAPD, Professor
R. Thomas, PhD, Senior Research Fellow
D.P. Reidlinger, PhD, APD, RD (UK), Assistant Professor
Correspondence: K. Odgers-Jewell, Bond Institute of Health and Sport (BIHS), 2 Promethean Way, Robina, QLD 4226, Australia.
Email: kodgersj@bond.edu.au

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self-efficacy and treatment satisfaction, as well as significant reductions in body weight, systolic blood pressure and the need for diabetes medication.[10,11]

Despite the evidence supporting group-based education for the management of T2DM, it is surprisingly difficult to define the ideal content and process by which effective group-based education should be delivered.[12] Group-based education programs can be structured or unstructured, depending on the level of prescription in the content covered and the delivery. Structured programs contain lesson plans with clearly defined content, which can allow programs to be replicated by multiple group facilitators; however, they are more likely than unstructured programs to utilise a didactic facilitation style, reducing the time for patient interactions and discussion.[13] Unstructured or patient-directed programs utilise a non-didactic facilitation style and can allow participants to explore their own agenda, interests and needs rather than content that may not interest or assist them in improving their self-management skills or knowledge.[14]

Within Australia, dietitians in particular overwhelmingly favour the provision of individual patient education services over group-based education. The utilisation of group services for T2DM management provided by dietitians has continued to decrease in recent years, whilst individual dietetic services have consistently increased.[15] Previous research has proposed that service system issues, workforce capacity, awareness among practitioners and practitioner attitudes and preferences are the main factors impeding the utilisation of group-based education by Australian dietitians.[16] A recent study exploring group facilitators' perceptions and experiences of group-based chronic disease management (CDM) programs found that interventions were being delivered with limited quality control and that facilitators had inadequate knowledge of the evidence base underpinning the programs they were facilitating.[13] An additional surprising finding from the present study was that the outcome measures being utilised by facilitators in practice were minimal, with many only collecting an overview of patient satisfaction through surveys, which, as a solitary measure, is inadequate in assessing patient outcomes or improving the quality of future programs.[13]

The development of a group-based intervention informed by the literature and formative research, followed by feasibility testing and a rigorous process evaluation, may result in an intervention that can be easily translated into practice by health professionals interested in delivering group-based education programs and unsure where to start. Additionally, the dissemination of findings from feasibility studies could contribute to health practitioners' knowledge by furthering an understanding of the methodological and practical challenges of developing and implementing intervention studies in a 'real-world' setting and may highlight outcome measures that are suitable for the evaluation of intervention effectiveness.[17]

The aim of the present study was to develop and evaluate a patient-centred, patient-directed, group-based education program for the management of T2DM using two process evaluation frameworks, the Medical Research Council (MRC) framework for developing and evaluating complex interventions and the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework.

Methods

The development and process evaluation of the intervention using the two frameworks occurred over a number of phases (Figure 1). In brief, this involved a formative evaluation, including a scoping of the literature, interviews with facilitators and participants of existing CDM group programs; recruitment and initial assessment of participants; and baseline outcome measurements, the facilitation of the intervention, follow-up outcome measurements and the completion of telephone interviews with participants to assess the acceptability of the intervention.

The MRC framework for developing and evaluating complex interventions (2008) was used to guide the intervention development and evaluation.[18] The framework incorporates four phases: development, feasibility and piloting, evaluation and implementation, which aim to help researchers recognise and adopt appropriate measures for the design and evaluation of complex health behaviour change interventions.[18] The RE-AIM framework is an evaluation framework that includes multiple process indicators to evaluate various aspects of an intervention: reach, effectiveness, adoption, implementation and maintenance.[19,20] The RE-AIM framework not only evaluates the effectiveness or strengths of an intervention but also the program's translatability, feasibility and limitations, which can potentially be improved upon in future research.[21] Combining both the MRC and RE-AIM frameworks in the process evaluation of the intervention ensures a thorough and rigorous evaluation of all aspects of the program, including development, and enables the identification of strengths and limitations.

To develop the intervention, data were collected from three sources: a preliminary literature review and scoping of group-based interventions for T2DM management, a formative evaluation based on interviews with facilitators of a range of existing CDM group education programs and their participants and a review of the Medicare group services information pack, which is evidence-based, available to Australian health professionals and is likely to influence the development of group-based education programs in practice.[22] Triangulation was achieved by comparing the attributes of effective group-based education interventions with the results obtained from the group facilitator and group participant interviews and the information provided in the Medicare group services information pack.[22] Triangulation is commonly utilised in health service research as an evaluation method as it enables the integration of methods and approaches to conduct better evaluation studies.[23]

The intervention design, resulting from the systematic development process, was a patient-centred, patient-directed, group-based education program. The program content employed a non-didactic approach; group discussions were encouraged; and the content covered in the group

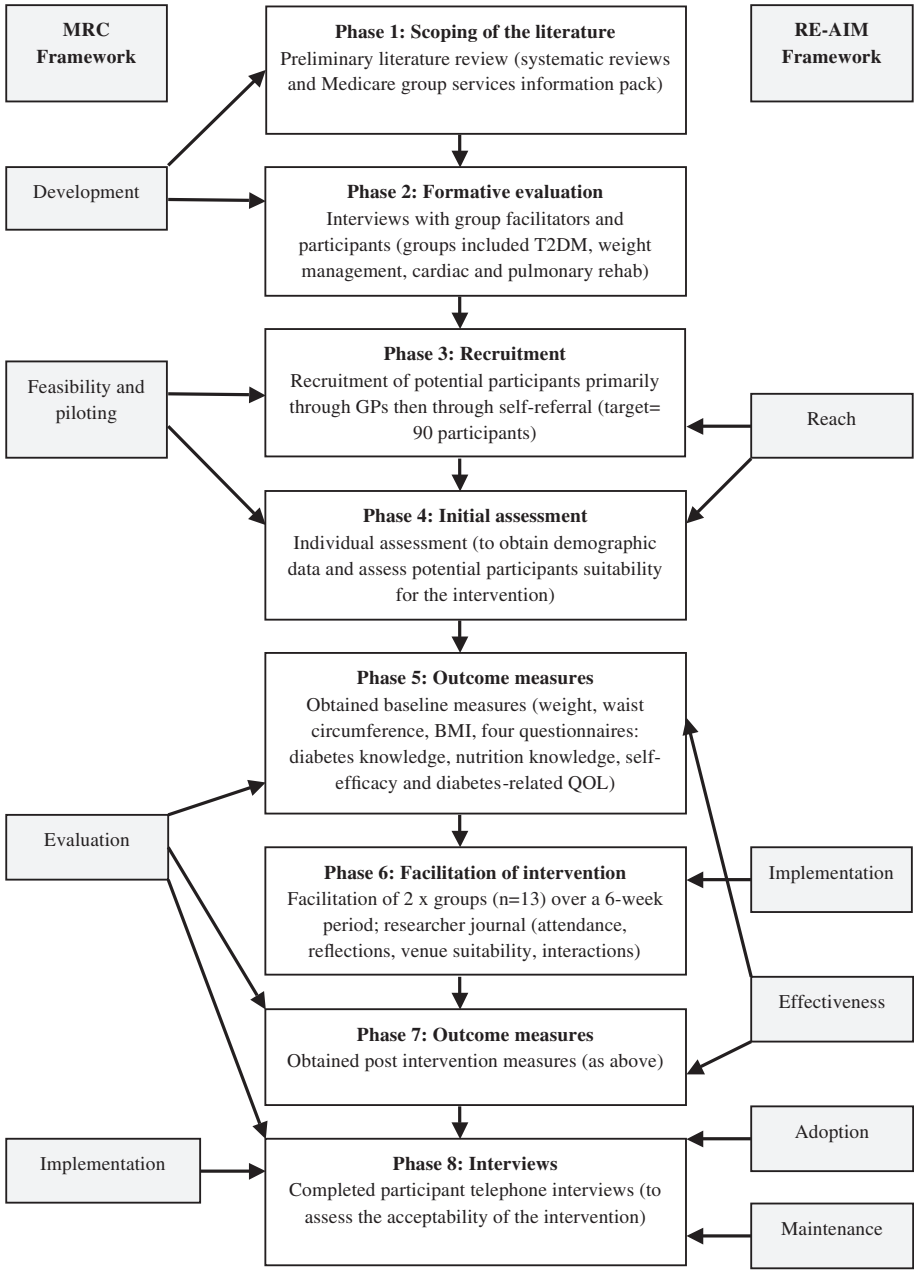

Figure 1 Phases involved in the diabetes group program development and evaluation. BMI, body mass index; GP, general practitioner; MRC, Medical Research Council; QOL, quality of life.

education sessions was decided by group participants in the first session. The intervention is described using the template for intervention description and replication (TIDieR) checklist and guide (Appendix SI, Supporting Information).[24]

A recruitment target of 90 participants for the single-arm feasibility study was set. The sample size, although not necessary for a feasibility study, was determined from a practice perspective. The sample size of 90 participants was originally calculated for a two-armed study, in which each intervention group would be composed of 45 participants, allowing for at least 20% attrition, resulting in three groups of 12 participants (per intervention group). General practitioner (GP) referrals were chosen as the primary recruitment strategy for the feasibility study, based on literature suggesting they are the 'gatekeepers' of primary care and the initial point of contact for patients who require primary or non-emergency health care.[25] Invitation letters were mailed to all medical centres (n = 132) within a 50-km radius of the intervention site, and each medical centre was followed-up by telephone within two weeks of postage.

Participants were included if they self-reported a diagnosis of T2DM or were referred by their GP as a diagnosed T2DM patient, were 18 years of age or over, had adequate

cognitive ability and had a sufficient understanding of English. Ethical approval was obtained from the Bond University Human Research Ethics Committee (protocol number RO1815), and written informed consent was obtained from each participant prior to the commencement of the intervention, which was provided free of charge.

An Accredited Practising Dietitian (KOJ) conducted all of the initial consultations and intervention sessions. Participants attended an initial individual consultation to assess whether they met the inclusion criteria and to obtain demographic and baseline data. Group-based education sessions were conducted at a local community centre to ensure easy access for group participants. The participants were allocated to one of two groups; both groups were facilitated using the same approach. Group allocation depended on participant availability, and participant numbers were fewer than 12 per group to align with the Medicare CDM group service item guidelines. Groups were facilitated on a weekday morning for two hours for a six-week period.

The group intervention was evaluated using process and participant measures, including questionnaires and anthropometric data to assess the feasibility of the intervention and semi-structured interviews with group participants to assess the acceptability of the intervention. Additionally, the group facilitator (KOJ) kept a researcher journal throughout the intervention to record reflections and logistics, such as participant attendance, suitability of the venue and peer interactions.

Baseline (two to three weeks prior to commencing the intervention) and end-point data (taken during the final group session of the program) included weight, waist circumference and height measurements and four validated questionnaires assessing nutrition knowledge,[26] diabetes self-efficacy,[27] diabetes knowledge[28] and diabetes-related QOL.[29] Only the first two sections (related to dietary recommendations and nutrient sources) from the nutrition knowledge questionnaire[26] were administered because of the relevance and length of the questionnaire.

Data were assessed for normality and analysed, where appropriate, using the statistical package SPSS (Statistical package for the social sciences, version 23.0). Prior to analysis, each dataset was assessed for normality. Normally distributed data was analysed using paired sample *t*-tests to assess differences in the baseline and end-point measures of the group participants for the five normally distributed measures. Wilcoxon-signed rank tests were performed on two measures that were not normally distributed.

The adoption, implementation and acceptability of the intervention were measured by the number of face-to-face sessions attended and by individual telephone interviews conducted by an independent research assistant following the completion of the group-based intervention. The interview questions were developed from earlier research (Odgers-Jewell *et al*. 2016).[13] The interviews were audio-recorded, transcribed, checked, anonymised and corrected against the audio files by the first author (KOJ). Content was extracted from the interview transcripts by the first author and confirmed with the senior author (DPR) in order to answer the predefined set of questions, which explored the acceptability of the intervention. Responses to the demographic questions were categorised and enumerated.

Results

Three sources were used to develop the intervention. The literature review indicated that patient-centred group education with the following attributes were favoured: patient involvement in the design, planning, goal setting and decision-making process; regular reinforcement after education; individualised content; and non-didactic facilitation by an individual or multidisciplinary team or peer leaders.[10,11] These were combined with information provided to allied health professionals in the Medicare group services information pack, including the need for programs to be patient-centred, facilitated by a multidisciplinary team, developed according to a plan with achievable and measurable goals and objectives; to incorporate group rules; and to allocate time for patients to discuss their experiences.[22] Finally, formative interviews with group facilitators and participants from existing CDM group education programs indicated a preference for a strong focus on group interactions by providing patients with a non-didactic, interactive, discussion-based program; the importance of group rules set at the commencement of the group-based education sessions; and goal-oriented and patient-centred content.

After triangulating these data, the elements used in the development of the final intervention included a non-didactic, patient-centred approach, the incorporation of group rules and adequate time for group discussions. There was a lack of consensus on the materials or educational content ideally provided to patients in a group-based education setting, suggesting that more emphasis should be placed on encouraging group interactions rather than a sole focus on the content of sessions. There was divergence in the appropriate length and number of sessions; however, two-hour sessions were chosen as the literature review and formative interviews indicated that this was an appropriate amount of time to allow group participants to have in-depth discussions. Additionally, it was decided that the sessions would run for six weeks, again to align with the findings of the literature review and formative interviews and to ensure that the time commitment from patients was not unreasonable.

Recruitment targets through GPs were not met; only two out of 132 (1.5%) medical centres responded to multiple requests to display recruitment flyers in waiting rooms or consultation rooms. As a result of this low response rate, alternative strategies were used, including advertisements and stories in two local newspapers, recruitment flyers in six local pharmacies and an advertisement on the University website. Group participants were all recruited through feature stories in a free local newspaper.

An accurate estimation of the reach of the recruitment strategy was not possible; however, it is estimated that the number of persons diagnosed with T2DM within the

50-km recruitment radius would be approximately 950 persons.[30] A total of 33 (approximately 3.5% of the estimated area population with T2DM) potential participants made initial contact with the researcher, of which a total of 16 participants enrolled in the study. Three did not complete the intervention (Figure 2).

Demographics of the 13 group participants who attended the program and completed the telephone interviews are

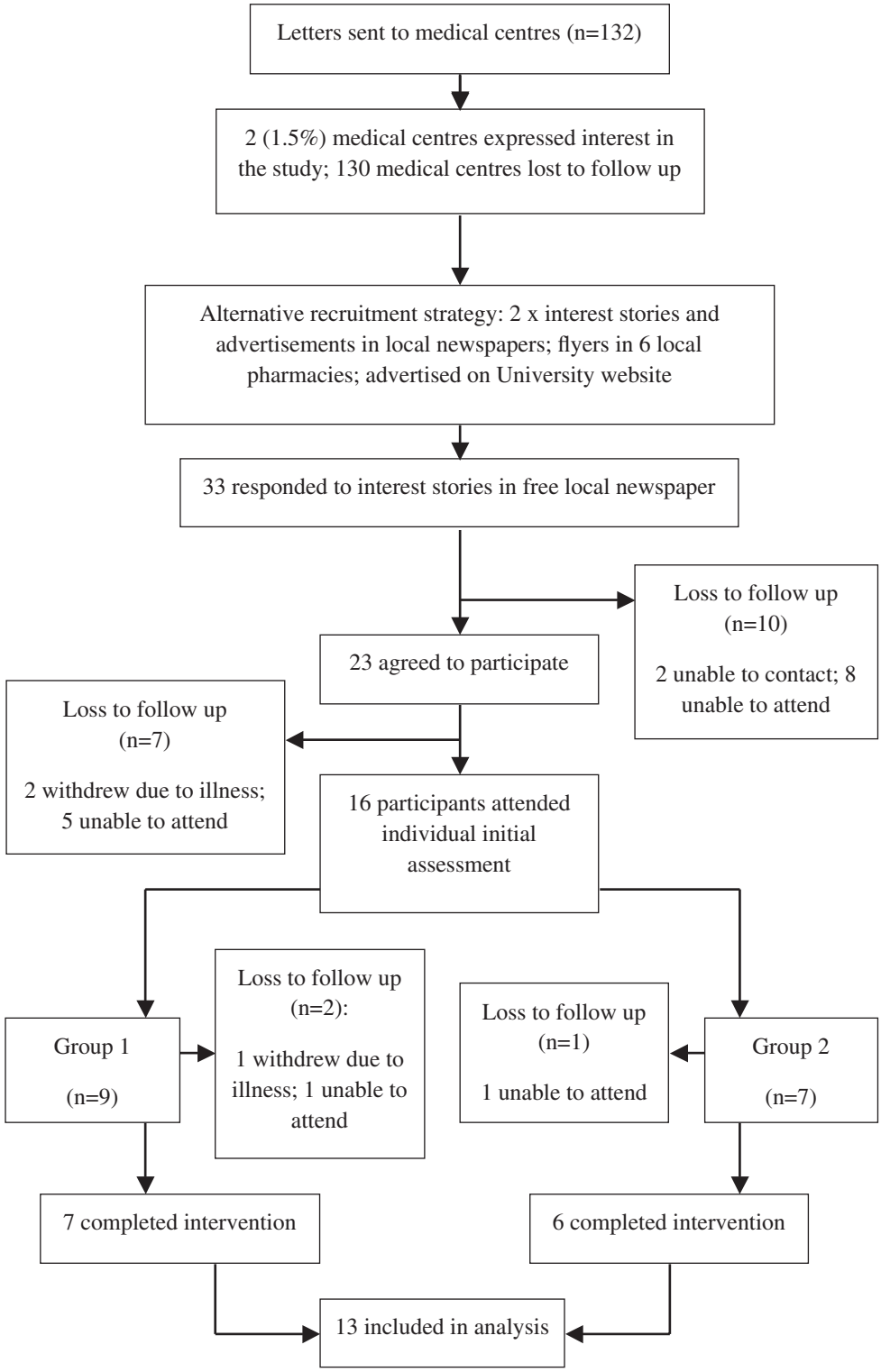

Figure 2 Flowchart of participants for the feasibility study.

Table 1 Group participant sample attributes summary (n = 13)

Attribute	*N*
Gender	
Male	7
Female	6
Age (years)	
55–64	3
65–74	5
≥75	5
Marital status	
Married	8
Divorced	2
Separated	1
Widowed	2
Education	
Primary	1
Secondary	6
Tertiary	6
Employment	
Casual	1
Self-employed	1
Retired	11
Years since diagnosis (years)	
<1	2
1–3	2
4–6	4
7–9	2
≥10	3
Previous group attendance	11

presented in Table 1. The intervention participants were predominantly Australian; however, some participants were born in Europe (United Kingdom, Croatia, France, Poland and Germany).

The results of the four questionnaires and anthropometric measures are shown in Table 2. The results suggest reductions in body weight, body mass index (BMI), waist circumference and increased diabetes knowledge, nutrition knowledge, diabetes self-efficacy and diabetes-related QOL. However, despite two of these outcomes reaching statistical significance, the small sample size of the study was not sufficiently powered to reliably detect significant statistical differences. The key results of the process evaluation of the intervention study are summarised in Table 3.

Telephone interviews were used to explore the acceptability of the program, participants' preferences for group program structure and facilitation and their perceptions of the effect of group interactions. The group-based intervention was acceptable, with all group participants stating that they would recommend the program to friends or family as they found it informative, indicated they enjoyed speaking with other people who had been diagnosed with T2DM and found the information provided interesting. Participants noted that the aspects they liked most were group interactions, the facilitators' relaxed attitude and the length of the group program. A few participants stated a preference for sessions where they perceived that discussions remained on the agreed topic. Participants frequently reported that other group members helped their learning through peer identification and from others' experiences. Participants from both groups exchanged contact details at the completion of the intervention with the intention to maintain contact beyond the program.

Discussion

The present study reports on the process evaluation of a single-arm patient-centred, patient-directed, group-based education program, and this paper has described its development, feasibility testing and evaluation. Two frameworks were used to capture each phase of the development and evaluation. The triangulation of data from three sources resulted in the development of a non-didactic, patient-centred intervention, which was delivered to participants weekly for a six-week period. The results of the evaluation suggest that the intervention was feasible and acceptable to the target group. However, the recruitment strategy was inadequate and resulted in an insufficient reach of the target population. As such, the maintenance phase of the RE-AIM framework, or the equivalent implementation phase of the MRC framework for developing and evaluating complex interventions, could not be explored.

Table 2 Change in anthropometry and questionnaire outcomes (n = 13)

	Pre-intervention; mean (SD)	*Post-intervention; mean (SD)*
Paired *t*-tests		
Body weight (kg)	87.1 (14.88)	86.4 (14.52)[a]
BMI (kg/m^2)	30.5 (5.3)	30.3 (5.22)[a]
Waist circumference (cm)	108.7 (16.29)	107.7 (17.44)
Diabetes Knowledge[b]	13.38 (4.13)	13.92 (4.19)
Diabetes-related QOL[b]	121.5 (47.42)	112.08 (46.63)
Wilcoxon-signed rank tests		
Nutrition Knowledge[b]	44.77 (11.56)	47.54 (7.83)
Diabetes Self-Efficacy[b]	60.6 (17.96)	67.15 (12.88)

[a] Post-intervention measures were assessed as significant ($P \leq 0.05$).
[b] Improved scores post-intervention, ns.
BMI, body mass index; QOL, quality of life.

Table 3 Summary table of evaluation results

MRC framework for complex interventions[16]	*Key findings*	*RE-AIM process evaluation framework*[17,18]
Development phase	Literature scoping Two systematic reviews[9,10]: recommendations were 5–16 participants per group; 8–52 hours of facilitator–patient contact time over 6–12 sessions Medicare group services information pack[20]: recommendations were 2–12 participants per group, minimum of eight × one-hour sessions (eight hours of facilitator–patient contact time), individual assessment prior to commencement Formative evaluation Facilitator and participant interviews: recommendations were 5–25 participants per group; 10–24 hours of contact time over four sessions	–
Feasibility and piloting	Recruitment of participants Thirty-three potential participants made initial contact with the researcher; a total of 16 participants enrolled (3 dropouts) in the study; 13 completed the study (14.4% of the initial target) Initial assessment 100% met the inclusion criteria, were suitable to participate and provided demographic data	Reach
Evaluation	Baseline measures—anthropometry Mean body weight (±SD) (kg): 87.1 (14.88); mean BMI (±SD) (kg/m2): 30.5 (5.3); mean waist circumference (±SD) (cm): 108.7 (16.29)	Effectiveness
–	Delivery of intervention Participants from both groups attended 4–6 (67–100% attendance) sessions; those who missed sessions were unable to attend because of other medical appointments, illness or travel plans	Implementation
Evaluation	Follow-up measures—anthropometry Mean body weight (±SD) (kg): 86.4 (14.52); mean BMI (±SD) (kg/m^2): 30.3 (5.23); mean waist circumference (±SD) (cm): 107.7 (17.44)	Effectiveness
Implementation[(a)]	Interviews Program structure: Aspects liked most: group interactions and facilitator's relaxed attitude Aspects liked least: discussions can go off topic Recommended changes: program could have gone for longer Ideal program length: six weeks, for two hours per week (as delivered) Group interactions: Helped/hindered learning: helped; peer identification and learning from others' experiences Role of group facilitator: facilitating the group; explaining points Patient satisfaction: Recommend program: yes	Adoption

[(a)] The implementation phase of the MRC framework refers to aspects of maintenance more aligned with the adoption and maintenance phases of the RE-AIM framework.
BMI, body mass index; MRC, Medical Research Council.

Group education research has established the ineffectiveness of didactic education techniques when compared to non-didactic patient education.[11,31] Evidence supports the use of a patient-centred approach, care that is respectful of—and responsive to—individual patient preferences, needs and values, and has shown that engaging patients in their health-care decisions can enhance their adherence to therapy.[32] Within T2DM, patient-centred interventions have been effective in improving patient knowledge, blood glucose levels, weight and medication usage and have been shown to improve self-management behaviours.[17] A patient-directed approach, in which the content of the group education program is decided by the patients, reflects patients' own needs and questions and includes discussions initiated by patients, has been successfully utilised by various group-based education studies for the management of T2DM.[33,34] Allowing patients to direct their own learning through negotiated topics proposed by group members may support self-management.

A key finding and limitation of this feasibility study was the ineffectiveness of recruiting people with T2DM through GPs. The overall poor recruitment rate may have been because of the use of GPs as a primary strategy and the generally low uptake of group education programs by T2DM

patients. Despite their principal role in the management of T2DM patients in the primary health-care setting, engaging GPs and recruiting participants through GPs was difficult. Barriers to recruitment through GPs have previously included time and workload pressures,[35,36] negative attitudes towards research, concerns about researchers' motives, a lack of interest in the topic of research and a lack of recognition.[37] Monetary and non-monetary incentives, endorsement by relevant authorities and multiple reminder contacts with clinicians may have boosted research response rates.[38] In addition, clinicians may have felt overwhelmed with requests for research participation, desired a greater involvement in the study or been concerned about the potential lack of effectiveness of a new trial that would not be an ongoing addition to the health-care system.[39]

The generally poor uptake of group-based programs for the management of T2DM may have also contributed to the reduced recruitment.[30,40–42] A recent study found that the three main reasons for non-attendance of group programs, as reported by T2DM patients, were the lack of information or perceived benefit of the programs, unmet personal preferences such as poor timing or accessibility of group locations and the shame and stigma of diabetes.[43] Practitioners should consider how health professionals in primary care communicate with their T2DM patients with regards to group education programs, the optimal timing and location of group programs and focus on recruitment methods that minimise any health-related stigma around T2DM.[43]

The evaluation found modest improvements in body weight, BMI and waist circumference as well as the QOL domains, nutrition knowledge, diabetes knowledge and self-efficacy measures. Despite the improvements in these measures, the results should not be overstated because of the small sample size, short follow-up period and natural fluctuations in weight, BMI and waist circumference, which may have occurred over the same time period. Feasibility study results should, in general, be interpreted cautiously as effects may be smaller or more variable when a full-scale study is conducted.[18] The effectiveness of feasibility studies should primarily be measured using descriptive statistics, qualitative analysis and basic process evaluation data such as administrative data.[44]

The participant evaluation component of this feasibility study, through interviews with each participant, provided insightful and valuable data from which various conclusions can be drawn. These included satisfaction with the intervention, willingness of patients to recommend the intervention and the positive evaluations of group interactions. Patient satisfaction has been shown to be clinically relevant, with satisfied patients being more likely to comply with treatment and to self-manage their condition.[45] The majority of group participants found other group members added to their learning, generally through peer identification and learning from others' experiences. Providing social support to patients with T2DM has been shown to extensively affect patient behaviour.[46] In particular, group interactions and peer identification may promote self-efficacy, self-esteem, self-perception, awareness and positive attitudes towards T2DM and reduce disease-related anxiety.[46,47] The group interactions and discussions encouraged in the present study are likely to have had a positive impact on the acceptability and effectiveness of the intervention.

Conducting a feasibility study, which trials components of a randomised controlled trial (RCT), as opposed to a pilot study, which trials the operation of all aspects of the developed RCT, allows researchers to assess the design, methodology and feasibility of a larger pilot study and to identify and prepare for the challenges of evaluating an intervention.[17,44] Intervention studies are commonly plagued with problems of acceptability, compliance, delivery of the intervention, recruitment and retention and smaller-than-expected effect sizes, which could have been predicted, and potentially avoided, through feasibility testing and piloting.[17] Testing the feasibility of an intervention prior to completing a pilot study additionally allows researchers to assess the acceptability of an intervention and enhances the scientific rigour of the larger study.[17]

There were a number of strengths of the study. The utilisation of two complementary development and process evaluation frameworks enabled a comprehensive evaluation of all aspects of the program and may provide a useful guide for the development of interventions in the future. The developed intervention reflects facilitator–patient contact time that is suitable for Australian health professionals planning to facilitate group-based education programs through the Medicare CDM group service rebates. The implementation of the intervention in a real-world setting enabled the researchers to explore the feasibility of the program in the context in which diabetes is usually managed. The inclusion of interviews to assess the acceptability of the intervention from the perspective of group participants, and the inclusion of participants from a range of backgrounds and with a range of years since diagnosis, ensured that participant evaluation was robust.

There were also several limitations. Recruitment utilising GPs as a primary recruitment strategy was unsuccessful; however, this resulted in key learnings, which may be applied when translating the program to practice. Recruitment to future interventions may be improved through the additional use of specialist clinics, such as diabetes outpatient clinics, which utilise electronic health records, enabling the identification and monitoring of participants,[30] involving participants in trial design,[48] using shorter and more informative recruitment flyers[49] and providing monetary incentives to participants.[50] The potential for sampling bias cannot be ruled out; the sample characteristics of the group participants were dissimilar to the characteristics of participants in the AusDiab study.[51]

This process evaluation indicated that a patient-centred, patient-directed, group-based intervention for the management of T2DM was both feasible and acceptable to patients. Additionally, a number of factors were identified as requiring refinement prior to the facilitation of a pilot study, particularly with regards to recruitment issues. Health professionals should consider the use of the RE-AIM and MRC frameworks in the development of group-based

interventions to ensure a thorough and complete design and the evaluation of all phases of the intervention. Furthermore, describing an intervention using the TIDieR checklist and guide can improve the completeness of intervention reporting and enable replicability.[24] Further research trialling additional recruitment strategies, evaluating further measures of effectiveness and utilising lengthier follow-up periods is required.

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Conflict of interest

The authors declare that there are no conflicts of interest with respect to the authorship and/or publication of this article.

Authorship

KOJ undertook this project as part of her Doctor of Philosophy and had a principal role in study design, data collection and analysis and wrote the manuscript. DPR assisted with the study design and data analysis. All four authors commented critically on the manuscript and approved it for submission. We thank Professor Roger Hughes and Dr Michael Leveritt for their early assistance in the study design process. We thank the participants who kindly volunteered their time and openly shared their experiences for the present study.

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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:

APPENDIX SI Intervention study design using the template for intervention description and replication checklist and guide

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ORIGINAL RESEARCH

Optimising the effectiveness of diabetes education in an East Asian population

T. S. T. CHOI, K. Z. WALKER, C. B. LOMBARD and C. PALERMO
Department of Nutrition and Dietetics, Monash University, Notting Hill, Victoria, Australia

Abstract
Aim: To explore the collective patterns of learning behaviours and preferences of Chinese people during diabetes education. The study was carried out across three countries and aimed to identify strategies that could be used to tailor diabetes education to Chinese people.
Methods: A case study approach was undertaken in three countries (Australia, China and Singapore) using participant observations and qualitative interviews. Purposive sampling was used to select field sites before a snowball technique was employed to identify relevant interviewees. Thematic analysis with pattern matching was used for data analysis.
Results: A total of 39 participant observations and 22 interviews were conducted. Chinese people with diabetes were observed seeking advice and recommendations from health professionals. When told clearly what to do, they strived for full compliance. They tended to be submissive during diabetes education and were not likely to raise concerns, negotiate or participate in making medical decisions. They appeared to prefer prescriptive concrete instructions rather than more flexible conceptual education and to believe that behavioural change should be achieved by individual willpower and determination, resulting in an 'all-or-nothing' approach. Regular repeated information sessions were reported to establish rapport and trust.
Conclusions: For diabetes education to be culturally modified for Chinese people, there is a need to consider their unique philosophies and behaviours during education to support lifestyle changes. Building trust from the early stages of education was achieved by encouraging rapport through the provision of clear and precise instructions. This should be done before engaging in an open discussion of implementation strategies. Once the trust is built, healthy behaviour change may follow.

Key words: education, migrant/refugee health, qualitative research, type 2 diabetes.

Introduction

A healthy diet and regular physical activity are the 'cornerstones of management' for people with type 2 diabetes.[1] Although diabetes education that focuses on facilitating a healthy lifestyle has the potential to optimise glycaemic control and reduce diabetes complications,[2] the translation of education programs into real-world health-care settings is often problematic.[3] This challenge becomes even more significant when working with diverse population groups as health professionals need to be aware of cultural differences and deliver a service that is sensitive to the specific group's cultural beliefs, behaviours and needs.[4]

T. S. T. Choi, BND (Hons), APD, PhD Candidate
K. Z. Walker, PhD, APD, Associate Professor
C. B. Lombard, PhD, APD, Associate Professor
C. Palermo, PhD, APD, Associate Professor
Correspondence: T.S.T. Choi, Department of Nutrition and Dietetics, Monash University, Level 1, 264 Ferntree Gully Road, Notting Hill VIC 3168, Australia. Tel.: (+61) 9902 4199.
Email: tammie.choi@monash.edu

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The burden of type 2 diabetes is disproportionally higher among Asian populations, with the Chinese being the world's largest and rapidly growing population with this disease.[5] Despite this, robust evidence on the most effective delivery of diabetes education to Chinese is still lacking. Current Chinese Guidelines for Type 2 Diabetes Care and Education[6] remain predominantly based on Western literature, and the transferability of this evidence to support behaviour change in Chinese people remains unknown. Despite efforts to incorporate 'cultural sensitivity' when tailoring interventions for non-Western communities,[7] translated diabetes education models based on Western participatory approaches have been found to be foreign, contributing to stress, frustration and even anger for the Chinese.[8] Furthermore, 'culturally modified' interventions may not increase effectiveness.[9] A change in approach is needed whereby diabetes education programs are designed that specifically address cultural philosophies and behaviours rather than rely on simply language-translating or 'culturally modifying' the Western diabetes education model.

The objective of this study was to explore the collective patterns of learning behaviours and preferences of Chinese

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people during diabetes education across three countries and identify cultural-specific tailoring strategies that appear successful in the diabetes education directed at Chinese people.

Methods

A case study approach[10] was employed using ethnographic data collection methods including participant observations and qualitative interviews. Case study was the most appropriate method as it allowed in-depth exploration of diabetes education in its naturalistic setting bounded by time and location. Data collection was conducted between August 2012 and December 2014 in Cantonese, Mandarin or English at seven field sites across three countries: China (Beijing, Guangzhou and Hong Kong), Singapore and Australia (Melbourne, Sydney and Perth). These field sites were purposefully chosen for inclusion to capture traditional populations (Beijing and Guangzhou), Western-influenced Chinese populations (Hong Kong and Singapore) and Chinese living in a Western country (Australia). The diversity allowed an exploration of consistent cultural behaviour patterns of the Chinese across different countries. The study was approved by the Monash University Human Research Ethics Committee (Project no. CF12/1186–2012000582).

This study was informed by health behaviour and cultural value theories. The *theory of reasoned action*,[11] *protection motivation theory*,[12] *self-regulation theory*[13] and the *trans-theoretical model*[14] explain people's behaviours when presented with information from health professionals. They suggest that behaviours are driven by normative beliefs, perceived benefits and threats of intended actions and feelings of self-efficacy. These theories have informed much of the health education design for people with type 2 diabetes.[15] In the present study, these health behaviour theories helped to ground the researcher in the principles of behaviour change promotion while observing patterns of diabetes education, providing a deeper understanding of the delivery and facilitation formats health professionals employed. In particular, data on health professionals' persuasive communication techniques were recorded to understand the underlying Chinese-specific cultural elements in behaviour change promotion. During observations, attention was given to the transferability of self-regulation and stages-of-change theories for the Chinese population by examining the behaviour change process of Chinese people with diabetes. The present study also recognised that culture shapes beliefs, health behaviours and practices, including the understanding of symptoms, perceived necessary health-promoting actions, help-seeking habits and coping strategies for dealing with chronic disease.[16] While many health professionals may modify diabetes education content to be more culturally appropriate for diverse groups, they may omit adapting their delivery format to cater for the other factors that can influence learning or lifestyle behaviours during diabetes education. Education researchers who have studied students from Confucian-heritage cultures (including the Chinese) have highlighted their dominant learning approaches, including *memorisation with understanding*, *effort attribution* (the belief that ability can be improved by working hard) and the *Confucian influence on an unquestioning acceptance of knowledge from their teacher*.[17] While the authors acknowledge that Confucianism is only one of major ancient philosophies in the Chinese culture influencing behaviours,[18] the influence of these learning approaches has not previously been examined in the context of diabetes education. In the present study, this novel focus has provided new insights during our interpretation of the analysed data.

The first author (TC) is a dietitian of Chinese cultural background and is fluent in Mandarin, Cantonese and English. Participant observations and interviews across all field sites were therefore conducted from an 'emic' or insider's perspective,[19] allowing TC to draw on her own cultural knowledge and minimise any compromise of data quality in translation.

Observation is a systematic and purposeful research method that has the strong advantage of unfolding the complexity of phenomenon in the natural environment.[20] During participant observations, the researcher sat in on the diabetes education session, with an observation template, blending with participants and collecting observational data on the behaviour of both the facilitating clinicians and the participants, as is recommended in observational methods.[20]

Only diabetes education sessions targeted at Chinese people were chosen for inclusion in the study. Sessions were purposefully selected to capture a variety of settings, size, delivery methods and demographics of participants to enhance richness of data.[21] Diabetes education services across the three countries were identified and recruited into the study.

In the Melbourne case study, TC used a reflective log to collect data post-consultations with Chinese people with type 2 diabetes. Opportunistic interviews, with health professionals and people with type 2 diabetes from the same services recruited via snowball sampling, were used to supplement the collected data from observations. Interview questions for health professionals were designed to further explore individual health professionals' cultural understanding, their experience of modifying diabetes education to suit Chinese culture and the perceived effectiveness of their approaches. Interview questions for the people with diabetes focused on their experience of the attended diabetes education sessions and if their diabetes management needs and expectations were met. Verbal consent was obtained from all participants prior to interviews. Where possible, in addition to notes, the interviews were tape-recorded, transcribed and translated. Data collection continued until theoretical data saturation was achieved.[22]

Thematic analysis with pattern matching[23] was adopted, whereby patterns were identified and matched using comparative analysis, within and across case studies, to strengthen credibility. The analysis was also grounded by the abovementioned health behaviour and cultural value

theories to help explain and interpret the collected data. This was assisted by QSR-Nvivo 10 (V10.0.138.0 (64bit), QSR, Australia). Analysis involved the open coding of text, grouping codes into categories, and then generating themes from these categories. Both methodological triangulation and investigator triangulation were applied, whereby data analysis of different data sources was first undertaken by TC followed by a second researcher (CP). All interviews, with health professionals (HP) and person with diabetes (PWD), and field notes (FN) from participant observations quoted here were made originally in Chinese and then translated to English by TC. Translation was verified by an independent bilingual researcher.

Results

A total of 39 participant observations and 22 interviews (Table 1) were conducted across the seven case studies. The participant observations were undertaken in various settings and in different formats, including individually, in small groups and in large lecture-style formats; by diabetes nurse educators or dietitians; and in both public and private health system settings. This diversity provided depth and breadth, enhancing richness of the findings. Analysis of these data yielded eight main themes (Table 2).

Health professionals repeatedly described the Chinese as a hard-to-engage group. They described difficulties at two levels: attracting people to attend diabetes education services and engaging people with diabetes during consultations to discuss self-management. While health professionals in Asia employed various strategies to attract Chinese people to attend diabetes education sessions, such as multiple invitations, the health professionals in Melbourne reported that, despite years of effort, diabetes services targeted at Chinese Australians remained poorly attended. They suggested that this could be because of a mismatch between the clinicians' expectations and service users' needs.

An experienced diabetes nurse working in a Melbourne suburb where many Chinese congregated complained:

> '*I don't know why they* [*the Chinese*] *are not knocking down my door*! *And they should be*, *because we are right in the centre of a huge Chinese population*, *with well-known high prevalence of diabetes*!' (Melbourne HP1)

The poor attendance of Chinese people at diabetes education programs was found to be multifactorial. One diabetes nurse educator shared her view that logistical barriers, including transport and language barriers, reduced service access. An experienced dietitian felt that people were turning away from services employing the culturally conflicting Western participatory approaches as clients appeared uneasy, and sometimes frustrated, when invited to collaborate in care planning. She reported:

> '*They* [*Chinese clients*] *don't want to participate in care-planning*, *they kept saying* "just tell me what to do, I will try hard!"' (Singapore HP1)

Chinese people were observed to be passive learners at diabetes education sessions, whereby they readily accept instructions from health professionals. A Singaporean dietitian noted how her Chinese clients '*sit back*, *listen and nod to everything recommended*' (FN from *Singapore*). A dietitian interviewed in Melbourne described similar passive and regimental behaviours shown by her Chinese clients:

> '[*They say*]: "Ok! This food is not good? I must change!". *They were very firm*, *verbally*. *And they tend to be very black-and-white*, *yes or no*, *good or bad*, *very distinct*. *And very little negotiation*'. (Melbourne HP2)

Chinese people were observed exhibiting a strong determination to change and readily accepted lifestyle recommendations given to them. They appeared studious during the observed diabetes education classes and did not question their health professional educators. Chinese people usually sat up straight, listened attentively and wrote down

Table 1 Details of collected qualitative data

Case study	*Participant observations*	*Interviewees*
Beijing, China	NA	Two diabetes program coordinators
Guangzhou, China	Six small group educations in hospital setting; didactic delivery	Two diabetes nurses
Hong Kong	Five patient-led sessions in community setting; group education	One patient-leader Two dietitians
	One lecture in hospital setting One lecture in community setting	Three diabetes nurses
Singapore	Six small group sessions in community setting; interactive workshop One diabetes walking group	One diabetes nurse Three dietitians
Melbourne, Australia	Sixteen individual consultations with dietitian in a community health centre	One endocrinologist Three diabetes nurse Three dietitians
Sydney, Australia	Three group educations in a public library, with patient participation	NA
Perth, Australia	NA	One diabetes nurse

NA, not applicable.

Table 2 Themes and descriptions emerging from acquired qualitative data regarding philosophies and behaviour of Chinese patients

Themes	*Descriptions*
Hard to engage	Chinese patients were described as a hard-to-engage community, both at service attendance and during care planning in individual consultations.
Readily accept instructions	Chinese patients appeared as passive learners during diabetes education sessions where they would politely agree to all clinician-recommended lifestyle changes.
Focus on management details	Appreciation of precise diabetes management detail was very strong.
Reluctant to argue or raise concerns	While Chinese patients appeared highly compliant and did not negotiate with their clinician, they failed to raise their concerns or openly discuss implementation challenges.
Perceived requirement to comply with any set of 'gold-standard' recommendations	An individualised care plan was not appreciated. Chinese patients looked for a set of 'gold-standard' recommendations. They strongly believed that despite their individual needs, they should try and achieve these goals though will power and self-determination.
Attracted to factual information	Chinese patients were attracted to factual information, and many adopted self-education techniques for gathering diabetes management information.
Unique motivators to change	Other than factual information, Chinese patients were motivated to change behaviours by authority reinforcement.
Unique behaviour change pattern	Once clinicians built trust with their Chinese patients, behaviour change happened very quickly.

most things the health professionals said, sometimes photographing the information slides.

Some interviewed Chinese people with diabetes reported that they sought detailed management information to ensure complete compliance with their health professional's recommendations. Such 'focus on management details' behaviours was described by an interviewed Australian dietitian:

> '*They presented to be very thirsty for information and knowledge. I mean, they just have so many questions*—"Can I eat this product? Can I eat that brand of bread? Why?" *A lot of questions, specific questions*'. (Melbourne HP2)

This demand for very specific and precise information caused some health professionals to avoid Chinese clients because of the time and effort they demanded. A bilingual dietitian in Melbourne, with 30 years of local and overseas clinical experience, revealed that she had to close her Chinese-specific clinic as she found working with Chinese people was just too exhausting.

Health professionals repeatedly reported that their Chinese clients would specifically ask for a detailed meal plan prescribing a range of appropriate food choices. In extreme cases, people requested 30-day meal plans (FN from Singapore), so they could be entirely compliant and do exactly as they were told every day of the month. The interviewed dietitian claimed that the Chinese clients did not appreciate the concept of self-regulation, saying:

> '*Asians like to be spoon-fed*'. (Singapore HP2)

Diabetes education delivered by health professionals trained in the West was criticised by Chinese people with type 2 diabetes for focusing on a conceptual understanding of diabetes and facilitation of self-care. Such teaching was not appreciated for its lack of practicality:

> '*The clinicians only provide patients with the theory, but they [the clinicians] don't realise that when I eat out, there isn't information on how I could count the carbohydrate of my pork-chop noodles*'. (Hong Kong PWD1)

Health professionals also described their Chinese clients as rigid thinkers who demanded very clear instruction. Dietary instructions had to be specific, with lists of '*foods to avoid*', rather than more ambiguous recommendations, like '*eat in moderation*'. Singapore interviewee A reported:

> '*Terms like* "once in a while" *and* "sometimes food" *are dangerous. I had an experience of naming Mars Bars as a* "sometimes food" *and the patient misinterpreted it as a* "*dietitian-said-ok*" *option and ended up replacing his regular chocolate with Mars Bars. Since then, I label it as a* "no-no food"'. (Singapore HP2)

The Chinese people were observed to be largely compliant, reluctant to argue or raise concerns with their health professional, raise concerns or openly discuss implementation challenges. In Sydney, the researcher observing a group diabetes education session overheard participants disagreeing among themselves with the dietitian's instruction for a strict restriction of rice intake. However, no one openly challenged this or raised concerns on the practicality of the recommendation. Among themselves, they quietly agreed to ignore it.

In a similar context, the researcher recorded another experience in Hong Kong that again highlighted the habit of Chinese people in keeping quiet about their concerns. During a 2-hour didactic lecture discussing diabetes from a traditional Chinese medicine perspective, attended by about

100 participants and delivered by a Beijing professor, the researcher noted:

> '*I was finding it extremely difficult to understand this professor speaking in her very-heavy-Mandarin-accent Cantonese. I saw people in the audience frowning, losing attention, and fidgeting. However, no one voiced out the problem to the presenter! Until half-way through the presentation, the professor suddenly stopped and asked if everyone could understand her well. It was only then people shouted out that they couldn't catch a single word*!' (FN from *Hong Kong*)

Similarly, in Melbourne, the researcher documented her frustration in providing dietetic advice to a Chinese client with suboptimal glycaemia who insisted on 'trying harder' rather than engaging in an open discussion about barriers to behaviour change. The researcher noted:

> '*If he discussed his work and family situation with me, I could have given him alternative dietary suggestions*!' (FN from *Melbourne*)

People with diabetes indicated that it was not important for health professionals to know about their existing lifestyle, dietary preferences and implementation challenges as they perceived that it was a requirement to comply with any set of 'gold-standard' recommendations through their strong willpower and determination. They saw health professionals as experts who would provide prescriptive scientific-based dietary and exercise plans. Their role was then to do their best in complying with these recommendations.

Collecting dietary history information from Chinese people was found to be difficult. A dietitian reported finding that when Chinese clients were asked to report their usual diet, they were either reluctant to provide any information at all or reported an idealised meal pattern designed to impress. At times, asking for a diet history appeared to impede rapport building.

Seeking audience participation and inputs at diabetes group education was also observed to be challenging. People with type 2 diabetes were observed to avoid making eye contact at a Sydney diabetes workshop when the facilitator invited participants to indicate what they already knew about diabetes.

Chinese people were seen to be attracted to factual information. A presentation given by a Singaporean exercise physiologist was observed to have a strong focus on the diabetes pathophysiology of exercise. He later claimed that this fact-laden approach attracted participants' attention and gained their trust in performing recommended physical activities. Chinese people with diabetes, across all observations, also appeared very proactive in seeking diabetes management information. The strong self-education and reading culture of China was evident in the Chinese diabetes community in Guangzhou. The researcher observed many people reading diabetes books in bed in the hospital ward. When interviewed, many Chinese people with diabetes told the researcher that the first thing they did at diagnosis was buy a pile of books to read up on diabetes. The hospital visited in Guangzhou attempted to support this self-directed learning by providing diabetes information booklets at the group education sessions and by putting up posters on diabetes management in the hospital corridor. Patients and family were often seen in the corridor reading these posters.

Other than written materials, people also reported gathering diabetes information from the media, including television programs and social media. In both Guangzhou and Hong Kong, people with diabetes described collecting management information from well-known television programs where doctors were invited to speak about many health issues, including diabetes.

The researcher observed Singaporean Chinese people with diabetes busily signing up for physical activity programs after an exercise physiologist had concluded a talk on the physiological benefits of exercise. A set of unique motivators for change was noted, and that the promotion of a strong hierarchical health professional–patient relationship also appeared to motivate behaviour change in Chinese people. The Chinese appeared to see their health professionals as the authoritative figure in diabetes care. Apart from providing reputable health information, health professionals were perceived as 'diabetes police' who keep their clients on track with diabetes management. In an observed dietetic consultation in Melbourne, the client claimed that her regular appointments with a dietitian had pushed her to adopt a healthier lifestyle as she then felt responsible to the dietitian. At the end of each consultation, she often said:

> '*I feel bad. You care for me so much, I must listen to you and do what you said*'. (Melbourne PWD1)

A diabetes nurse interviewed in a Hong Kong public hospital shared her experience in using 'top–down' hierarchy to motivate behavioural change. She would ring her 'naughty patients' fortnightly to check on their progress and '*nag them on making changes*' (FN from *Hong Kong*). She highlighted that her regular contact with clients became a motivator to change lifestyle behaviours and that such unique relationships kept the clients disciplined which supported diabetes management.

Health professionals reported that regular repeated interventions in themselves may contribute to strengthening rapport. Chinese Singaporean people with diabetes were described as '*slow to warm up*' (FN from *Singapore*) and were reported to take up to three sessions before the health professional was perceived as one of '*my people*' (my friends) to be more readily engaged in discussion of their problems. Only once rapport and trust were built could the behaviour change process commence.

An observed unique behaviour change pattern across various diabetes education sessions was 'instant' behaviour change. Chinese people generally presented with a strong belief that they could control their desires and change their habits by exerting willpower. In several informal interviews

with Chinese participants attending the Melbourne diabetes support group, the participants told the researcher that diabetes management was simply a matter of '*being told what to do*' (FN from *Melbourne*). Once they had clear instructions, implementation was straightforward.

> '*There seems to be no stages of change. It was a matter of gaining trust either over time or with presentation of knowledge, then providing the recommendations for the Chinese patients to make the change. The change process is just natural, no argument or negotiation*'. (FN from *Melbourne*)

Discussion

This study explored the collective patterns of learning behaviours and preferences of Chinese people during diabetes education sessions across three countries and identifies cultural-specific tailoring strategies that appear successful in the diabetes education directed at Chinese people. To our knowledge, this is the first study to explore and understand recruitment, engagement and satisfaction with diabetes education in Chinese people consistently presented across three countries. The novel findings will inform optimal Chinese-specific tailoring of diabetes education and have implications for practice. The findings suggest that Chinese people tend to rely on self-education for diabetes information and only seek advice and recommendations from health professionals as the last resort. During diabetes education, they need to be told clearly what to do and then strive for complete compliance. They also tend to be submissive during diabetes education and are not likely to raise concerns, negotiate or participate in care planning. In general, they prefer prescriptive concrete instructions rather than more flexible conceptual education. Regular education over time facilitates therapeutic trust. Their motivators of change were unique; instead of taking action upon perceiving a threat to their health in a step-wise gradual change pattern, the Chinese appeared to believe a healthy lifestyle for diabetes management is achieved by individual willpower and determination, with an 'all-or-nothing' behaviour change pattern.

The findings identified a significant clash of cultures between a Western-orientated diabetes education approach and Chinese cultural philosophies and learning style, contributing to frustration expressed by both the health professionals and Chinese people in this study. Chinese people with diabetes collectively displayed a set of unique philosophies and behaviours that influenced all the stages of diabetes education, from building therapeutic relationships with health professionals to integrating education messages into their lifestyle. This cultural mismatch suggests a new way of understanding what 'person-centred care' in diabetes education means when working with the Chinese. Previous research has reported that Westerners value autonomy, independence and worldly success, while the Chinese virtues focus on societal hierarchy, respect for authorities and duty to the group.[24] Such cultural differences could explain why translated approaches that draw on individual's pre-existing attitudes and behavioural intentions based on theory of reasoned action does not work well for Chinese people. Our findings confirm previous research which has highlighted that a structured and directive counselling approach is more effective than an autonomy-promoting approach.[25] Additionally, a facilitative person-centred approach has been criticised for not conforming to Chinese traditional cultural values and is likely to impact negatively on health professional–patient relationships.[26]

Confucianism, the major Chinese philosophy that forms the foundation of Chinese social structure and moral values and shapes behaviour development, may explain Chinese people's behaviours observed in this study. Confucian teaching emphasises how everyone should play their delineated role to maintain social harmony and a stable hierarchical social structure.[24] It has been reported that in Chinese culture, the fixed role in society, rather than personal preferences, determines behaviours.[27] Chinese people constantly relate self to others, exercising self-regulatory practices to suppress personal desires[24] and pursuing continuous learning towards self-perfection.[28] Furthermore, Chinese people have a strong belief that success comes from effort and willpower.[29] Chinese people, in this study, were observed to be readily educated and agreed to 'try hard' on adopting healthy behaviours as they may believe that keeping themselves healthy was the duty of each citizen to achieve harmony within the collective society.

The hierarchical structure and its ordering of relationships are seen as very important Chinese values, and people are to enact upon their role in the hierarchical structure.[30] As health professionals are regarded by the Chinese as authority figures, knowledgeable and highly respected,[26] Chinese persons take up the role as obedient listeners, with no 'talking back' or voicing opinions.[30] This hierarchical structure also defines the relationships between people, with a clear distinction between 'in-group people' (family, peers and those with established relationships) and 'out-group people'. Individuals will only connect closely to known 'in-group people', and they will treat 'out-group people' as strangers.[30] When attending diabetes education with a health professional whom the Chinese client has not met before, this study found that the person with diabetes experienced some difficulty in interacting with this 'out-group' person and could not openly discuss their problems. This could explain why Chinese people observed in the present study were described as 'slow to warm up', whereby trust took time to develop before the health professional gained the status as an 'in-group person'.

Western evidence indicates that health professionals who adopt a parental-like role and expect their clients to just 'follow orders' are likely to invoke negative attitudes in their clients with subsequent reduced compliance.[31] In comparison, we found that health professionals were instead seen employing the power in the hierarchical clinician–patient relationship to enhance treatment effectiveness. Potentially influenced by the rigid system social structures found in Chinese society, it appeared normal to trust information presented by an authority and do as one was told. Some

health professionals were seen employing innovative strategies to highlight their expert role by exhibiting extensive knowledge on diabetes management, while others took up a parenting or policing role in disciplining their clients.

These differences between Western and Chinese approaches to diabetes education deserve to be better understood. A more comprehensive understanding of how Chinese cultural values shape behaviours will allow better cultural tailoring of Chinese diabetes education. However, it should also be noted here that culture is only one of the factors shaping any human being.[32] Traditional cultural values may be fading among younger Chinese and those living outside China.[33] The Chinese should not be seen as a culturally homogeneous group. Cultural modification of diabetes education for Chinese should not be 'one-size-fit-all' but carefully designed to match the target population's demographics, including age, attachment to traditional cultural values, preference of health education style and constantly evolving relationship between health professional and the person with diabetes. Our study has limitations. As health professional-centred diabetes education sessions appeared dominant across the field sites, there was a lack of data collected when a person-centred approach was employed. We, therefore, may have missed exploring how Chinese people behave when they were given autonomy. However, it could be argued that a person-centred approach was so inappropriate for the Chinese that it was not practised. Also, the interviewees in this study were predominantly health professionals, with limited data obtained from the care-receivers' perspectives, which may present a more health professional-centred viewpoint. The health professionals in this study appeared to respond negatively to Chinese clients, and this may have presented a rather negative image of the Chinese people with diabetes. Lastly, it was not our objective to study the diversity of learning behaviours of the Chinese sub-populations. Further research on comparing the needs of Chinese sub-populations would be informative in designing a diabetes education strategy specific for the Chinese population.

In conclusion, there is a clear need for diabetes education to be culturally modified for the Chinese, with considerations of their unique behaviours during education and when making lifestyle changes. Chinese people tend to take a submissive learner role during diabetes education, especially at the beginning of care. Building strong trust from the early stages is achieved by encouraging rapport with Chinese clients and engaging them in an open discussion of implementation strategies. Once the trust is built, healthy behavioural change may follow.

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Conflict of interest

No conflicts of interest to declare.

Authorship

TSTC was involved in project design, data collection and analysis and drafting of this manuscript, with CP and KZW supervising the process. CP was also involved in investigator triangulation in data analysis. CBL provided support in writing the manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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ORIGINAL RESEARCH

Telephone-delivered weight management services in the hospital outpatient setting: Decision-makers' perceptions of their use in routine practice

Megan E. WHELAN,[1] Ana D. GOODE,[1] Ingrid J. HICKMAN,[2,3] Elizabeth G. EAKIN[1] and Marina M. REEVES[1]

[1]Cancer Prevention Research Centre, School of Public Health, The University of Queensland, Herston, Australia, [2]Department of Nutrition and Dietetics, Princess Alexandra Hospital, Brisbane, Australia, and [3]The Mater Medical Research Institute, Brisbane, Australia

Abstract

Aim: Providing effective weight management services to the growing number of overweight or obese hospital patients necessitates long-term service provision; however, it is arguably not within the acute-care hospital remit to provide such extended services. Referral to community-based programs is required to provide continuing weight management services. The Get Healthy Service is a free six-month, telephone-delivered lifestyle program, now offered in several states of Australia with potential for wide population reach. However, health practitioner referral into the service has been low. The study aimed to examine awareness and suitability of the Get Healthy Service for referral of hospital outpatients for weight management, among key health-care decision-makers.

Methods: Nine key decision-makers from metropolitan and rural Queensland Health hospitals took part in semi-structured telephone interviews that were audio-recorded (January–July 2014), transcribed verbatim and thematically analysed.

Results: Interviews revealed that most decision-makers had limited awareness of the Get Healthy Service but perceived the telephone service to be suitable for patient referrals. Incorporating Get Healthy Service referrals into patient care was seen to be potentially valuable and relatively easy to implement, with most interviewees suggesting that they would provide a Get Healthy Service brochure to patients who could then self-refer into the service.

Conclusions: The Get Healthy Service provides a referral model for weight management service provision that appears feasible for use in Queensland hospital settings. Increased awareness and a more integrated approach to referrals would likely result in improved enrolment to the service, with future research needed to demonstrate this.

Key words: dietetics, health services, public health, research translation.

Introduction

Obesity and its related co-morbidities are major public health challenges worldwide.[1] In Australia, the large acute care hospitals in metropolitan areas typically offer outpatient weight management services delivered as group-based programs.[2] Such weight loss programs can be effective at achieving significant weight loss in patients; however, their enrolment rate is generally low, limiting their impact.[3] Telephone-delivered services have the potential to address barriers to accessing weight management services and have been effective in promoting weight loss[4] and improving diet and physical activity behaviours[5,6] in both controlled trial settings and within dissemination contexts.[7,8]

The Get Healthy Service is a free, state government funded, six-month telephone-delivered healthy lifestyle program (targeting physical activity, healthy diet and weight). The program (offered in Queensland since 2012) is now offered in several states of Australia, with the New South Wales Ministry of Health centrally coordinating the program. All residents of participating states can access the service via self-referral or by referral from a health practitioner. The service has been shown to achieve mean (self-reported) weight loss of −3.6 kg (SD ±4.8) after six months and significant improvements in dietary intake and physical activity,[8] with changes largely maintained at six months after program completion.[9]

Addressing the obesity epidemic is on the agenda for both federal and state governments,[10–12] including the need

M.E. Whelan, MDietSt, PhD Candidate
A.D. Goode, PhD, Teaching and Research Fellow
I.J. Hickman, PhD, AdvAPD, Principle Research Fellow
E.G. Eakin, PhD, AdvAPD, Director
M.M. Reeves, PhD, AdvAPD, Senior Research Fellow
Correspondence: M.E. Whelan, The University of Queensland, School of Public Health, Herston, QLD 4006, Australia. Tel: +61 7 33655527; Fax: +61 7 33655540. Email: m.whelan1@uq.edu.au

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to increase the reach of sustainable evidence-based weight management programs offered in the community. The Get Healthy Service is one such evidence-based program with the potential for wide population reach. However, health practitioner referral into the service has been low, proposing a research to practice gap.[9]

This paper describes a qualitative investigation undertaken to examine perceptions among key decision-makers on the awareness, suitability and feasibility of implementation of the Get Healthy Service in the context of outpatient weight management services across Queensland Health hospitals. Gaining an understanding of such decision-maker perceptions will advance our understanding of the evidence to practice gap, and inform possible future implementation.

Methods

Twenty-three hospitals were initially identified by selecting at least one hospital of each different bed size (50–100 beds; 100–200 beds; 200–500 beds; and >500 beds), when possible, with an on-site dietetics service across each Queensland Health Service District (metropolitan, regional and rural areas), and invited to participate. Of the 23 initial hospitals identified, n = 12 did not respond to the authors' attempts to gain research governance required to complete research at the individual hospital sites, and n = 2 declined participation, therefore had no further follow-up. Decision-makers included heads of Nutrition and Dietetic departments or senior dietitians overseeing weight management services. Interviews with decision-makers continued until information saturation was reached,[13,14] which was achieved after nine interviews. Ethical approval for this trial was obtained from the Human Research Ethics Committees of The University of Queensland and the Royal Brisbane and Women's Hospital in accordance with the Australian National Health and Medical Research Council's guidelines and conforms to the provisions of the Declaration of Helsinki (as revised in Brazil in 2013). All decision-makers provided written consent.

One interview was conducted face-to-face and eight interviews were conducted over the telephone between January and July 2014 by one study investigator (MEW). A semi-structured interview guide (Table 1) was developed consisting of a small number of open-ended questions with the flexibility to prompt throughout the interview. Interviews examined current practices within the hospital for managing weight loss referrals; awareness and understanding of the Get Healthy Service; the perceptions of key decision-makers on the use of telephone-delivered weight management services; and the perceptions of key decision-makers on how referral into the Get Healthy Service could be implemented within existing procedures in the acute-care hospital setting. Interviews were conducted over the telephone, audio-recorded, transcribed and transcripts were compared with original recording to ensure accuracy.

Qualitative data from the interviews were analysed by thematic content analysis[15] (i.e. comparing responses, identifying consistent or unique patterns of responses, grouping responses into themes). Two authors (MEW, ADG) independently reviewed five transcripts (56%) using open coding to generate initial themes. Transcripts were then coded using agreed themes and investigators revisited themes throughout the coding process until consensus was reached.

Results

Of the nine interviews conducted (mean length: 29 minutes, range: 21–38 minutes), three were with decision-makers from large metropolitan hospitals, and six from hospitals in regional or remote areas. Themes that emerged from the interviews were consistent with the guided questions, with no new themes emerging.

Many decision-makers reported that weight management services were not currently offered to patients by the hospital. The few sites that did provide weight management services predominantly offered a group-based outpatient service, with few hospitals providing individual dietetic consultations for weight management.

Most hospitals manage referrals for patients requiring weight management services by providing an information pack detailing options available to them, including healthy lifestyle brochures, local general practitioners, private practice dietitians, commercial programs (i.e. Weight Watchers) or community-based programs (mostly face-to-face, group-based formats). It is then the responsibility of the patient to organise participation in these services.

> 'We don't accept referrals for weight management…for outpatients. We do accept referrals for other conditions, chronic disease conditions, for which weight management becomes a component but generally we don't have any specific weight management programs or services. We also don't have any weight management programs for inpatients…If we do get referrals…for weight management we will send them an information pack.' (Decision-maker 4)

The majority of key decision-makers perceived that current services, including the group-based and individual services offered by hospitals, as well as those available in the community are poorly received and attended by patients referred for weight management services. Reasons for this included a perceived lack of motivation for patients to commit to, and engage in the services offered; patient aversion to particular service delivery modes (group-based *vs* individual); lack of service accessibility due to travel cost, time and patient mobility issues and work or carer commitments. Many decision-makers also reported retention of patients to these services to be challenging with low numbers of patients completing outpatient programs offered by the hospitals.

> 'I'm not sure if it's that well received by the clients themselves. We've tended to have a bit of struggle getting patients to engage in programs – that's been sort of a long standing thing.' (Decision-maker 1)

Table 1 Semi-structured interview guide

1. How are weight management services currently delivered in your department?

Prompts for question 1:

a. What is the referral pathway for overweight and obese patients from a systems perspective?
b. What are your thoughts about the current delivery of weight management services?
c. What proportion of services in your department is dedicated to weight loss?

2 Had you heard of the Get Healthy information and coaching service prior to being invited into this study?

Prompts for question 2:

a. What is your understanding of the service?

Description of the QLD Get Healthy Service

b. Does your department currently refer patients into the service?
c. Are you aware of any community-based telephone-delivered weight loss services available in your health service district? What can you tell me about them?

3 Do you think referring patients to the Get Healthy Service is appropriate for overweight and obese patients requiring weight management? Why/why not?

Prompts for question 3:

If YES:

a. What do you see the advantages/limitation/conflicts to be over existing services?
b. How do you think referrals to this service would fit within existing workflow and systems that are in place in your department?
c. What are your recommendations for implementing a referral pathway to these services into current practice?
d. What additional protocols would need to be put in place to facilitate referrals?
e. What will be the biggest challenges to implement this process?
f. Do you perceive any risk or threat of referring to such a service (i.e. loss of activity-based funding due to referring patients to external services, lack of dietetic expertise for patients)?
g. Would feedback on individual patient outcomes and number of referrals to the referral setting be of value?
h. How can referrals to such a service be promoted to clinicians/patients?
i. Is there further assistance from internal or external sources that would be necessary to initiate and/or maintain a referral pathway for overweight and obese patients to community-based, telephone-delivered services?
j. Do you think such a service could replace existing face-to-face services?
k. What steps need to occur to maintain such procedures long-term?

If NO:

a. What are the limitations of such a service compared to existing services?
b. What are the challenges/barriers that you perceive for referring patients to this service?
c. Could anything be changed to make it appropriate for this population/enable the uptake? How?

Decision-makers identified a number of barriers to the integration of referrals to community-based services for inpatients requiring weight loss service. There are currently very limited services available in the community and those that are available, as well as related public health campaigns, are often fragmented. The fragmentation of services was perceived to be a consequence of frequent changes in the allocation of government funding, resulting in restructuring of such services making it difficult to keep track of what is available for use by patients. A further barrier identified by many decision-makers was the lack of capacity to remain informed of what campaigns and services are available, develop resources and promote these services to health practitioners and patients so that they can be utilised to their potential.

> 'The problem is that the community has been so disorganised and mobile that these things change often. They keep changing all the time whether it's the 'how do you measure up' or the…what's the latest?' (Decision-maker 2)

Most decision-makers reported a limited awareness of the Get Healthy Service, expressing that they knew little

other than that the program was a telephone-delivered program targeting weight loss.

> 'Um I have heard of it. It's telephone-based counselling isn't it?' (Decision-maker 5)

The limited awareness of the Get Healthy Service among decision-makers was reflected in the small number of departments currently referring into the service. The referral process involved patients being provided with an information pamphlet and then self-referring into the Get Healthy Service.

> 'We send them an information pack which has got in it the Australian Guide to Healthy Eating, private practitioners, and other services that are available like the Get Healthy Information and Coaching Service flyer.' (Decision-maker 4)

The majority of decision-makers agreed that a telephone-based service would address the challenges of accessing weight management services for patients, particularly those residing in rural locations or patients with work commitments making attendance at face-to-face appointments during the day difficult.

> 'It maybe provides a degree of flexibility, you know, they can do it over the phone for people who have access issues. I think that's an important one.' (Decision-maker 1)

Despite telephone delivery being perceived to provide greater reach to patients currently not accessing weight management services, it was reported by decision-makers that there will always be a need for the provision of face-to-face services. Most decision-makers expressed that while some patients may prefer individual telephone-based contact, others respond better to face-to-face, group-based delivery modalities due to the social support aspect provided by the group environment. It was also reported by some decision-makers that face-to-face modalities, where available, may be preferred by health practitioners as they can directly track the progress of their patients.

> 'Face-to-face seems to be preferred by a lot of the patients particularly those who are dealing with depression and anxiety. In a group situation everything is more normalised and they [patients] are not feeling so alone… and not having to do it on their own. Also being able to physically see someone's progress and address it.' (Decision-maker 7)

Decision-makers identified the qualification of coaches delivering the Get Healthy Service as a potential concern, if they were not accredited practising dietitians, particularly for those with obesity-related co-morbidities. Many decision-makers expressed a preference for a dietitian to deliver medical nutrition therapy to patients as they have the expertise for management of specific chronic diseases.

> 'I think I would have reservations about the qualification of the people giving the advice out…if there's a person with lots of co-morbidities but they're not talking to a dietitian and the coach may be a little bit out of scope to give recommendations.' (Decision-maker 3)

Practical suggestions were provided by decision-makers for integrating referrals to the Get Healthy Service. Most decision-makers envisioned that information brochures could be provided to patients who then self-refer into the program. Interestingly, decision-makers did not mention using the established Get Healthy Service referral pathway where practitioners are able to send through a referral form and Get Healthy Service staff directly follow up the patients to enrol them to the program.

> 'We have a discharge weight pack that a lot of dietitians use which contains a lot of that information – a lot of self-referral stuff. We could just add it [Get Healthy Service brochure] to that.' (Decision-maker 2)

The process of offering the Get Healthy Service as a service delivery option for patients requiring weight management services was perceived to be easy for all hospitals and would fit well within existing referral processes.

> 'That would be quite simple to do – I don't think there would be any issues with that.' (Decision-maker 6)

Most decision-makers suggested that the Get Healthy Service could be incorporated into a 'suite' of options for weight management services with decision-makers agreeing that the service could provide an alternative to the limited existing options currently available and facilitate continuity of care for patients.

> 'Well the advantage I think is that it provides an option for the clients which, you know, there's very limited sort of options available to them…at the moment, you know, we're an acute hospital so that's where our focus is. Community. There's very little in the way of dietetics services out in the community and there's also, very minimal private services as well so it just provides another option for them.' (Decision-maker 1)

Many decision-makers also suggested that referral to the Get Healthy Service could provide a follow up weight loss service for patients who have been seen by a dietitian for co-morbidities (such as hypertension and diabetes) and require ongoing weight management services to complement medical nutrition therapy for specific disease conditions.

> 'So we're thinking of it as a possibility that, you know, we're seeing people two or three times and provided some education specific to the condition that they were referred for and if they need long-term support for weight loss which in the long run will help manage their condition we may be able to refer them into this system.' (Decision-maker 1)

Some decision-makers suggested a solution to fragmented weight management campaigns could be development

of a standardised weight management pack detailing what services are offered across Queensland. This would ensure that patients all around the state are offered similar weight management services, enabling the adoption of such services into the hospital outpatient setting across Queensland.

> 'Ideally, the best way would be for Queensland Health to develop a generic standardised weight reduction pack for use in tertiary hospitals to refer to the appropriate things out in the community and circulate that around.' (Decision-maker 2)

Decision-makers reported that hospital-specific feedback would be important to maintain ongoing referrals into the service. Feedback of particular interest to decision-makers was the number of referrals to, enrolment and completion rates of the Get Healthy Service, as well as the outcomes that patients achieved throughout participation in the program.

> 'If we are getting people to use a telephone program then I need to be able to say that yes, people are engaged and yes, people are getting good outcomes.' (Decision-maker 5)

Discussion

Providing access to effective weight management services for the growing number of overweight and obese Australians remains an ongoing challenge for the public health system. While the Get Healthy Service has the potential to address barriers to accessing weight management services faced in clinical practice, data from the Get Healthy Service in New South Wales indicate that only 10% of referrals into the service are through health practitioners,[9] suggesting this service is under-utilised. This highlights a research to practice gap where despite evidence supporting the effectiveness of the Get Healthy Service, practitioner referral into such programs does not occur in practice. This study aimed to examine awareness and suitability of the Get Healthy Service for referral of hospital outpatients for weight management, among key health-care decision-makers.

Interviews revealed several key findings relating to the current provision of weight management services in Queensland. These included that few hospitals offer such services, with those currently offered having poor patient participation. Additionally, decision-makers stated that few services exist for weight management in the community, and the community health sector was perceived to be fragmented due to changes in funding allocation. Resultant discontinuation of such health-care services reportedly discouraged health practitioners from referring to community-based programs. These present as barriers to patient engagement in weight management services in Queensland. Findings also indicated that most decision-makers reported a limited awareness of the Get Healthy Service but perceived referral of hospital patients into the service would be appropriate for patients requiring weight management. Incorporating Get Healthy Service referrals into patient care was seen to be relatively easy to implement, with interviewees suggesting the service to be used adjunct to medical nutrition therapy for obesity-related co-morbidities. Most interviewees suggested that they would provide a Get Healthy Service brochure along with information on other services to patients who could then self-refer into the service.

Most decision-makers reported a limited awareness of the Get Healthy Service and only a small number of departments currently referred into the service. A practical suggestion given by decision-makers to address this was the development of a standardised weight management pack, detailing what services are offered across Queensland to help increase awareness of existing services available to patients requiring weight management. The development of such a resource requires a partnership between the department of health, the hospital sector, community sector and the primary care setting to create awareness of public health and community-based programs that are available for overweight and obese patients requiring weight management. As services change frequently, these information packs would need to be regularly updated and be available via a medium that can be readily amended as necessary, such as an electronic database with online access. This would ensure that practitioners are informed of weight management services available across the state, and consistent information and services are offered to all patients. Additionally, as suggested by key decision-makers, feedback to the referring hospital departments on the number of referrals, as well as enrolment and completion rates of the Get Healthy Service, and outcomes that patients achieved throughout the program would be important in order to maintain ongoing practitioner referral into the service.

Incorporating Get Healthy Service referrals into patient care was seen to be relatively easy to implement, with interviewees suggesting the service could be used as an adjunct to medical nutrition therapy for obesity-related co-morbidities. Most interviewees suggested that they would provide a Get Healthy Service brochure along with information on other services to patients who could then self-refer into the service. Self-referral is a challenge to patient engagement (passive referral), only effective in reaching the small portion of patients who are highly motivated to seek out healthcare.[16] Integrating active referral protocols into the hospital setting may increase the number of patients engaging in such services. A pre–post observational study examined referral source of the Get Healthy Service.[17] Participants referred by general practitioners compared with self-referral participants were more likely to request coaching compared with other referral sources that were more likely to request an information kit only.[17] This has also been demonstrated in smoking support services where improved reach[18,19] and representativeness[20] into smoking cessation support services was achieved when active referral processes were used compared with relying on self-referral alone. The Get Healthy Service facilitates a more integrated approach such as those seen in smoking cessation through

an established practitioner referral pathway where health professionals can directly refer patients into the service (via email or facsimile), with Get Healthy Service staff then contacting patients by telephone to invite them to participate in the service. Interestingly, decision-makers did not report any intentions to use the established Get Healthy Service referral pathway. Further research is required to assess incentives for staff to increase active referral rates.

Within the current health-care system, it remains unclear where the responsibility for overseeing weight management services lies. Effective weight management requires long-term intervention;[21] however, it is arguably not within the acute-care hospital remit to provide such extended services. The gap between referral for weight management and provision of effective services may contribute to poor engagement with established services for both patients and practitioners, limiting the public health impact of weight management services in Australia. Referral to community-based programs is required for the health-care system to provide ongoing weight management services.[22,23] The integrated service provision models currently implemented for chronic diseases such as cardiovascular disease can be used as examples to inform better integration and provision of weight management services.[24,25]

There is a need to evaluate alternative models of delivering weight management services, including the integration of community-based services. The Get Healthy Service appears to be a suitable and feasible service delivery model for referring overweight and obese patients identified in Queensland acute-care hospital settings for provision of weight loss support; however, due to low referral rates it is currently under-utilised. Increased awareness and implementation of direct referral pathways would likely result in improved patient enrolment to the Get Healthy Service, with future research needed to demonstrate this.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

MEW conducted and interpreted the thematic analysis, wrote and edited the manuscript. ADG interpreted the thematic analysis and edited the manuscript. IJH, EGE and MMR edited the manuscript.

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ORIGINAL RESEARCH

Energy drink consumption is associated with reduced sleep quality among college students: a cross-sectional study

"Mo'ez Al-Islam" E. FARIS,[1] Haitham JAHRAMI,[2] Marwa M. AL-HILALI,[1] Noor J. CHEHYBER,[1] Sara O. ALI,[1] Sara D. SHAHDA[1] and Reyad S. OBAID[1]

[1]Department of Clinical Nutrition and Dietetics, College of Health Sciences/Sharjah Institute for Medical Research (SIMR), University of Sharjah, Sharjah, UAE and [2]Rehabilitation Services, Periphery Hospitals, Ministry of Health, Manama, Bahrain

Abstract

Aim: Intake of caffeinated energy drinks has significantly increased, specifically among young adults and adolescents. College students are prone to developing unhealthy eating habits and dependence on stimulants, which puts them at a greater risk of sleep problems. This study aims to investigate the prevalence of caffeinated energy drink consumption and its association with sleep quality in college students.

Methods: A sample of 919 randomly selected adults (237 males and 682 females) from various colleges at the University of Sharjah/United Arab Emirates participated in this cross-sectional study. Data were collected using an online validated questionnaire.

Results: The current study revealed that 376 students (41%) were consuming energy drinks on a regular basis. Approximately half of the students had normal sleep patterns; the other half had sleep problems (anxiety and intermittent sleep). Results of the present study revealed a significant ($r = -0.10$, $P < 0.05$) relationship between the consumption of energy drinks and sleep quality and patterns.

Conclusions: Moderate consumption of energy drinks was reported among college students. Consumption of energy drinks was significantly associated with changes in sleep quality and patterns of students.

Key words: college students, energy drinks, sleep.

Introduction

Energy drinks (ED) are caffeinated beverages designed to enhance alertness levels and provide an energy boost to the consumer.[1] Caffeine is the most significant ingredient in ED because of the stimulation effect it has on the central nervous system of humans. Guarana, taurine and sugar derivatives are examples of other ingredients added to ED, which may produce synergistic stimulatory impacts beyond the effects of caffeine.[2] However; excessive consumption of ED has serious negative effects, such as cardiovascular, cognitive and nervous disturbances.[3]

Sufficient sleep has been positively related to good academic performance and enhanced memory.[4,5] In contrast, inadequate sleep has been shown to negatively impact the nervous, endocrine and immune systems and can increase the risks of cardiometabolic disturbances, such as alteration of metabolism and body composition.[6] Furthermore, sleep deprivation is linked with a wider range of behavioural, cognitive and physical disturbances.[7,8]

The effect of ED consumption on sleep patterns among college students has been investigated elsewhere.[9,10] Among 2230 Ethiopian college students, a high frequency of poor quality of sleep was associated with stimulant use, including ED.[11] In another study including 496 college students from the United States, 51% of participants have reported consuming more than 1 ED every month, where inadequate amount of sleep was highlighted as the most common reason for ED intake by 67% of the ED consumers.[12]

The Arabian Gulf area represents one of the areas with the highest ED consumption rates. However, studies on ED consumption and its impact on health outcomes are relatively scarce. In a study that included 125 college students,

M.A.I.E. Faris, PhD, Assistant Professor
H. Jahrami, PhD, Chief, Rehabilitation Services
M.M. Al-Hilali, BSc, Research Assistant
N.J. Chehyber, BSc, Research Assistant
S.O. Ali, BSc, Research Assistant
S.D. Shahda, BSc, Research Assistant
R.S. Obaid, PhD, Professor and Head of Department
***Correspondence:** M.A.I.E. Faris, Department of Clinical Nutrition and Dietetics, College of Health Sciences, Sharjah Institute for Medical Research (SIMR), University of Sharjah, Sharjah 27272, UAE.
Tel: 00971–6505–7514. Fax: 00971–6505–7515,
Email: mfaris@sharjah.ac.ae; moezfaris@hotmail.com

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the authors found that 92% of the sample consumed ED.[13] However, the relatively small sample size limits the ability to draw clear conclusions about prevalence of ED consumption and their health implications. Other research focused on college and non-college students in Saudi Arabia revealed that ED consumption was high at 46%, with demonstrated associations between higher consumption of ED and irregular sleep, smoking, unsafe behaviours and poor breakfast.[14]

In the United Arab Emirates (UAE), an increase in the prevalence of ED consumption among adolescents and adults has been observed.[15] However, there is a gap in knowledge regarding the magnitude of ED consumption among college students in UAE and the effect of ED on sleep quality among this group. In the current research, it was hypothesised that ED consumption is high amongst college students in UAE. Therefore, the primary objectives of the current study were to determine the prevalence of ED consumption among college students, to identify lifestyle factors affecting ED consumption and to explore the effect of ED consumption on sleep quality among college students.

Methods

This cross-sectional study was conducted between February and April 2014 at the University of Sharjah (UOS)/UAE, which has an approximate population of 13 000 adult college students (17–25 years old). The sample included local students from the seven governorates of the UAE and international students representing 93 nationalities. A sample of 919 students (237 males and 682 females), representing about 7% of total UOS population, was selected for the study. Eligibility criteria included any male or female registered student from any of the university colleges at any level.

Data were collected using a 20-item tool adapted from a previously developed and validated questionnaire by Faris.[14] The instrument was slightly modified to enhance compatibility with college students in the UAE and enable testing of research objectives regarding sleep patterns. Initially, pilot testing was performed to examine the clarity and comprehension of the questionnaire. The questionnaire consisted of four domains: demographics, dietary and lifestyle, ED consumption and sleep pattern and quality. Questions pertaining to sleep were derived from the Pittsburgh Sleep Quality Index.[16] Questions included asking about sleep duration, pattern of sleep (whether normal or intermittent or anxiety), sleep quality, time to sleep and bed time.

Subsequent to approval and validation, the questionnaire was converted to an electronic version with the aid of Google Drive. The questionnaire is stored in a public repository and can be found via the link: http://goo.gl/forms/EZBaQ4oaSR. The electronic questionnaire was distributed to eligible participants via email after ethical approval from the Research Ethics Committee/UOS, Sharjah, UAE was obtained. Furthermore, social media were used to invite students to participate until the target number of students was reached. Participation was entirely voluntary, with no monetary or non-monetary incentives offered.

Verbal or written consent was not possible to obtain due to the electronic nature of distribution and administration of the questionnaire. Thus, completion of questionnaire after reading the introduction was considered as an approval for enrolment in the study. Use of online questionnaires in health research has been reported to be as accurate as paper questionnaires, with a greater than 97% agreement with face-to-face interviews as well as a number of benefits and a wider application use than paper questionnaires.[17]

Analyses were reported based on the guidelines advocated by Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[18] Data were entered, processed and analysed using SPSS software 22.0. Descriptive statistics using frequencies and percentage distributions were used for demographics, ED consumption, lifestyle and sleep quality and patterns. Chi-square statistic, Pearson or Spearman coefficients were used to elucidate the relationship between sleep patterns and consumption of ED. Odds ratios (OR) were computed using 2×2 contingency tables to measure associations between dietary and lifestyle behaviours (smoking, eating breakfast and regular physical activity) as exposures and ED consumption as an outcome (data not shown). Results were considered significant at $P < 0.05$.

Results

Selected lifestyle habits and demographic characteristics of participants are presented in Table 1. Of the 919 students, the majority of participants were females (74.2%), and about one-quarter (25.8%) were males. Less than one-third (27.5%) of the participants were freshmen, and 44.3% were from medical colleges. The vast majority (83.4%) of the participants highlighted that they do not smoke. More than two-thirds (77.8%) of participants reported a lack of regular exercise or no exercise at all. Less than half of the study participants (46.9%) reported that they eat breakfast usually, and 45.6% reported that they eat breakfast sometimes.

Table 2 demonstrates the frequency of ED and behavioural factors related to its consumption among the study participants. Around two-thirds of the participants responded 'no' when asked whether they consumed ED or not. Among ED consumers, 11.4, 22.3 and 66.3% reported consumption on a daily, weekly and monthly basis, respectively. Results indicate a greater prevalence of ED consumption among females (OR 2.5; 95% CI 1.9–3.5).

The majority of consumers had started drinking ED during and after high school. The most common three locations of the first experience of ED consumption differed, with home being the most (24.2%), followed by coffee shops (17.8%) and gyms/malls (14.4%). Roughly half of the sample (46.3%) was introduced to ED consumption by a friend.

Table 1 Personal and lifestyle characteristics of study participants

Variable		*Frequency (n = 919)*	*%*
Gender	Male	237	25.8
	Female	682	74.2
Educational level	First year	253	27.5
	Second year	222	24.2
	Third year	193	21.0
	Fourth year	177	19.3
	Fifth year	74	8.1
College	Medical & Health Sciences	407	44.3
	Basic & Applied Sciences	320	34.8
	Human & Social Sciences	175	19.0
	Graduate	17	1.8
Current smoking status	Never smoked	770	83.8
	Smoking cigarette	35	3.8
	Smoking water pipe	79	8.6
	Combined smoker	35	3.8
Physical Activity	Regularly	204	22.2
	Irregularly	412	44.8
	Never	303	33.0
Breakfast intake	Usually	431	46.9
	Sometimes	419	45.6
	Never	69	7.5

The vast majority (87.5%) of ED consumers reported that they were not consuming ED with meals. Home and university (about 48%) were the two preferred places for ED consumption. Results of the current study showed that the highest rates of ED consumption occurred when participants were highly stressed (50%), as in the case of final exams and project/report submission.

About two-thirds of the study participants reported having normal sleep patterns (59.0%). More than half of the sample went to sleep after midnight (55.2%). Most participants reported falling asleep within half an hour, with about one-third taking less than 15 minutes and about 42% taking 15–30 minutes to sleep. It was observed that the vast majority (76.7%) of participants received less than 6 hours of sleep per night, which is roughly 2 hours less than the recommended sleep duration (7–9 hours).[19] Moreover, more than two-thirds of the participants (68.6%) reported having good sleep quality, and about one-third (31.4%) reported bad sleep quality.

Differences in the sleep characteristics between ED consumers and non-consumers are displayed in Table 3. While 29.5% of the non-consumers reported bad sleep quality, 34.3% of the ED consumers reported bad sleep quality, with about 5% difference. The same trend was observed for sleep patterns, with a higher percentage of students reporting normal sleep patterns among non-ED consumers as compared with ED consumers (64.4% and 50.8%, respectively). Additionally, non-consumers were having longer durations of sleep, that is, more than 6 hours (24.2%), in comparison with ED consumers (22.1%). However, these trends did not reach statistical significance. No association was found between ED consumption and time to sleep. Significant relationships were noted between ED consumption and sleep pattern and bed time ($r = 0.1$, $P = 0.001$) and subjective sleep quality ($r = 0.1$, $P = 0.002$) as perceived by participants. Results also indicate a marginal association between ED consumption and sleep duration, yet it did not reach significant difference ($r = 0.01$, $P = 0.06$). Among ED consumers, only 5.6% reported very good sleep quality in comparison with 12.7% of non-consumers; a report of very good sleep quality was more than twofold higher (12.7%).

Several associations between ED consumption and dietary and lifestyle behaviours were examined to further understand the relationship between ED and sleep quality.

Smoking (OR 0.15; 95% CI 0.1–0.2) and eating breakfast (OR 0.61; 95% CI 0.38–1.0) decreased the likelihood of consuming ED. In contrast, physical activity appeared to slightly increase the risk (OR 1.1; 95% CI 0.8–1.4) of ED consumption.

Discussion

To our knowledge, this is the first large-scale study to examine sleep patterns and quality in relation to ED consumption in the Arab and Gulf region.

The gender distribution in the present sample is comparable to the demographics of the UOS, which comprised about 70% of female students. Approximately half of the students (46.9%) reported that they usually eat breakfast, and around 78% of participants of the study were either found to be not exercising at all or not engaging in regular physical activity, giving an insight into the UOS students' lifestyle and dietary habits.

About 16% of the study participants were smokers, which is relatively low when compared to other relevant

Table 2 ED consumption and sleep characteristics of study participants

Variable		*Frequency*	*%*
Energy drink consumption			
Current consumption of ED (n = 919)	Yes	376	40.9
	No	543	59.1
Frequency of consumption (n = 376)	Daily	43	11.4
	Weekly	84	22.3
	Monthly	249	66.3
First time of experience with ED (n = 376)	Middle school	90	23.9
	High school	147	39.1
	University	74	19.7
	Do not remember	65	17.3
First place of experience with ED (n = 376)	Home	91	24.2
	Gym, mall	54	14.4
	Street	46	12.2
	Coffee shop	67	17.8
	Dorms	15	4.0
	Other	49	13.0
	Do not remember	54	14.4
First person who introduced ED (n = 376)	Friend	174	46.3
	Family	67	17.8
	No one	95	25.3
	Other	40	10.6
ED and meals (n = 376)	With meal	26	6.9
	Without meal	329	87.5
	No preference	21	5.6
Highest consumption place (n = 376)	Home	90	23.9
	Coffee shop	70	18.6
	Car	63	16.8
	University	92	24.5
	Gym	12	3.2
	Combined	49	13.0
Highest consumption time (n = 376)	Stress	188	50.0
	Vacation	56	14.9
	Driving	28	7.4
	Gym	10	2.7
	No specific time	94	25.0
Sleep characteristics			
Sleep pattern (n = 919)	Normal	542	59.0
	Intermittent	178	19.4
	Anxiety	199	21.6
Bed time (n = 919)	9–10 p.m.	49	5.3
	10–12 p.m.	363	39.5
	after 12 a.m.	507	55.2
Time to sleep (n = 919)	≤15 min	288	31.3
	15–30 min	381	41.5
	30–60 min	177	19.3
	≥60 min	73	7.9
Sleep hours during the night (n = 919)	<5 h	167	18.2
	5–6 h	538	58.5
	6–7 h	190	20.7
	≥7 h	24	2.6
Perceived sleep quality (n = 919)	Very good	90	9.8
	Fairly good	540	58.8
	Fairly bad	231	25.1
	Very bad	58	6.3

Table 3 Differences in sleep characteristics between ED consumers and non-consumers

		Consume energy drink					
		Yes		*No*			
Variable		*n*	*%*	*n*	*%*	χ^2 *statistic*	P-*value*
Sleep duration	<5 h	65	17.3	102	18.8	7.5	0.06
	5–6 h	228	60.6	310	57.1		
	6–7 h	68	18.1	122	22.5		
	≥7 h	15	4	9	1.7		
Sleep pattern	Normal	191	50.8	351	64.6	24.3	0.001*
	Intermittent	75	19.9	103	19		
	Anxiety	110	29.3	89	16.4		
Time to sleep	≤15 min	120	31.9	168	30.9	6.2	0.100
	15–30 min	142	37.8	239	44		
	30–60 min	76	20.2	101	18.6		
	≥60 min	38	10.1	35	6.4		
Bed time	9–10 p.m.	20	5.3	29	5.3	22	0.001*
	10–12 p.m.	115	30.6	248	45.7		
	After 12 a.m.	241	64.1	266	49.0		
	Very good	21	5.6	69	12.7		
Sleep quality	Fairly good	226	60.1	314	57.8	1486	0.002*
	Fairly bad	99	26.3	132	24.3		
	Very bad	30	8	28	5.2		

*Chi-square difference comparing ED consumers to non-consumers. Significant difference at $P < 0.05$.

studies conducted in other countries such as the United States.[20,21]

Furthermore, the findings from the present analysis indicate that consumption of ED is popular amongst the students, with 41% of students reporting consumption of ED. Nonetheless, the observed percentage of ED consumption in the current study is considerably lower than that found in other research in the UAE, where about 92% of students were found to consume ED.[13] Furthermore, the frequency of ED consumption in the current study was lower as compared to other studies on college students, such as Sanchez *et al*. in Peru (52.0% of males and 58.4% of females),[10] Malinauskas *et al*. in the United States (51%),[12] Buxton *et al*. in Ghana (62.2%)[22] and Attila and Çakir in Turkey (48.3%),[23] but higher than that reported by Bulut *et al*. in Turkey (about 25%).[24]

About 44% of the students participating in this investigation were from medical colleges, suggesting that those students might be more aware of the negative health implications of ED consumption than non-medical students.

In a survey among US college students, 51% of the students were found to consume at least one ED per month, with the majority of participants engaging in habitual consumption (several times a week).[12] These results are consistent with findings from the present study, which showed that 11.4% of students consumed ED on a daily basis, 22.3% on a weekly basis and 66.3% consumed ED on a monthly basis.

The results also indicated that friends were the most likely individuals to have first introduced ED to participants. These findings are comparable to Attila and Çakir, who observed that most college students who had ever drunk ED reported their first encounter to be with friends.[23] Bulut and colleagues also found that consumption of ED by friends was a risk factor (OR 3.6; 95% CI 2.6–5.0) for consumption of ED among university students.[24]

Surprisingly, home was the first place of experience with ED and was the second most preferred location for ED consumption. Approximately two-thirds of consumers started drinking ED in middle and high school. These findings may suggest a lack of parental guidance and/or knowledge regarding the harmful effects of ED. Results of the current study reinforce the impact of the surrounding social and environmental factors in adopting and developing unhealthy dietary and lifestyle behaviours.

Inadequate sleep is a medical condition that may significantly compromise overall well-being and is associated with a host of unfavourable consequences.[25] Consumption of caffeinated beverages has been suggested as a factor that contributes negatively to sleep quality.[26] For example, one study noted that stimulant drinks intake was linked to risks of poor sleep quality, especially among those consuming caffeinated beverages.[27] Other investigations, including a sample of men and women (n = 63), revealed that consumption of caffeinated coffee post-dinner, even in small amounts (1 cup), results in poorer sleep quality.[28]

Overall, sleep problems are common among college students and are associated with aggressive behaviours, poor well-being, impaired driving skills, diminished cognitive capacity, interpersonal problems and lower academic performance.[29] In a study focused on relationships between sleep disorders and academic achievement among college

students, Gaultney et al. indicated that having sleep disorders were overrepresented among students facing academic risk and difficulties.[30]

Studies have shown that college students build their utilisation of ED, expand their multitasking propensities and use over-the-counter medicines to conform their sleep cycle in order to enhance academic performance, work and social exercises.[31] A number of adverse behaviours have been observed to be associated with the frequent consumption of ED, including sexual risk-taking behaviour, use of marijuana, seatbelt omission and fighting along with drinking alcohol, vehicle accidents while smoking and illicit prescriptions of drugs.[32,33] According to Marczinski,[34] ED have become the fastest growing segment in the beverage industry and eventually became a popular mixer for alcoholic beverages. The author found that the use of alcohol-mixed ED is riskier than the use of simple alcohol. The likelihood of engaging in risky behaviours, such as drinking and driving, increases as the caffeine intake misleads the consumer into feeling less drunk and more coordinated and balanced than they actually are.[34] Additionally, a more recent study revealed that ED users drink alcohol more frequently than non-users. Side effects reported after ED consumption included palpitations, insomnia and irritability in 35, 21 and 20% of the ED users, respectively.[35]

The current research findings are consistent with previous studies that highlight that ED consumers reported less sleepiness and increased alertness, especially when taken 6 hours prior to sleeping.[36] We found a significant relation between ED consumption and sleep quality ($P = 0.002$), with only a small percentage of ED consumers reporting very good sleep quality. Findings of the current study are in agreement with the report by Lohsoonthorn and colleagues,[9] which demonstrated a statistically significant and positive relationship between stimulant use and poor quality of sleep (OR 1.50; 95% CI 1.28–1.77).

In reference to the findings of the current study, cigarette smoking and eating breakfast were associated with reduced ED consumption. This could be explained by the fact that smokers and breakfast eaters are usually feeling energised and stimulated by virtue of the stimulating effect of tobacco or stimulant hot drinks such as coffee or tea taken at breakfast.

Although students in this university represented a heterogeneous population from diversified socioeconomic and family backgrounds, the sample cannot be used for generalising the overall population of UAE consisting of different age groups. Other limitations include omitting to ask about other types of caffeinated beverages that were consumed during the day. The questionnaire measured ED using an approximate measure, which may be prone to reporting bias. The greater contribution of female students than males slightly limits the generalisability of the data. Finally, the cross-sectional nature of the study restricts the ability to infer causation.

In summary, it was found that most of the UOS students were not ED consumers, as opposed to data reported in other studies. The reported prevalence of ED consumption was lower than that in other countries. From the results of this study, it can be concluded that a significant correlation exists between ED consumption and sleep quality and that sleep pattern and bedtime are significantly associated with ED consumption. However, no significant association between ED consumption and sleep hours or time to sleep was observed. The findings of our study highlight the need for educating students and adults on the significance of sleep and the impact of their lifestyle and dietary behaviours on health, specifically on sleep quality.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

'Mo'ez Al-Islam' Faris contributed to the conception and design of the work; Marwa Al-Hilali, Noor Chehyber, Sara Ali and Sara Shahda participated in the acquisition, analysis and interpretation of data for the work; Reyad Obaid contributed to drafting the work and in the final approval of the version to be published; and Haitham Jahrami contributed to statistical analysis, revising the manuscript critically for important intellectual content and the final approval of the version. This is to verify that the content has not been published or submitted for publication elsewhere and that all authors are in agreement with the manuscript.

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ORIGINAL RESEARCH

Dietary sodium and potassium intake and their association with blood pressure in a non-hypertensive Iranian adult population: Isfahan salt study

Noushin MOHAMMADIFARD,[1,2] Arsalan KHALEDIFAR,[3,4] Alireza KHOSRAVI,[2,4] Fatemeh NOURI,[1] Ali POURMOGHADAS,[4] Awat FEIZI,[5,6] Ahmad ESMAILLZADEH[7,8,9] and Nizal SARRAFZADEGAN[1]

[1]Isfahan Cardiovascular Research Centre, [2]Hypertension Research Centre, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan and [3]Department of Cardiology, School of Medicine, Hajar Hospital, Modeling in Health Research Centre, Shahrekord University of Medical Sciences, Shahrekord, [4]Interventional Cardiology Research Centre, [5]Epidemiology and Biostatistics Department, [6]Cardiac Rehabilitation Research Centre, Cardiovascular Research Institute, [7]Food Security Research Centre, [8]Department of Community Nutrition, Isfahan University of Medical Sciences, Isfahan, and [9]Department of Community Nutrition, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran

Abstract

Aim: The association of sodium (Na) and potassium (K) intake with blood pressure (BP) is an ongoing debate, especially in central Iran. We aimed to examine the mean Na and K intake, major sources of Na and the relationship between BP and dietary and urinary Na and K.

Methods: This cross-sectional study was performed in central Iran in 2013–2014. A total of 796 non-hypertensive adults aged >18 years were randomly recruited. The semi-quantitative food frequency questionnaire was used to assess dietary Na and K intake. Moreover, 24-hour urine samples were collected to measure 24-hour urinary Na (UNa) and K (UK) as biomarkers. BP was measured twice on each arm using a standard protocol.

Results: The mean Na and K intake were 4309.6 ± 1344.4 and 2732.7 ± 1050.5 mg/day, respectively. Table and cooking salt were the main sources of Na. Odds ratio (OR) (95% confidence interval (CI)) of the crude model in the highest quartile of UNa indicated a significant association with the higher risk of prehypertension (OR (95% CI): 2.09 (1.09–4.05); *P* for trend = 0.007). After adjustment for potential confounders, prehypertension was significantly associated with increasing dietary Na/K ratio (OR (95% CI): 1.28 (1.01–1.57); *P* for trend = 0.046) and UNa/UK ratio (OR (95% CI): 2.15(1.08-4.55); *P* for trend = 0.029).

Conclusions: Increasing dietary and urinary Na/K ratios and UNa were associated with elevated BP and prehypertension occurrence. These findings support the necessity of developing a salt reduction programme in our country.

Key words: blood pressure, diet, urine, Iran, potassium, sodium.

Introduction

Hypertension is a major public health issue affecting almost one quarter of adults worldwide. Its prevalence is on a rapid rise in developing countries[1] and has reached 17.3% among Iranian adult population.[2] Hypertension control has, hence, turned into a global public health priority.[3] Dietary modifications may regulate blood pressure (BP) and subsequently control hypertension.[4] Among dietary factors, high sodium (Na) and low potassium (K) intakes are associated with higher BP[5] and have been reported to increase overall mortality and the risk of cardiovascular diseases in the American population.[6] Na reduction may thus be the most cost-effective approach to hypertension control in both low- and high-income countries.[7] Although several epidemiological and interventional studies have shown BP to be independently associated with Na and K levels,[8,9] a population-based study rejected the relationship between K levels and BP.[8] However, two recent meta-analyses on 22 randomised clinical trials (RCTs) and population-based studies in 21 countries reported an inverse relationship between K levels and BP.[10,11] While most studies have

N. Mohammadifard, MSc, PhD Candidate
A. Khaledifar, MD, Associate Professor
A. Khosravi, MD, Associate Professor
F. Nouri, MSc, Statistician
A. Pourmoghadas, MD, Associate Professor
A. Feizi, PhD, Associate Professor
A. Esmaillzadeh, PhD, Professor
N. Sarrafzadegan, MD, Professor
Correspondence: A. Khaledifar, Department of Cardiology, School of Medicine, Hajar Hospital, Modeling in Health Research Center, Shahrekord University of Medical Sciences, P.O. Box 8813833435, Shahrekord, Iran Tel: +98-3833333448, Fax: +98-3833351040, Email: khaledifara@yahoo.com

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measured Na and K intake through dietary assessment methods, such as 24-hour dietary recall or semi-quantitative food frequency questionnaire (FFQ), evaluating the urinary excretion of Na and K using 24-hour urine collection is still considered the most valid and reliable method to determine daily intake of these two elements.[12] Furthermore, population-based studies have failed to establish obvious relationships between Na and K levels and hypertension. Because of the ongoing debate over these relationships,[13,14] especially in Eastern Mediterranean and Middle East regions, the present study aimed to evaluate the associations between dietary Na and K intake and BP using data from the Isfahan salt study in 2013–2014.[15]

Methods

The present study was performed on healthy adults aged >18 years in Isfahan city, Iran in 2013–2014. In order to select the participants using multi-stage cluster sampling, a number of households were first selected, and the study objectives and procedures were explained to them. One adult from each household was then recruited. Sample size was determined according to a previous study,[15] and a total of 796 healthy individuals were enrolled. While the only inclusion criteria was age greater than 18 years, the exclusion criteria were a history of diabetes insipidus, diabetes mellitus, hypertension, a special dietary regimen or fasting at the time of sampling, history of using diuretics, renal insufficiency, menstruation or pregnancy and excessive sweating on the day of urine collection. In addition, we excluded the participants with less than 500 mL urine/day, reporting more than one missed voiding. Male and female subjects who were younger than 50 years with 24-hour urine creatinine (UCr) to body weight ratios of less than 20 and 15 mg/kg/day, respectively, along with those who were aged 50 years and over with UCr to body weight ratios of less than 10 and 7.5 mg/kg/day, respectively. The study was approved by the Research Council of Isfahan Cardiovascular Research Centre (ICRC), a World Health Organization (WHO) collaborative centre, ethics committee. Written informed consent was obtained from all participants. This paper was prepared based on the strengthening the reporting of observational studies in epidemiology (STROBE) statement for cross-sectional studies.

The medical history of all subjects was taken, and clinical examinations followed by blood and urine tests were performed. Height and weight were measured using standard methods. Body mass index (BMI) was calculated as weight divided by height squared (kg/m^2). BP was measured manually by a trained operator using a mercury sphygmomanometer according to standard protocol,[16] twice from right and left arms in sitting position after five minutes of rest. We kept the BP measurement environment silent to hear Korotkoff sound. The first Korotkoff sound was recorded as the systolic blood pressure (SBP), and the disappearance of the sounds (V phase) was considered the diastolic blood pressure (DBP). The mean of the two BP readings on the arm with higher BP was used in the analyses. According to the Joint National Committee7 (JNC7) and WHO guidelines, prehypertension was defined as an SBP of 130–139 mmHg and/or a DBP of 80–89 mmHg.[1]

Dietary assessment was carried out by a 136-item semi-quantitative FFQ. The FFQ was validated against the gold standards of 24-hour urine samples and 12-monthly 24-hour dietary recalls in 113 participants. The FFQ was also recompleted with a one-year interval to examine its reproducibility. The criterion validity and reproducibility were presented by correlation and intra-class correlation coefficients, respectively. The criterion validity of FFQ for assessment of Na and K was 0.60 and 0.56 compared with 24-hour dietary recall and 0.31 and 0.38 against 24-hour urine Na and K excretions, respectively. The reproducibility was 0.43 and 0.40 for Na and K intake, respectively. The FFQ was coded by giving a gram weight to every portion reported. All dietary data were entered into the Iranian Food Consumption Program (IFCP), designed by ICRC,[17] and analysed. The IFCP calculated nutrient intake and food group servings for all foods reported in the FFQ. It had a research quality nutrient database analysing Na and K for a variety of food items using the Iranian Food Composition Table,[18] which was modified based on the US Department of Agriculture National Nutrient Database. Trained nutritionists assisted in the design and validation of the dietary questionnaire. The FFQ included some questions about dietary supplements and five questions regarding discretionary salt consumption, including salt used at the table and salt for food preparation at home. The salt intake questions comprised using the salt shaker, the weight of the salt package that they usually use, how long before the salt package was consumed, the total number of family members and their age to estimate salt consumption by each participant.

Urine samples were collected from 7 a.m. to 7 a.m. the next day (after excluding the first sample of the first day). The samples were poured into sterile plastic containers labelled with the participants' name and a special code. Inappropriately collected samples along with those with a low volume of urine were excluded from the analysis. If a person was unable to deliver the urine sample to the laboratory, we collected it at his/her home. Venous blood samples were taken on the same day to measure serum biochemical indices, including fasting blood sugar, serum albumin level and lipid profile. Total 24-hour urinary Na (UNa) was calculated by multiplying Na concentration by the urine volume in litres. Urinary chemical parameters including UNa, 24-hour urinary K (UK) and 24-hour UCr were measured. In order to assess the accuracy of urinary samples as 24-hour specimens, we measured the concentration of UCr using Jaffe method (technical SMA 12-60).

Categorical variables were presented as frequencies, mean and standard deviations were used to summarise the values of continuous variables. As our data were fairly complete, a simple approach (i.e. complete-case) was adopted to handle missing data. Chi-square and Student's *t*-tests were used to compare baseline characteristics between normotensive and prehypertensive participants. As the percentage of food contribution in Na intake was not normally

distributed, we utilised a Mann–Whitney *U* test to compare the two groups. An analysis of variance (ANOVA) test was applied to compare the mean of normally distributed variables. In cases where the data did not have a normal distribution, Kruskal–Wallis tests in UNa, UK and UNa/UK ratio quartiles were used.

Hierarchical logistic regression was used to determine effect sizes according to different categories of confounders. In fact, simple logistic regression was first fitted to evaluate the crude relationships between prehypertension and the quartiles of dietary and urinary Na, K and Na/K ratio. Multiple logistic regression was then applied to find the adjusted associations, considering the reference category as those at the first quartile. The initial adjusted model was defined to comprise age and gender as covariates (Model 1). We fitted Model 2 to assess additional adjustment for BMI (kg/m^2). The confounder effect of 24-hour UCr (mg/day) was additionally adjusted in Model 3. Using the median of dietary and urinary Na, K and Na/K ratio in each quartile in the logistic models, the trend of odds ratios (ORs) were evaluated by finding the P values for each trend. Statistical analyses were performed using SPSS for windows 18.0 (SPSS Inc, Chicago, IL, USA). The significance level was set at $P < 0.05$.

Results

The study sample included 796 individuals (349 men and 447 women). As Table 1 shows, the mean Na and K dietary intake and Na/K ratios in all participants were 4309.6 ± 1344.4, 2732.7 ± 1050.5 mg/day and 1.6 ± 0.8, respectively. The mean 24-hour UNa, UK and UNa/UK ratios in the whole population were 4069.6 ± 1655.3, 2242.9 ± 1636.5 mg/day and 1.8 ± 1.0, respectively. Normotensive and prehypertensive participants had no significant differences in the mean dietary and urinary Na, K and Na/K ratio ($P > 0.05$). However, the mean age, SBP, DBP, BMI (all $P < 0.001$) and UCr ($P = 0.003$) were significantly higher in prehypertensive subjects than in normotensive participants. Moreover, prehypertension was marginally significant more frequently in men than in women ($P = 0.05$). Normotensive and prehypertensive participants had non-significant differences in terms of nuts and seeds, fruits and vegetables, fast food, dairy products, canned food, salty snacks, processed meat, sweats and soft drinks ($P > 0.05$); however, only grain consumption was significantly more in prehypertensive *versus* normotensive ($P = 0.040$).

The main sources of Na intake were table and cooking salt, grains, cheese, fruits and vegetables, other dairy products, meats, fast foods, sweets and soft drinks, salty snacks, canned foods and nuts and seeds (Table 2). There was a non-significant difference between sources of Na intake in normotensive and prehypertensive participants ($P > 0.05$). The mean SBP and DBP were not significantly related with urinary and dietary Na and K levels ($P > 0.05$) (Table 3). However, SBP and DBP significantly increased with higher dietary Na/K ratio ($P = 0.006$ and 0.039, respectively) and UNa/UK ratio ($P < 0.001$ and 0.003, respectively).

According to the obtained ORs (95% confidence interval (CI)) for the crude and adjusted models, there were no

Table 1 Basic characteristics of participants according to blood pressure

	Total	*Normotensive*	*Prehypertensive*	P-*value*[(a)]
Age (years)	38.9 ± 11.4	37.8 ± 11.0	43.6 ± 11.7	<0.001
Gender (male) (%)	349 (43.3)	309 (42.2)	40 (54.1)	0.050
Dietary sodium (mg/day)	4309.6 ± 1344.4	4309.9 ± 1366.9	4308.2 ± 1240.6	0.989
Dietary potassium (mg/day)	2732.7 ± 1050.5	2710.8 ± 1049.0	2832.6 ± 1055.2	0.208
Dietary sodium to potassium ratio	1.6 ± 0.8	1.6 ± 0.9	1.5 ± 0.8	0.409
24-hour urine sodium (mg/day)	4069.6 ± 1655.3	4070.6 ± 1684.4	4065.3 ± 1521.1	0.973
24-hour urine potassium (mg/day)	2242.9 ± 1636.5	2202.7 ± 1609.7	2125.8 ± 1547.6	0.335
24-hour urine sodium to potassium ratio	1.8 ± 1.0	1.8 ± 1.0	1.9 ± 0.9	0.264
Systolic blood pressure (mmHg)	112.0 ± 10.9	108.9 ± 8.5	126.2 ± 9.2	<0.001
Diastolic blood pressure (mmHg)	70.8 ± 8.7	68.1 ± 6.5	83.5 ± 5.7	<0.001
Body mass index (kg/m^2)	25.7 ± 4.4	25.4 ± 4.5	28.4 ± 4.5	<0.001
24-hour urine creatinine (mg/day)	1611.8 ± 555.4	1585.32 ± 557.4	1732.5 ± 531.6	0.003
Dietary intake (g/day):				
Grains	358.6 ± 132.1	353.0 ± 150.6	374.6 ± 157.4	0.040
Nuts and seeds	7.6 ± 10.2	7.6 ± 7.9	7.2 ± 9.5	0.675
Fruits and vegetables	298.2 ± 165.1	294.8 ± 186.5	314.3 ± 141.5	0.151
Fast food	33.9 ± 30.5	33.8 ± 30.9	34.5 ± 29.7	0.176
Dairy products	362.0 ± 218.9	356.5 ± 211.3	387.3 ± 250.1	0.171
Canned food	7.3 ± 10.2	7.5 ± 10.3	6.6 ± 8.3	0.483
Salty snacks	5.1 ± 4.2	5.4 ± 4.5	3.7 ± 7.6	0.064
Processed meat	8.9 ± 6.7	8.9 ± 7.0	8.7 ± 6.9	0.231
Sweats and soft drinks	138.1 ± 114.2	139.0 ± 119.2	136.3 ± 126.6	0.623

[(a)] *P*-value: comparison between normotensive and prehypertensive participants.

Table 2 Food contribution in sodium intake according to blood pressure

Food item (%)	*Total*	*Normotensive*	*Prehypertensive*	P-*value*[(a)]
Salt at table and preparing food	48.8 ± 14.1	49.1 ± 13.9	48.4 ± 14.9	0.594
Grains	18.1 ± 7.8	18.1 ± 7.9	18.3 ± 7.7	0.723
Cheese	8.8 ± 6.2	8.5 ± 5.9	9.2 ± 7.3	0.327
Fruits and vegetables	7.3 ± 3.5	7.3 ± 3.9	8.7 ± 7.9	0.867
Other dairy products	6.1 ± 3.8	6.1 ± 3.7	6.5 ± 4.1	0.258
Meats	3.8 ± 2.5	3.8 ± 2.6	3.7 ± 2.0	0.739
Fast food	2.1 ± 3.1	2.1 ± 3.1	2.1 ± 3.0	0.857
Sweats and soft drinks	1.6 ± 1.8	1.6 ± 1.9	1.5 ± 1.7	0.316
Salty snacks	0.8 ± 1.4	0.8 ± 1.4	0.6 ± 1.2	0.143
Canned food	0.5 ± 1.0	0.5 ± 1.0	0.5 ± 0.9	0.873
Nuts and seeds	0.1 ± 0.4	0.1 ± .0.4	0.1 ± 0.5	0.416
Others	1.5 ± 1.9	1.9 ± 1.9	1.0 ± 1.2	0.129

[(a)] *P*-value: comparison between normotensive and prehypertensive participants by the Mann–Whitney *U* test.

significant relationships between dietary Na and K levels and Na/K ratio except for the OR (95% CI) of the highest quartile of dietary Na/K ratio against reference in the fully adjusted model (OR (95% CI): 1.28 (1.01–1.57); *P* for trend = 0.046) (Table 4).

As seen in Table 5, OR (95% CI) of the crude model in the highest quartile of UNa indicated a significant association with the higher risk of prehypertension (OR (95% CI): 2.09 (1.09–4.05); *P* for trend = 0.007). The OR increased in Model 1 with adjustment for age and gender (OR (95% CI): 2.35 (1.17–4.71); *P* for trend = 0.005). The ORs in Model 2 with additional adjustment for BMI and Model 3 with additional adjustment for UCr were not significantly related to UNa levels in the second, third and fourth quartiles compared to the first quartile. However, the trend of ORs in these models showed a significant increase (*P* for tend = 0.033 and 0.045, respectively). Nevertheless, there were non-significant associations between prehypertension and UK in the crude and multivariate models (Table 5). The OR of prehypertension was not significantly associated with the UNa/UK ratio in the crude model and the model adjusted for age and gender (model 1). In contrast, the OR (95% CI) of UNa/UK ratio in the Model 2 with additional adjustment for BMI was significantly associated with a higher risk of prehypertension in the highest quartile of the UNa/UK ratio (OR (95% CI): 2.14(1.01–4.55); *P* for trend = 0.030). Similar results were seen in Model 3 with additional adjustment for UCr (OR (95% CI): 2.15 (1.08–4.55); *P* for trend = 0.029) (Table 5).

Discussion

There was a significant positive association between dietary Na/K ratio and prehypertension in the fully adjusted model. The present study also showed significant positive

Table 3 Mean blood pressures based on quartiles of dietary and urinary sodium, potassium and sodium to potassium ratio

	Q1	*Q2*	*Q3*	*Q4*	P-*value*[(a)]
Quartile of sodium intake	<3270	3270–4083	4084–5256	>5256	
Systolic blood pressure (mmHg)	111.7 ± 10.6	112.7 ± 11.6	111.3 ± 10.9	112.3 ± 10.1	0.569
Diastolic blood pressure (mmHg)	70.8 ± 9.1	71.2 ± 8.7	70.4 ± 8.5	71.0 ± 8.3	0.233
Quartile of potassium intake	<2008	2008–2549	2550–3198	>3198	
Systolic blood pressure (mmHg)	111.8 ± 11.5	112.3 ± 9.8	111.1 ± 10.4	112.8 ± 11.6	0.344
Diastolic blood pressure (mmHg)	71.1 ± 9.3	69.9 ± 8.0	70.9 ± 8.6	71.5 ± 8.6	0.213
Quartile of sodium to potassium ratio intake	<1.22	1.22–1.59	1.60–2.03	>2.03	
Systolic blood pressure (mmHg)	109.8 ± 10.8	112.9 ± 10.9	112.0 ± 10.7	113.2 ± 10.4	0.006
Diastolic blood pressure (mmHg)	69.4 ± 9.4	71.4 ± 8.4	71.0 ± 8.7	71.6 ± 10.4	0.039
Quartile of urinary sodium	<2865	2865–3780	3781–5011	>5011	
Systolic blood pressure (mmHg)	112.9 ± 12.3	111.6 ± 11.1	111.6 ± 9.8	111.2 ± 10.4	0.594
Diastolic blood pressure (mmHg)	69.7 ± 8.1	70.9 ± 8.2	71.2 ± 9.1	71.3 ± 9.3	0.202
Quartile of urinary potassium	<1474	1474–2008	2009–2626	>2626	
Systolic blood pressure (mmHg)	112.9 ± 10.7	111.6 ± 10.8	112.7 ± 10.4	111.8 ± 11.9	0.341
Diastolic blood pressure (mmHg)	70.8 ± 8.2	69.5 ± 7.8	71.6 ± 8.7	71.0 ± 8.8	0.247
Quartile of urinary sodium to potassium ratio	<1.39	1.39–1.87	1.88–2.63	>2.63	
Systolic blood pressure (mmHg)	109.2 ± 11.0	112.1 ± 10.6	112.6 ± 11.6	114.0 ± 9.8	<0.001
Diastolic blood pressure (mmHg)	69.2 ± 9.0	71.1 ± 7.8	70.7 ± 8.7	72.4 ± 7.9	0.003

[(a)] *P*-value: for parametric analysis, ANOVA test and for nonparametric analysis, Kruskal–Wallis test was used.

Table 4 Odds ratios (95% CI) of prehypertension based on quartiles of dietary sodium, potassium and sodium to potassium ratio

					P *for trend*
Quartiles of sodium intake					
Crude model	1	1.29 (0.76–2.20)	1.66 (0.99–2.79)	1.21 (0.70–2.07)	0.052
Model 1[(a)]	1	1.21 (0.69–2.12)	1.50 (0.87–2.60)	1.13 (0.64–1.99)	0.105
Model 2[(b)]	1	1.21 (0.69–2.13)	1.50 (0.87–2.60)	1.13 (0.64–1.99)	0.112
Model 3[(c)]	1	1.17 (0.66–2.05)	1.48 (0.85–2.56)	1.11 (0.63–1.97)	0.115
Quartiles of potassium intake					
Crude model	1	0.75 (0.45–1.23)	0.87 (0.52–1.40)	0.79 (0.35–1.12)	0.161
Model 1[(a)]	1	0.79 (0.46–1.33)	0.85 (0.51–1.43)	0.76 (0.32–1.09)	0.129
Model 2[(b)]	1	0.78 (0.46–1.33)	0.85 (0.51–1.43)	0.76 (0.32–1.08)	0.125
Model 3[(c)]	1	0.78 (0.46–1.32)	0.87 (0.52–1.47)	0.77 (0.33–1.09)	0.131
Quartile of sodium to potassium ratio intake					
Crude model	1	1.18 (0.91–1.50)	1.13 (0.89–1.46)	1.19 (0.94–1.51)	0.123
Model 1[(a)]	1	1.20 (0.92–1.53)	1.15 (0.88–1.45)	1.22 (0.95–1.53)	0.116
Model 2[(b)]	1	1.24 (0.95–1.54)	1.21(0.92–1.51)	1.25 (0.97–1.56)	0.105
Model 3[(c)]	1	1.26 (0.97–1.56)	1.23 (0.95–1.52)	1.28 (1.01–1.57)	0.046

[(a)] Model 1: adjustment for age and gender.
[(b)] Model 2: additional adjustment for body mass index.
[(c)] Model 3: additional adjustment for 24-hour urinary creatinine.

Table 5 Odds ratios (95% CI) of prehypertension based on quartiles of urinary sodium, potassium and sodium to potassium ratio

					P *for trend*
Quartiles of sodium					
Crude model	1	0.79(0.36–1.73)	1.20(0.59–2.45)	2.09(1.09–4.05)	0.007
Model 1[(a)]	1	0.89(0.39–1.99)	1.25(0.59–2.65)	2.35(1.17–4.71)	0.005
Model 2[(b)]	1	0.89(0.38–2.04)	1.15(0.52–2.56)	1.98(0.94–4.16)	0.033
Model 3[(c)]	1	0.85(0.37–1.96)	1.12(0.50–2.49)	1.89(0.89–3.97)	0.045
Quartiles of potassium					
Crude model	1	1.01(0.51–2.03)	0.88(0.43–1.82)	1.39(0.73–2.69)	0.318
Model 1[(a)]	1	0.82(0.40–1.69)	0.70(0.33–1.50)	1.11(0.56–2.18)	0.683
Model 2[(b)]	1	0.64(0.30–1.37)	0.49(0.22–1.12)	0.74(0.35–1.55)	0.564
Model 3[(c)]	1	0.63(0.29–1.37)	0.47(0.21–1.07)	0.68(0.32–1.46)	0.440
Quartile of sodium to potassium ratio					
Crude model	1	0.99(0.48–2.05)	1.19(0.59–2.39)	1.49(0.76–2.93)	0.176
Model 1[(a)]	1	1.04(0.49–2.21)	1.35(0.66–2.79)	1.87(0.93–3.77)	0.051
Model 2[(b)]	1	1.02(0.46–2.25)	1.33(0.63–2.80)	2.14(1.01–4.55)	0.030
Model 3[(c)]	1	1.00(0.45–2.21)	1.31(0.62–2.77)	2.15(1.08–4.55)	0.029

[(a)] Model 1: adjustment for age and gender.
[(b)] Model 2: additional adjustment for body mass index.
[(c)] Model 3: additional adjustment for 24-hour urinary creatinine.

relationships of BP with both UNa and UNa/UK ratio, which are a proxy for unhealthy diet after adjustment for potential confounders such as age, gender, BMI and UCr. However, there was no significant association between K and BP. Moreover, SBP and DBP significantly increased with increasing dietary and urinary Na/K ratios.

Similar to our findings, large-scale observational studies such as INTERSALT,[19] European Prospective Investigation into Cancer in Norfolk[20] and Prospective Urban Rural Epidemiological Study, as well as some recent meta-analyses of RCTs, illustrated a positive relationship between Na and BP that was greater in hypertensive than normotensive populations.[22–26] Other population-based studies reported that reducing Na intake could reduce BP in both hypertensive and normotensive adults.[11,27,28]

The evidence regarding the association between K intake and BP is inconsistent. Contrary to our findings, several epidemiological and clinical trials indicated an inverse relationship between dietary K intake and BP.[20,27–29] The INTERSALT study showed a negative association between UK and BP in a large population from around the world.[20] Several double-blind RCTs reported that reducing K intake increased BP in both hypertensive and normotensive participants.[20,27–29] Moreover, Siani *et al*. concluded that a

high-K diet decreased the need for antihypertensive medications in patients with normal renal function.[30]

Appel *et al*. suggested that the high natural K content of fruits and vegetables in combination with low Na intake, according to the Dietary Approach to Stop Hypertension (DASH), reduced SBP and DBP in both hypertensive and normotensive participants.[31] However, the exact role of K in the beneficial effects of DASH cannot be determined as the antioxidant content of fruits and vegetables might actually be responsible for BP reduction.[32] Nevertheless, a recent meta-analysis incorporating 22 RCTs reported that a K supplement reduced BP only in adults with primary hypertension.[10] One former meta-analysis including 33 RCTs found that the beneficial effect of dietary K supplementation on SBP and DBP remained in participants with high salt intake.[33] Therefore, K supplementation can be recommended as an appropriate strategy to decrease BP in hypertensive patients who cannot reduce their salt intake.[31] In fact, K intake can, to some extent, blunt the undesirable effects of high Na intake.[34]

However, a systematic review on six RCTs confirmed our findings and indicated that dietary K supplementation had no significant effects on SBP and DBP.[35]

Several potential reasons, including various polymorphisms in some relevant genes and maternal hypertension history, may lead to different reactions of persons to dietary K intake.[36,37] Furthermore, in most previous studies, few participants had stage II hypertension. In the present study, however, no individuals with mild hypertension (SBP and DBP of 140–159 and 90–99 mmHg, respectively) were included. Finally, using the most valid biomarker of Na and K intake in the present study has probably increased the accuracy of our estimations compared to those in previous studies.

Consistent with the findings of previous studies,[14,38,39] the present study showed the incidence of prehypertension to be more strongly related with the UNa/K ratio than with either UNa or UK alone. We found that the OR of prehypertension occurrence was more than doubled in the highest quintile of the UNa/K ratio compared to its lowest quintile. Likewise, the National Health and Nutrition Examination Survey (2001–2006) and another population-based study reported that while the combination of Na and K had a positive relationship with the risk of elevated BP, no such relationships were present in case of Na and K alone.[14,39]

The average Na intake in the present study (167 mEq/day) was about two times higher than the 88 mEq/day (2000 mg/day) recommended by the WHO.[40] Moreover, the average K intake (63 mEq/day) among our participants was slightly lower than the recommended amount (2700–3100 mg/day).[40]

In the present study, the dietary Na/K ratio were 1.6 and 1.5 in normotensive and prehypertensive subjects and UNa/UK ratios were 1.8 and 1.9 in normotensive and prehypertensive participants, respectively. This ratio was 1.65 in the North American population[6] and 1.79 in Brazilian adults.[34] However, much lower values (about 0.06) were reported in the past decades.[41] Therefore, changes in dietary habits along with the adoption of the Western diet, including refined and processed foods, provide huge amounts of salt consumption and decreased their dietary K intake. Such changes will undoubtedly exert adverse health effects.[42,43] High Na intake may not only thicken and narrow the resistance arteries but also inhibit nitric oxide production and release sympathetic systems. These mechanisms will raise BP and lead to the development of hypertension.[44] While the mechanism through which K intake decreases BP is still unclear, induction of nitric oxide synthesis by increasing intracellular K content might be responsible for this effect.[44]

The strengths of the present study were using 24-hour urine collection as the standard approach for the measurement of Na and K intake. To the best of our knowledge, this was the first study in Iran and the Middle East to examine the associations of BP with not only Na and K intake but also 24-hour UNa and UK, which surrogate Na and K intakes in subjects without a diagnosis of hypertension.

As urine samples of a particular day may not accurately reflect one's usual dietary habits, collecting urine samples on a single day can be regarded as a limitation of the current research. Moreover, because of its cross-sectional design, the present study might have been unable to clarify the causality effect.

In conclusion, this population-based cross-sectional study showed elevated BP and prehypertension to be significantly related with increased dietary Na/K ratio, UNa and UNa/K ratio, which can be considered to be surrogates of an unhealthy diet. However, we failed to find significant relationships between BP and dietary Na, K and UK alone. Further clinical trials are thus warranted to investigate the causality effects of dietary Na and K intake on BP. Our findings supported the need for the development of a salt reduction programme in Iran.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

AKH contributed to drafting the article and final approval of the version to be published; ARKH contributed to study concept and design and interpretation of data; NM contributed to study concept and design, interpretation of data, drafting the article data, analysis and interpretation of data and revising content; FN and AF contributed to the analysis and interpretation of data and revising content; AE, JG and NS contributed to study concept and design and revising critically. All authors read and approved the final manuscript.

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ORIGINAL RESEARCH

Comparison of malnutrition inflammation score, anthropometry and biochemical parameters in assessing the difference in protein-energy wasting between normal weight and obese patients undergoing haemodialysis

Elham ALIPOOR,[1] Mohammad Javad HOSSEINZADEH-ATTAR,[1] Mitra MAHDAVI-MAZDEH,[2] Mehdi YASERI[3] and Narges S. ZAHED[4]

Departments of [1]Clinical Nutrition, School of Nutritional Sciences and Dietetics, [2]Iranian Tissue Bank & Research Centre and [3]Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences and [4]Department of Nephrology, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Abstract

Aim: Protein-energy wasting (PEW) is prevalent in haemodialysis. Obesity is an independent risk factor of kidney insufficiency, but it is proposed to have beneficial roles in better outcomes in the final stage of disease. Better nutritional status and body reserves are among probable mechanisms, but direct examinations are limited. The present study aimed to investigate whether obese patients have preferable nutritional status compared to normal weight patients based on malnutrition inflammation score (MIS) and other PEW parameters in haemodialysis.

Methods: This case–control study investigated 52 normal weight (18.5 < body mass index (BMI) < 25 kg/m^2) and 48 obese (BMI≥30 kg/m^2) patients on regular haemodialysis. PEW was assessed based on anthropometric and biochemical factors, recent weight changes, appetite, anorexia, dietary intake and MIS.

Results: Obese patients had better MIS compared with the normal weight group ($P < 0.001$), although varying degrees of wasting were prevalent among this group too (75% mild and 25% moderate wasting). The obese group had less significant weight loss (4.2 *vs* 8%) and anorexia and better appetite. However, a considerable percentage of patients in both groups showed muscle (94.6% of normal weight and 19.5% of obese) and peripheral fat tissue (89.2% of normal weight and 31.7% of obese) losses compared to the 50th percentile. Biochemical parameters were not significantly different between groups except for triglyceride ($P = 0.001$), transferrin and total iron-binding capacity ($P = 0.028$).

Conclusions: MIS was significantly better in obese patients; however, both groups showed degrees of wasting based on MIS and other PEW parameters. Nutritional status of obese haemodialysis patients should be monitored regularly because of high risk of PEW like other BMI categories.

Key words: haemodialysis, malnutrition inflammation score, obesity, protein-energy wasting.

Introduction

The endocrine and metabolic functions of the kidney are disrupted in uraemia, which could lead to numerous disorders such as anaemia, altered metabolism of nutrients, inflammation and consequent malnutrition and wasting.[1] According to the International Society of Renal Nutrition and Metabolism panel, 'Protein-Energy Wasting (PEW)' is the preferred terminology compared with malnutrition in kidney failure.[2] PEW indicates a disorder accompanied with loss of body protein and fat masses, which is not corrected merely through improvement of dietary intake.[2,3] The aetiology of PEW is multifactorial and more complicated than malnutrition. It includes (but is not limited to) inflammation, acidaemia, the accumulation of uraemic and

E. Alipoor, MSc, Researcher
M.J. Hosseinzadeh-Attar, MD, PhD, Professor
M. Mahdavi-Mazdeh, MD, PhD, Professor
M. Yaseri, PhD, Assistant Professor
N.S. Zahed, MD, PhD, Assistant Professor
Correspondence: M.J. Hosseinzadeh-Attar, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, No#44 Hojjatdoost Street, Naderi Avenue, Keshavarz Boulevard, Tehran, Iran.
Tel: +98 218 8993059; Fax: +98 218 8984861.
Email: hosseinzadeh.md.phd@gmail.com

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unexcreted toxins, increased energy expenditure, anorexia, loss of nutrients during haemodialysis and endocrinopathies such as insulin resistance.[1,2,4] The high prevalence of PEW in haemodialysis can induce higher mortality, hospitalisation and poor outcomes and quality of life.[2] Malnutrition inflammation score (MIS) has been introduced as a valid tool to assess wasting status in dialysis patients.[5]

Obesity is a well-known independent risk factor of both kidney failure and other risk factors of kidney dysfunction such as diabetes and hypertension.[6] Although obesity could affect the initiation and progression of kidney dysfunction, it plays a controversial role in the final stage of kidney insufficiency and haemodialysis. In fact, contrary to the normal population, overweight and obesity have desirable effects on decreasing mortality in haemodialysis patients. This phenomenon was called 'reverse epidemiology' or 'obesity paradox'.[7] It has been proposed that obesity might potentially have favourable effects in haemodialysis patients through better nutritional reserves and attenuating the extent of wasting.[8] Nevertheless, few studies have examined this hypothesis directly. The present study was conducted to investigate whether obese patients under haemodialysis have less wasting and better nutritional reserves compared to normal weight patients based on MIS and other PEW parameters.

Methods

In this case–control study, 52 normal weight and 48 obese patients were investigated. The main parameter in calculating sample size was MIS. Calculation of sample size showed that in order to observe a 30% difference between groups with 80% power, 41 patients in each group would be sufficient. Moreover, based on post-hoc power analysis, the power of the study for determining MIS differences between the two groups was almost 99%. Patients were recruited from five dialysis centres at educational hospitals under supervision of medical science universities. All dialysis units had the same treatment protocol. Patients underwent regular haemodialysis thrice a week for at least six months. Participants were included in normal weight and obese groups with $18.5 <$ body mass index (BMI) < 25 kg/m^2 and BMI ≥ 30 kg/m^2, respectively. Patients were not included if they had a history of chronic inflammatory or infectious disorders, liver failure, cancer, hypo- or hyperthyroidism. In addition, patients with myocardial infarction (MI), cerebrovascular accident, trauma, major surgery or any other critical conditions and intentional weight changes during the past three months were excluded from participating in this study. This study was performed according to the Declaration of Helsinki guidelines. The eligible patients were included after obtaining informed consent. The study was approved by the ethics committee of Tehran University of Medical Sciences & Health Services. The compliance with STROBE has been addressed in this study.

Different parameters were used to examine PEW in this study, including MIS, anthropometries and biochemical biomarkers. The quantitative valid MIS was used as the main variable to determine PEW, as described.[5] MIS has 10 components; each could be scored from 0 to 3 (normal to very severe). Seven components from the conventional subjective global assessment (SGA) and three additional components were measured, including BMI, serum albumin and total iron-binding capacity (TIBC) concentrations. The total score of each individual could be between 0 and 30.[5] In this study, a score of 0–7 was considered normal to mild, 8–18 as moderate and 19–30 as severe wasting initially.[9] However, as only one patient had a score > 19, two groups were merged, and a score > 8 has been considered moderate wasting. Dry weight changes during the past three to six months were assessed through medical records and patients' self-report. Unintentional weight losses of 5–10% were considered significant. Self-rated appetite was assessed through two questions; the first was inspired by the Appetite and Diet Assessment Tool questionnaire, and the second was asked to assess the anorexia during the last month.[10] The mean intakes of energy and protein were assessed through four days of dietary recalls (two dialysis and two non-dialysis days). Dietary data were analysed using Nutritionist IV software (N Squared Computing, San Bruno, CA, USA) adapted for some local foods.

Anthropometric measurements including dry weight, height, waist circumference (WC), triceps skinfold thickness (TSF) and mid upper arm circumference (MUAC) were performed within 30 minutes following the termination of haemodialysis in order minimise the probable effects of oedema and fluid retention. Triple MUAC and TSF measurements were performed on the non-vascular access arm using previously published standard techniques,[11] and the mean was recorded. Then, BMI and mid arm muscle circumference (MAMC) were calculated as indicated below:

$$\text{BMI}\left(\text{kg/m}^2\right) = \text{Weight}\,(\text{kg}) \,/\, (\text{Height}\,(\text{m}))^2$$

$$\text{MAMC}\,(\text{cm}) = \text{MUAC}\,(\text{cm}) - \pi \times \text{TSF}\,(\text{cm})$$

Moreover, MUAC and TSF values were classified into percentiles according to NHANES III. WC was compared with normal values of 102 cm for men and 88 cm for women. Anthropometric measurements were performed by the same professional and trained research assistant for all the patients and on the same day of blood taking.

Prior to haemodialysis, 10 mL of blood samples were obtained following 10–12 hours of fasting. Albumin, transferrin, cholesterol, triglyceride (TG), Low-density lipoprotein (LDL) and creatinine serum levels were measured using commercial kits (Pars-Azmoon, Tehran, Iran). TIBC and total lymphocyte count (TLC) serum levels were calculated by the formulas:

$$\text{TIBC(mg/dL)} = \text{Transferrin}\,(\text{mg/dL}) \times 1.25$$

$$\text{TLC} = \%\,\text{lymphocytes} \times \text{WBC}/100$$

Lipid profile was compared with the recommended cut-off points of the National Cholesterol Education Program 2002 to investigate the probable hypo-/hyperlipidaemia in patients.

To check the normality assumption, we used the Kolmogorov-Smirnov test and Q-Q plot. The differences between groups in nominal variables were evaluated using chi-square or Fisher's exact test. To assess differences between the two groups, a *t*-test was used for normal continuous variables and Mann–Whitney test for non-normal continuous and ordinal variables. To consider the effects of possible confounders including age, gender, dialysis duration and diabetes, binary logistic regression, ordinal logistic regression and analysis of covariance were used whenever appropriate. All statistical analyses were performed using SPSS (IBM SPSS Statistics for Windows, IBM Corp., Version 21.0. Armonk, NY, USA). *P*-value less than 0.05 was considered statistically significant.

Results

The mean age of the patients (57 ± 14 years normal *vs* 57 ± 10 years obese group; $P = 0.949$), duration of the haemodialysis therapy (51 ± 42 months normal *vs* 45 ± 38 months obese group; $P = 0.406$), gender (44.2% female normal *vs* 60.4% obese group; $P = 0.106$) and the underlying cause of disease ($P = 0.116$) were not significantly different between the two groups. Diabetes prevalence was significantly higher in the obese (56.3%) compared with the normal weight group (35.3%); ($P = 0.036$).

Based on MIS, different degrees of PEW were observed in almost all the patients (Figure 1). However, the distribution of wasting severity was significantly different between groups ($P < 0.001$) (Table 1). Other parameters related to nutritional status are shown in Table 1. Following adjustments for age, gender, dialysis duration and diabetes, the differences between groups remained statistically significance (Table 1).

Anthropometric measurements are shown in Table 2. The comparison of MUAC and TSF with NHANES III percentiles showed that 94.6% of normal weight and 19.5% of obese patients had MUAC values under the 50th percentile values specified for age and gender. TSF values of 89.2% of normal weight patients and 31.7% of obese patients were under the 50th percentile value specified for age and gender (Figure 2). The distribution of patients in different percentiles of MUAC and TSF were statistically different between groups ($P < 0.001$). WC was higher than standard values in 2.8% of normal weight patients (0% men and 6% women) and 95% of the obese group (88% men and 100% women) ($P < 0.001$).

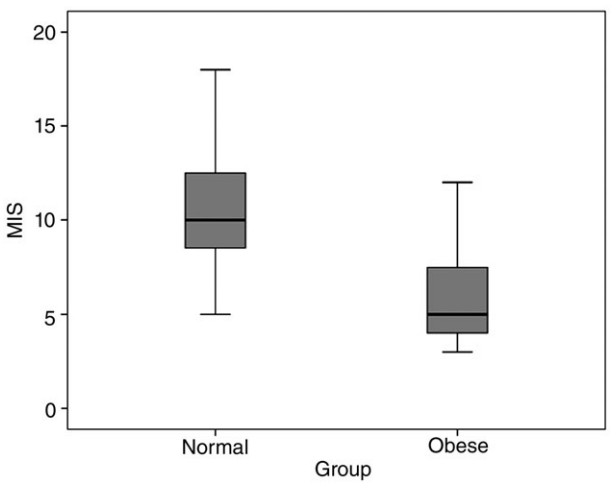

Figure 1 Distribution of malnutrition inflammation score (MIS) among study groups.

Biochemical parameters related to nutritional status were not significantly different between the two groups apart from TG ($P = 0.001$), transferrin and TIBC serum levels ($P = 0.028$), which were significantly higher in the obese group (Table 3). TLC and cholesterol levels were marginally higher in the obese group ($P = 0.059$ and $P = 0.051$, respectively). The comparison of lipid profile showed that 95% of obese and 92.9% of normal weight patients had cholesterol levels below 200 mg/dL. In addition, 10 and 16.7% of patients in these groups, respectively, had cholesterol levels lower than 100 mg/dL. TG serum levels were below 150 mg/dL in 81% of normal weight and 43.6% of obese participants. LDL levels in 85.7% of the normal weight and 79.5% of the obese group were below 100 mg/dL. MIS was inversely correlated with TG ($r = -0.36$, $P < 0.001$) and cholesterol ($r = -0.22$, $P = 0.028$) levels in the whole study population. Lower levels of TG and cholesterol were associated with higher wasting indicated by MIS.

Discussion

Currently, there is no gold standard for examining PEW in haemodialysis. Different methods including evaluation of dietary intake, body composition, nutritional scoring systems and biochemical factors are applied now, alone or in combination.[12] MIS was used as the main determinant of wasting in the present study. Other parameters of PEW were also assessed. MIS is a useful, repetitive and valid tool for nutritional assessment in haemodialysis patients. Previous studies suggested that MIS might be a better predictor of short term outcomes compared to SGA.[5,13] In the present study, the normal weight group had mild, 9.6%, and moderate wasting, 90.4%, based on MIS, whereas the obese group had mild, 75%, and moderate, 25%, wasting. Regardless of the differences in methodology of previous studies, most reported considerable degrees of PEW in all BMI groups, including overweight and obese patients. For example, in the study of 328 ESRD patients, Honda *et al.* reported that the prevalence of PEW was 60% in patients with BMI < 20 kg/m^2, 39% in those with BMI 20–25 kg/m^2 and 16% in BMI > 25 kg/m^2.[14] In addition, Stenvinkel *et al.* reported a significant difference of wasting prevalence in 268 dialysis patients with BMI < 20 kg/m^2 (62%), BMI 20–25 kg/m^2 (45%) and BMI > 25 kg/m^2 (17%).[3] An SGA score of 2 or more was considered to represent the presence of PEW in these studies. Malgorzewicz *et al.* used an SGA 7-point scale in a small sample size of 36 haemodialysis patients and reported signs of mild malnutrition (score of

Table 1 MIS, dry weight changes, appetite, anorexia and dietary intake of study population

			Group			
		Total	*Normal (n = 52)*	*Obese (n = 48)*	P	*Adjusted* P[(b)]
MIS	0–7	41 (41.0%)	5 (9.6%)	36 (75.0%)	<0.001[(c)]	<0.001[(e)]
	>8	59 (59.0%)	47 (90.4%)	12 (25.0%)		
Dry weight changes in the past six months	Increase	16 (16.3%)	2 (4.0%)	14 (29.2%)	0.028[(d)]	0.033[(f)]
	Stable	60 (61.2%)	36 (72.0%)	24 (50.0%)		
	Non-significant decrease	16 (16.3%)	8 (16.0%)	8 (16.7%)		
	Significant decrease	6 (6.1%)	4 (8.0%)	2 (4.2%)		
Appetite[(a)]	Very good	12 (14.3%)	3 (7.5%)	9 (20.5%)	0.030[(d)]	0.042[(f)]
	Good	47 (56.0%)	21 (52.5%)	26 (59.1%)		
	Fair	12 (14.3%)	9 (22.5%)	3 (6.8%)		
	Poor	6 (7.1%)	2 (5.0%)	4 (9.1%)		
	Very poor	7 (8.3%)	5 (12.5%)	2 (4.5%)		
Anorexia in last month[(a)]	None	53 (63.1%)	20 (50.0%)	33 (75.0%)	0.019[(d)]	0.003[(f)]
	Sometimes	11 (13.1%)	6 (15.0%)	5 (11.4%)		
	Moderately	7 (8.3%)	6 (15.0%)	1 (2.3%)		
	High	13 (15.5%)	8 (20.0%)	5 (11.4%)		
	Very high	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Energy intake (kcal/kg)	Mean	32.5 ± 12.8	32.8 ± 12.5	32.2 ± 13.2	0.930[(d)]	0.593[(g)]
	Median (IQR)	30.8 (23.5–36.4)	29.8 (22.2–39)	31.2 (25.1–35)		
Protein intake (g/kg)	Mean	1.33 ± 0.51	1.4 ± 0.48	1.25 ± 0.53	0.127[(d)]	0.540[(g)]
	Median (IQR)	1.25 (0.95–1.54)	1.35 (0.99–1.71)	1.25 (0.87–1.51)		

[(a)] n = 40 in normal weight group and n = 44 in obese group.
[(b)] Adjusted *P*: Adjusted *P*-value for age, gender, dialysis duration and diabetes.
[(c)] Based on chi-square test.
[(d)] Based on Mann–Whitney test.
[(e)] Based on binary logistic regression.
[(f)] Based on ordinal logistic regression.
[(g)] Based on analysis of covariance.
IQR, interquartile range; MIS, malnutrition inflammation score.

4 or 5) in 28.5% of overweight and 54.5% of normal weight groups.[15] However, similar to the study of Vannini *et al.*,[16] which used the same method for investigating malnutrition in 52 patients, no statistical difference was observed between normal weight and patients with BMI > 25 kg/m^2. These studies did not include MIS to assess wasting.

Dry weight changes during the past six months were significantly different between groups; unintentional weight loss was almost twice greater in normal weight compared to obese patients (8 *vs* 4.2%), which was in line with significant difference of MIS between the two groups. Consistent with these results, appetite and severity of anorexia were considerably different between groups. During the last month, 50% of normal weight patients versus 25% of the obese group experienced varying degrees of anorexia. The number of patients with severe anorexia in the normal weight group were nearly double that of the obese group (20 *vs* 11.4%). The mean reported intake of energy and protein in both groups have fulfilled the patients' needs compared to the recommendations[17] but did not differ significantly between groups.

Significantly higher energy and protein intakes were expected in the obese group considering higher BMI and also because of the significant differences between the groups in terms of MIS, appetite, anorexia and recent dry weight changes. Guida *et al*. reported higher dietary intakes of energy and protein in obese compared to normal weight and overweight patients under haemodialysis.[18] Thus, it seems that some patients in the present study had an unrealistic report of dietary intake. An inverse correlation has been stated between the reported energy intake and BMI in haemodialysis patients.[19] In addition, previous studies indicated that under-reporting of energy intake is more prevalent in overweight haemodialysis patients and increases with increasing BMI.[19–21]

MUAC, MAMC and TSF were considered indicators of muscle mass and fat tissue in this study. A significant difference was observed in the distribution of patients at various percentiles of MUAC and TSF between groups, although a substantial percentage of patients had muscle mass and peripheral fat tissue losses in both groups (Figure 2). MUAC and TSF values were under the 50th percentile in almost 95 and 90% of patients in the normal weight group and in nearly 20 and 32% of patients in the obese group, respectively. Low lean body mass, assessed by dual energy X-ray absorptiometry, was reported as a predictor of worse

Table 2 Anthropometric measurements of the study population

	Total		*Group*				
			Normal (n = 52)		*Obese (n = 48)*		
	Mean ± SD	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	P
Dry weight (kg)	68.1 ± 16.2	64.2 (56–81.2)	55.1 ± 7.3	56.5 (50.5–60.2)	82.1 ± 10.4	82.3 (74.2–88)	<0.001[(a)]
Height (cm)	158 ± 9	158 (151–164)	159 ± 9	158 (152–165)	157 ± 10	157 (150–162)	0.457[(a)]
BMI (kg/m^2)	27.3 ± 6.2	24.5 (22.1–32.4)	21.9 ± 2.1	22.2 (20.5–23.6)	33.2 ± 3	32.5 (30.9–35.2)	<0.001[(b)]
WC (cm)	97.8 ± 16.1	98 (82–113)	83.4 ± 8.4	82 (79–90)	110.8 ± 8.6	113 (102–115.8)	<0.001[(b)]
MUAC (cm)	25.5 ± 4.2	25.1 (22.5–28.8)	22.3 ± 3	22.3 (20.8–24)	28.3 ± 2.9	28.7 (25.9–29.8)	<0.001[(a)]
TSF (mm)	18 ± 6.9	17.5 (12.5–23)	13 ± 4.3	13 (11.5–14.5)	22.6 ± 5.4	22.5 (20–26.5)	<0.001[(a)]
MAMC (cm)	31.2 ± 5.9	30.1 (26.8–36)	26.4 ± 3.6	26.8 (24.3–28.5)	35.4 ± 3.9	35.8 (33–37.8)	<0.001[(a)]

[(a)] Based on *t*-test.
[(b)] Based on Mann–Whitney test.
BMI, body mass index; IQR, interquartile range; MAMC, mid arm muscle circumference; MUAC, mid upper arm circumference; SD, standard deviation; TSF, triceps skinfold thickness; WC, waist circumference.

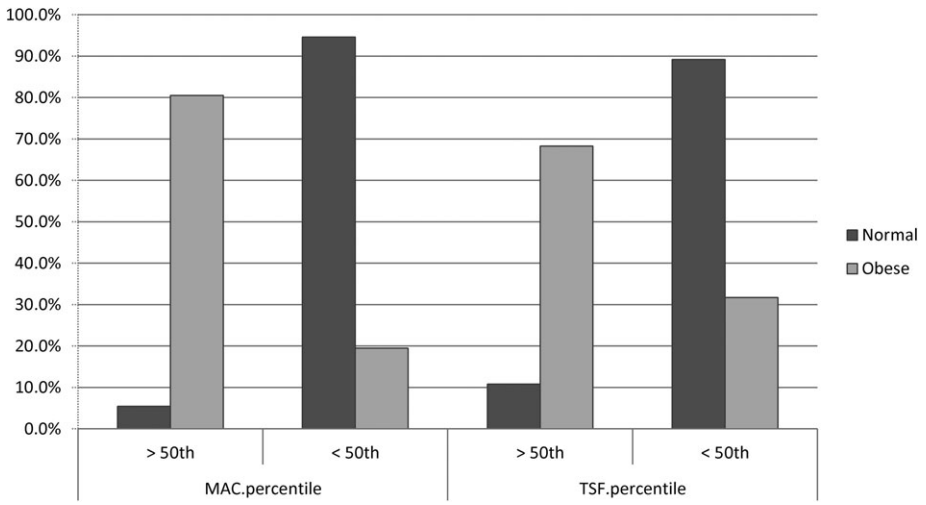

Figure 2 The distribution of mid upper arm circumference (MUAC) and triceps skinfold thickness (TSF) based on NHANES III percentiles.

survival because of the reflection of poor nutritional status and inflammation.[14] Higher muscle mass might dilute uraemic toxins because it is the primary location of intracellular water.[22] However, it remains to be determined in clinical studies whether lower muscle mass or muscle wasting might be associated with higher uraemic toxins in dialysis patients. In addition, low fat mass in haemodialysis is accompanied with higher mortality contrary to normal population.[23] Although protective effects have been stated for peripheral fat mass, central fat accumulation is considered a strong risk factor for mortality in both normal population and haemodialysis patients.[24] This would be especially important in obese patients. In this study, 95% of obese patients, including 88% of men and 100% of women, had abdominal obesity compared to the standard values. Thus, not only do these patients have protective factors including muscle and fat masses lower than expected, but they were also exposed to potent probable risk factors associated with high WC, including insulin resistance, metabolic syndrome and cardiovascular disorders.[25]

In the present study, no statistically significant differences were observed in haemoglobin, haematocrit, MCV, MCH, MCHC, TLC, cholesterol, LDL, creatinine and albumin serum levels between the normal weight and obese groups, except for TG, transferrin and TIBC, which were significantly higher in the obese group. Previous studies observed improvement in nutritional-related parameters with BMI increase.[26] On the other hand, Gallar-Ruiz *et al*. did not find significant differences in total protein, albumin, pre-albumin and haemoglobin serum levels between haemodialysis patients with BMI < and >25 kg/m^2,[27] and Torun *et al*. reported lower levels of albumin and BUN in obese patients with haemodialysis.[28] The possible underlying mechanisms of these discrepancies were not explained

Table 3 Biochemical parameters of the study population

	Total		*Group*				
			Normal (n = 52)		*Obese (n = 48)*		
	Mean ± SD	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	*P*
Haemoglobin (g/dL)	11 ± 2	11 (10–12)	11 ± 2	11 (10–12)	11 ± 2	11 (9–12)	0.954[(b)]
Haematocrit (%)	35.4 ± 4.9	34.7 (32–39.1)	35.3 ± 4.6	34.7 (32.2–38.5)	35.6 ± 5.2	35.1 (31.4–39.5)	0.960[(b)]
MCV (fL)	92.6 ± 7.1	94.2 (89–96.8)	92.6 ± 5.7	94.5 (88.5–96.5)	92.6 ± 8.4	93.9 (90–97.5)	0.659[(c)]
MCH (pg)	28.4 ± 2.8	28.6 (27.3–30.2)	28.6 ± 2.1	28.6 (27.1–30.2)	28.3 ± 3.3	28.6 (27.4–30.2)	0.882[(c)]
MCHC (g/dL)	30.6 ± 1.5	30.4 (29.9–31.4)	30.8 ± 1.2	30.4 (30–31.5)	30.5 ± 1.8	30.5 (29.3–31.3)	0.562[(c)]
TLC (cells/mm^3)	1934 ± 781	1785 (1387–2257)	1714 ± 595	1664 (1242–2046)	2119 ± 876	1965 (1469–2582)	0.059[(c)]
Cholesterol (mg/dL)[(a)]	145 ± 43	141 (115–171)	139 ± 38	138 (107–159)	152 ± 47	151 (125–184)	0.051[(b)]
Triglyceride (mg/dL)[(a)]	155 ± 117	124 (88–191)	121 ± 66	108 (84–139)	191 ± 147	175 (102–231)	0.001[(c)]
LDL (mg/dL)[(a)]	78 ± 24	77 (59–92)	74 ± 23	77 (56–91)	81 ± 25	80 (61–99)	0.175[(b)]
Creatinine (mg/dL)	9 ± 2.5	9.1 (7.5–10.9)	9 ± 2.4	9.2 (7–10.5)	9.1 ± 2.6	8.9 (7.7–10.9)	0.095[(b)]
Albumin (mg/dL)	4.1 ± 0.4	4.2 (4–4.4)	4.1 ± 0.4	4.2 (3.9–4.4)	4.2 ± 0.3	4.2 (4–4.4)	0.682[(c)]
Transferrin (mg/dL)	156 ± 45	151 (124–184)	147 ± 41	140 (118–174)	165 ± 47	159 (134–186)	0.028[(c)]
TIBC (mg/dL)	195 ± 56	188 (154–229)	183 ± 51	174 (147–217)	207 ± 59	199 (167–233)	0.028[(c)]

[(a)] People with lipid-lowering drugs (n = 13) were excluded for this test.
[(b)] Based on t-test.
[(c)] Based on Mann–Whitney test.
IQR, interquartile range; MCV, Mean corpuscular volume; MCH, mean corpuscular haemoglobin; MCHC, mean corpuscular haemoglobin concentration; TLC, total lymphocyte count; TIBC, total iron-binding capacity.

appropriately. It is likely uraemia has a dominant role in determining biochemical factors compared to body fat mass. It seems that higher BMI is not necessarily accompanied with better nutritional status indicated by biochemical factors.

The results did not show hyperlipidaemia in this study. Inversely, a substantial percentage of patients had cholesterol, LDL and TG levels below cut-off values in both groups. For example, 95% of obese and 92.9% of normal weight patients had cholesterol levels lower than 200 mg/dL; moreover, 10 and 16.7% of them, respectively, had cholesterol levels below 100 mg/dL. At first glance, this decline might seem unexpected and even protective considering high prevalence of cardiovascular disorders in haemodialysis. Nevertheless, hypocholesterolaemia is an independent predictor of mortality even after adjusting for age, BMI and albumin levels in haemodialysis.[29,30] Total cholesterol below 100 mg/dL is considered a criterion in the diagnosis of PEW in dialysis.[2] Cholesterol levels may decline because of systemic inflammation and malnutrition.[31] LDL hypercholesterolaemia and hypertriglyceridaemia are also proposed to have a paradoxical correlation with better survival in haemodialysis.[32] However, their cut-off points to discriminate the prognosis are still not defined. Considerable lipids decline could indicate poor nutritional status in both the normal weight and obese groups. The inverse relationship of MIS with TG and cholesterol strengthens this assumption.

As stated earlier, obesity is assumed to lead to better prognosis in haemodialysis through better nutritional and body reserves. Overall, the obese group had minor wasting compared to the normal weight group in the present study. However, it should be considered that the obese group also had degrees of PEW according to MIS, muscle and peripheral fat tissue losses and biochemical parameters. Moreover, around 95% of obese patients had central obesity, which is a potent risk factor for mortality through inducing metabolic disorders. Therefore, it is understandable that higher BMI does not necessarily indicate better nutritional reserves and is not a reliable diagnostic factor of wasting status. The precise mechanisms of obesity paradox are not well known and are complicated.[8] Novel variables including adipose tissue metabolism, adipokines' gene expressions and concentrations and inflammation may play a role.

This is the first study that used the preferred MIS method for evaluating PEW between BMI categories in haemodialysis. Moreover, other dietary, clinical and biochemical complementary variables were assessed to achieve a more comprehensive insight. Despite almost all previous studies that compared patients with BMI < and >25 kg/m^2, BMI > 30 kg/m^2 was considered for the obese group, which could reflect the effect of obesity more accurately and distinctively.

The present study had some limitations. First, there is no gold standard to evaluate nutritional status in haemodialysis patients. In the ISRMN meeting, PEW and its constitutive parameters were established in the American population. Thus, there is a question whether these criteria could be extended to other areas and races. PEW is not currently categorised and is difficult to be interpreted as a single score to evaluate wasting. Another limitation was the comparison of TSF and MUAC values with NHANES III percentiles because of the lack of reliable reference data in our population. The same problem existed for WC cut-off points.

In conclusion, obese patients with haemodialysis had significantly better PEW according to MIS compared to the normal weight group. However, wasting was also prevalent in this group based on MIS and other PEW parameters, including body muscle and peripheral fat tissue losses and biochemical factors. Thus, obesity might not necessarily mediate protective effects in haemodialysis through better nutritional status and body reserves, and other factors may be involved. Moreover, high prevalence of detrimental central obesity in obese patients would be an undesirable consequence of increasing BMI. Further studies are required to define the precise protective mechanisms of obesity in advanced kidney failure. Nutritional status of obese patients under haemodialysis needs special attention and regular monitoring because they remain at high risk of PEW and body mass losses similar to other BMI categories.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

EA was responsible for the conception and design of the study, collection and interpretation of data, drafting of the manuscript and approval of the final version of the manuscript. MJHA was responsible for the conception and design of the study, supervision of the collection and analysis of data and approval of the final version of the manuscript. MMM was responsible for the design of the study, supervision of data collection and approval of the final version of the manuscript. MY was responsible for the design of the study, analysis and interpretation of data and approval of the final version of the manuscript. NSZ was responsible for the supervision of data collection and analysis and approval of the final version of the manuscript. All authors are in agreement with the manuscript and declare that the content has not been published or submitted for publication elsewhere.

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ORIGINAL RESEARCH

Reliability and relative validity of a diet index score for adults derived from a self-reported short food survey

Gilly A. HENDRIE,[1] Megan A. REBULI[2] and Rebecca K. GOLLEY[3]

[1]CSIRO Food and Nutrition Flagship, [2]Department of Nutrition and Dietetics, Flinders University and [3]Public Health Group, Sansom Institute for Health Research, School of Pharmacy and Medical Sciences, Division of Health Sciences, University of South Australia, Adelaide, South Australia, Australia

Abstract

Aim: Assess the reliability and relative validity of a diet index score for adults derived using a 38-item online survey.

Methods: The short food survey (SFS) measured 'usual' intake of seven food groups, three food choice indicators and variety; and was completed by 61 adults aged 19–50 years from Adelaide, Australia. A score was applied to assess compliance with the 2013 Australian Dietary Guidelines. Reliability of the survey was measured between two administrations one week apart; and validity by comparing the first administration to the average of three 24-hour dietary recalls. Statistical analyses included paired samples *t*-tests, intra-class correlation coefficient (ICC), percentage agreement, Cohen's kappa coefficients and Bland–Altman plots.

Results: Estimates of daily food group servings were reliable (within 0.3 servings, $P > 0.05$) but not valid for all foods groups. The mean total index score was approximately 70 points (out of 100) on both SFS administrations (ICC = 0.71 (95% CI 0.56:0.81). Relative validity analysis showed moderate correlation between SFS#1 and 24-hour recalls (ICC = 0.43 (0.21:0.62, $P < 0.001$)), with 51% agreement in allocation to tertiles of diet quality between methods (k = 0.262, $P = 0.004$). The survey overestimated the diet index score by an average of 12.7 points out of 100 [–20.11:42.94] in comparison to recalls.

Conclusions: The survey overestimated compliance with guidelines relative to dietary recalls. It demonstrated good reliability; however, the validity of estimating intake of some food groups needs improvement. Future refinement will provide a valuable online tool to assess compliance with the Australian dietary recommendations.

Key words: diet questionnaire, dietary assessment, reliability, short food survey, validity.

Introduction

Diet indexes provide a means of comparing population food intake against dietary guidelines as a measure of diet quality.[1] To monitor population compliance against dietary guidelines, we need to be able to measure food intake accurately and reliably through methods that are feasible in large studies and surveys. Short food questionnaires are appealing as they are relatively quick to administer, but few validated tools exist.[2–5] Online delivery of dietary assessment is also appealing for researchers as it can enhance accessibility and reduce the time and cost of administration and analysis.[6] Technology is increasingly being used to assist data collection in health research,[6,7] but there is a lack of validated tools to collect information about dietary intake. In particular, there is a need for a short, online survey that has been validated to measure food intake.

A review identifying short dietary assessment tools appropriate for use in large populations found 11 tools with validation studies, three measuring adult food intake.[8] Of these three tools, two are limited to the assessment of fruit and vegetable intake. The third covers a broader range of foods, including fruit, vegetables, fibre-rich foods, high fat and sugar foods, meat, meat products and fish; however, the limitation of this tool is that key food groups are missing (e.g. grain foods), and therefore, compliance with all dietary guidelines cannot be evaluated. This review recommends that dietary assessment tools are fit for purpose, developed and tested for a specific purpose with particular population groups.[8] It is also clear from the review that a comprehensive tool that measures intake of all food groups, yet is still short enough to be used in large population studies, is needed.

The aim of the present study is to explore the reliability and relative validity of an online, self-reported short food survey (SFS) to (1) measure food intake in adults and (2) estimate a diet index score measuring compliance with the 2013 Australian Dietary Guidelines (ADGs) for adults.

G.A. Hendrie, PhD, Research Scientist
M. Rebuli, BND (Hons), APD, Honours Student
R. Golley, PhD, APD, Senior Research Fellow
Correspondence: G.A. Hendrie, CSIRO Food and Nutrition Flagship, PO Box 10041, Adelaide, SA 5000, Australia. Tel.: +61 08 8305 0662, Email: gilly.hendrie@csiro.au

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The ADGs were developed to promote good health and well-being. These guidelines include practical information about the type and amount of food Australians should consume each day for health. However, as researchers, we know little about how the population complies with these guidelines. This tool will provide a resource for this purpose. It will build on our original work, which developed and validated a similar SFS to assess food intake and dietary guideline compliance in children and adolescents.[9–11] Importantly, having this tool available will enable, for the first time, food intake and compliance with current ADGs to be measured and evaluated using a consistent methodology across the lifespan (2–50+ years).

Methods

The present cross-sectional study included a convenience sample of adults recruited in two phases, August to November 2013 and March to May 2014. The study was approved by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Animal Food and Health Sciences, Human Research Low Risk Review Panel (LR14/2013) and the University of South Australia Human Research Ethics Committee (protocol number 32560). Participants provided informed consent before commencing the study.

Inclusion criteria were healthy adults aged 19–50 years, living in Australia, with adequate written and spoken English knowledge, internet access, with no conditions affecting dietary intake and with no plans to initiate dietary changes within the next month. Participants were recruited by public advertising, word of mouth and through the CSIRO and University of South Australia volunteer email lists in Adelaide, South Australia. Participants were required to complete two online surveys and three 24-hour diet recalls by telephone. Brief demographic information and postcode of residence was collected. Socio-economic status was assigned based on postcode using the Australian Bureau of Statistics Socio Economic Index for Area (SEIFA), where the lowest quintile (Q1) represents areas of most disadvantage and the highest quintile (Q5) areas of least disadvantage.[12] Anthropometric data was not collected as no face-to-face contact was required for the present study, and self-reported height and weight were considered inadequate.[13] Participants received either a gift voucher or personal dietary evaluation as reimbursement for their time.

The SFS, a 38-item survey, was administered online through Survey Monkey (http://www.surveymonkey.com). The development and selection of questions included in the survey has been described in detail previously.[11] The current version of the SFS was designed to assess adult compliance with the 2013 ADGs and Australian Guide to Healthy Eating.[14] The survey questions asked about individual's own frequency and quantity (in servings) of consumption of fruits, vegetables, grains, meat and alternatives, dairy, discretionary foods (cakes, confectionary, processed meats, alcohol, take-away foods) and beverages, as well as addressing the quality of core foods (frequency of wholegrain and reduced fat dairy) and variety within core food groups (Table S1, Supporting Information). The standard size of servings was defined in the SFS in terms of metric measurements (cups and grams) or usual portions (slices or pieces) consistent with those provided in the ADG. Participants completed the SFS twice, seven days apart, to test the survey reliability.

To provide a comparison method, participants also completed three 24-hour dietary recalls by telephone, including one weekend and two weekdays. Dietitians conducted the recalls using the three-pass methodology, and participants were provided with a food model booklet to assist with their estimation of portion size (this was posted in the mail).[15] Briefly, in the first pass, participants listed all items consumed in the previous 24 hours; in the second pass, detailed information about all items was entered into FoodWorks Professional Software version 7, using the 2007 AUSNUT Australian food composition database[16]; and the third pass reviewed information provided and prompted for forgotten items. The 24-hour recalls were conducted within 14 days following the second SFS. The mean of three recalls was compared with the first SFS for validity.

The dietary guideline index (DGI) derives a total diet score representing compliance with ADGs, as was used as an estimate of diet quality. It comprises 11 components reflecting the concepts of variety, adequacy, quality and moderation reflected in the ADGs. It asks about the frequency and quantity of five core foods groups as well as discretionary foods, quality of some food choices (low fat dairy, wholegrain, trimming of fat and type of spread), beverages and variety of foods consumed within each core food group. The scoring algorithm compares reported intake to age- and gender-specific cut-off points to derive food group score and a total index score.[14] This DGI has been validated for use in an adult sample using food intake data derived from a food frequency questionnaire,[17] and also in children (aged 2–16 years) using 24-hour recall data[9,10] and food intake data reported in the SFS.[11] The index scoring system was applied to the two SFS and 24-hour recall data providing a diet index score estimated from each method (out of 100), with higher scores indicating better compliance with the dietary guidelines.

Food intake reported in the SFS#1 and #2 was converted to food group servings per day. Items reported in the recalls were converted from grams of food and beverages to food group servings per day using the AUSNUT hierarchy of food codes. Descriptive statistics (mean and standard deviation) are presented for food group servings, DGI indicator and total diet index scores for the two SFS administrations and the mean of three 24-hour recalls. The significance of the difference in mean estimates of intake was assessed using a paired sample *t*-test. Reliability was assessed using intra-class correlation coefficient (ICC) two-way random models as ICC is a superior method of correlation to measure agreement and repeatability.[18] The level of significance for ICC was $P < 0.01$.

Relative validity was assessed by comparing the mean of three 24-hour recalls to the first administration of the SFS

using an ICC two-way mixed model analysis of variance to assess the strength and direction of the relationship between reported food group intake and indicator scores. Bland–Altman plots were used to determine whether the difference between the measurements of two methods was related to the magnitude of measurements.[18,19] The difference between the means (SFS#1-mean of 24-hour recalls) was plotted on the *y*-axis, and the mean of both methods ((SFS#1 + 24-hour recalls)/2) was plotted on the *x*-axis.[19] The line of mean bias and 95% limits of agreement (±1.96 SD) are also shown on the Bland–Altman plots (Figure S1).[19] Linear regression analysis was used to examine the slope of the bias to examine the consistency of the bias and determine any systematic difference between the methods.

Percent agreement and Cohen's kappa coefficient were used to estimate agreement for reliability and validity between tertiles, with a kappa value of 1.0 representing perfect agreement.[20] Analyses were conducted using SPSS statistical software package version 22 (IBM Corp, Armonk, NY).

Results

Sixty-eight adults were recruited, with 61 completing all dietary assessments. Seventy-two percent of participants were female, with a mean age of 34.1 (range: 25–44) years. Over half the sample resided in higher socio-economic areas, based on their postcode of residence (Q1–Q2: 23%; Q3:21%; Q4: 26%; Q5:26%).

The difference between the estimated food servings per day between SFS#1 and SFS#2 was 0.3 servings or less for all food groups (all $P > 0.05$, Table 1).

Mean food group intake estimated from the 24-hour recalls was lower than from the SFS administrations for fruit, vegetables and dairy but higher for breads and cereals, meat, beverages and discretionary foods. The difference between the SFS and recalls was not statistically significant for discretionary foods (–0.31 servings, $P = 0.29$); however, the difference in estimates of intake, in servings, were significantly different between the recalls and SFS for all other food groups. The absolute difference was 0.6–0.7 servings for fruit, vegetables and breads and cereals but greater than one serving for meat, beverages and dairy foods.

Table 2 shows total diet index and indicator scores for the two SFS administrations and the SFS#1 *versus* dietary recalls. The ICC for the reliability in estimating food group indicator scores ranged from 0.63 for discretionary foods to 0.91 for beverages, and among the food choice indicators from 0.64 for variety to 0.91 for healthy fats (all $P < 0.001$). The ICC for the reliability of estimating the total diet index score was 0.71 ($P < 0.001$).

The ICC for validity of the diet index indicator scores were lower but still all statistically significant, except meat (ICC = 0.10, $P = 0.22$), and for all food choice indicators except healthy fats (ICC = 0.14, $P = 0.13$). The ICC for the validity of the diet quality score overall was 0.43 ($P < 0.001$). The total diet index score derived from the SFS tended to overestimate compared to the 24-hour recalls by an average of 12.7 points (out of 100). The Bland–Altman plot shows that the estimate from the SFS ranged from 20% below to 43% above the total diet index score derived from the 24-hour recalls. The slope of this bias was statistically significant (r = –0.325, $P = 0.001$), indicating variation in the bias across the level of diet index score. The greatest bias was observed for variety (4.7 points out of 10, r = 0.199, $P = 0.04$) and wholegrains (1.94 points out of 5, r = –0.120, $P = 0.19$). All Bland–Altman plots are presented in Figure S1.

In 74% of cases, the diet index score derived from the two administrations of the SFS placed individuals in the same tertile, and the Cohen's kappa value suggests moderate agreement between the two administrations (k = 0.606, $P < 0.001$). The level of agreement between the SFS#1 and the 24-hour recalls was fair (k = 0.262, $P < 0.01$), with

Table 1 Comparisons of food group intakes estimated from the two administrations of the SFS and the 24-hour dietary recalls (n = 61)

	Intake (servings/day)			*Difference in estimated intake between methods (servings/day)*[a]			
	SFS #1	*SFS #2*[b]	*Dietary recalls*[c]	*SFS#1 versus SFS#2*		*SFS#1 versus recalls*	
Food groups	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*Mean (95% CI)*	P-*value*	*Mean (95% CI)*	P-*value*
Fruit	1.86 (1.09)	1.77 (1.03)	1.18 (0.85)	0.10 (–0.1:0.29)	0.33	0.69 (0.44:0.93)	<0.001
Vegetables	3.60 (2.11)	3.90 (2.55)	3.02 (2.07)	–0.30 (–0.82:0.21)	0.24	0.58 (0.04:1.12)	0.04
Breads and cereals	3.24 (2)	3.37 (4.27)	3.83 (2.14)	–0.14 (–1.09:0.81)	0.77	–0.60 (–1.07:-0.13)	0.01
Meat and alternatives	1.80 (1.59)	1.88 (1.68)	2.97 (2.4)	–0.08 (–0.21:0.05)	0.20	–1.17 (–1.86:-0.48)	0.001
Dairy	2.19 (1.53)	2.20 (1.32)	0.94 (0.75)	–0.02 (–0.32:0.28)	0.90	1.24 (0.85:1.64)	<0.001
Beverages	7.37 (3.48)	7.21 (3.59)	9.52 (3.96)	0.16 (–0.74:1.06)	0.73	–2.16 (–3.08:-1.23)	<0.001
Discretionary foods	2.53 (2.07)	2.36 (1.9)	2.83 (2.05)	0.17 (–0.22:0.55)	0.39	–0.31 (–0.88:0.26)	0.29

SFS, short food survey.
[a] Difference between two methods assessed using paired sample *t*-test.
[b] Two administrations of the SFS were one week apart.
[c] Mean of three dietary recalls.

Table 2 Reliability and validity of the Dietary Guidelines Index total and indicator scores calculated using the SFS and 24-hour dietary recalls (n = 61)

					Validity		
Indicators (possible score)	*SFS#1 Mean (SD)*	*SFS#2 Mean (SD)*	*Dietary recalls Mean (SD)*[a]	*Reliability ICC (95% CI)*[b], P-*value*	*ICC (95% CI)*[c], P-*value*	*Bias*[d] *[95% limits of agreement]*[e][e]	*Slope of bias,* P-*value*
Total DGI score (/100)	70.05 (10.11)	70.62 (10.20)	57.37 (14.87)	0.71 (0.56:0.81), $P < 0.001$	0.43 (0.21:0.62), $P < 0.001$	12.68 [–20.11:42.94]	–0.325, $P = 0.001$
Food groups							
Fruit (/10)	7.68 (3.22)	7.57 (3.15)	5.36 (3.32)	0.83 (0.73:0.89), $P < 0.001$	0.56 (0.36:0.71), $P < 0.001$	2.32 [–3.83:8.47]	–0.034, $P = 0.78$
Vegetables (/10)	6.21 (2.83)	6.48 (2.98)	5.33 (3.19)	0.80 (0.69:0.88), $P < 0.001$	0.50 (0.28:0.67), $P < 0.001$	0.88 [–5.17:6.92]	–0.121, $P = 0.28$
Breads and cereals (/5)	2.60 (1.47)	2.40 (1.58)	3.01 (1.49)	0.81 (0.69:0.88), $P < 0.001$	0.63 (0.45:0.76), $P < 0.001$	–0.41 [–2.96:2.13]	–0.018, $P = 0.90$
Meat and alternatives (/10)	5.92 (2.5)	6.08 (2.5)	7.71 (2.89)	0.84 (0.74:0.9), $P < 0.001$	0.10 (–0.15:0.34), $P = 0.22$	–1.80 [–9.05:5.46]	–0.081, $P = 0.26$
Dairy (/5)	3.45 (1.52)	3.61 (1.45)	1.82 (1.33)	0.83 (0.73:0.89), $P < 0.001$	0.40 (0.17:0.59), $P = 0.001$	1.63 [–1.49:4.76]	0.109, $P = 0.27$
Beverages (/10)	9.25 (1.16)	9.23 (1.17)	7.09 (2.01)	0.91 (0.85:0.94), $P < 0.001$	0.33 (0.09:0.53), $P = 0.005$	2.15 [–1.65:5.95]	–0.374, $P < 0.001$
Discretionary foods (/20)	16.31 (6.26)	16.94 (6.06)	14.23 (7.34)	0.63 (0.45:0.76), $P < 0.001$	0.21 (–0.05:0.43), $P = 0.05$	2.08 [–20.00:20.00]	–0.100, $P = 0.21$
Food choices							
Wholegrains (/5)	3.82 (1.47)	3.75 (1.59)	1.88 (1.74)	0.83 (0.73:0.9), $P < 0.001$	0.33 (0.09:0.54), $P = 0.004$	1.94 [–1.79:5.67]	–0.120, $P = 0.19$
Reduced fat dairy (/5)	2.21 (2.1)	2.01 (2.03)	2.19 (1.95)	0.85 (0.76:0.9), $P < 0.001$	0.32 (0.08:0.53), $P = 0.005$	0.02 [–4.69:4.74]	0.052, $P = 0.57$
Healthy fats (/10)	5.23 (3.15)	5.33 (2.92)	6.08 (3.55)	0.91 (0.86:0.95), $P < 0.001$	0.14 (–0.11:0.38), $P = 0.13$	–0.85 [–9.65:7.95]	–0.070, $P = 0.35$
Variety (/10)	7.37 (1.12)	7.21 (1.18)	2.66 (0.88)	0.64 (0.46:0.76), $P < 0.001$	0.38 (0.15:0.58), $P = 0.001$	4.71 [0.78:6.98]	0.199, $P = 0.04$

DGI, dietary guideline index; ICC, intra-class correlation; SFS, short food survey.

[a] Mean of three 24-hour dietary recalls.

[b] ICC calculated using a two-way random model, type: consistency.

[c] ICC calculated using a two-way mixed model, type: consistency.

[d] Positive value for difference = SFS higher than 24-hour recall (SFS overestimates); negative value means SFS lower than 24-hour recall (SFS underestimates).

[e] 95% limits of agreement = ±2 SD, slope of bias is regression.

51% of individuals ranking in the same tertile of the index score using the different methods.

Discussion

The present study investigated the reliability and relative validity of a diet index score derived using an online SFS. The SFS was found to be consistent in estimating food group intake and assessing Australian adults' compliance with the dietary guidelines overall (total diet index score) and for individual food groups (indicator scores), when tested two weeks apart. However, the SFS significantly underestimated or overestimated intake by more than one serve for meat, dairy and beverages in comparison to 24-hour dietary recalls. For overall compliance with the dietary guidelines, the SFS overestimated the total diet index score by 12.7% relative to recalls (range: –20.1 to +42.9%).

The reliability of the SFS was demonstrated with the majority of ICC for food groups above 0.8, and the ICC for the total diet quality score was 0.71. These results are similar or better than those of other recently validated Australian tools, such as a three-item tool measuring total vegetable intake, which reported Pearson correlation coefficients of 0.64 when administered one month apart,[21] or an alternative measure of diet quality, the Australian Recommended Food Score, which was developed from a 70-item food frequency questionnaire, and reported ICC of 0.62–0.79 for food group scores and 0.87 for the overall diet quality score.[22]

Taking into consideration the range of analyses performed, the SFS showed moderate validity for estimating overall compliance with the dietary guidelines compared to 24-hour recalls. However, the performance of the SFS to estimate compliance with guidelines was below an acceptable level for several individual aspects, particularly compliance with the meat guideline, where the ICC was below an acceptable level, and the estimation of intake was greater than one serve different from recalls. The ICCs for compliance with the discretionary foods and healthy fat recommendations were also below an acceptable level, and these sections of the survey require additional work.

The SFS performed as well as, or better, than a previous validation study in a sample of Australian children (children's dietary intake as reported by parents).[11] The SFS outperformed the Short Form Food Frequency Questionnaire validated in UK adults, which is currently recommended for use in public health monitoring.[8] The relative validity data for the SFS were consistent with the data comparing the EPIC FFQ against 9–12 24-hour dietary recalls administered over 12 months[23,24] and the Monitoring of Trends and Determinants in Cardiovascular Disease FFQ compared with multiple 24-hour recalls.[25,26] This indicates that the SFS performance is not because of its short nature but reflects limitations of dietary assessment through questionnaire more broadly. Our results support previous research demonstrating the challenge of developing brief methods to measure dietary intake, particularly the overall diet quality. Despite the difficulty, it is important to develop user-friendly methods to estimate intake of food groups and measure population compliance with ADGs, and our future work will continue to refine this tool to improve its accuracy.

The poorer performance of the SFS to estimate meat, discretionary foods and healthy fats compliance may reflect the questions within the SFS, the ability of individuals to report their usual intake of these foods, or real day-to-day variation in individuals eating habits. If day-to-day variation is high, then individuals may have difficulty in quantifying their usual intake. In addition, meat is often consumed as part of a composite dish with other foods, such as in stir fries or casseroles, making it more difficult to estimate the amount consumed. Also, the number of questions relating to each food group is important. Fruit intake was estimated in one question, whereas for meat, individuals were asked to think about the different types of meat and alternatives in five separate questions, and all the different categories of discretionary foods were asked across 10 questions. The rationale for having additional questions is to assist individuals to estimate consumption across such diverse food categories. Conceptually, it might be more difficult, and therefore less accurate, to ask individuals to remember, estimate and then add up their usual consumption of so many different types of food, for example, ice cream, chocolate bars, processed meat, soft drinks and take-away foods all in one step. Continual refinement is required to balance the number of questions with the accuracy of responses. Regardless, the questions associated with these poorer performing indicators needs to be refined to better capture intake within the defined time period and to better estimate compliance with the dietary guidelines.

Limitations of this validation study included the small homogeneous sample, possibly biased towards higher socio-economic status and women. The recruitment strategy resulted in a small sample of convenience with an unknown response rate (presumably low).[17,27] Additional demographic data, for example, body mass index, education and employment status, would have also enhanced the understanding of study representativeness. It is important not to assume that the validity of this tool will remain the same in populations that are demographically different to the study sample.[8] Small samples can be problematic in validation studies; therefore, to ensure that this tool can be used more broadly, further validation in a larger, and more representative sample would be ideal. Despite the limitations, a major strength of the present study is that it is the first short survey for Australian adults that can be used to measure compliance with the dietary guidelines, represented as a total diet score.[28,29] The survey is also computer-administered, reducing the time required for data collection and data analysis.[6,10] Future adjustment to the tool to improve the accuracy may include refinement of questions for certain food groups or modification of the design in how questions are delivered. The survey, like most food questionnaire-type tools, would benefit from cognitive testing to better understand how respondents conceptualise individual questions and explain the reasons

for the results observed. Following refinement, a larger scale usability and validation study is necessary.

In conclusion, this SFS performs adequately for assessing compliance of adult food intake against current dietary guidelines using a diet index score. It is able to estimate individuals' intake of food groups consistently; however, its performance in estimating individual's food group intake when compared to 24-hour recalls was poor. Future refinement of this tool will provide a valuable online tool to assess compliance with the dietary recommendations in the Australian population.

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Conflict of interest

The authors declare no conflict of interest.

Authorship

GH and RG were responsible for the study design. MR collected the data. GH and MR undertook the data analysis. All authors were involved in preparation and approval of the manuscript. The authors confirm that this content has not been published elsewhere.

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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. Details of short food survey questions, responses and Dietary Guideline Index for Adults (DGI-AD) scoring criteria
Figure S1. Bland Altman Plots for the Dietary Guideline Index (DGI) score and the food group indicator scores.

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ORIGINAL RESEARCH

Relative validity of a 2-day 24-hour dietary recall compared with a 2-day weighed dietary record among adults in South China

Hongmei XUE,[1†] Mingzhe YANG,[2†] Yan LIU,[1] Ruonan DUAN,[1] Guo CHENG[1] and Xiao ZHANG[3]

[1]Department of Nutrition, Food Safety and Toxicology, West China School of Public Health and [3]West China School of Public Health, No. 4 West China Teaching Hospital, Sichuan University, Chengdu and [2]Nutrition and Health Research Centre, By-Health Co. LTD, Guangzhou, China

Abstract

Aim: To determine the relative validity of a 2-day 24-hour dietary recall (HR) designed to assess energy and nutrient intake among Chinese adults compared with a 2-day weighed dietary record (WD).

Methods: Data were obtained from an ongoing population-based, prospective cohort study of adults aged 18–65 years in South China. A total of 41 adults completing a HR and a WD within 14 days were included in the present analysis. Estimations of individual mean differences, Spearman's correlation coefficients, cross-classifications and Bland–Altman plots were used to assess the agreement between the intakes of energy and 18 nutrients obtained from the HR and the WD.

Results: With the exception of total fat, saturated fatty acids, thiamine, potassium and magnesium, the energy and nutrient intakes between the HR and WD showed no significant differences. All dietary intakes that were evaluated by the HR were correlated significantly with the dietary intake from the WD (de-attenuated correlation coefficients ranged from 0.10 to 0.87). The proportion of participants classified into quartiles correctly ranged from 61% for tocopherol intake to 90% for energy intake. The weighted k values ranking the participants ranged from 0.11 for tocopherol intake to 0.41 for the intakes of energy and calcium. The Bland–Altman plots showed moderate/good agreement among all the dietary intakes that were estimated from the HR and WD, except for total fat.

Conclusions: This study suggests that an HR could be a valid tool for estimating the energy and nutrient intakes among adults in South China at the group level.

Key words: 24-hour dietary recall, adult, dietary intake, validation, weighed dietary record.

Introduction

Epidemiological studies have shown that dietary factors can contribute to many chronic diseases in adults.[1,2] Given the need for the accurate estimation of nutrient intake in adults, a valid, precise and practical dietary assessment method is essential. Common instruments for collecting information on food and beverage consumption include the food frequency questionnaire (FFQ), the weighed dietary record (WD) and the 24-hour dietary recall (HR). The FFQ, a widely used methodology, aims to record the frequency of food consumed from a selected list over a certain period,[3] but among its limitation is the broad variation in design characteristics, for example, the number of items influencing the intake of energy and nutrients reported.[4] Although regarded as a gold standard in nutrition assessment,[5] WD is expensive and time-consuming, and it require a considerable commitment of the participants.[6]

The HR, with its small literacy requirement and relatively low respondent burden,[3,7] is a very easy and rapid method to conduct. Because of the open-ended interview,[7] more detailed and complete information about food consumed can be collected by the HR. Unlike the diary method, dietary recall occurs after consumption, thus having less possibility of the

H. Xue, MPH, PhD Student
M. Yang, MM, Research Associate
Y. Liu, BSc, MPH Student
R. Duan, BD, Master Student
G. Cheng, PhD, Professor
X. Zhang, MSc, Scientific Research Manager
Correspondence: X. Zhang, West China School of Public Health, No. 4 West China Teaching Hospital, Sichuan University, Chengdu, China. Tel: +86 28 85502220, Email: royantaul_zx@126.com
[†]These authors contributed equally to this study and share first authorship.

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assessment method interfering with dietary behaviour.[3] Although the HR is usually dependent on the memory of the respondent,[6,7] which might constrain its use among young children and the elderly, it is still commonly used to assess dietary intake in adults younger than 75 years old.[8,9] Moreover, it is relatively less expensive than WD.[3]

To date, most of the existing validation studies conducted among Chinese adults have examined the validity of the FFQ using the HR,[10–14] yet studies focusing on the validity of the HR using the WD as a reference method are lacking.

In recent years, the prevalence of chronic, non-communicable diseases has increased rapidly in China,[15] which might be relevant to the level of dietary nutrient intake to a large extent.[16–18] To investigate the impact of dietary factors on the health (especially chronic diseases) of adults in South China, a population-based, prospective cohort study collecting information on diet, anthropometry, physical activity and metabolic factors was conducted beginning in 2013, in which a two-day HR was used to collect information about food and beverage consumption among adults in South China. To ensure the accuracy and fidelity of the data collected by this method in this cohort study, we aimed to determine the relative validity of the two-day HR-assessed energy and nutrient intakes in adults using a two-day WD as the reference method.

Methods

To investigate the impact of nutritional factors on the development of several chronic diseases or the worsening of quality of life, a population-based, prospective, open-cohort study was conducted with adults (age range: 18–65 years old) in 21 communities of Chengdu, Guizhou and Xiamen beginning in September 2013. The participants were invited to the study centre for interviews. Generally, each visit included anthropometric measurements, medical examinations, questionnaires and face-to-face interviews by trained investigators about nutrition-related behaviours (dietary habits, food and beverage intake), lifestyles and social status. Participants who were cooperative, who volunteered and who signed an informed consent form were included in this cohort study. However, the following participants were excluded from the cohort study: (i) if they were not local residents, or they were not planning to be long-term residents; (ii) if they had major organ diseases, including heart, liver or kidney disease; (iii) if they had mental diseases; (iv) if they were taking hormone-based drugs and other medicines that affect blood glucose and lipids; or (v) if they were pregnant or lactating women. This study was approved by the ethics committee of Sichuan University, and all the examinations were performed with the participants' consent.

For the validation of the two-day HR used in the study, a subsample (recruited by the screening questions) of the large cohort collected in 2013 (n = 368) was asked to report food and beverage intakes using a two-day HR.

All the participants received a cover letter describing the procedures of the validation study. The two-day HR was completed on two random days (one weekday and one weekend day) within a given individual time frame of seven days by trained investigators in face-to-face interviews. With an interval of two to three days from the HR, the two-day WD (one weekday and one weekend day) was subsequently completed, also within a given individual time frame of seven days. Participants were asked to weigh all foods and beverages that they consumed and to record the time and location where the food was eaten, as well as the brand or name of the food. A box of materials necessary for completing the WD was given to all the participants. The box included instructions on how the WD should be completed, dietary record forms and an electronic food scale (which could be kept by the participants after the completion of data collection as a token of appreciation for their participation). During the investigational phase, all the finished questionnaires were checked, and a follow-up with the respondent was also conducted to clarify and obtain any missing information on the dietary report. In addition, the participants in this validity study could contact a support hotline in case of any other potential questions.

The HR was unstructured and open ended. The food and beverage consumption of the participants was collected over two days (one weekday and one weekend day) by investigators in two separate face-to-face interviews, including foods eaten outside and nutritional supplements. In the HR, the participants were unaware of the day on which their dietary intake was going to be collected prior to the interview. The second recall was reported one to five days after the first recall, depending on the day of the week of the first recall. All the investigators were trained, for example, in how to estimate the portion size and questioning skills with neutral attitudes. The participants were asked by the HR to recall the amounts of all foods and beverages consumed and the corresponding timing. To guarantee the conduct of the 24-hour recall, the participants were required to supply an uninterrupted listing of all foods and beverages consumed and to answer a series of main food category questions for additional foods. Information on recipes or the types and brands of food items, the corresponding meal occasions and cooking methods were also asked in the interviews. The estimation of serving sizes in terms of household measurements was given special attention. Standardised tableware, commonly used in Chinese households, was provided instead of household tableware for determining serving sizes, namely, one type of bowl that could hold 200 g of rice, one type of dish that could hold 100 g of potatoes and two types of glasses holding either 200 or 400 mL of water. In addition, a photo book was provided to facilitate the completion of the HR. This photo book included not only several commercial foods and beverages from the continuously updated in-house nutrient database reflecting the China Food Composition[19] but also commercial foods and beverages especially consumed by adults in South China. The names, as well as the pictured serving sizes on the common commercial packaging (e.g. one carton), were provided in the photo book. In total, approximately 200 food items could be found in this photo book.

As the reference method, a two-day WD (one weekday and one weekend day) was completed with an interval of two to three days after the two-day HR. Similar to the HR, the second weighed record was recorded one to five days after the first record. The participants were asked to weigh all foods and beverages consumed to the nearest 0.1 g with the help of an electronic food scale. Semi-quantitative recording (e.g. number of spoons, scoops) was allowed when exact weighing was not possible, for example, foods eaten away from home or snacks. However, our analysis revealed that more than 93% of all foods that were consumed were weighed. Information on recipes or the types and brands of food items, as well as the meal occasions and cooking methods, were also requested.

The quantities of foods and beverages reported by the HR were converted from portion sizes that were estimated using standardised tableware into grams for each food and beverage according to the standard system.[20]

For the aim of the longitudinal study, the individual intakes of energy and of 18 nutrients (protein, animal protein, total fat, saturated fatty acid (SFA), monounsaturated fatty acid (MUFA), polyunsaturated fatty acid (PUFA), carbohydrate, fibre, retinol, ascorbic acid, tocopherol, thiamine, sodium, potassium, iron, calcium, magnesium and zinc) relating to metabolic diseases on each day of the two-day HR and the two-day WD were calculated according to the China Food Composition.[19]

Anthropometric measurements were performed by trained medical workers. An ultrasonic weight meter was used. Standing heights were measured to the nearest 0.1 cm, and weight was assessed to 0.1 kg, calculating body mass index (BMI, kg/m^2) for each participant. With a tape, waist circumference and hip circumference were measured to the nearest 0.1 cm to calculate the waist-to-hip ratio (WHR). Additionally, the participants provided information about their families, socioeconomic characteristics, etc.

The SAS statistical software package (SAS, version 9.3, 2011, SAS Institute Inc., Cary, NC, USA) was used for data analyses. All the analyses were performed with a significance level of $P < 0.05$, except for the interaction, where $P < 0.1$ was considered statistically significant. To test for interactions with gender, we used linear regression models with energy and nutrient intakes estimated from the WD as the dependent variables and energy and nutrient intakes estimated from the HR and gender as the independent variables. The analyses indicated no interaction with gender ($P = 0.3$). Thus, data from women and men were pooled for all the analyses. Additionally, participants with implausible energy intake were determined using a classic equation according to age, gender and basal metabolic rate,[21] and all the nutrients were also energy-adjusted (as energy density) in the analysis procedure. Because most nutrients were not normally distributed, non-parametric methods were used to evaluate the validity of the HR in comparison with the WD. The data in the results and tables are presented as medians (Q1, Q3).

For different aspects, individual mean differences, correlation coefficients, weighted kappa coefficients and Bland–Altman plots were used. Individual mean differences were calculated to obtain conclusions on a population level about the extent of over- or underestimation of energy and nutrient intakes by the HR. The significance of the differences in energy and nutrients intakes between the HR and WD was tested using Wilcoxon's signed-rank test. To assess the associations between the energy and nutrient intakes obtained by both methods, Spearman's rank correlation coefficients were calculated. To minimise the random effect of the within-person error that was measured using the HR and WD, the de-attenuation coefficients were calculated.[22] Additionally, participants were grouped into quartiles for energy intake and each nutrient to test the agreement in ranking the participants according to their dietary intakes, as estimated from using the two methods. The proportion of participants who were classified into the same, adjacent or opposite quartiles for each method was calculated. The degree of agreement was evaluated by the weighted kappa coefficient (k). A k value of ≤ 0.2 was selected to indicate the existence of slight agreement, 0.21–0.4 for fair agreement, 0.41–0.6 for moderate agreement, 0.61–0.8 for substantial agreement and ≥0.81 for almost perfect agreement.[23]

Moreover, Bland–Altman plots were used to illustrate the differences in energy and nutrient intakes between the HR and WD compared with the mean of the two methods. A log-transformation of the data for the study participants was performed to normalise the data.[24] The horizontal dashed line indicated the mean of the differences (HR–WD). The limits of agreement (LOAs) were calculated by the mean difference plus or minus two standard deviations (mean ± 2 SDs). The mean differences and LOAs were anti-logged to provide more meaningful data. To examine whether the agreement between the methods varied with the magnitude of energy and nutrient intakes, the differences between the methods were plotted against their means. Pearson's correlation coefficient was calculated to test the associations between the differences and the means of the two methods. Ideally, the mean difference between the methods should be zero with no discernible bias; that is, the mean differences should cluster on the horizontal, continuous line of equality (y = 0). Any deviation of the mean difference line from the line of equality indicates a bias. Furthermore, any systematic variation of the differences in dietary intake across the range of dietary intakes suggests the presence of additional systematic bias, which would provide further evidence of limited agreement between the methods.[25]

The estimates of the least detectable effect sizes (the least detectable degree to which the null hypothesis is indexed by the discrepancy between the null hypothesis and alternate hypothesis) specific to the study sample and the types of analyses were calculated. These power analyses were performed using PROC POWER in SAS under the following conditions: power = 80%, $\alpha = 0.05$ and two-tailed; thus, the estimated sample size was 60–64. The statistical power

for our analysis (correlation coefficients and cross-classifications) yielded a power of 65–73%.

Results

In the present analysis, 52 adults were initially recruited. Of them, 11 adults with metabolic disease (n = 3) or who did not meet the requirements, such as consecutive recalls/weight records or both recalls/weight records on weekdays/weekend days (n = 3) or implausible energy intake[21] (n = 5), were excluded. Therefore, the present analysis was based on a final sample of 41 participants (11% of the participants of the large cohort).

The median time between the WD and HR was 2.6 days. A total of 41 participants were included in the present analysis (female 56%). The median (Q1, Q3) age of the adults was 25.3 (23.2, 42.3) years, with a range from 18 to 65 years. The median (Q1, Q3) of BMI and WHR were 21.0 (19.9, 23.8) kg/m^2 and 0.82 (0.8, 0.9), respectively. With regards to clinical characteristics, such as BMI, and socioeconomic characteristics, e.g., family annual income, these 41 participants were in agreement with those in our large cohort and also with the general population (Table S1, Supporting Information).[26]

Table 1 presents the nutritional characteristics of the study sample. Absolute dietary intakes recorded in the HR were lower than the dietary intakes calculated from the WD, except for the animal protein, total fat, SFA, PUFA, thiamine and retinol intakes. For nutrient density, the levels of protein and magnesium recorded by the HR were lower than those calculated from the WD, yet the intakes of animal protein total fat, SFA, retinol, thiamine, iron and ascorbic acid from the HR were higher than those calculated from the WD.

The individual mean differences and correlations of dietary intakes between the HR and WD with and without adjustment for energy intake are shown in Table 2. The absolute intakes of total fat, SFA and thiamine were significantly higher using the HR compared with using the WD, but the absolute intakes of energy and the other nutrients did not differ between the HR and WD. Similar results were observed in the energy-adjusted data except for the intakes of magnesium and potassium, which were lower using the HR than the WD. Additionally, the intakes of protein and zinc were slightly underestimated and overestimated using the HR, respectively, compared with using the WD, although the difference was not statistically significant. The de-attenuated correlation coefficient between the HR and WD for energy intake was 0.76. After energy adjustment, the de-attenuated correlation coefficients between the HR and WD ranged from 0.10 to 0.87 for all dietary intakes. High de-attenuated correlation coefficients (≥0.70) were observed for energy-adjusted intakes of MUFA, retinol and ascorbic acid. The de-attenuated correlation coefficients were moderate (0.40–0.69) for intakes of animal protein, PUFA, potassium, calcium, magnesium and zinc, while the correlations were weak for protein, total fat, SFA, carbohydrate, fibre, tocopherol, thiamine, sodium and iron (<0.40).

The potential misclassifications of energy and the intakes of 18 nutrients reported by the HR compared with the WD are presented in Table 3. The proportion of our participants classified within the same or the adjacent quartile ranged from 60.96% for tocopherol intake to 90.24% for energy intake. Classification into the opposite quartile was less than 10% for all dietary intakes except for the carbohydrate intake (12.20%). Moderate agreement (k: 0.41–0.6) in the ranking of the participants according to their intakes between the HR and WD was observed for energy and calcium. Acceptable agreement (k: 0.21–0.4) was observed for 12 nutrients (protein, animal protein, SFA, MUFA, PUFA, carbohydrate, retinol, ascorbic acid, thiamine, sodium, potassium and magnesium), and slight agreement (k: 0.00–0.20) was found for the other four nutrients (total fat, fibre, tocopherol, and zinc).

The individual differences in 13 nutrients (protein, total fat, MUFA, carbohydrate, fibre, retinol, ascorbic acid, thiamine, sodium, potassium, iron, magnesium and zinc) between the two methods were not significantly associated with the means from using the two methods (Pearson's correlation coefficient: –0.27–0.007, $P \geq 0.06$), which indicated that the variability and direction of the difference did not depend on intake level. The geometric mean difference for energy and for the 10 nutrients (animal protein, PUFA, carbohydrate, fibre, tocopherol, sodium, potassium, calcium, magnesium and zinc) estimated using the HR was comparable (with a range of 2% above to 3% below) to those with the WD. On average, the HR underestimated protein and iron intakes by 8 and 12%, respectively, compared to the WD. Furthermore, the LOAs indicated that the HR could estimate protein intake within a range of 66% above to 49% below and iron intake from 119% above to 64% below their intakes as reported in the WD for most of the participants. The geometric mean difference for the intakes of total fat, SFA, MUFA, retinol, ascorbic acid and thiamine between the two methods indicated that the HR overestimated the intakes of these nutrients from 13 to 104% compared with the WD (Table S2).

For example, Bland–Altman plots for total fat intake are presented in Figure 1. The upper and lower LOAs of 0.62–6.67 indicated that the HR could estimate total fat intake, for most participants, within a range of 567% above to 38% below the total fat intake reported in the WD.

Discussion

In the present study, we compared the dietary intakes of adults in South China estimated using a two-day HR with the dietary intakes estimated using a two-day WD (as the reference). The nutrient intakes in the present analysis were comparable with the average intake levels of the Chinese population.[27] Our results suggested that the HR provided a relatively valid estimation of dietary intake among adults on a group level.

Correlation coefficients are useful for determining whether there is a linear trend in the responses between the test and reference methods. To minimise the effect of intra-

Table 1 Nutrient intake of the participants in the present study[(a)] (n = 41)

Nutrient intake	*24-hour dietary recall*	*Weighed dietary record*
Energy intake (MJ/d)	6.16 (5.44, 9.16)	6.61 (5.31, 9.98)
Energy-unadjusted		
Protein (g/d)	53.70 (40.49, 77.76)	61.68 (46.56, 84.11)
Animal protein (g/d)	21.69 (10.15, 38.57)	16.36 (10.15, 38.70)
Total fat (g/d)	42.74 (32.06, 68.84)	39.00 (23.61, 66.28)
Saturated fatty acid (g/d)	7.60 (5.37, 15.41)	3.51 (2.25, 6.38)
Monounsaturated fatty acid (g/d)	9.11 (6.86, 15.02)	10.18 (6.44, 13.42)
Polyunsaturated fatty acid (g/d)	4.65 (3.26, 6.34)	4.49 (3.33, 6.78)
Carbohydrate (g/d)	246.55 (198.45, 298.46)	255.48 (162.20, 357.04)
Fibre (g/d)	9.27 (7.35, 11.77)	9.49 (5.81, 14.04)
Retinol (μg/d)	352.88 (183.90, 498.64)	261.56 (162.54, 554.68)
Ascorbic acid (mg/d)	78.19 (46.15, 114.14)	90.80 (35.58, 141.81)
Tocopherol (mg/d)	15.98 (12.71, 21.92)	17.82 (12.19, 23.55)
Thiamine (mg/d)	1.69 (1.30, 2.34)	0.98 (0.6, 1.32)
Sodium (g/d)	2.81 (2.29, 4.09)	2.89 (2.26, 3.86)
Potassium (g/d)	1.57 (1.09, 1.95)	1.65 (1.15, 2.41)
Iron (mg/d)	15.85 (11.70, 21.46)	18.02 (13.61, 29.04)
Calcium (mg/d)	289.30 (213.15, 498.68)	350.04 (198.69, 519.94)
Magnesium (mg/d)	224.42 (176.10, 265.86)	248.02 (185.44, 375.08)
Zinc (mg/d)	8.80 (6.32, 10.81)	9.59 (7.07, 13.55)
Energy-adjusted		
Protein (g/MJ)	8.25 (6.86, 9.22)	8.44 (7.26, 10.52)
Animal protein (g/MJ)	3.19 (1.48, 4.31)	2.74 (1.47, 5.30)
Total fat (g/MJ)	11.89 (9.46, 15.70)	10.11 (6.71, 17.11)
Saturated fatty acid (g/MJ)	1.26 (0.73, 2.43)	0.57 (0.29, 0.99)
Monounsaturated fatty acid (g/MJ)	1.37 (1.14, 2.13)	1.50 (0.98, 2.31)
Polyunsaturated fatty acid (g/MJ)	0.69 (0.49, 0.97)	0.77 (0.48, 1.04)
Carbohydrate (g/MJ)	37.33 (33.34, 39.78)	37.70 (26.94, 46.15)
Fibre (g/MJ)	1.29 (1.07, 1.83)	1.37 (0.88, 1.96)
Retinol (μg/MJ)	42.14 (27.14, 70.47)	39.58 (21.02 65.74)
Ascorbic acid (mg/MJ)	11.72 (5.29, 19.18)	8.56 (5.51, 21.60)
Tocopherol (mg/MJ)	2.39 (1.85, 3.00)	2.45 (1.82, 3.01)
Thiamine (mg/MJ)	0.26 (0.21, 0.32)	0.14 (0.10, 0.17)
Sodium (g/MJ)	0.42 (0.35, 0.51)	0.41 (0.32, 0.55)
Potassium (g/MJ)	0.21 (0.17, 0.28)	0.26 (0.16, 0.35)
Iron (mg/MJ)	0.37 (0.22, 0.40)	0.28 (0.25, 0.31)
Calcium (mg/MJ)	45.69 (29.60, 68.47)	44.59 (33.02, 71.96)
Magnesium (mg/MJ)	32.35 (28.42, 37.46)	35.29 (31.58, 42.91)
Zinc (mg/MJ)	1.30 (1.09, 1.50)	1.44 (1.22, 1.72)

[(a)] Data are presented as median (Q1, Q3).

subject variability of intake measured using the HR and WD, the de-attenuation coefficients were calculated.[21] The de-attenuated correlation coefficients for the intakes of energy, MUFA, retinol, ascorbic acid, calcium and zinc in the present study were greater than 0.5, which has been proposed to indicate validity.[28] However, correlation coefficients address only one aspect of the validation procedure; additional statistical assessments employing weighted k and Bland–Altman statistics are required to ascertain validity. The weighted k statistic should be >0.4 to confirm at least a moderate agreement.[22,29] A previous study revealed that it was more useful and meaningful to present the weighted k value along with the percentages of items correctly classified and misclassified (the recommendation was >50% correctly classified and <10% misclassified) because the weighted k provides a single value to represent agreement.[29] In our study, the weighted k values for energy and calcium intakes were greater than 0.4. The proportions of our participants who were correctly classified were greater than 60%, and the misclassification rate was 10% or less for most of the nutrient intakes except for carbohydrates. Additionally, the Bland–Altman plots were produced as a comparative tool for the assessment of different methods.[30] The Bland–Altman method, combining the quantitative LOAs and qualitative scatter plots, is the most popular method used in agreement research and can assess the agreement of quantitative data accurately.[31] The Bland–Altman plots in our analysis suggested good agreement for the dietary intakes estimated using the HR and WD, indicating that the HR and WD that were used for estimating the dietary

Table 2 Individual mean difference and Spearman's rank correlation (de-attenuated correlation coefficients) between daily intakes of energy and nutrients reported in the 24-hour recall (HR, test method) and weighed dietary record (WD, reference method) in adults from South China (n = 41)

Nutrient intake	*Individual mean difference*[(a)]	P[(b)]	*De-attenuated correlation coefficients*	P
Energy intake (MJ/d)	−0.60 (−1.77, 1.13)	0.2	0.76	<0.0001
Energy-unadjusted				
Protein (g/d)	−10.48 (−20.50, 5.93)	0.07	0.65	0.0002
Animal protein (g/d)	−2.24 (−11.86, 9.18)	0.8	0.57	0.002
Total fat (g/d)	34.83 (17.89, 63.05)	<0.0001	0.44	0.1
Saturated fatty acid (g/d)	3.16 (1.54, 10.33)	0.003	0.31	0.0502
Monounsaturated fatty acid (g/d)	0.59 (−3.98, 4.83)	0.7	0.73	0.003
Polyunsaturated fatty acid (g/d)	−0.54 (−2.22, 1.74)	0.4	0.65	0.004
Carbohydrate (g/d)	−0.34 (−72.06, 54.58)	0.6	0.89	<0.0001
Fibre (g/d)	−0.51 (−4.58, 4.72)	0.6	0.57	0.06
Retinol (μg/d)	58.74 (−101.85, 203.18)	0.3	0.93	0.002
Ascorbic acid (mg/d)	1.89 (−44.90, 33.03)	0.6	0.91	0.0002
Tocopherol (mg/d)	−1.86 (−7.16, 5.46)	0.3	0.54	0.02
Thiamine (mg/d)	0.68 (0.34, 1.46)	<0.0001	0.47	0.002
Sodium (g/d)	−0.26 (−0.80, 0.38)	0.6	0.47	0.002
Potassium (g/d)	−0.34 (−0.82, 0.28)	0.06	0.61	<0.0001
Iron (mg/d)	−0.04 (−8.36, 3.73)	0.2	0.56	0.003
Calcium (mg/d)	−19.39 (−145.46, 77.39)	0.2	0.77	<0.0001
Magnesium (mg/d)	−11.66 (−109.12, 32.72)	0.053	0.81	<0.0001
Zinc (mg/d)	−0.31 (−4.59, 1.55)	0.08	0.60	0.0009
Energy-adjusted				
Protein (g/MJ)	−0.42 (−2.80, 1.04)	0.07	0.32	0.1
Animal protein (g/MJ)	0.00 (−1.52, 1.59)	0.8	0.47	0.02
Total fat (g/MJ)	1.14 (−6.39, 8.18)	<0.0001	0.10	0.8
Saturated fatty acid (g/MJ)	0.66 (0.18, 1.56)	<0.0001	0.30	0.06
Monounsaturated fatty acid (g/MJ)	−0.05 (−0.43, 0.65)	0.6	0.87	0.001
Polyunsaturated fatty acid (g/MJ)	−0.06 (−0.31, 0.24)	0.4	0.49	0.04
Carbohydrate (g/MJ)	−0.07 (−9.53, 7.08)	0.6	0.27	0.3
Fibre (g/MJ)	0.10 (−0.67, 0.68)	0.9	0.14	0.7
Retinol (μg/MJ)	7.67 (−17.65, 40.74)	0.3	0.84	0.006
Ascorbic acid (mg/MJ)	−0.63 (−6.53, 4.98)	0.6	0.79	0.0003
Tocopherol (mg/MJ)	−0.25 (−0.97, 0.69)	0.5	0.18	0.5
Thiamine (mg/MJ)	0.13 (0.07, 0.17)	<0.0001	0.25	0.1
Sodium (g/MJ)	4.93 (−163.32, 114.49)	0.8	0.32	0.04
Potassium (g/MJ)	−51.64 (−115.65, 28.98)	0.02	0.50	0.0009
Iron (mg/MJ)	0.09 (−1.02, 0.61)	0.2	0.31	0.7
Calcium (mg/MJ)	−7.16 (−23.03, −11.19)	0.2	0.65	<0.0001
Magnesium (mg/MJ)	−2.94 (−8.91, 2.50)	0.02	0.43	0.003
Zinc (mg/MJ)	0.05 (−0.43, 0.14)	0.07	0.61	0.01

[(a)] Individual mean difference was calculated by energy and nutrient intakes from HR minus those from WD. Data are presented as median (Q1, Q3).
[(b)] For difference between HR and WD obtained by Wilcoxon signed-rank test.

intakes of adults were interchangeable in the present analysis to some extent; that is, we could use the HR instead of the WD. As evidenced from the correlation coefficients, cross-classifications and Bland–Altman plots, the overall level of validity of the energy and nutrient intakes in our study was thus moderate to good among the participants from our cohort.

To date, few studies in adults have been conducted to validate dietary intakes reported by the HR compared with dietary intakes estimated from WDs.[32] The correlation coefficients observed in our study were comparable with those reported in other studies.[32–34] Moreover, the percentages of participants who were correctly classified for energy and nutrient intakes in the present study were greater than those in other studies.[32–34] Although Bland–Altman plots are considered the gold standard in studies of methodical comparisons,[24] few validation studies in nutritional epidemiology in adults have used this method in past years.[35,36] The Bland–Altman plots in our study compared favourably with those in studies of 348 Denmark adults aged 30–60 years old and in 65 Brazilian women aged 18–57 years old.[35,36]

Table 3 Cross-classification for agreement between daily intakes of energy and nutrients reported in the 24-hour dietary recall (HR, test method) and weighed dietary record (WD, reference method) in adults from South China (n = 41)

	Agreement for quartiles				
	Same/adjacent[(a)]		*Opposite*[(a)]		
Nutrient intake	*n*	*%*	*n*	*%*	*Weighted Kappa*[(b)]
Energy intake (kJ/d)	37	90.24	2	4.88	0.41 (0.21, 0.60)
Energy-unadjusted					
Protein (g/d)	36	87.80	2	4.88	0.45 (0.25, 0.65)
Animal protein (g/d)	32	78.04	1	2.44	0.33 (0.11, 0.55)
Total fat (g/d)	33	80.48	1	2.44	0.37 (0.16, 0.58)
Saturated fatty acid (g/d)	33	80.48	3	7.32	0.25 (0.03, 0.47)
Monounsaturated fatty acid (g/d)	32	78.04	1	2.44	0.28 (0.06, 0.49)
Polyunsaturated fatty acid (g/d)	35	85.36	2	4.88	0.33 (0.12, 0.54)
Carbohydrate (g/d)	38	92.68	1	2.44	0.41 (0.22, 0.60)
Fibre (g/d)	31	75.60	4	9.76	0.13 (–0.09, 0.35)
Retinol (μg/d)	32	78.04	2	4.88	0.25 (0.04, 0.46)
Ascorbic acid (mg/d)	37	90.24	1	2.44	0.33 (0.14, 0.52)
Tocopherol (mg/d)	29	70.72	1	2.44	0.17 (–0.05, 0.39)
Thiamine (mg/d)	36	87.80	2	4.88	0.29 (0.07, 0.51)
Sodium (g/d)	34	82.92	0	0.00	0.37 (0.17, 0.57)
Potassium (g/d)	34	82.92	3	7.32	0.41 (0.21, 0.61)
Iron (mg/d)	32	78.04	1	2.44	0.25 (0.04, 0.46)
Calcium (mg/d)	35	85.37	1	2.44	0.41 (0.20, 0.61)
Magnesium (mg/d)	36	87.80	1	2.44	0.37 (0.17, 0.56)
Zinc (mg/d)	36	87.80	2	4.88	0.29 (0.10, 0.48)
Energy-adjusted					
Protein (g/MJ)	29	70.72	3	7.32	0.37 (0.15, 0.50)
Animal protein (g/MJ)	26	63.41	0	0.00	0.27 (0.09, 0.38)
Total fat (g/MJ)	27	65.84	4	9.76	0.13 (–0.10, 0.36)
Saturated fatty acid (g/MJ)	29	70.72	2	4.88	0.21 (0.01, 0.44)
Monounsaturated fatty acid (g/MJ)	33	80.48	0	0.00	0.25 (0.06, 0.44)
Polyunsaturated fatty acid (g/MJ)	30	73.16	2	4.88	0.25 (0.03, 0.47)
Carbohydrate (g/MJ)	29	70.72	5	12.20	0.35 (0.16, 0.57)
Fibre (g/MJ)	28	68.28	3	7.32	0.13 (–0.10, 0.37)
Retinol (μg/MJ)	33	80.48	1	2.44	0.29 (0.09, 0.49)
Ascorbic acid (mg/MJ)	34	82.92	2	4.88	0.33 (0.11, 0.54)
Tocopherol (mg/MJ)	25	60.96	3	7.32	0.11 (0.05, 0.22)
Thiamine (mg/MJ)	29	70.72	1	2.44	0.25 (0.03, 0.48)
Sodium (g/MJ)	28	68.28	2	4.88	0.21 (–0.03, 0.45)
Potassium (g/MJ)	32	78.04	1	2.44	0.33 (0.11, 0.55)
Iron (mg/MJ)	27	65.84	4	9.76	0.21 (0.01, 0.34)
Calcium (mg/MJ)	36	87.80	2	4.88	0.41 (0.21, 0.61)
Magnesium (mg/MJ)	31	75.60	2	4.88	0.29 (0.07, 0.51)
Zinc (mg/MJ)	31	75.60	3	7.32	0.13 (–0.08, 0.34)

[(a)] 'Same' quartile – 100% for complete agreement, that is, subjects classified into the same fourth by HR and WD; 'Adjacent' quartile – partial disagreement, that is, subjects differing by one category; 'Opposite' quartile – 0% for complete disagreement, that is subjects differing by two categories.[29]
[(b)] Values are median (Q1, Q3).

The estimation of portion size introduces imprecision into diet records.[7] Except for animal protein, total fat and retinol intakes (acceptable overestimated), energy and other nutrient intakes that were estimated using the HR were close to those estimated using the WD. The estimated inaccuracy of food and beverage intakes consumed in our study might have occurred because of the difference between standard tableware and the tableware that our participants usually used. In addition, the HR has systematically lower levels of intake, such as missing foods or beverages reported by the HR (perhaps because of memory problems). These misestimations might be large for individuals; however, when calculating mean intakes at the group level, this error might be small and of little importance.[24] In nutritional epidemiology, participants are commonly grouped by their intake levels, so

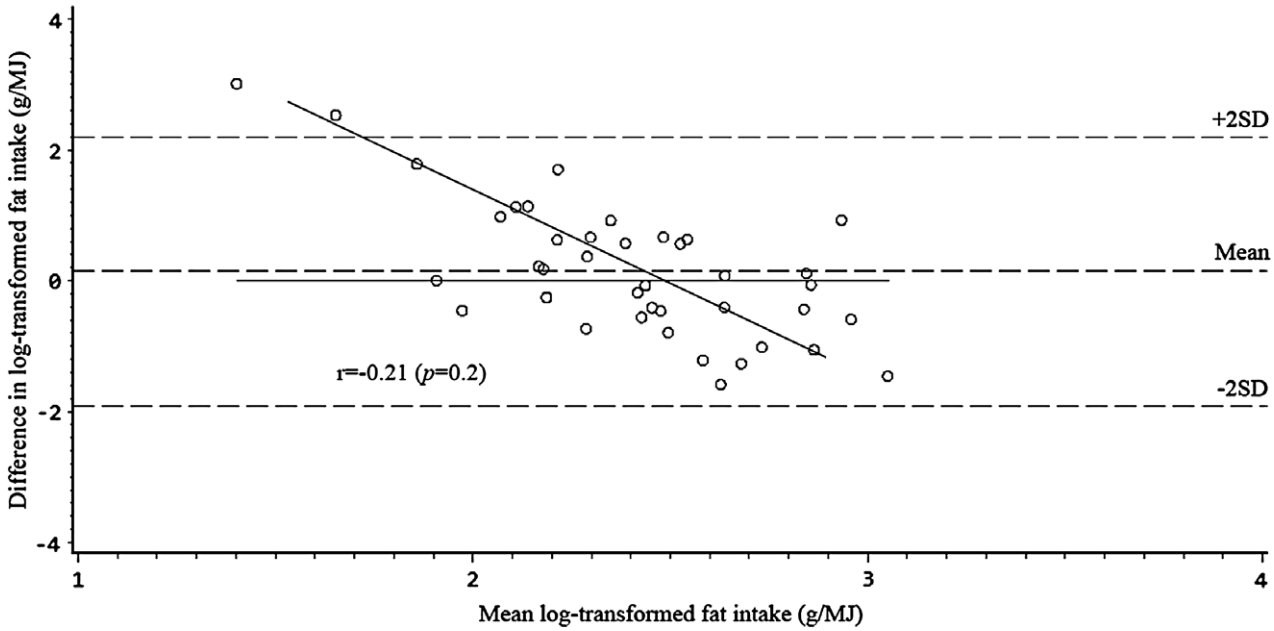

Figure 1 Bland–Altman plot of agreement between fat intake (g/kcal) reported in the 2-day 24-hour dietary recall (HR, test method) and the 2-day weighed dietary record (WD, reference method) in Chinese adults aged 18–65 years (n = 41). Data are log-transformed values. The difference between fat intake calculated from the HR (test method) and estimated from the WD (reference method) for each participant (y-axis, displayed as log (WR–HR)) is plotted against the mean fat intake averaged from the two methods (x-axis, displayed as log ((WR + HR)/2))). — — (in the middle) represents the mean of the difference; — — (upper and lower) represent the upper and lower 95% limits of agreement (mean ± 2 SD), respectively; —— represents the line of equality (y = 0); ╲ represents the fitted regression line. Pearson's correlation coefficient of the individual differences in fat intake between the two methods with the mean reported by the two methods was –0.21 (P = 0.2).

such slight misestimations are acceptable for the analyses of groups.

In the current study, the HR proved to be a valid assessment method for estimating dietary intakes in adults at the group level compared with the WD. It appears worthwhile to consider that nutritional intake could be recorded with more detail and more accurately by face-to-face interviews. Additionally, the good precision of the procedure of converting portion sizes into grams might also have contributed to the high validity that was observed. Furthermore, the meal occasions and cooking methods in the HR, listed according to the typical meal structure among adults in South China, could have improved the concentration and accuracy of the participants performing the dietary recording.

Given that the HR is easier to understand and a more complete assessment than the WD, it was well accepted by most of our participants, both in the present study and in the large cohort. For the researchers, this HR might incur more errors than the WD. However, the use of the photo book, which covered not only several commercial foods and beverages from China Food Composition[19] but also commercial foods and beverages especially consumed by adults in South China, could have reduced errors to some extent. In addition, this HR could offer an advantage in terms of the personnel costs compared with the costs for completion of the WD, especially with a large-scale study sample.

Our study had several strengths, including the representative study sample that was selected from our cohort. The conclusion from the present results could thus be extended to general populations, for example, to those adults whose dietary patterns are similar to adults in South China. Unlike other studies, which could be confounded by the use of standard sizes to convert raw information into nutrient data, we carefully converted the dietary intakes that were recorded in the HR from serving sizes into grams according to the China Food Composition.[19] A further advantage lay in the use of different statistical methods to determine agreement: Spearman's correlation coefficients, cross-classification and Bland–Altman plots, which have been considered the gold standard in studies of methodical comparisons. In addition, the utilisation of the multiple pass method guaranteed the conduct of 24-hour recalls.

Some limitations should be mentioned as well. This study had a relatively small sample size, which was less than the number of participants required to detect the effect size with 80% power (n = 60). N increases with an increase in the desired power.[37] However, to achieve the desired power, we had to increase the present sample size by 50%, which was considered 'low cost-effective' in a population-based study considering the difficulty of recruiting more participants during a limited study period when the WD requires high accuracy and compliance to record all types of food and beverage consumption. Moreover, our sample size of 41 adults was acceptable compared with other

validation studies in adults.[34] Thus, it was sufficient to draw conclusions in the present analysis, although the results should be interpreted cautiously. The length of the dietary records or recalls was another limitation. Compared with the dietary data that were recorded by FFQ (information was obtained during the selected month) or repeated dietary recall (one day for men and two days for women) in studies conducted in Shanghai, China,[10,11] the use of a two-day dietary recall might not be representative of habitual dietary intake. However, in practice, we found that it was difficult to collect detailed and precise dietary data for longer than two days per interview in a multicentre, structured, longitudinal study with a representative study sample, that is, to avoid only participants with higher socioeconomic status entering the study. A further limitation lay in the lack of external biomarkers in the current study because they are now recognised as the best parameters to evaluate self-report dietary instruments, although they are not always available and are more expensive.

The present analysis suggested that the HR could be used to estimate the mean energy and nutrient intakes of the population at a similar level to that of a WD. The findings of this study should be further confirmed using methods representative of habitual dietary intake in a larger cohort.

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Conflict of interest

The authors declare that they have no conflict of interest.

Authorship

HX and MY conducted the analyses, drafted the manuscript and assisted in the study design. YL and RD provided dietary data. XZ and GC conceived the project and supervised the study. XZ supervised the manuscript revision. All authors read and approved the final manuscript and reviewed the manuscript for important intellectual content. The participation of all families is gratefully acknowledged. We also thank the study staff for carrying out the data collection; they are Jiao Luo, Guo Tian, Yanrong Chen and Yuxin Bao. Special thanks to Professor Min Yang for her kind help with the statistics during the revision phase.

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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. General characteristics of the participants in the present study (n = 41)

Table S2. Values of Bland–Altman plots for agreement between daily intakes of energy and nutrients reported in the 24-hour dietary recall (HR, test method) and weighed dietary record (WD, reference method) in adults from South China (n = 41)

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ORIGINAL RESEARCH

Accuracy and precision of estimation equations to predict net endogenous acid excretion using the Australian food database

Benjamin H. PARMENTER,[1] Gary J. SLATER[1] and Lynda A. FRASSETTO[2]

[1]Faculty of Health, Science and Engineering, University of the Sunshine Coast, Queensland, Australia and [2]School of Medicine, University of California San Francisco (UCSF), California, USA

Abstract

Aim: The gold standard of measurement for net endogenous acid production (NEAP) is net acid excretion (NAE), a test that is not readily available, and consequently, estimative equations by Remer and Manz and Frassetto *et al.* are often used. These equations rely on nutrient databases and it is recommended that their validity be assessed using a country's database before their application in research in that country. We sought to delineate the accuracy and precision of these estimation equations using the Australian food database.

Methods: In a double blind, randomised, cross-over fashion, healthy participants (n = 13) residing in regional Australia were exposed to varying net acid loads while they collected weighted food diaries and 24-hour urine samples for measurement of NAE.

Results: In comparison to the Frassetto *et al.* equations (equation one bias = −57.1 mEq/day, equation two bias = −32.8 mEq/day), only the Remer and Manz equation was accurate (bias = −5.4 mEq/day); however, all equations were imprecise.

Conclusions: Using the Australian database, the performance of these equations to predict NEAP appears equal to other databases; however, caveats apply in their application. For future research, the equation by Remer and Manz is preferential for group estimates. None of the equations are recommended for individual estimates.

Key words: acid, base, diet, estimation.

Introduction

The homeostatic regulation of acid–base status is essential for physiological functioning, and the clinical consequences of acid–base disorders are well known. Another factor known to influence physiological acid–base systems is the dietary acid load.[1] The ratio of diet-derived fixed acid to base is estimated by the potential renal acid load (PRAL), and when endogenously produced organic acid is factored, cumulatively, this determines the net endogenous acid production (NEAP) for an individual.[1] When diet chronically releases fixed acid in excess of fixed base, the surplus acid has been hypothesised to be a contributing factor to chronic disease.[2,3] While an elevated (acid) NEAP does not result in clinical metabolic acidosis,[4] research is being conducted to determine its relationship to sarcopenia,[5,6] gout,[7,8] renal stones,[9,10] metabolic syndrome,[11] chronic renal insufficiency,[12] late metabolic acidosis in preterm infants,[13] hypertension,[14,15] insulin resistance,[16,17] non-alcoholic fatty liver disease,[18] impaired sports performance[19,20] and osteoporosis,[21,22] while the involvement of NEAP in obesity[23] and cancer[4] has been theorised.

For the research-focused investigation of NEAP, its accurate quantification is essential. To directly measure NEAP, 24-hour urinary net acid excretion (NAE) is the criterion method.[24,25] However, measurement of NAE is a labour- and laboratory-intensive technique and is not readily available.[26] As such, estimative equations from dietary intake were developed. Remer and Manz's equation ($NEAP_R$) factors for endogenously produced organic acid plus the PRAL, that is, the ratio of dietary conjugate bases of potassium, magnesium and calcium to conjugate acids of phosphorus- and sulphate-containing protein.[27] Conversely, the Frassetto *et al.* equations ($NEAP_F$) were developed to allow faster calculations and utilise the more easily obtained inputs of dietary protein and potassium intake.[28] However, world experts have recommended that before these equations are applied within a country, their accuracy is assessed with that country's food

B.H. Parmenter, BNut&Diet (Hons), Student
G.J. Slater, PhD, Senior Lecturer
L.A. Frassetto, MD, Non-Senate Acad Emeritus (WOS), Associate Clinical Professor of Medicine
Correspondence: B.H. Parmenter, Faculty of Health, Science and Engineering, University of the Sunshine Coast, 90 Sippy Downs Dr, Sippy Downs, QLD 4556, Australia. Tel: +61 4 2353 6798.
Email: b_p026@student.usc.edu.au

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database.[24,29] To date, this has only been investigated using German[29] and American[28] databases. Consequently, for future research investigating NEAP within Australia, we sought to delineate the accuracy and precision of estimate $NEAP_R$ and $NEAP_F$ using the Australian food database. We hypothesise that estimate $NEAP_R$ and $NEAP_F$ would predict NAE to a similar degree when using the Australian food database as they do when using other databases.

Methods

The design of the trial is described in detail in our companion paper.[30] In summary, in a double blind, randomised, cross-over fashion, healthy participants (n = 13) residing in regional Australia were exposed to varying NEAP loads while they collected weighted food diaries and 24-hour urine samples. To vary the NEAP loads, the participants consumed a fruit and vegetable concentrate or placebo for three days each, with diet standardised throughout. The urine samples were collected under thymol and paraffin oil in portable cooler boxes with ice packs for the subsequent analysis of NAE, pH and creatinine. Compliance to 24-hour urine collections was measured by creatinine index; those with a daily excretion <0.1 mmol/kg body weight were excluded.[31] Diet compositions were determined using Foodworks Professional (Xyris, Brisbane, Australia) using the Australian food database (NUTTAB 2010 Australian Government Nutrient Database, Canberra, Australia). When food items were missing, nutrients were entered according to nutrient information on the food label before proceeding to estimate $NEAP_R$ and two $NEAP_F$ equations (Table 1). The methods were approved by the University of the Sunshine Coast's Human Ethics Committee (reference number: S/14/70), and all participants signed informed consent. The trial was designed to adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines, and the trial protocol was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000417482).

For the assessment of physique, in the week prior to commencing the study, volunteers presented to the laboratory in a rested state after an overnight fast. After bladder evacuation, participants had their stretch stature measured to the nearest 0.1 cm using a technique previously described,[32] with a Harpenden stadiometer (Holtain Limited, Crymych, UK) and undertook air-displacement plethysmography for assessment of body composition (BODPOD®; COSMED USA, Inc., Concord, CA, USA). The manufacturer's recommended procedure was followed,[33] and a predicted thoracic lung volume was used.[34] During the procedure, the participants wore skin-tight clothing, a silicone cap and removed all metal objects. Following the procedure, body mass index (BMI) was calculated conventionally, while the system's software (Version 5.3.2; COSMED USA, Inc., Concord, CA, USA) estimated fat mass and fat-free mass using the model defined by the Siri equation.[35]

The 24-hour urine samples were analysed on the day of their return for urine pH, creatinine and NAE. For the determination of pH, samples were analysed by a calibrated labChem pH meter (TPS Pty Ltd, Melbourne, Australia) at ambient temperature and 36.5 ± 0.5 °C. Creatinine was measured spectrophotometrically by a colorimetric detection kit Cat no. 09151410 (Enzo Life Sciences, Farmingdale NY, USA) using a multi-scan GO plate reader (Thermofisher Scientific, Waltham, MA, USA). Ammonium was measured using methods of Rice *et al.*[36] by flow injection analysis using a Lachat QuikChem 8000 (Lachat Instruments, Milwaukee, WI, USA). Titratable acids and bicarbonate were measured in duplicate by using the methods of Litkowski and Wilson[37] with the following modifications. Briefly, after addition of 0.05 M hydrogen chloride to 20 mL of urine samples, simmering occurred for 20 minutes at 90 °C. Concurrently, a blank was run in the same manner using MilliQ water (Milliport Corp., Bedford, MA, USA). After samples cooled, bicarbonate was determined as the amount of 0.05 M sodium hydroxide necessary to titrate back to the initial pH at ambient temperature less the corresponding value for the blank. Thereafter, titratable acid was determined as the amount of 0.05 M sodium hydroxide necessary to titrate to pH 7.4 from the bicarbonate endpoint. The mean of the duplicates was used for the calculation of NAE (Table 1), and the intra-assay CV was 8.0%.

Table 1 Equations to estimate the potential renal acid load, the net endogenous acid production and to calculate net acid excretion

Equation	*Formula*
$NEAP_F$ (mEq/day)	Equation 1 = (0.91 × protein (g/day)) – (0.57 × potassium (mEq/day)) + 21 Equation 2 = (54.5 × protein (g/day)/potassium (mEq/day)) – 10.2
$NEAP_R$ (mEq/day)	=PRAL (mEq/day) + organic $acids_{anthro}$
PRAL (mEq)	=0.488 × protein (g/day) + 0.0366 × phosphorus (mg/day) – 0.0205 × potassium (mg/day) – 0.0263 × magnesium (mg/day) – 0.0125 × calcium (mg/day)
Organic $acids_{anthro}$, (mEq/day)	=body surface area × 41/1.73
Body surface area (m^2)	=0.007184 – height $(cm)^{0.725}$ – weight $(kg)^{0.425}$
NAE (mEq)	=titratable acids (mEq) + ammonium (mEq) – bicarbonate (mEq)

Anthro, anthropometrical; NAE, net acid excretion; NEAP, estimate net endogenous acid production where subscript R pertains to the equation by Remer and Manz[27] and subscript F pertains to the equations by Frassetto *et al.*[28]; PRAL, potential renal acid load.

Table 2 Characteristics of participants completing the study

	All participants	*Males*	*Females*
n	13	6	7
Age (years)	35 ± 13	30 ± 9	39 ± 16
Height (cm)	172 ± 7	177 ± 6	166 ± 3
Weight (kg)	73 ± 10	77 ± 7	69 ± 11
Fat mass (kg)	19 ± 10	12 ± 7	25 ± 9
Fat-free mass (kg)	54 ± 11	65 ± 4	44 ± 4
BMI (kg/m^2)	25 ± 3	24 ± 1	25 ± 5

Values are means ± SD.

Table 3 Net acid excretion and estimation of the net endogenous acid production using the Australian food database during the placebo period, supplement period and for all observations

	n	*Placebo*	*Supplement*	*Combined placebo and supplement*
NAE (mEq/day)	10	40 ± 19	7 ± 25	23 ± 27
$NEAP_R$ (mEq/day)	10	48 ± 26	8 ± 26	28 ± 33
NAE (mEq/day)	11	38 ± 18	12 ± 30	25 ± 27
$NEAP_{F^1}$ (mEq/day)	11	85 ± 55	79 ± 55	82 ± 53
$NEAP_{F^2}$ (mEq/day)	11	63 ± 34	53 ± 28	57 ± 30

Values are means ± SD.
NAE, net acid excretion; NEAP, estimate net endogenous acid production where subscript R pertains to the equation by Remer and Manz[27] and subscripts F^1 and F^2 pertain to equations one and two by Frassetto *et al.*[28].

To statistically assess the agreement between estimated and analysed NEAP, the Bland–Altman method for repeat non-constant observations was used (i.e. one observation during the placebo period and one observation during the supplement period on the same participant).[38] Equations were computed using dietary data from the concurrent 24-hour urine collection periods. The distribution of the differences was checked and outliers (±>3.0 SD of the difference) excluded.[39] Those with missing data were excluded.[38] A priori limits of agreement were set at ±15 mEq/day as this would permit a reasonable estimation of NEAP in individuals and also account for imprecision in the criterion method. All statistical analyses were completed using MedCalc (MedCalc Software; MedCalc, Mariakerke, Belgium).

Results

Of the 16 enrolled individuals, 13 completed the study; their characteristics are described in Table 2. Conversely, their dietary intake and a CONSORT diagram are presented in our companion paper.[30] During phase two, one participant returned an incomplete 24-hour urine sample, while another failed to replicate their food and fluid from phase one; both were excluded from analysis. One outlier was identified in the dataset of $NEAP_R$, while none where identified in either $NEAP_F$. The mean ± SD of NAE, $NEAP_R$ and $NEAP_F$ during the placebo period, supplement period and for all observations is presented in Table 3, while Table 4 presents the Bland–Altman bias and limits of agreement for all observations. $NEAP_R$ showed the best agreement with an acceptable accuracy; however, all equations were beyond the a priori limits of agreement to predict NAE in individuals.

Discussion

To our knowledge, this is the first time the estimate NEAP equations have been assessed using the Australian food database. This is important because it impacts the choice of equation potentially used in future research conducted in Australia. Using the Australian database, the performance of these estimate NEAP equations appears similar to their performance reported using other databases. However, known imprecisions within the equations themselves are apparent, which precludes their application to individuals. Of the equations investigated, $NEAP_R$ appears more accurate for group estimates, and its use is, therefore, preferentially encouraged.

Using the Australian food database, the performance of the estimate NEAP equations appears similar to their performance reported using other databases. Similar to the German database, our results show a reasonable group estimate using $NEAP_R$, evident by the small bias (–5.4 mEq).[29] Compared to the American database, investigations were completed under steady-state conditions, which are known to increase the magnitude of accuracy.[28,40] Taken together, there is no reason to suggest that the equations performance is altered when using the Australian database.

Table 4 Bland-Altman agreement between measured 24-hour net acid excretion and net endogenous acid estimation equations in repeat non-constant observations in participants consuming non-steady-state diets using the Australian food database

	n	*Bias*	*95% CI for the bias*	*Limits of agreement*	*95% CI for the upper limit of agreement*	*95% CI for the lower limit of agreement*
$NEAP_R$ (mEq/day)	10	–5.4	–19.8, 9.0	–54.2, 43.3	18.3, 68.3	–79.1, –29.2
$NEAP_{F^1}$ (mEq/day)	11	–57.1	–82.0, –32.2	–146.6, 32.4	10.7, 75.5	–189.7, –103.5
$NEAP_{F^2}$ (mEq/day)	11	–32.8	–48.6, –16.9	–90.7, 25.1	–2.3, 52.5	–118.1, –63.3

NEAP, estimate net endogenous acid production where subscript R pertains to the equation by Remer and Manz[27] and subscripts F^1 and F^2 pertain to equations one and two by Frassetto *et al.*[28]

However, $NEAP_R$ was imprecise, which precludes its application to individuals. This may be because of known errors within the equation surrounding dietary protein and exogenous organic acids.[29] To account for this, Sebastian *et al.*[41] developed another equation that incorporates dietary cystine and methionine intake. Yet, as the Australian database has limited amino acid records, this equation was not computed. That said, no equations currently factor for exogenous organic acids. As such, researchers may wish to revise the equations by factoring for the variability in protein composition as well as exogenous organic acids, perhaps based on food groups.[29]

The inaccuracy of the $NEAF_F$ equations may have been caused by the experimental conditions. That is, the predominance of the supplements base was delivered by a large calcium dose (1.7 g/day); however, both $NEAP_F$ equations do not factor for calcium. Consequently, it appears that these equations are less robust under such circumstances, and $NEAP_F$ is not universally applicable. Moreover, negative-feedback control of endogenous acid production may have influenced NAE in some individuals, further contributing to the equations' imprecision.[42] To this end, it may be most beneficial for future investigations to collect not only urinary PRAL (electrolytes measured in 24-hour urines) but also total urinary organic acids alongside dietary data so as to aid in the elucidation of the issues associated with endogenous and exogenous organic acids and NAE prediction. This may be pivotal in the interpretation of investigations delineating the relationship between NAE and various chronic degenerative diseases as NAE includes both organic acid components, wherein the exogenous component may provide an acid-forming yet health-supporting effect in vivo.[43]

The limitations of the present study include measurement error within the NAE technique, the use of weighted food diaries and small sample size. However, our CV (8.0%) for NAE was below all other studies that reported a CV (10.1–10.9%).[44,45] Consequently, this appears to be a common limitation. The use of free-living weighted food diaries may have introduced error (e.g. under-reporting); however, it may also provide re-assurance that the $NEAP_R$ equation has a reasonable capacity to perform group estimates under free-living conditions. Finally, the small sample size impacts the analysis by the creation of large confidence intervals around the upper and lower limits of agreement. Yet, given that estimations of NEAP are not utilised in a critical clinical setting, the data adequately serves to illustrate which method is preferential for research purposes in Australia. In conclusion, the estimate NEAP equations studied should not be applied to individuals, and $NEAP_R$ is preferential for group estimates.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

We thank GS and BP for the project conception; BP for conducting the research and obtaining donations, Dr Peter Brooks for developing the analytical methods, Daryle Sullivan for the measurement of ammonium and LF for methodological contributions; Michael Nielsen for sourcing essential reagents and materials; BP for performing the statistics and writing the paper; and GS and LF for critical revision of the manuscript and study supervision. All authors have read and approved the final manuscript. The content has not been published or submitted for publication elsewhere.

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ORIGINAL RESEARCH

Spot-testing urine pH, a novel dietary biomarker? A randomised cross-over trial

Benjamin H. PARMENTER,[1] Gary J. SLATER[1] and Lynda A. FRASSETTO[2]

[1]Faculty of Health, Science and Engineering, University of the Sunshine Coast, Queensland, Australia and [2]School of Medicine, University of California San Francisco (UCSF), California, USA

Abstract

Aim: Spot-tests of urine pH are claimed to be an accessible biomarker of net acid excretion (NAE), and as such, they may be able to determine changes in an individual's intake of acid- or base-forming foods. To test this hypothesis, we aimed to determine if spot-tests of urine pH could index NAE and relay the consumption of a fruit and vegetable (F&V) concentrate whilst determining this concentrate's capacity to modulate NAE.

Methods: In a double blind, placebo-controlled, cross-over trial, healthy adults (n = 13) were allocated by simple randomisation to receive a F&V concentrate or placebo for three days each, with diet standardised throughout. Measurements of 24-hour NAE, 24-hour urine pH and spot-tests of urine pH were taken throughout the study.

Results: The 24-hour urine pH predicted 24-hour NAE ($P = <0.0001$). However, spot-tested urine pH displayed prediction intervals too wide to infer 24-hour NAE and inconsistent ability to reflect concentrate ingestion, despite 24-hour NAE and 24-hour urine pH decreasing (−25.8 mEq, 95% CI −44.3 to −7.4, $P = 0.01$, $d = 0.94$) and increasing (+0.51, 95% CI 0.25–0.79, $P = 0.002$, $d = 1.3$), respectively, following supplementation.

Conclusions: Spot-tests of urine pH are not a valid dietary biomarker of daily NAE and were unable to reliably track changes, despite a F&V concentrate clearly modulating the daily rate of NAE.

Key words: acid, base, diet, pH, urine.

Introduction

The search for dietary biomarkers that accurately assess dietary intake is an active area of investigation.[1] For example, both plasma vitamin C and carotenoids have been considered as biomarkers of usual fruit and vegetable (F&V) intake.[2] Effectively, such biomarkers could be useful to inform dietitians, patients and researchers alike of intake of specific foods and/or dietary constituents.[1] Indeed, biomarkers that are cost-effective, non-invasive, rapid and accurate may be useful to objectively assess dietary intake, confirm compliance of dietary interventions, help encourage the consumption of healthier food choices and aid researchers to clearly elucidate diet–disease relationships.[1] To this end, the rate of urinary net acid excretion (NAE), also termed the dietary acid load, is predominantly influenced by the intake of fixed acid (in meats and cereals) and fixed base (in F&V), and consequently, it may be useful to inform an individual's intake or avoidance of acid- or base-forming foods. Yet NAE measurements are labour- and laboratory-intensive, and consequently, spot-testing urine pH was recently proposed as a surrogate cost-effective and accessible biomarker.[3,4]

Spot-testing is based on the association between 24-hour urine pH and the rate of daily NAE.[3,5] It has been suggested that by increasing the intake of base-forming foods, there is a decrease in NAE and consequently, an increase in urine pH, a metabolic effect with favourable outcomes associated with chronic degenerative disease.[3,4,6] While many research groups have suggested or utilised spot-tests to reflect the dietary acid load or to track its modulation,[7–15] data supporting their efficacy is limited to two studies with conflicting results.[4,16] Moreover, as urine pH fluctuates over the course of a day,[17] it is unlikely that spot-tests would accurately index NAE. Nonetheless, if NAE can be accurately determined, interventions that influence NAE may be easily monitored.

One purported intervention to facilitate a more basic pH is F&V concentrate, a strategy advocated by industry as a convenient alternative to addressing the low consumption rates of F&V within Australia.[18] However, if applying interventions such as this, there is a need to monitor effectiveness and, moreover, their effect on NAE remains equivocal. As such, we aimed to determine the capacity of spot-tests

B.H. Parmenter, BNut&Diet (Hons), Student
G.J. Slater, PhD, Senior Lecturer
L.A. Frassetto, MD, Non-Senate Acad Emeritus (WOS), Associate Clinical Professor of Medicine

Correspondence: B.H. Parmenter, Faculty of Health, Science and Engineering, University of the Sunshine Coast, 90 Sippy Downs Dr, Sippy Downs, QLD 4556, Australia. Tel: +61 4 2353 6798. Email: b_p026@student.usc.edu.au

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to index NAE and relay the consumption of an F&V concentrate whilst determining this concentrate's capacity to modulate NAE. We hypothesise that spot-tested urine pH would not reasonably infer or track changes to NAE despite an F&V concentrate eliciting a corresponding reduction in NAE and an increase in 24-hour urine pH relative to a placebo.

Methods

A convenience sample of apparently healthy men and women were recruited from the Sunshine Coast region, Queensland, Australia. Enrolment began in May, 2015 and was completed in August, 2015. Participants were included if they were between 18 and 65 years old and were excluded if they used medication (except birth control), alkaline water or mineral and herbal supplements. Furthermore, those with a diagnosed health issue, BMI of <18 kg/m^2 or pregnant were excluded. Methods were approved by the University of the Sunshine Coast's Human Ethics Committee (reference number: S/14/70), and all participants provided informed consent. The trial was designed to adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000417482).

The study was a double blind, randomised, placebo-controlled, cross-over trial with a four-day wash out period between two phases (Figure 1). The wash out period was selected as large base loads are excreted within one to two days following caseation.[19] Calculation of an a priori power using G*power 3 (Düsseldorf University, Düsseldorf, Germany) identified a required sample size of 11 participants to observe an expected change of 0.45 pH units in the first morning fasting urine following a potential renal acid load (PRAL) modulation of -23 mEq/day.[11] Consequently, 16 adults were recruited and had their physique assessed using air displacement plethysmography, using protocols described elsewhere.[20]

During phase one, participants were allocated by simple randomisation (computer-generated list) to receive an F&V concentrate or a relatively neutral concentrate, which acted as a placebo (both supplied by Morlife, Gold Coast, Australia). Participants consumed one serve (15 g/serve) at breakfast, lunch and dinner in water. The F&V concentrate had a total alkali load (PRAL = −43.7 mEq/day) equivalent to approximately 11 extra serves of F&V per day or (PRAL = −14.6 mEq/serve) approximately 3.5 serves per meal (assuming a standard serve of fresh F&V is 100 g, and the average alkalinity per 100 g fresh F&V is −3.7 mEq). The placebo (PRAL = −3.6 mEq/day) was identical in size and similar in appearance, taste and smell. Supplements were preweighed, sealed in silver bags and labelled A and B by a third party (Morlife). This concealed allocation to the investigator who generated the allocation sequence and enrolled the participants. Participants maintained an ad libitum intake and recorded all food and fluid consumed in a weighted food dairy (Tanita Co., Tokyo, Japan). Meanwhile, participants completed an exercise record to enable

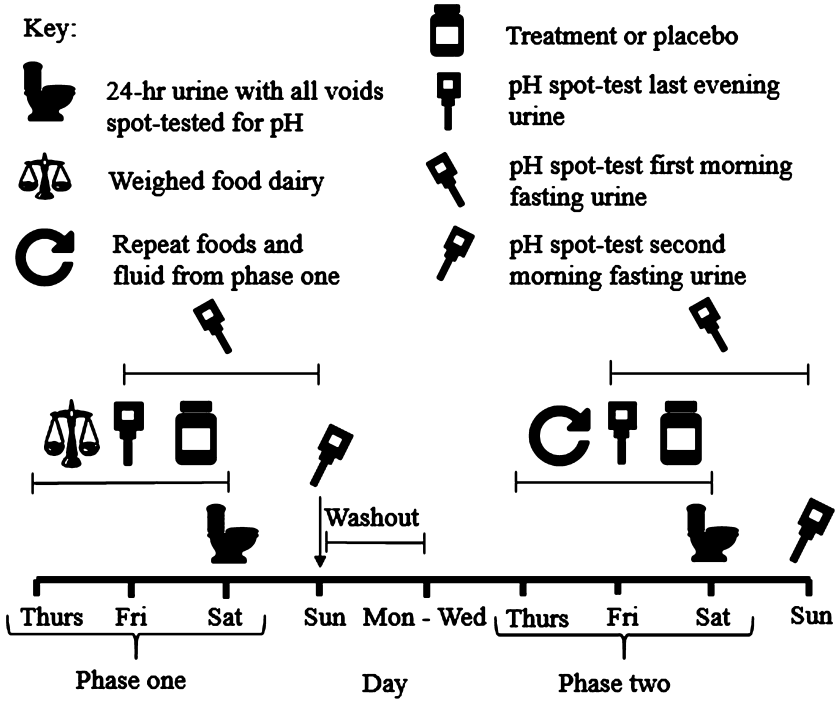

Figure 1 Experimental design during the 11-day trial highlighting the testing procedure. Twenty-four hour urinary net acid excretion (NAE) and pH comprised the primary and secondary outcomes, respectively, whereas spot-tests were incorporated to identify if they could index NAE and track changes to fruit and vegetable concentrate supplementation.

calculation of their ratio of energy intake (EI) to energy expenditure (EE) to screen for inaccurate diet reporters.[21,22] Those with an EI:EE <0.50 or >1.50 were identified and questioned on their intake to confirm accuracy of records.

During phase two, participants replicated food and fluid from phase one while the intervention crossed over. To ensure compliance, participants were given the meal plan of their previous intake, asked to record any changes and the time foods were eaten. Participants were met daily and questioned on their intake. The concentrates' elemental compositions were analytically determined before, proceeding to analyse the diet composition. The concentrates were analysed for nitrogen in duplicate by combustion analysis using a Leco TruMac N CNS analyzer (Leco Corporation, St. Joseph, MO, USA). Element composition was determined by 5:1 nitric-perchloric acid digests and Inductively Coupled Plasma Optical Emission Spectrophotometry using a 700-ES Series Axial (Aligent Corporation, Palo Alto, CA, USA) by the Analytical Services of the Land, Food and Crop Sciences Department (University of Queensland, Brisbane, Australia; Table 1). Diet compositions were determined by Foodworks Professional (Xyris, Brisbane, Australia) using the Australian food database (NUTTAB 2010 Australian Government Nutrient Database, Canberra, Australia). When food items were missing, nutrients were entered according to nutrient information on the food label before proceeding to estimate net endogenous acid production (NEAP) by the Remer and Manz equation.[23]

For the urinary parameters, two 24-hour urine samples were collected on the third day of each phase and analysed as described elsewhere.[20] To spot-test urine, participants were trained to evacuate their bladder, collect a sample mid-stream and immediately test the pH at different time points on different days throughout the study (Figure 1). During the 24-hour collections, samples were spot-tested prior to their addition to 24-hour vessels. Spot-tests were completed using electronic Hanna HI98103 Checker meters (Hanna Instruments, Woonsocket, RI, USA), which quantify pH within ±0.1; these were calibrated daily.

To determine whether pH could index NAE, regression analyses with 95% prediction intervals were used. The 24-hour pH was compared to the same day's 24-hour NAE. Only the last evening pH on the days of 24-hour sampling was compared to 24-hour NAE. The first and second morning spot-tests were taken the morning following 24-hour collection and compared with the previous day's 24-hour NAE. Independent samples were assumed, and prior checking occurred for linearity, independence of error terms (Durbin-Watson), normality of residuals, heteroscedasticity and outliers (±>3 SD). To assess the ability of spot-tests (last evening and first morning) to track changes following NEAP modulation, a two-way analysis of variance (ANOVA) with repeated measures (days X treatment) was used. Data were checked for normality, outliers (±>3 studentised residuals) and sphericity (Mauchly's test). In the instance a participant's food intake drifted resulting in a PRAL deviation of >3 mEq on any day during cross over, the participant was excluded from the ANOVA. Non-normal data was transformed by square root and, again, assumptions checked. Effects sizes were calculated as partial eta squared (η^2). Additionally, the average of the maximum and minimum spot-tests on the days where all voids were spot-tested is reported, as is the percent of participants who had maximum and minimum pH units >1.5 pH units apart.

To assess the concentrate's capacity to modulate NEAP, paired t-tests were computed for the primary (24-hour NAE) and secondary (24-hour pH) endpoints. In addition, such analysis was carried out on the second morning spot-test. For these analyses, only participants whose intake drifted (>3 mEq) on the day of the 24-hour collections were excluded. Outliers (by boxplot) and normality of difference scores was checked, whereas effects sizes were calculated as Cohen's *d*. All statistical analyses were completed using Microsoft Excel (XP professional edition; Microsoft Corp, Redmond, WA, USA), SPSS version 11 (SPSS Inc., Chicago, IL, USA) and MedCalc (MedCalc Software, MedCalc, Mariakerke, Belgium). Summary data are presented as mean ± SD. Two-tailed significance was accepted at $P \leq 0.05$, and the Shapiro–Wilk test was used to accept normality at $P \geq 0.05$.

Table 1 Nutrient analysis of the powered fruit and vegetable supplement and the placebo

	Supplement	*Placebo*
Protein (g/45 g)	5.57	1.85
Phosphorus (mg/45 g)	70	42
Potassium (mg/45 g)	880	237
Magnesium (mg/45 g)	360	21
Calcium (mg/45 g)	1720	54

Results

Of the 16 enrolled individuals, 13 completed the study (Figure 2); their characteristics are described in our companion paper.[20] Two participants were identified as potential inaccurate diet reporters, yet both revealed a reason why their intake was low. One participant was time restriction fasting and consequently consuming a hypocaloric diet, whereas the other reported limited food access that week. As their EI:EE ratio was not impacted by misreporting, both were included in the analysis. However, one participant misplaced their written recipes following phase one, resulting in a change of meals, and another returned an incomplete 24-hour urine sample in phase two. The two aforementioned, along with a third, were identified as having drifted >3 mEq in their food intake on the second day of phase two. For participants who successfully completed all requirements, their dietary intake is presented in Table 2. One participant reported slight occasional bloating when consuming the F&V supplement; however, no other adverse events occurred.

Concerning the capacity of spot-tests to index NAE, only the single-incomplete 24-hour urine was excluded in the

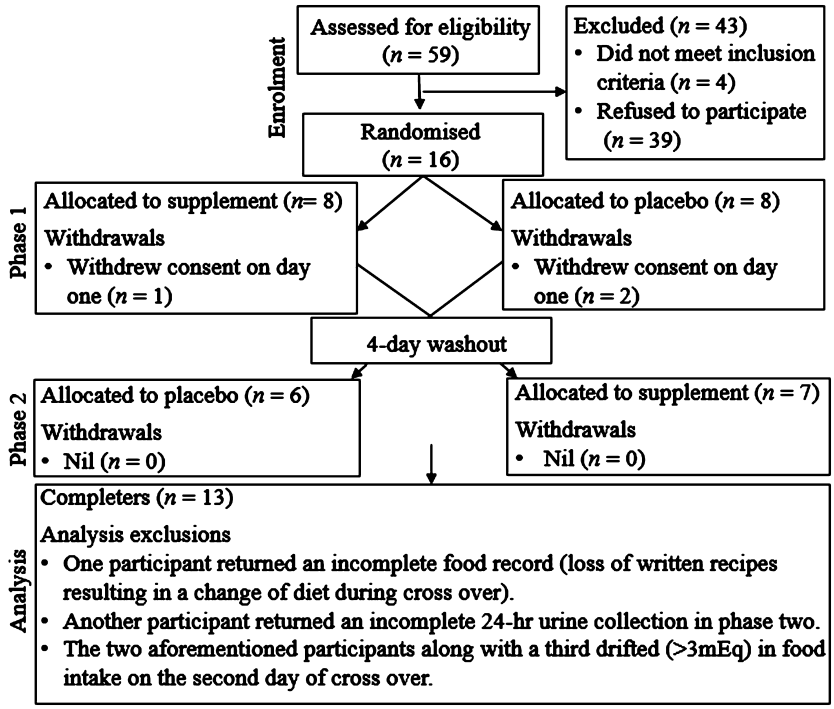

Figure 2 Consolidated Standards of Reporting Trials (CONSORT) diagram describing the flow of participants through the trial.

Table 2 Daily nutrient intake (including supplementation) for participants. Nutrient data for participants identified as altering their food intake during phase two or returning an incomplete urine collection are omitted from that day for both phases

	Supplement			*Placebo*		
	Thursday (n = 11)	*Friday (n = 10)*	*Saturday (n = 11)*	*Thursday*	*Friday*	*Saturday*
Energy (MJ)	9.0 ± 3.6	9.8 ± 3.5	9.6 ± 3.3	8.9 ± 3.6	9.8 ± 3.5	9.6 ± 3.3
Protein (g)	141 ± 58	143 ± 63	143 ± 67	138 ± 58	139 ± 63	139 ± 67
Phosphorous (g)	1.7 ± 0.8	1.9 ± 0.9	1.7 ± 0.7	1.7 ± 0.8	1.9 ± 1.0	1.6 ± 0.7
Potassium (g)	5.6 ± 2.0	5.3 ± 1.6	4.9 ± 1.5	4.9 ± 2.0	4.7 ± 1.6	4.3 ± 1.5
Magnesium (g)	0.9 ± 0.3	0.9 ± 0.3	0.8 ± 0.3	0.6 ± 0.3	0.6 ± 0.3	0.5 ± 0.3
Calcium (g)	2.6 ± 0.6	2.7 ± 0.5	2.7 ± 0.5	0.9 ± 0.6	1.1 ± 0.6	1.0 ± 0.5
$NEAP_R$ (mEq)	−39 ± 39	−29 ± 45	18 ± 40	1 ± 39	12 ± 45	58 ± 40
$NEAP_{R\ supp} - NEAP_{R\ placebo}$ (mEq)	−40	−40	−40			

Values are means ± SD.
NEAP, estimate net endogenous non-carbonic acid production where subscript R pertains to the equation by Remer and Manz.[23]

analyses. It was found that 24-hour pH predicted 24-hour NAE ($F(1,23) = 108.7$, $P = <0.0001$), where 82.5% of the variability in 24-hour NAE was explained by the variability in 24-hour pH. Conversely, both the first ($F(1,23) = 2.8$, $P = 0.11$) and second ($F(1,23) = 0.83$, $P = 0.37$) morning fasting pH could not significantly predict NAE, and their variabilities explained 10.9 and 3.5% of NAE variability, respectively. While the last evening spot-tests predicted NAE ($F(1,23) = 10.2$, $P = 0.004$), the variability in spot-tests accounted for 30.8% of the variability in NAE, and the 95% prediction intervals are markedly wide (Figure 3). The mean maximum and minimum of all spot-tested voids captured during the 24-hour collection days was 7.0 ± 0.6 to 5.4 ± 0.4, where 64% of participants had maximum and minimum pH units >1.5 units apart.

Concerning the effects of the F&V concentrate on the urinary indices, in the last evening void, two outliers were identified and removed. There was neither two-way interaction ($F(2, 14) = 1.5$, $P = 0.27$, partial $\eta^2 = 0.17$) nor was there a main effect of time ($F(1,7) = 0.19$, $P = 0.83$, partial $\eta^2 = 0.03$); however, there was a main effect of treatment ($F(1,7) = 8.5$, $P = 0.02$, partial $\eta^2 = 0.55$), where on average the pH in the supplement group was +0.31 (95% CI, 0.06–0.56) higher than the placebo. Conversely, in the

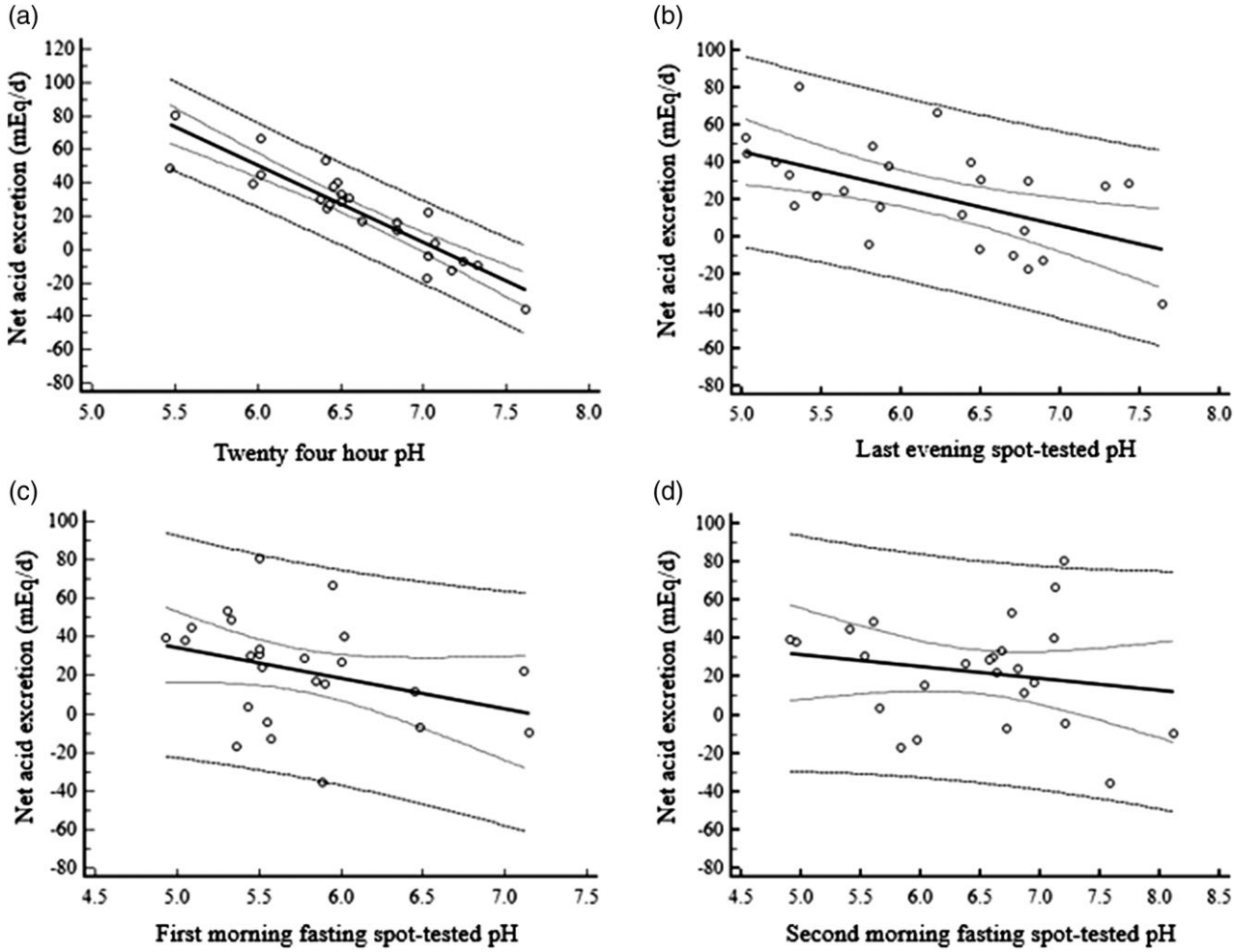

Figure 3 Linear regression with 95% confidence intervals for the regression line and 95% prediction intervals of urinary pH to predict 24-hour net acid excretion in participants (n = 25 (assuming independent observations)) for (a) pH measured in the same day's 24-hour urine collections at 36.5 ± 0.5 °C, (b) pH spot-tested in the last void of that evening, (c) pH spot-tested in the following morning's first void in the fasted state and (d) pH spot-tested in following morning's second void in the fasted state.

following morning's first spot-tested pH, after transformation of the data, there was neither two-way interaction between treatment and time ($F(2,18) = 0.263$, $P = 0.77$, partial $\eta^2 = 0.03$) nor was there a main effect of treatment ($F(1,9) = 2.30$, $P = 0.12$, partial $\eta^2 = 0.25$) or time ($F(1,9) = 0.20$, $P = 0.82$, partial $\eta^2 = 0.02$). Again, the change in the second morning fasting spot-test of +0.41 (95% CI, −0.09–0.91, $t(10) = 1.814$, $P = 0.1$, $d = 0.55$) was not significant; however, in the 24-hour urine, there was a significant decrease in NAE of −25.8 mEq/day (95% CI, −44.3 to −7.4, $t(10) = -3.12$, $P = 0.01$, $d = 0.94$) and increase in pH of +0.51 (95% CI, 0.25–0.79, $t(10) = 4.23$, $P = 0.002$, $d = 1.3$) following supplementation.

Discussion

Spot-testing urine pH has been considered a potential biomarker for NAE. The major finding of our study is that spot-testing urine pH is not an efficacious measure of NAE. Secondly, while an F&V concentrate modulated the rate of NAE, spot-tested urine pH was unable to reliably identify this change. Taken together, spot-testing urine pH is unreliable to inform dietitians and researchers of NAE and, seemingly, changes in alkali food intake; spot-testing urine pH to do either is not recommended.

Spot-tests of urine pH have been considered a potential biomarker for dietary acid load. While we found that 82.5% of the variability in 24-hour pH explained the variability in 24-hour NAE, the variability in spot-tests did not reasonably explain the variability in 24-hour NAE, and their prediction intervals were too wide to reasonably infer 24-hour NAE. Our data also captured the known fluctuation in urine pH over a day where 64% of participants had maximum and minimum pH >1.5 units apart. In light of these findings, we agree with Remer *et al.*[24] that spot-tested urine pH does not predict the dietary acid load. Consequently, it may be necessary to interpret data from groups that have utilised spot-tests to reflect the dietary acid load or to track

its modulation with caution.[7–15] While future research groups may suggest averaging multiple spot-tests throughout the day to index NAE, it is advised that urine is a complex buffered solution that precludes averaging.[25] In summary, 24-hour collections are required for NAE measurement.[24]

As spot-tests did not reasonably index 24-hour NAE, not surprisingly, their efficacy to track consumption of the F&V concentrate was inconsistent. Yet, other studies tracking modulation of the diet's acid load with spot-tests all reported significant changes.[9–12] While we found that the last evening spot-test significantly increased during supplementation, no significant change occurred in the following morning's spot-test despite a reasonable effects size. The most plausible explanation is that following supplementation at dinner, the excess base was mostly excreted that evening. This elevated the pH of the last evening void, and consequently, as the excess base was excreted, this removed the effect on the following morning's spot-tests. This explanation concurs with the findings of other studies that have measured NAE pre- and post-prandial.[26–28] These studies report NAE significantly altered following a meal when the base load was modulated. Given the relationship between pH and NAE of the same sample, it appears reasonable to suggest that pH also alters. Indeed, if nutrient transition times impact urine pH, this may explain the findings of other studies. For example, Anton *et al.*[9] found significant changes when they supplemented with powdered F&V prebed and spot-tested the following morning's void, whereas others have reported high variability in day-to-day spot-tests.[10,12] As a result, the data suggest spot-tests are unreliable to track NAE modulation, yet they may crudely reflect the acid–base constituents of the last meal.

Following supplementation at dinner, we found that the last evening's spot-test significantly changed. As such, it may be that spot-tests following a meal have the capacity to inform dietitians of the acid–base constituents of that meal. However, in the context of the real world, this is unlikely as NAE is reflective of a ratio of dietary acid to base intake. Consequently, if there is an increase in base intake and a concurrent equivalent increase in acid intake, the NAE and thus pH remains unaltered. Likewise, simply lowering meat intake may result in an alkalised pH, which may be mistaken as an increase in F&V intake. In this light, the capacity for spot-tests to inform dietitians of the relative constituents of the last meal becomes non-sensical. Indeed, the reason why we found a significant change in the last evening pH is likely because we standardised dietary intake. Moreover, spot-tests are likely to be further confounded by the consumption of multiple meals throughout the day and the potential for overlapping in the excretion of their respective metabolites, coupled with variations in urination times, on top of differing rates of endogenous organic acid production.

This is the first study to examine the effect of short-term F&V concentrate ingestion on NAE, and we found that this supplement significantly alkalised NAE and 24-hour pH. Given that the intervention was implemented for both genders with a wide age bracket, this appears reasonably generalisable. Although, investigators should be aware that different concentrates likely differ in effect because of their different quantities of bases. Moreover, the decrease in NAE was –25.8 mEq, whereas the expected change was –40.1 mEq. This may be because of limitations in NEAP calculation models. That is, the supplement contained powdered F&V, and consequently, it also contained an unknown concentrated quantity of plant-derived organic acids. As models do not factor for plant-derived organic acids, there may have been an over-estimation in the dose.[23] In brief, our findings show that this supplement tangibly modulates NAE, although we are unsure of any impact on clinical outcomes.

The study is limited by the use of ad libitum diets and temperature issues in the measurement of NAE. That is, participants were responsible for replicating their food and fluid intake during phase two and it is possible some may have deviated. However, the dietitian met daily with the participants to ensure compliance, and the urine data appears to suggest that for the most part, the participants where compliant. Finally, titration of urine at ambient temperature theoretically introduces a slight error; however, the magnitude would be too small to markedly alter the results, and the 24-hour pH was standardised to the temperature of spot-tested pH. In conclusion, spot-tests of urine pH are not a valid biomarker of the dietary acid load and were unable to reliably track changes to it, despite an F&V concentrate clearly modulating 24-hour NAE.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authorship

We thank GS and BP for the project conception; BP for conducting the research and obtaining donations, Dr. Peter Brooks for developing the analytical methods, Daryle Sullivan for the measurement of ammonia and L.F. for methodological contributions; Michael Nielsen for sourcing essential reagents and materials; BP for performing the statistics and writing the paper; and GS and LF for critical revision of the manuscript and study supervision. All authors have read and approved the final manuscript. The content has not been published or submitted for publication elsewhere.

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