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CHILDREN AND ADOLESCENTS

Dietary strategies for achieving adequate vitamin D and iron intakes in young children in Ireland

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Abstract

Background: Inadequate intakes of vitamin D and iron have been reported in young children in Ireland. The present study aimed to identify the main foods determining vitamin D and iron intakes and to model the impact of dietary strategies to improve adequacy of these micronutrients in young children.

Methods: The present study is based on the Irish National Pre-School Nutrition Survey (NPNS), which estimated food and nutrient intakes in a representative sample (n = 500) of children (aged 1–4 years) using a 4-day weighed food record. Dietary strategies were modelled using DaDiet© software (Dazult Ltd, Co. Kildare, Republic of Ireland) and the usual intake distribution, prevalence of inadequate intakes and risk of excessive intakes were estimated using the National Cancer Institute method.

Results: Fortified foods and nutritional supplements were the key foods influencing the intakes of vitamin D and iron. Adding a 5 μg day^{-1} vitamin D supplement, fortifying cow's milk (CM) with vitamin D or replacing CM with growing-up milk (GUM) would modestly increase intakes of vitamin D. A combined strategy of fortifying CM with vitamin D or replacing CM with GUM plus a 5 μg day^{-1} vitamin D supplement would increase mean intakes of vitamin D (from 3.5 μg day^{-1} at baseline to ≥11 μg day^{-1}) and substantially reduce the prevalence of inadequate intakes (from >95% to 12–36%). Fortifying CM with iron or replacing CM with GUM would increase mean intakes of iron (from 7.3 mg day^{-1} to >10 mg day^{-1}), achieving adequate intakes across all ages.

Conclusions: Based on real food consumption data in a representative sample of Irish children, we have shown that through targeted dietary strategies adequate intakes of iron are achievable and intakes of vitamin D could be greatly improved.

Introduction

Low intakes of vitamin D and iron [1–7] and biochemical evidence of poor vitamin D and iron status have been widely reported in young children in Ireland and across Europe [8–11]. As a result of the negative impact of inadequate vitamin D and iron status on childhood growth and development and lifelong health status [12,13], effective dietary strategies to improve the intakes of these nutrients in young children are required.

Fortified foods and supplements can represent an opportunity to improve intakes and adequacy of vitamin D and iron in all population groups [14–20]. The practical and theoretical impacts of vitamin D fortification of dairy products have been widely investigated, demonstrating that it is an effective strategy for increasing dietary intake and serum 25-hydroxyvitamin D (25(OH)D) concentrations in many population groups [21–26]. Furthermore, it has been frequently reported that the consumption of breakfast cereals (primarily ready-to-eat breakfast cereals, which are commonly fortified with a number of nutrients including iron), is associated with higher iron intakes and a better dietary nutritional profile among all age groups [18,27,28]. Several countries, particularly those at Northerly latitudes, currently recommend vitamin D supplements for many population subgroups [29–32]; however, despite recommendations for younger infants and older children and adults in Ireland to take a vitamin D supplement daily, there are currently no recommendations for young children aged 1–4 years [33,34].

For young children in particular (aged 1 and 2 years), fortified growing-up-milks (GUM), also known as young child formula (milk-based drinks intended for children aged 12–36 months), can provide an effective approach for improving intakes and adequacy of vitamin D and iron (among other nutrients). The association between GUM consumption and increased intakes and improved status of vitamin D and iron has been widely reported [16,17,35–37] and a recent dietary modelling approach in the UK has demonstrated that replacing cow's milk (CM) with GUM would be an effective strategy for increasing intakes of vitamin D and iron and would also lead to nutritional intakes more in line with recommendations in young children [38].

The Irish National Pre-School Nutrition Survey (NPNS) database contains detailed food consumption data linked with updated food composition data as required for theoretical modelling of dietary strategies. The present study aimed to use the NPNS data to identify the key sources and determinants of vitamin D and iron intake in Irish pre-school children and to model the potential impact of dietary strategies for achieving recommended intakes of vitamin D and iron in Irish pre-school children aged 1–4 years.

Materials and methods

Study sample

Analyses for the present study were based on data from the Irish National Pre-School Nutrition Survey, which was a cross-sectional survey conducted in the Republic of Ireland in 2010–2011 by the Irish Universities Nutrition Alliance (IUNA) units at University College Cork and University College Dublin with the aim of establishing a database of habitual food and beverage consumption in a representative sample of children aged between 1 and 4 years (n = 500). A detailed survey methodology is available at www.iuna.net and an overview of the methods relevant to this study is provided below. The study was conducted in accordance with guidelines laid down in the Declaration of Helsinki and ethical approval was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork (Ref: ECM 4 (a) 06/07/10). Written informed consent was obtained from parents/guardians.

Sampling and recruitment methodology

Eligible participants were children aged between 12 and 59 months, inclusive, who had not yet started primary school. A total sample of 500 participants (251 boys and 249 girls) were selected from a database of names and addresses compiled by 'eumom' an Irish parenting resource or from randomly chosen childcare facilities in selected locations. A second level of recruitment was used in which names and addresses were compiled through referrals from participants and participation was invited for those that were contactable. In all cases, participation was dependent on the prospective participant 'opting in'. Demographic analysis of the sample has shown it to be nationally representative of young Irish children with respect to age, sex and geographical location compared to Irish Census 2006 data [39]. The final sample contained a higher proportion of children of professional workers and a lower proportion of children of semi-skilled and unskilled workers than the general population and all data reported in the present study were weighted to adjust for these differences.

Food consumption data

Food and beverage intake data were collected using a 4-day weighed food record. For all participants, the study period included at least 1 weekend day. The researcher made three visits to the participant and the caregiver during the 4-day recording period: an initial training visit to demonstrate how to complete the food diary and use the weighing scales; a second visit 24–36 h into the recording period to review the diary, check for completeness and clarify details regarding specific food descriptors and quantities; and a final visit 1 or 2 days after the recording period to check the recording from the final days and to collect the diary. Caregivers were asked to record detailed information regarding the amount, type and brand of all food, beverages and nutritional supplements consumed by the child over the 4-day period and, where applicable, the cooking methods used, the packaging size and type and details of recipes and any leftovers. Participants were also encouraged to keep packaging of foods consumed to provide further information.

A food quantification protocol established by the IUNA[40], which uses a hierarchical approach, was adapted for the NPNS. Further details can be found on www.iuna.net . In summary, food was quantified by: (i) being weighed by participants or based on manufacturer weights (which was used to quantify 85% of foods and drinks consumed in the NPNS); (ii) use of a photographic food atlas [41] (6% of foods and beverages); (iii) IUNA average portion weights (0.5% of food and beverages); (iv) food portion sizes [42] (1% of food and beverages); (v) household measures (6% of food and beverages); and (vi) estimated quantities (1.5% of food and beverage items).

Food composition and nutrient intake data

Dietary intake data were analysed using WISP© (Tinuviel Software, Anglesey, UK), which estimates nutrient intakes using data from *McCance and Widdowson's The Composition of Foods*, sixth and fifth editions, plus all nine supplemental volumes, as described elsewhere [43–45]. During the NPNS, modifications were made to the food composition database to include recipes of composite dishes, infant specific products and generic Irish foods that were commonly consumed. The vitamin D and iron contents of all fortified foods and nutritional supplements were recorded from product labels. *The Composition of Foods* does not contain vitamin D values for some potentially important sources such as milk, fish, meat and mushrooms; hence, vitamin D values from other food composition databases were included. Data from the US Department of Agriculture National Nutrient Database for Standard Reference – Release 23 (USDA SR23, September 2010) were used to update vitamin D values for white fish, smoked salmon, processed meat (including ham) and mushrooms [46]. The Danish Food Composition Databank version 7.01 (2009)[47], was used to update values for whole, semi-skimmed and skimmed milk because the fat contents of milks in Denmark are equivalent to those in Ireland according to Council Regulation (EC) No. 1234/2007 and Danish milk has recently been analysed for vitamin D [48].

Percentage contribution of food groups to micronutrient intakes

The percentage contribution of food groups to intakes of vitamin D and iron was calculated by the mean proportion method as defined by Krebs-Smith *et al.* [49] using SPSS, version 20.0 (SPSS, Inc., IBM, Chicago, IL, USA). This method provides information about the sources that are contributing to the nutrient intake 'per person'. The mean proportion method is the preferred method when determining important food sources of a nutrient for individuals in the population group as opposed to investigating the sources of a nutrient within the food supply.

Dietary determinants of micronutrient intakes

The dietary determinants of vitamin D and iron intakes in young Irish children were investigated using tertile analysis; participants were split into thirds of (vitamin D or iron) intake, stratified by age, and the mean intake among the low, medium and high consumers (tertile 1, 2 and 3, respectively) was calculated. The contribution of food groups to intakes in each consumer group was established and the food groups accounting for the difference in intakes between high and low consumers were determined.

Modelling strategies to achieve adequate intakes of micronutrients

The modelling scenarios were conducted using DaDiet©, version 15.05 (Dazult Ltd, Co. Kildare, Republic of Ireland) and were based on the foods/food groups that contributed to the difference in intakes of vitamin D and iron between high and low consumers.

Dietary strategies for achieving adequate vitamin D intakes:

Scenario 1: Addition of a 5 μg of vitamin D supplement daily for all children. The effect of a 5 μg day^{-1} vitamin D supplement on dietary intakes of vitamin D for all children aged 1–4 years was modelled. All current vitamin D containing supplements at baseline were removed for these analyses.

Scenario 2: Fortification of all commercially available cow's milk with vitamin D. The effect of fortification of CM was modelled at three levels of vitamin D: (i) 1 μg/100 mL; (ii) 1.5 μg/100 mL; and (iii) 2 μg/100 mL. The levels of CM fortification were based on published scenarios from other studies [23,50] and also the levels of vitamin D in fortified milks currently available on the Irish and other European Union (EU) markets. Within the database, all commercially available CM and beverages made up with CM (including milkshakes, hot chocolate recipes etc.) were identified for fortifying with vitamin D.

Scenario 3: Replacing all cow's milk with growing-up milk for 1- and 2-year-old children. For 1- and 2-year-old children, the effect of replacing all CM with GUM on dietary intakes of vitamin D was modelled (as GUM are intended for children aged 12–36 months). The nutritional composition of GUM was based on that of the market leader, which currently contains 3.1 μg of vitamin D per 100 mL. Within the database, all milks, such as CM/GUM/infant milk formula (IMF) (excluding beverages made up with CM; e.g. drinking chocolate powder, milk shake powder, etc.), were identified for replacement with GUM at the levels of current consumption.

Scenario 4: Fortification of all commercially available cow's milk with vitamin D plus an additional daily intake of

5 μg of vitamin D in supplemental form for all children. Scenarios 1c and 2 were modelled together to investigate the combined effect of fortification of all commercially available CM (with vitamin D) and an additional intake of 5 μg of vitamin D supplement daily on dietary intakes of vitamin D in all children aged 1–4 years.

Scenario 5: Replacement of all cow's milk with growing-up milk plus an additional daily intake of 5 μg of vitamin D in supplemental form for 1- and 2-year-old children. Scenarios 2 and 3 were modelled together to investigate the combined effect of replacing all CM with GUM and an additional intake of 5 μg of vitamin D supplement daily on dietary intakes of vitamin D in 1- and 2-year-old children.

Dietary strategies for achieving adequate iron intakes:

Scenario 6: Fortification of all commercially available cow's milk with iron. The effect of fortification of CM with 1.2 mg of iron per 100 mL was modelled. The levels of CM fortification were based on the levels of iron in fortified milks currently available on the Irish and other EU markets. Within the database, all commercially available CM and beverages made up with CM (including milkshakes, hot chocolate recipes etc.) were identified for fortifying with iron.

Scenario 7: Replacing all cow's milk with growing-up milk for 1- and 2-year-old children. For 1- and 2-year-old children, the effect of replacing all CM with GUM on dietary intakes of iron was modelled. The nutritional composition of GUM was based on that of the market leader, which currently contains 1.2 mg of iron per 100 mL. Within the database, all milks, such as CM/GUM/IMF (excluding beverages made up with CM; e.g. drinking chocolate powder, milk shake powder, etc.), were identified for replacement with GUM at the levels of current consumption.

Estimation of usual intakes

Usual intake distributions for vitamin D and iron for each of the above models were estimated using the validated National Cancer Institute (NCI)-method [51]. The NCI-method has been implemented in SAS macros, version 2.1 (www.riskfactor.cancer.gov/diet/usualintakes/macro.html). For these analyses, the covariate used was age. Using these macros, the usual intake distributions of nutrients were estimated for the total population (aged 1–4 years) and by age.

Adequacy of micronutrient intakes

The prevalence of inadequate vitamin D and iron intakes was estimated using estimated average requirements (EARs) as cut-off points. This method has been shown to be effective in obtaining a realistic estimate of the prevalence of dietary inadequacy [52]. The US Insitiute of Medicine EAR of 10 μg day^{-1} was used to assess the prevalence of inadequate vitamin D intakes [53] and the 5 mg day^{-1} EAR published by the European Food Safety Authority (EFSA) was used to assess the prevalence of inadequate iron intakes [54]. Because under-reporting of food consumption can result in an overestimate of the prevalence of inadequacy in a population group [55], under-reporters (URs) were identified and excluded from the analysis when assessing adequacy. Basal metabolic rate (BMR) was predicted for each participant from standard equations using body weight and height [56] and minimum energy intake cut-off points, calculated as multiples of BMR [57] (ratio of energy intake to BMR < 1.28), were used to identify URs (24% of total sample).

Risk of excessive intakes of micronutrients

The risk of excessive intake of vitamin D and iron was evaluated using the tolerable upper intake level (UL) as a reference value. The UL is defined as the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans [58]. For vitamin D, the UL for children published by EFSA of 50 μg day^{-1} was used to assess the risk of excessive intake [59], whereas the 40 mg day^{-1} UL for children established by the US Food and Nutrition Board was used to assess the risk of excessive intake of iron [60]. As there was no difference in the proportion of the population with intakes above the UL when URs were included or excluded (0% versus 0%), all participants were included in this analysis.

Results

Dietary sources and determinants of vitamin D intake

For 1- and 2-year-old children, the key food group contributing to vitamin D intakes was 'fortified milks including growing-up-milks (GUM)' contributing 26% for 1-year-old children and 19% for 2-year-old children (see Supporting information, Table S1). 'Unfortified milks' (15% and 14%) and 'meat and meat products' (12% and 15%) were also important sources of vitamin D for 1- and 2-year-old children, respectively. For 3- and 4-year-old children, 'meat and meat products' were the key source of vitamin D, contributing 18% and 22% of vitamin D intakes, respectively, followed by milks (both fortified and unfortified) which contributed 16% and 18% of intakes in 3- and 4-year-old children, respectively.

The difference in intakes of vitamin D between high and low consumers was greatest for 1-year-old children (8.0 μg day^{-1}) and decreased slightly with increasing age (6.8 μg day^{-1} for 2-year-old children, 5.2 g day^{-1} for 3-year-old children and 4.7 g day^{-1} for 4-year-old children) (see Supporting information, Table S2). For 1- and 2-year-old children, 'milks' were the key contributor to the difference in intakes between high and low vitamin D consumers; attributable to GUM/IMF (64% for 1-year-old children and 49% for 2-year-old children) and fortified milks (6% for 1-year-old children and 14% for 2-year-old children) (Table 1). Nutritional supplements containing vitamin D were consumed by 17% of children aged 1–4 years and were important contributors to the difference in intakes for 1- and 2-year-old children, contributing 18% and 29%, respectively. For 3- and 4-year-old children, nutritional supplements were the key contributor to the difference in intakes of vitamin D contributing almost half of the difference (55% and 44%, respectively). Fortified milks also contributed 17% of the difference in vitamin D intakes between high and low consumers for 3-year-old children and 25% of the difference for 4-year-old children.

Table 1 Contribution of food groups to the difference in vitamin D intakes between high and low consumers of vitamin D by age in Irish children aged 1–4 years

	1 year olds (*n* = 126)	2 year olds (*n* = 124)	3 year olds (*n* = 126)	4 year olds (*n* = 124)
	% Difference			
Milks	67.7	59.3	29.0	30.3
GUM/IMF	*63.6*	*48.5*	*11.2*	5.3
Fortified milks	*6.2*	*13.8*	*17.0*	24.9
Unfortified milks	*−2.1*	*−3.0*	*0.8*	0.2
Nutritional supplements	18.3	28.5	54.5	43.5
Breakfast cereals	5.7	3.2	2.6	3.8
Infant cereals	*4.9*	*0.8*	0.0	0.0
Ready-to-eat breakfast cereals	*0.7*	*2.4*	2.6	3.8
Other breakfast cereals	*0.0*	*−0.1*	0.0	0.0
Yoghurts	2.6	2.1	4.6	5.8
Fish & fish dishes	2.3	1.0	2.6	5.0

GUM, Growing-up milks/IMF, Infant milk formula.
Italic values report the % contribution from the disaggregated component of the larger food group.

Dietary strategies for achieving recommended vitamin D intakes

Scenario 1 (5 μg day^{-1} vitamin D supplement) increased intakes of vitamin D from 3.5 μg day^{-1} at baseline to 7.8 μg day^{-1} (Table 2). Scenarios 2a, 2b and 2c (fortifying CM with vitamin D at a level of 1.0, 1.5 or 2 μg/100 mL) increased intakes of vitamin D to 5.4, 6.6 and 7.8 μg day^{-1}, respectively. Scenario 3 (replacing all CM with GUM) resulted in mean intakes of vitamin D approximately three times that at baseline for 1- and 2-year-old children (from 3.8 to 12.8 μg day^{-1}). Scenarios 4 (a combination of vitamin D fortified CM at 2 μg/100 mL plus a 5 μg day^{-1} vitamin D supplement) and 5 (a combination of replacing all CM with GUM plus a 5 μg day^{-1} vitamin D supplement) represented the greatest increase in vitamin D intake, resulting in mean intakes ranging from 12.1 to 17.2 μg day^{-1} for children aged 1–4 years.

The observed increase in vitamin D intake under each modelling scenario led to an expected decrease in the prevalence of vitamin D inadequacy (below the 10 μg day^{-1} EAR). For scenarios 1 (a 5 μg day^{-1} vitamin D supplement), 2a, 2b, 2c (fortifying CM with vitamin D at 1.0, 1.5 and 2.0 μg/100 mL) and 3 (replacing all CM with GUM), the prevalence of inadequate vitamin D intakes was decreased by 11%, 5%, 15%, 27% and 65%, respectively, from baseline. Modelling scenarios 4 (combination of vitamin D fortified CM at 2 μg per 100 mL plus a 5 μg day^{-1} vitamin D supplement) and 5 (combination of replacing all CM with GUM plus a 5 μg day^{-1} vitamin D supplement for 1- and 2-year-old children only) resulted in a prevalence of inadequate vitamin D intakes ranging from 5% to 24% for 1- and 2-year-old children and ranging from 21% to 35% for 3- and 4-year-old children (reduced from 95% to 97% at baseline).

The proportion of the population with intakes of vitamin D greater than the upper level (UL) of 50 μg day^{-1} was zero for all age groups under all modelling scenarios (see Supporting information, Table S3). The 95th percentile intake did not exceed 30 μg day^{-1} for any scenario.

Dietary sources and determinants of iron intake

Breakfast cereals were the key source of iron across children aged 1–4 years, contributing almost one-third of the mean daily iron intake for each age group (30–32%) (see Supporting information, Table S4). GUM/IMF and 'meat & meat products' were also important sources of iron for children aged 1 years, providing 12% and 11% of iron intakes, respectively. For 2-, 3- and 4-year-old children, other key sources of iron included 'bread & rolls' (13–15% contribution across ages) and 'meat & meat products' (10–13%).

Table 2 Mean usual vitamin D intake (μg day^{-1}) and the proportion (%) of the population with intakes of vitamin D below the estimated average requirement (EAR) by age in Irish children aged 1–4 years at baseline and based on all modelling scenarios for vitamin D

	All (*n* = 500)			1 year olds (*n* = 126)			2 year olds (*n* = 124)			3 year olds (*n* = 126)			4 year olds (*n* = 124)		
	Mean	SD	<EAR††	Mean	SD	<EAR††	Mean	SD	<EAR††	Mean	SD	<EAR††	Mean	SD	<EAR††
	μg day^{-1}		%	μg day^{-1}		%	μg day^{-1}		%	μg day^{-1}		%	μg day^{-1}		%
Baseline*	3.5	0.8	96.7	3.9	0.9	95.4	3.6	0.9	97.1	3.2	0.8	97.4	3.2	0.8	97.2
Scenario 1†	7.8	0.6	85.5	8.5	0.6	75.9	8.0	0.6	86.7	7.3	0.6	91.3	7.4	0.6	89.1
Scenario 2a‡	5.4	0.9	91.7	6.4	0.9	85.1	5.7	0.9	91.4	4.8	0.9	95.2	4.8	0.9	95.5
Scenario 2b‡	6.6	1.1	81.8	7.8	1.1	70.3	7.0	1.1	81.2	5.8	1.0	87.4	5.8	1.0	88.9
Scenario 2c‡	7.8	1.3	69.6	9.2	1.3	55.3	8.3	1.3	67.9	6.9	1.2	76.8	6.9	1.2	79.1
Scenario 3§	12.8	2.0	31.4	13.7	2.0	24.9	12.0	1.9	39.0	–	–	–	–	–	–
Scenario 4¶	12.1	1.2	26.8	13.8	1.2	12.4	12.5	1.1	23.5	11.0	1.0	35.4	11.2	1.1	21.3
Scenario 5**	17.2	1.9	7.6	18.4	2.0	4.7	16.2	1.9	11.5	–	–	–	–	–	–

*Baseline refers to the un-modelled usual intake of vitamin D.
†Scenario 1: A 5 μg day^{-1} vitamin D supplement was added to the diets of all children.
‡Scenario 2a to 2c: Cow's milk was simulated to be fortified with vitamin D at three levels: (a) 1 μg/100 mL; (b) 1.5 μg/100 mL; and (c) 2 μg/100 mL.
§Scenario 3: All cow's milk was replaced with growing-up milks (GUM) for 1- and 2-year-old children only.
¶Scenario 4: scenarios 1 and 2c were combined: Cow's milk was fortified with vitamin D at 2 μg/100 mL plus a 5 μg day^{-1} vitamin D supplement for all children.
**Scenario 5: scenarios 1 and 3 were combined: All cow's milk was replaced with GUM plus a 5 μg day^{-1} vitamin D supplement for 1- and 2-year-old children only.
††Estimated average requirement [10 μg day^{-1} [1]] Under-reporters were excluded from adequacy analysis (1 year olds, *n* = 109; 2 year olds, *n* = 93; 3 year olds, *n* = 81; 4 year olds, *n* = 96).

Table 3 Contribution of food groups to the difference in iron intakes between high and low consumers of iron by age in Irish children aged 1–4 years

	1 year olds (*n* = 126)	2 year olds (*n* = 124)	3 year olds (*n* = 126)	4 year olds (*n* = 124)
	% Difference			
Milks	53.1	40.2	11.9	4.3
GUM/IMF	*54.1*	*40.5*	11.4	3.4
Fortified milks	*0.0*	*0.5*	0.5	0.7
Unfortified milks	*−1.0*	*−0.8*	−0.1	0.2
Breakfast cereals	29.5	*30.1*	46.0	51.1
Infant cereals	11.6	2.3	0.0	−0.4
Ready-to-eat breakfast cereals	*11.2*	18.5	43.3	53.0
Other breakfast cereals	*6.8*	9.3	2.7	−1.5
Meat & meat products	*5.6*	5.0	4.6	0.0
Nutritional supplements	1.8	9.7	27.5	23.5
Bread & rolls	0.0	5.5	8.7	9.1

GUM, Growing-up milks /IMF, Infant milk formula.
Italic values report the % contribution from the disaggregated component of the larger food group.

The difference in intakes between high and low consumers was 6.2 mg day^{-1} for 1-year-old children, 6.1 mg day^{-1} for 2-year-old children, 5.0 mg day^{-1} for 3-year-old children and 5.2 mg day^{-1} for 4-year-old children. (see Supporting information, Table S5). GUM/IMF were the key contributors to the difference in iron intakes between high and low consumers at 1 and 2 years of age (accounting for 54% and 41% of the difference, respectively), while breakfast cereals contributed a further 30% of the difference for 1- and 2-year-old children (Table 3). For 3- and 4-year-old children, breakfast cereals were the key contributor to the difference in iron intakes, accounting for 46% of the difference for 3-year-old children and 51% for 4-year-old children. Nutritional supplements were also an important contributor to the difference in iron intakes providing 28% for 3-year-old children and 24% for 4-year-old children.

Dietary strategies for achieving recommended iron intakes

Scenarios 6 (fortifying CM with iron at 1.2 mg/100 mL) and 7 (replacing all CM with GUM) had similar effects on intakes of iron for young children (scenario 7 only applicable to children aged 1 and 2 years) (Table 4). Scenario 6 increased intakes of iron from 7.3 mg day^{-1} at baseline to 10.1 mg day^{-1} for children aged 1–4 years,

Table 4 Mean usual iron intake (mg day^{-1}) and the proportion of the population with intakes of iron below the EAR by age in Irish children aged 1–4 years at baseline and based on all modelling scenarios for iron

	All (n = 500)			1 year olds (n = 126)			2 year olds (n = 124)			3 year olds (n = 126)			4 year olds (n = 124)		
	Mean	SD	<EAR§	Mean	SD	<EAR§	Mean	SD	<EAR§	Mean	SD	<EAR§	Mean	SD	<EAR§
	mg day^{-1}		%	mg day^{-1}		%	mg day^{-1}		%	mg day^{-1}		%	mg day^{-1}		%
Baseline*	7.3	0.8	9.4	6.8	0.7	13.7	7.4	0.8	7.1	7.1	0.7	12	7.9	0.8	5.4
Scenario 6†	10.1	1.0	0.6	10.1	0.9	0.7	10.4	1.0	0.2	9.5	0.9	1.3	10.4	1.0	0.4
Scenario 7‡	10.2	0.9	0.5	10.2	0.9	0.7	10.3	1.0	0.3	–	–	–	–	–	–

*Baseline refers to the un-modelled usual intake of iron.
†Scenario 6: Cow's milk was simulated to be fortified with iron at a level of 1.2 mg/100 mL.
‡Scenario 7: All cow's milk was replaced with growing-up milks (GUM) for 1- and 2-year-old children only.
§Estimated average requirement [5 mg day^{-1} [(2)]] Under-reporters were excluded from adequacy analysis (1 year olds, n = 109; 2 year olds, n = 93; 3 year olds, n = 81; 4 year olds, n = 96).

while, for scenario 7, intakes of iron were increased from 6.8 to 10.2 mg day^{-1} for 1-year-old children and from 7.4 to 10.3 mg day^{-1} for 2-year-old children.

The increase in iron intakes observed under modelling scenarios 6 and 7 resulted in a large decrease in the proportion of the population with inadequate intakes of iron (below the 5 mg day^{-1} EAR). For both scenarios 6 and 7, the prevalence of iron inadequacy among all children aged 1–4 years was reduced to <1% from approximately 10% at baseline.

The proportion of the population with intakes of iron greater than the UL of 40 mg day^{-1} was zero for all age groups under both modelling scenarios (see Supporting information, Table S6). The 95th percentile intake did not exceed 20 mg day^{-1} for any scenario.

Discussion

The present study reports the key foods that determine the intakes of vitamin D and iron in Irish pre-school children and is the first study to use nationally representative data to model the effects of fortification and supplementation strategies on intakes, adequacy and risk of excessive intakes of these micronutrients in young Irish children. The study used a systematic approach based on the dietary intake data to identify possible strategies to increase intakes of vitamin D and iron in young children. This approach identifies what foods/food groups contribute to the differences in intakes of the nutrients between high and low consumers with a view to targeting increased intake of these foods in low consumers to match the intakes seen to be acceptable in high consumers. The main finding was that, based on food consumption data and modelling of commercially available products, adequate intakes of iron are achievable and intakes of vitamin D could be greatly improved. Furthermore, none of the strategies examined would result in intakes above the UL for any proportion of this population, indicating that there would be no risk of excessive intakes of these micronutrients in young children even for the highest consumers.

Vitamin D

We proposed dietary strategies for improving vitamin D intakes based on fortifying CM with vitamin D (2 μg per 100 mL) and/or replacing all CM with GUM for 1- and 2-year-old children because 'fortified milks including GUM' were a key source of vitamin D in young Irish children (10–26% contribution across ages). These milks also accounted for a large proportion of the difference in intakes between high and low consumers, particularly for 1- and 2-year-old children (70% and 63%, respectively). These findings are in agreement with other studies that have widely reported 'milk & milk products' as key sources of vitamin D in young children across Europe (providing 20–37% of intakes) [(61–63)] and a major source in the US providing 74% of vitamin D intakes [(64)], highlighting the impact of vitamin D fortified milks [(21)]. Furthermore, many studies have also reported that the consumption of vitamin D fortified milk/GUM effectively increases dietary intakes and serum 25(OH)D concentrations in many population groups, including young children [(16,22,23,26,35,36)]. It is important to note that only a small proportion (20%) of 12–36-month-old Irish children consume GUM [(65)] and, despite milk being an important food group in the diets of young children (consumed by 99% of 1–4-year-old children) [(43)], few commercially available cows' milks are currently fortified with vitamin D in Ireland. We found that fortifying CM with 2 μg of vitamin D/100 mL would decrease the prevalence of inadequacy from 97% at baseline to <70% for 1- and 2-year-old children and <80% for 3- and 4-year-old children. Replacing all CM with GUM would result in a decrease in the prevalence of inadequacy to 25% and 39% of 1- and 2-year-old children, respectively.

We also investigated the addition of a 5 μg day^{-1} vitamin D supplement to the diets of all children as nutritional supplements were important contributors to the difference in vitamin D intake between high and low consumers at all ages (18–55% range across ages) but particularly for 3- and 4-year-old children, accounting for 55% and 44% of the difference, respectively. The relationship between vitamin D supplement use and a low prevalence of inadequate intakes [19,66] and an increase in serum 25(OH)D levels [8] has been widely reported. Additionally, there are recommendations for younger infants (0–12 months) and older children (≥5 years) in Ireland [33,34] and young children in many countries worldwide [22,29–31,67] to take a vitamin D supplement; however, there are currently no guidelines for children aged 1–4 years in Ireland. In the present study, the addition of 5 μg of vitamin D supplement to all children would result in a modest decrease in the prevalence of vitamin D inadequacy from 97% to 76–91% for 1- to 4-year-old children.

To further increase intakes and improve the levels of inadequacy, a combined approach of either fortified CM or replacing CM with GUM in addition to a vitamin D supplement may be necessary. Both of these strategies would increase mean intakes of vitamin D to >10 μg day^{-1} at all ages at the same time reducing the prevalence of inadequate intakes to <25% for 1- and 2-year-old children and <40% for 3- and 4-year-old children. Our findings are in agreement with other studies in young children across the world that have shown that fortifying CM, providing vitamin D supplements or replacing CM with GUM would be effective strategies for increasing vitamin D intakes and status and improving the prevalence of inadequate intakes [16,17,22–24,38,50]. Similar dietary modelling approaches using data from the National Diet and Nutrition Survey in the UK have shown that fortifying CM [50] and replacing CM with young child formula [38] would be effective strategies for increasing intakes and improve status of vitamin D at a population level. The recent Kimi trial in Germany also found that the daily consumption of vitamin D fortified GUM in children aged 2–6 years prevented the decrease in serum 25(OH)D concentrations typically noted in the winter and could be an effective measure for improving vitamin D status in a young population [16]. In line with our findings, some studies also stated that ‘to achieve the recommended intake and consequent raise in serum 25 (OH)D concentrations additional foods for fortification, a higher level of fortification and/or vitamin D supplements (particularly during the winter) would be required’ [22,24]. It is important to note the 10 μg day^{-1} EAR used to assess adequacy of vitamin D intake in the present study. Data from a recent cross-sectional study in 2- to 5-year-old children in Canada have suggested that this EAR value may be too high for this age group [68]; therefore, further research aiming to determine the dietary requirements of young children based on the dose–response relationship between vitamin D intake and 25(OH)D concentrations is necessary.

Iron

The present study found that ‘breakfast cereals’ were a key source and an important contributor to the difference in iron intakes between high and low consumers at all ages (30–51% range across ages) in agreement with reports from other studies globally [18,62,64,69–72]. However, most breakfast cereals (70%) in the NPNS were fortified with iron (mean: 8.1 mg/100 g) and so we opted to evaluate the fortification of other food groups to improve iron intakes in this population group. Although nutritional supplements were important contributors to the difference in intakes between high and low consumers for 3- and 4-year-old children and supplement use has been shown to lower the prevalence of inadequate intakes of a number of micronutrients (including iron)[19], to the best of our knowledge, there are currently no recommendations for iron supplementation of young children in middle and high income countries in Europe or elsewhere. It is important to note that, although ‘meat & meat products’ were an important source of iron at all ages (>10%), this food group accounted for only a small proportion of the difference in intakes between high and low consumers at any age, indicating similar patterns of meat consumption in children who are high and low consumers of iron. Thus, there appears to be no feasible dietary strategy to increase iron intakes from meat in low iron consumers given current meat consumption behaviours in this age group.

GUM was an important source of iron for 1- and 2-year-old children and also contributed a large proportion of the difference in intakes between high and low consumers (54% and 41%, respectively), consistent with the widely reported association between iron-fortified milk/GUM consumption and increased iron intakes and improved status in young children [4,10,17,35,36,73]. Based on these findings and also on the importance of milk as a food group in the diets of young children, we investigated dietary strategies to improve intakes of iron based on fortifying CM with iron (1.2 mg/100 mL) and/or replacing all CM with GUM for 1- and 2-year-old children. We found that fortifying CM with iron or replacing all CM with GUM would increase the mean intake of iron to ≥10 mg day^{-1} for children at all ages with a subsequent reduction in the prevalence of inadequate intakes, resulting in <1% of the population having inadequate intakes of iron. A randomised controlled trial in New Zealand has reported that, in healthy non-anaemic toddlers, the consumption of iron-fortified toddler milk significantly increases iron intakes and is likely to prevent the decline in iron stores that occurs during the second-year of life [(17)]. Furthermore, a recent clinical trial conducted in older Moroccan children (7–9 years old) has shown that iron fortified milk is a feasible option and produces a positive effect on iron status among school children, reducing the prevalence of iron deficiency by 27% [(73)].

The feasibility of implementing the strategies reported in the present study is a matter for further investigation, although it would depend on a national policy on feeding of young children. Although few young children currently use vitamin D supplements in Ireland, there is potential to increase use through adoption of a national policy as has been achieved for the recommendation to provide infants up to 12 months in Ireland with 5 μg of vitamin D supplement daily. This has resulted in a high level of compliance as shown in the Cork Birth BASELINE Cohort study [(74)]. For the fortified CM strategy, a national policy for milk fortification would not require any change in milk consumption behaviour by children; however, it would be necessary to assess the potential effects on intakes of vitamin D and iron in other population groups in Ireland. In the absence of such a policy, a recommendation for young children to consume fortified milks such as GUM represents a strategy based on increasing the proportion of children consuming such milks (e.g. 20% of 12–36-month-old children currently consume GUM). Although this strategy is less ideal than a national policy for milk fortification and may have barriers to its implementation, it has been shown to be acceptable for a significant proportion of young children at present.

The key strengths of the present study are the nationally representative sample included in the NPNS, as well as the comprehensive dietary intake and composition data (particularly the ability to separate fortified foods and nutritional supplements from the base diet at brand level). Another important strength is the use of statistical modelling to estimate the 'usual intakes' of nutrients, resulting in a better estimate of the true distribution of usual intakes with shorter tails and the upper and lower ends, therefore improving the estimates of the proportions of the population with intakes above or below a particular reference value (e.g. EAR or UL), which would otherwise be overestimated. Although vitamin D and iron status measures were not available from the NPNS, in many other populations, it has been shown that the approaches suggested in the present study can effectively improve vitamin D and iron status in young children [(16,17,22–24,37,73)]. Misreporting or under-reporting of energy intake are known limitations with all dietary assessments; this issue was minimised by a high-level of researcher–participant interaction by trained nutritionists. We also accounted for this issue by identifying under-reporters of energy intake (24%) on the basis of the ratio of energy intake to basal metabolic rate and excluding them from the analysis on adequacy of micronutrient intake.

Conclusions

In conclusion, based on real food consumption data in a representative sample of young Irish children, the present analysis has shown that targeted dietary strategies can effectively increase intakes of vitamin D and iron. The dietary strategies examined in the present study would result in a substantial reduction in the prevalence of inadequate intakes of vitamin D and completely eliminate inadequate intakes of iron in young children. Furthermore, there would be no risk of excessive intakes of these micronutrients in young children for any of the strategies examined. These findings will provide tangible evidence to assist and support policy makers in developing dietary guidelines to improve intakes of vitamin D and iron in young children.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of this work is compliant with STROBE guidelines.

Conflicts of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

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AF was involved in the conception of the work and is a grant holder. AF, JW, BAM and APN contributed to the design and execution of the study and provided expert advice throughout. LK contributed to the design of the study, data analyses and wrote the first draft. All authors contributed to the writing of the final manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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Supporting information

Additional Supporting Information may be found online in the supporting information tab for this article:

Table S1. Percentage contribution of food groups to vitamin D intakes by age in Irish children aged 1–4 years.

Table S2. Contribution of food groups to the difference in vitamin D intakes between high and low consumers of vitamin D by age in Irish children aged 1–4 years.

Table S3. Distribution of vitamin D intakes by age in Irish children aged 1–4 years and proportion of the population with intakes of vitamin D above the upper level at baseline based on all modelling scenarios for vitamin D

Table S4. Percentage contribution of food groups to iron intakes by age Irish children aged 1–4 years.

Table S5. Contribution of food groups to the difference in iron intakes between high and low consumers of iron by age in Irish children aged 1–4 years.

Table S6. Distribution of iron intakes by age in Irish children and proportion of the population with intakes of iron above the upper level at baseline based on all modelling scenarios for iron.

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CHILDREN AND ADOLESCENTS

Factors associated with universal infant free school meal take up and refusal in a multicultural urban community

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Abstract

Background: Universal infant free school meals (UIFSM) were introduced in September 2014 and are available to all key stage 1 (4–7 years) children attending state-maintained infant and primary schools in England. The present study aimed to investigate the school-based factors, child and family socio-demographic characteristics, and parental beliefs associated with UIFSM take up in an urban community.
Methods: A cross-sectional questionnaire survey was completed in October to November 2015, amongst parents whose children attended eligible schools in Leicester, England. A questionnaire about school meals was also completed by each school.
Results: Parents reported their child did not take (non-UIFSM, n = 159) or took (UIFSM, n = 517) a UIFSM on most days. The non-UIFSM group were more likely to be White-British, have a higher socio-economic status, have English as a first language, and involve their child in the decision over whether or not to take UIFSM, compared to the UIFSM group. Cluster analysis revealed that non-UIFSM parents were either concerned over quality of meals and what/how much their child ate, concerned only by what/how much their child ate or whether their child did not like the food provided. Two subsets of parents in the UIFSM group were either very positive about UIFSM or appeared to take meals because they were free. Schools used a variety of measures to increase and maintain UIFSM take up.
Conclusions: Parents like to have control over what their child eats at school and children need to enjoy their school meals. Using a range of interventions to target subsets of parents may help local authorities, schools and caterers to increase UIFSM take up.

Introduction

In September 2014, the provision of universal infant free school meals (UIFSM) was introduced for all key stage 1 (4–7 years) children attending state-funded infant and primary schools in England [(1)]. UIFSM entitles all eligible children to a free lunch at school on school days (around 190 days per year in England). This follows recommendations set out in the 'School Food Plan' and the success of pilot schemes in Newham, Durham and Wolverhampton [(2,3)]. The initiative comes amidst ongoing work to raise standards of school food and evidence suggesting a positive effect of school meals on both children and the school community [(2–5)].

The benefits of a school lunch are well established. School lunch contributes around one-third of energy and micronutrient intake on school days, and has been shown to play a role in the development of healthy eating habits, academic achievement, improved behaviour and a reduction in picky eating behaviours at school [(3,6,7)]. Numerous studies have also shown that, on average, school lunches are of a superior nutritional quality to the food provided as a packed lunch in UK primary schools [(8–14)], with fewer than 1% of packed lunches meeting the nutrient-based framework that underlies current food-based standards for school food [8].

In 2015, around 1.6 million children aged 4–15 years were registered for a means-tested free school meal (FSM), available to families with a low income or in receipt of particular state benefits [15,16]. Around 14% of those registered for FSM, however, did not claim their entitlement [15,17]. Pupils in England are less likely to claim a FSM if they are living in a more affluent area, attending schools with a lower FSM registration rate, are White British, or are from families with a higher occupational status or a higher level of parental qualification [15].

Take up of UIFSM (85.6% in January 2015) was slightly lower than the Government target of 87% [18]. The practicalities of introducing UIFSM may have proved challenging for many schools [19] and these challenges have the potential to affect the school meal experience and both pupil and parental perceptions of school food [6,19,20]. Data collected from the UIFSM pilot schemes suggest that a lack of meal choice may prevent children from taking their free meal [3]. Furthermore, parents whose children took a UIFSM were more likely to rate meals positively, think school meals were healthier than a packed lunch, and agree that their child is willing to try new foods [3]. A study by Day *et al.* explored pupils' perceptions of school meals just prior to the introduction of UIFSM. It is clear that the acceptance of school meals is important to the child, although the extent to which the parent or child influences the decision is unclear [19,21]. A deeper understanding of the issues related to low UIFSM take up could be used to both facilitate an increase in take up, and enable caterers to target interventions aimed at pupils and parents.

In particular, attention needs to be paid to diverse local authorities where reasons related to non-take up may be complex. Capturing issues related to culture may be effective in helping to design appropriate interventions. One such diverse local authority is Leicester, situated in the East Midlands of England. Leicester has a high proportion of children living in poverty (37%) and 18.9% of children aged 4–18 years were registered for FSMs in 2015. FSM take up amongst nursery and primary school children was 85%, whereas UIFSM take up was 81.0% [17,22]. Leicester is an ethnically and socio-economically diverse community, with 45% of the population classified as White British, 5% Other White, 28% Indian or Indian British, and 21% other ethnic groups [23]. The present study therefore aimed to investigate school-based factors, child and family socio-demographic characteristics, and parental beliefs associated with UIFSM take up in Leicester, a multicultural urban community.

Materials and methods

Data on current UIFSM take up at all 64 state-maintained, local authority-catered infant and primary schools in Leicester city local authority area were obtained from the Spring 2015 school census [18]. Schools were ranked by current UIFSM take up (percentage), low, through high. The first 20 schools from the list, with the lowest UIFSM take up were selected. A letter and information sheet was sent to the headteacher at each school in September 2015, inviting them to participate in the study. Follow-up telephone calls were made 1 week later by a member of the research team. If a school declined to participate, the next school on the list was selected. A total of 27 schools were contacted and 19 schools agreed to participate within the data collection period.

At each school, every key stage 1 child (in foundation, year 1, and year 2 classes) aged 4–7 years was given an information sheet (detailing the purpose of the study) and a paper-based questionnaire to take home to their parents/carers (the term 'parents' is used to refer to parents, carers or relatives who complete the questionnaire). Consent was assumed where questionnaires were returned. Questionnaires were distributed to and collected from schools by a researcher in October and November 2015. The school was responsible for the distribution and collection of the questionnaires to and from parents. Parents self-completed information on demographic characteristics of the parent and the child, the extent to which various family members were involved in the decision to take UIFSMs, and one of two sections, dependent on whether or not their child took a UIFSM; categorised as UIFSM and non-UIFSM. For children categorised as UIFSM, parents were asked to respond Yes or No to 28 statements representing possible reasons for taking a UIFSM along with open questions for additional reasons and comments. Similarly, for the non-UIFSM group, parents were asked to respond Yes or No to a list of 31 statements representing possible reasons for not taking a UIFSM. The statements in both sections were informed using previous studies on FSM, and input from researchers and the local authority caterer [3,15,21]. Data were entered by two researchers and 10% of all data entry was double-checked. A short questionnaire was also completed by a member of staff at each school about characteristics of the school and the lunch service. The study was approved by the University of Nottingham Research Ethics Committee, School of Biosciences (SBREC150101A).

Socio-economic status was estimated by coding parental occupation using the Office for National Statistics Standard Occupational Classification coding tool [24] and

National Statistics Socio-economic Classification code (NS-SEC) [25]. NS-SEC codes were collapsed into four groups (I, Managerial and Professional Occupations; II, Intermediate Occupations; III, Routine & Manual Occupations; IV, Never Worked or Long-Term Unemployed). The highest NS-SEC code was assumed where occupation was provided for more than one parent.

Statistical analyses were carried out in SPSS, version 22 [26]. $P < 0.05$ was considered statistically significant. Data were screened for missing data, univariate outliers, and normality. Chi-squared or Fisher's exact tests with a Bonferoni adjustment were used to examine differences between those children who did and did not take a UIFSM for categorical variables (followed by post-hoc tests where appropriate) and *t*-tests were used for continuous variables (because normality was confirmed by a Shapiro–Wilk test). Two-step cluster analyses were used to identify natural groupings of respondents (UIFSM or non-UIFSM) on the basis of their endorsement of all/selected statements relating to the decision about taking USIFM. Participants were first preclustered into small subclasses, and then clustered into an appropriate number of larger classes, based on respondents with similar profiles [27]. Degrees of association between clusters of 0.5 or greater were considered important, similar to the analysis undertaken by Fleury *et al.* [27] Cluster analyses were followed by an analysis of variance (ANOVA) to test for any differences in demographic characteristics of resultant clusters.

Results

In total, 2964 questionnaires were distributed and 782 were returned, giving an overall response rate of 26.4%. Thirty-one questionnaires were excluded because only demographic information had been completed and questionnaires were also excluded if key data were missing; it was not possible to tell if the child took a school meal or not ($n = 2$), if parents had completed the wrong section of the questionnaire for their child's school meal status ($n = 12$), which school a child attended ($n = 5$), or if child's age, child's year group, child's ethnicity, if English was not the child's first language, it was not clear who completed the questionnaire, or if the family's socio-economic status could not be determined ($n = 58$). Participants excluded during list-wise deletion were significantly more likely to have one or more children registered for UIFSM, were more likely to have a child for whom English was not their first language, were less likely to be White British, and the questionnaire was less likely to be completed by the child's mother (data not shown; $P < 0.01$). Missing data on other demographic variables were treated in a pairwise deletion manner. A total of 676 questionnaires were therefore included in the analysis, 159 (23.5%) non-UIFSM and 517 (76.5%) USIFM (Table 1).

The non-UIFSM group were significantly more likely to be White British, to have a family NS-SEC of Class I or Class II, or to have English as their first language. Non-UIFSM children were less likely to be registered for FSM (Table 1). There was no significant effect of year group, having an older sibling, if the child had a food allergy (which may prevent children from taking school meals), other ethnicities, or a trend in the % children registered for a FSM at the school.

There were no significant differences between non-UIFSM and UIFSM parents with respect to the extent to which the respondent or their partner made the decision over whether the child takes a meal, although respondents were more likely to agree that children were involved in the decision in the non-UIFSM group (Fig. 1).

Among non-UIFSM, a two-step cluster analysis revealed three clusters of responses in relation to the reasons for their decision. Cohesion was poor (0.2) using the silhouette measure of cohesion and separation [26], although the ratio of the larger to smaller cluster was 2.19 (good) [27]. Four reasons were of importance amongst these parents (Table 2), 'I don't like the current menu' and 'I like to know how much food my child eats', 'I like to know what food my child eats' and 'I think school meals are of poor quality'. Cluster 1 (20%) endorsed all four of these statements but the order [1–5] indicates the areas of most concern were with the current menu and the quality of the food on offer (what and how much food children ate was of concern but not of the greatest importance). These parents also agreed they could provide a healthier packed lunch from home, although this was not significant in the cluster analysis (0.33). Only two reasons were important to cluster two (38%); concerns about what and how much their child eats. Parents within this cluster did not agree that they had any concerns about the quality of the current menu (100%) or the quality of the food on offer (94.1%). Cluster 3 (43%) did not have any clear reasons for their child not taking UIFSM. The only factor ticked was 'My child does not like the food provided' but this was rated of low importance overall (0.06).

ANOVAS examining differences between clusters, found respondents in cluster 3 of the non-UIFSM group were most likely to disagree that they ($F_{2,127} = 3.111$, $P = 0.042$) or their partner ($F_{2,149} = 3.248$, $P < 0.05$) made the decision over whether their child took UIFSM. There were no significant differences between clusters in terms of ethnicity, socio-economic status, year group, if the child suffered from an allergy, if the child had a sibling, if English was not the child's first language, if either

Table 1 Characteristics of parents, carers and their children

Descriptive	All (n = 676) Number (%)	Does not take UIFSM (n = 159) Number (%)	Takes UIFSM (n = 517) Number (%)	P
Child characteristics				
Male	327 (48.4)	91 (57.2)	236 (45.6)	0.007*
Year group				
Foundation	215 (31.8)	53 (33.3)	162 (31.3)	0.700†
Year 1	253 (37.4)	55 (34.6)	198 (38.3)	
Year 2	208 (30.8)	51 (32.1)	157 (30.4)	
% White British	238 (35.2)	69 (43.4)	169 (32.7)	0.020*
EAL	266 (39.3)	51 (32.1)	215 (41.6)	0.019*
Food allergy	42 (6.2)	11 (6.9)	31 (6.0)	0.393*
KS2 sibling‡	243 (35.9)	56 (35.2)	187 (36.2)	0.422*
KS2 sibling has a school meal§	116 (17.2)	12 (7.5)	104 (20.1)	>0.001†
Responder (parent or carer) characteristics				
Respondent working	333 (49.3)	90 (56.6)	243 (47.0)	0.020*
Partner working	364 (53.8)	99 (62.2)	265 (51.3)	0.009*
SES Class				
I	117 (17.3)	40 (25.2)	77 (14.9)	<0.001†
II	107 (15.8)	34 (21.4)	73 (14.1)	
III	270 (39.9)	58 (36.5)	212 (41.0)	
IV	182 (26.9)	27 (17.0)	155 (30.0)	
Any child registered for FSM¶	92 (13.6)	12 (7.5)	80 (15.5)	0.002*
Questionnaire completed by	543 (80.3)	183 (83.6)	410 (79.3)	0.648†
Mother	112 (16.6)	23 (14.5)	89 (17.2)	
Father	9 (1.3)	2 (1.3)	7 (1.4)	
Both parents	2 (0.3)	0 (0.0)	2 (0.4)	
Other relative carer	10 (1.5)	1 (0.6)	9 (1.7)	

EAL, English as an additional language; FSM, free school meal (FSM) (means-tested FSM); KS2, key stage 2 (aged 7–11 years); SES, socio-economic status (I, Managerial and Professional occupations; II Intermediate O; III Routine & Manual Occupations; IV, Never Worked or Long-Term Unemployed); UIFSM, Universal Infant FSM.
*Fisher's exact test.
†Chi-squared test.
‡Data missing for nine participants.
§Data missing for 12 participants.
¶Data missing for 91 participants.

the respondent or their partner were working, or if the child made the decision over whether they took a meal (data not shown).

Two clusters of parents within the UIFSM group were also identified (Table 3). Cohesion amongst this group was fair (0.3) using the silhouette measure of cohesion and separation [26] and the ratio of the larger to smaller cluster was 1.17 (good). Respondents in the first cluster answered Yes to a variety of questions, including 'there is enough choice each day', 'the dining room environment is pleasant', 'the variety of food on offer is good' and 'dining room staff are friendly/encouraging'. Respondents in the second cluster answered No to most questions and did not seem to have any clear reasons for taking school meals, other than their child being encouraged to try new foods, which was rated of low importance overall (0.37).

ANOVAS examining differences between clusters in the UIFSM group found no significant differences between clusters for any of the variables described above (data not shown).

The school questionnaire revealed (Fig. 2) that most schools allowed children to choose meals at the point of service or switch from UIFSM to packed lunch freely. Most schools encouraged children to try new foods and monitored packed lunches. Few schools, however, engaged children in school food issues via a School Nutrition Action Group (SNAG) or other method.

Discussion

The present study aimed to explore why the take up of UIFSM was lower than government targets in Leicester local authority, England. The results obtained suggest that children may not take UIFSM because either they do not like the food provided or their parents are worried about what or how much their child eats. A minority of families

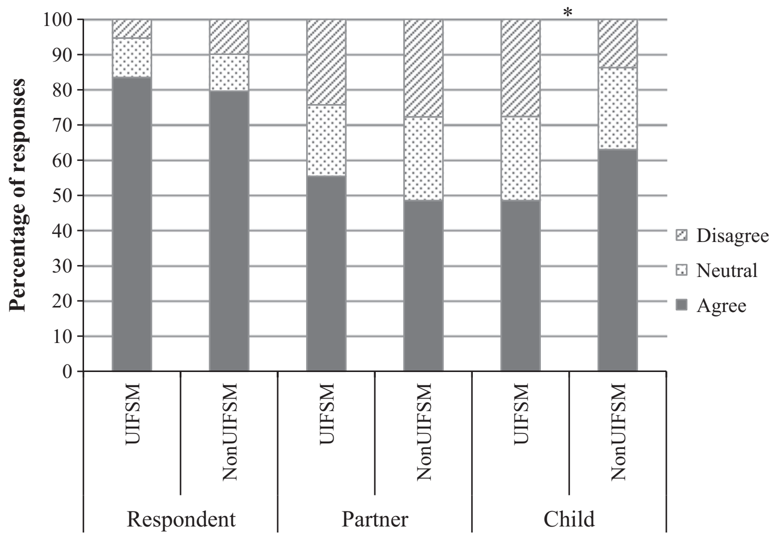

Figure 1 Responders who agree or disagree that that they, their partner (where applicable) or their child should decide on whether or not the child has a universal infant free school meal (UIFSM). *Between group difference using $\chi^2_{2,726} = 3.109$, $P = 0.001$.

also have concerns about the food on offer. Parents whose children took UIFSM were happy with many aspects of their child's meals and experience in the dining room or appeared content for their child to take a meal at school because it was free. Children of respondents who were not working or were of lower socio-economic status were more likely to take a UIFSM and evidence suggests that most schools are working to ensure a flexible and well-managed meals service.

In the present study, the child not liking meals was the most frequently cited factor in non-UIFSM, although parental concerns over the quality or variety of food were less of an issue than in earlier pilot studies [3]. This is possibly to do with improvements in school food or efforts by caterers involved. The cluster analysis, however, revealed the child not liking meals was not of great importance and subsets of parents existed, differing in their responses about UIFSM. Namely, those who have a variety of specific concerns over the food provided and their child's own experience, those whose only concern was what or how much their child eats, and those who have no concerns about school food except that their child does not like the food provided. These subgroups are comparable to those reported by Kitchen *et al.*[3], who classified those not taking UIFSM based on who made the decision: joint-led (similar to our first cluster), parent-led (similar to our second cluster) or child-led (similar to our third cluster). Overall, parents in the non-UIFSM group were more likely to involve the child in the decision-making process, similar to previous studies of non-take up of school meals or FSM [3,4,21,28].

In the parent-led cluster (cluster 2) of non-UIFSM, the quantity and type of foods eaten is of great importance, revealing concerns over fussy eating, children being hungry when at school, or a need for parental control. Fussy eating has been implicated in previous studies [21] but, despite being the fourth most frequently cited factor for not taking UIFSM, this was of low importance in the cluster analysis. Taking a school meal may help to alleviate fussy eating [3], although parents are clearly not prepared to risk their child going hungry. Parents may worry about a loss of control in providing food for their child [28], suggesting an authoritarian parenting style, characterised by low responsiveness (involvement of the child) and high demandingness (control and supervision) by the parent [29]. Providing a packed lunch may limit parental anxiety, allowing parents to retain control and monitor intake.

In the child-led cluster (cluster 3) of non-UIFSM, parents had little concern about the food or the school food environment and, although of low importance, their child did not like the food provided. This may be indicative of a more permissive parenting style, characterised by high responsiveness and low demandingness [30]. These parents may be associated with a lower level of routine dietary monitoring and their children may potentially receive poorer quality packed lunches containing their preferred foods [31].

The joint-led cluster (cluster 1) of non-UIFSM were the only respondents to have concerns about the food, the current menu and a belief that the quality of school meals was poor. Although UIFSM must meet the same nutritional standards (food-based standards) as all school meals in England, there is no guarantee that food is of a high standard (e.g. food could be over-cooked, under-cooked or lack flavour or visual appeal). The visual quality and standard of cooking of school meals can vary between schools and is difficult to control or measure. Parents considered that a healthier meal could be provided from home and expected their children not to like

Table 2 Two-step cluster analysis to examine patterns of parent/carer responses (non-UIFSM group)

Overall importance*	Rank† (% participants ticking 'yes')	Question	Cluster 1 n = 31 (19.5%) Yes/No (within cluster importance)‡ % responses	Cluster 2 n = 60 (37.7%) Yes/No (within cluster importance)‡ responses	Cluster 3 n = 68 (42.8%) Yes/No (within cluster importance)‡ responses	
1.00	12 (14.5)	I don't like the current menu	Yes (1) 74.2	No (3) 100	No (4) 100	Significant
1.00	2 (53.5)	I like to know how much food my child eats	Yes 87.1	Yes (1) 85.3	No (1) 100	
0.56	3 (50.3)	I like to know what food my child eats	Yes 74.2	Yes (2) 75.0	No (2) 90	
0.54	9 (15.7)	I think school meals are of poor quality	Yes (2) 61.3	No 94.1	No (5) 96.7	
0.41	14 (12.6)	The variety of the food on offer is poor	No (3) 51.6	No (5) 97.1	No 95.0	Nonsignificant
0.33	7 (19.5)	I can provide a healthier meal for my child as a packed lunch	Yes (4) 54.8	No 80.9	No (3) 98.3	
0.28	15 (12.6)	There is no choice each day (restricted menu)	No (5) 58.1	No 92.6	No 96.7	
0.23	11 (15.1)	My child has had a negative experience with school meals	No 58.1	No (4) 97.1	No 85.0	
0.15	21 (5.0)	I think school meals are unhealthy	No 80.6	No 97.1	No 100.0	
0.15	25 (3.8)	The dining room environment is unpleasant	No 83.9	No 100.0	No 98.3	
0.10	16 (10.1)	My child follows a religious diet – there are no suitable options	No 74.2	No 91.2	No 96.7	
0.10	18 (8.2)	My child has to queue for a long time	No 77.4	No 94.1	No 96.7	
0.09	19 (6.9)	Dining room staff are not friendly/encouraging	No 80.6	No 97.1	No 95.0	
0.08	5 (28.3)	My child wants to eat with friends who have a packed lunch	No 67.7	No 61.8	No 85.0	
0.08	26 (2.5)	The media has influenced my decision	No 90.3	No 98.5	No 100.0	
0.07	17 (8.8)	The school doesn't allow us to switch between school lunch and packed lunch	No 80.6	No 89.7	No 98.3	
0.06	13 (14.5)	My child does not have time to eat their school lunch	No 77.4	No 80.9	No 95.0	

Table 2. Continued

Overall importance*	Rank[†] (% participants ticking 'yes')	Question	Cluster 1 n = 31 (19.5%) Yes/No (within cluster importance)[‡] % responses	Cluster 2 n = 60 (37.7%) Yes/No (within cluster importance)[‡] responses	Cluster 3 n = 68 (42.8%) Yes/No (within cluster importance)[‡] responses
0.06	1 (54.7)	My child does not like the food provided	Yes 74.2	No 54.4	Yes 55.0
0.06	6 (22.0)	The food provided is unfamiliar to my child	No 67.7	No 73.5	No 88.3
0.04	27 (1.9)	It implies I cannot afford a meal for my child	No 93.5	No 100.0	No 98.3
0.04	30 (0.6)	My child eats too much at school	No 96.8	No 100.0	No 100.0
0.03	23 (4.4)	I did not know about UIFSM	No 96.8	No 98.5	No 91.7
0.02	21 (1.3)	The ordering process is too complicated	No 100.0	No 97.1	No 100.0
0.02	10 (15.7)	My child is not confident in choosing a meal	No 93.5	No 82.4	No 81.7
0.02	4 (40.9)	My child is a fussy eater and will not try the food	No 71.0	No 55.9	No 56.7
0.02	24 (4.4)	My own experience with school meals has influenced my decision	No 93.5	No 94.1	No 98.3
0.01	20 (5.7)	My child has a special diet – there are no suitable options	No 90.3	No 94.1	No 96.7
0.01	30 (0.6)	Other parents have influenced my decision	No 100.0	No 98.5	No 100.0
0.01	22 (5.0)	Eating a packed lunch carries more kudos for my child	No 96.8	No 92.6	No 96.7
0.00	8 (18.9)	My child eats too little at school	No 77.4	No 80.9	No 83.3
0.00	31 (0.0)	Other families at the school are not taking UIFSM	No 100.0	No 100.0	No 100.0

UIFSM, universal infant free school meal.
*Overall importance, rated 1.00–0.00 (with 1.00 being the highest and 0.00 the lowest).
[†]Rank (order of frequency cited as a reason not to take school meals) 1–31.
[‡]Within cluster importance. The top five most important reasons within each cluster are indicated.

Table 3 Two-step cluster analysis to examine patterns of parent/carer responses (UIFSM group)

Overall importance*	Rank† (% participants ticking 'yes')	Questions included	Cluster 1 n = 279 (54.0%) Yes/No (within cluster importance)‡ responses	Cluster 2 n = 238 (46%) Yes/No (within cluster importance)‡ responses	
1.00	14 (54.0)	There is enough choice each day	Yes (1) 84.9	No (1) 82.4	Significant
0.94	16 (50.5)	The dining room environment is pleasant	Yes (2) 80.6	No (2) 84.9	
0.90	9 (60.9)	The variety of food on offer is good	Yes (3) 89.6	No (3) 72.7	
0.86	13 (54.9)	Dining room staff are friendly/encouraging	Yes (4) 83.5	No (4) 78.6	
0.83	15 (51.6)	The food provided is familiar to my child	Yes (5) 79.9	No (5) 81.5	
0.83	5 (67.9)	I am confident my child will eat the meals	Yes 94.3	No 63.0	
0.81	11 (55.7)	I like the current menu	Yes 83.5	No 76.9	
0.68	10 (60.7)	I am confident my child eats enough	Yes 85.7	No 68.5	
0.67	6 (65.6)	My child likes the food provided	Yes 89.6	No 62.6	
0.66	1 (71.6)	I think school meals are of good quality	Yes 94.3	No 55.0	
0.66	2 (71.6)	I think school meals are a healthy option	Yes 94.3	No 55.0	
0.59	7 (62.7)	School meals help my child be confident in choosing a meal	Yes 85.7	No 64.3	
0.51	12 (55.1)	My child is encouraged to eat all the food on their plate	Yes 77.1	No 70.6	
0.47	8 (61.1)	My child wants to eat with friends that have a school meal	Yes 81.7	No 63.0	Nonsignificant
0.47	4 (68.9)	My child enjoy eating the same food as other children	Yes 87.1	No 52.5	

Table 3. Continued

Overall importance*	Rank[†] (% participants ticking 'yes')	Questions included	Cluster 1 n = 279 (54.0%) Yes/No (within cluster importance)[‡] responses	Cluster 2 n = 238 (46%) Yes/No (within cluster importance)[‡] responses
0.37	3 (71.0)	My child is encouraged to eat new foods	Yes 87.8	Yes 51.3
0.34	26 (21.3)	Eating a school meal carries more kudos for my child	Yes 87.8	No 95.8
0.30	17 (48.5)	I think school meals are healthier than a packed lunch	Yes 65.2	No 71.0
0.27	21 (33.5)	The school has been positive about school meals	No 51.6	No 84.0
0.26	18 (47.6)	I don't have to make a packed lunch – this saves time	Yes 63.1	No 70.6
0.21	25 (25.0)	Other parents have been positive about UIFSM	No 63.1	No 89.1
0.17	24 (29.0)	The media has positively promoted UIFSM	No 59.9	No 84.0
0.16	19 (43.9)	I don't have to make a packed lunch – this saves money	Yes 55.9	No 70.2
0.16	27 (17.8)	Other families at my child's school take UIFSM	No 73.1	No 92.9
0.16	22 (30.4)	The school allows us to switch between PL and SL	No 58.8	No 82.4
0.10	20 (39.8)	I enjoyed school meals as a child, this has influenced my decision	No 51.3	No 70.6
0.05	23 (29.6)	My child follows a religious diet – suitable options are available	No 64.5	No 77.3
0.05	28 (13.3)	My child follows a special diet – suitable options are available	No 82.4	No 91.6

PL, packed lunch; SL, school lunch; UIFSM, universal infant free school meal.
*Overall importance, rated 1.00–0.00 (with 1.00 being the highest and 0.00 the lowest).
[†]Rank (order of frequency cited as a reason to take school meals) 1–28.
[‡]Within cluster importance. The top five most important reasons within each cluster are indicated.

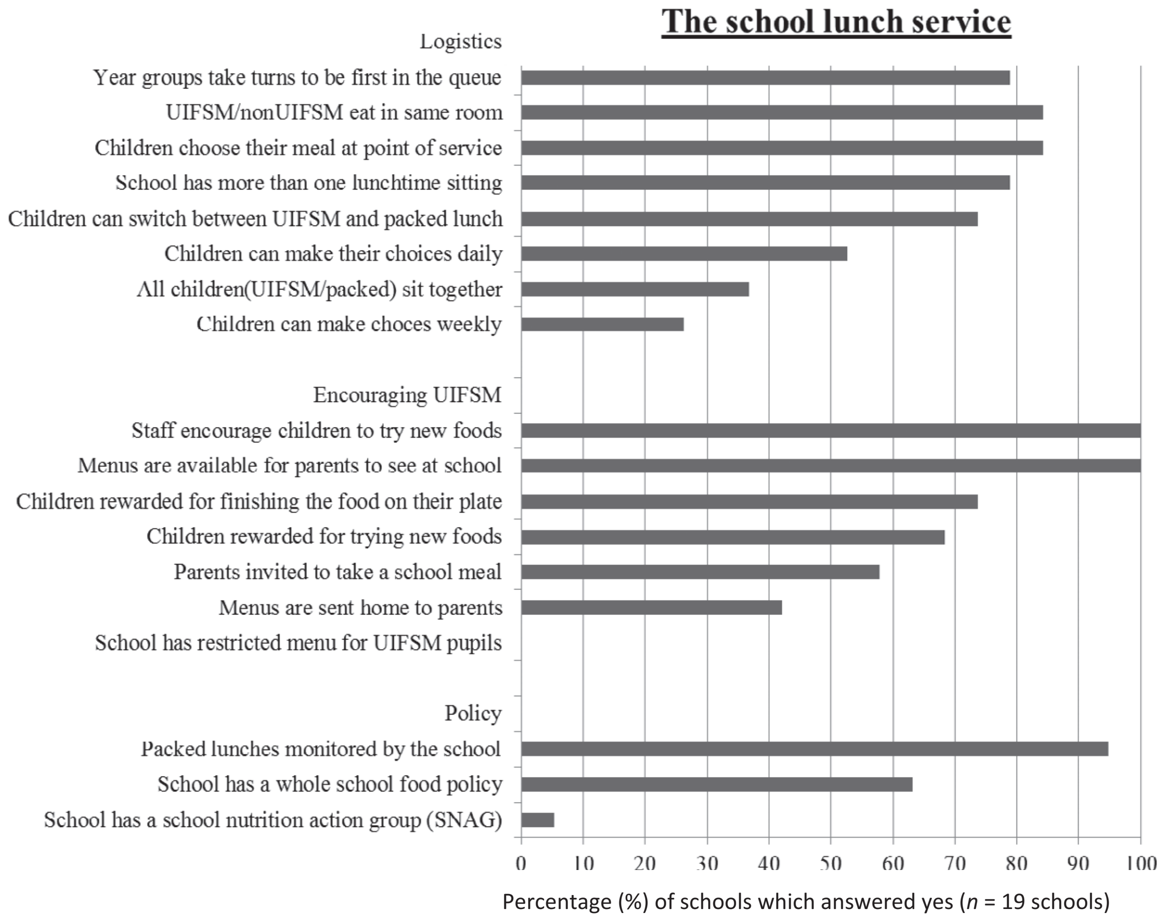

Figure 2 The school lunch service. UIFSM, universal infant free school meal.

the food on offer. These parents may not only be authoritative (as per the parent-led cluster), but also exhibit a highly demanding stance with respect to the nutrient intake of their children. This group may have strong feelings about their child's diet, feel the need to monitor their child's intake and may be the hardest group to convince of the benefits of school meals [29,32].

Parents whose child took a UIFSM reported that meals were of good quality, healthy and that their child was encouraged to eat new foods at school. Cluster analysis, however, revealed two subsets: it is likely that UIFSM parents in cluster 1 are supporters of school meals, whether (89.6% reported liking) or not their child likes the food on offer. Cluster 2 may take them just because they are free; regardless of whether or not (62.6% report not) the child likes the meals.

Parents of higher socio-economic status (as measured by occupation) were less likely to take a UIFSM, consistent with findings from Iniesta-Martinez and Evans [15] on FSM. Our study showed that, although parents regard school meals as being healthy (71.6%), only 48.5% considered that they were healthier than a packed lunch, a view that research suggests is inaccurate [8,10–13]. More advice on the variation needed within packed lunches to create the same nutritional diversity as that of school meals [10,33] and what constitutes a healthy packed lunches should be made available for parents.

This research also clearly highlights the need for multiple, tailored messages to promote UIFSM successfully to all groups of parents. Caterers should continue to promote meals to both parents (because the majority of parents, regardless of uptake, agreed it was their decision) and children, as recommended by the School Food Plan [34]. A record of their child's meal choices, perhaps via a cashless system where available, may help to alleviate parental concerns. Being invited to eat a school meal may also prevent a disparity between perceptions of school food and reality. Some parents (e.g. cluster 1, of the UIFSM group) may need to feel they have a choice and choose the best meals for their child, not just because they are free. Some parents (e.g. cluster 2 of the UIFSM group) may need support when children move to key stage 2 (aged 7–11 years) and the UIFSMs discontinue.

Most schools reported that they had a number of measures in place to support children in making food choices and were flexible in their approach to the meals service; for example, allowing children to switch between UIFSM and packed lunch. Children could be encouraged to take meals by making meals more visually appealing, by allowing children to sit with their friends who take a packed lunch and by regular tasting sessions at school [(2)]. Allowing children some ownership of school meals by setting up a SNAG or other group for children should be encouraged.

Furthermore, the present study demonstrates that, although concerns about menus persist amongst a minority of parents, it is possible, even in a diverse area such as Leicester, to provide food that appeals to families from non-White backgrounds and which does not violate religious standards. Future work might usefully explore how to further engage White British families and those who still find the food unfamiliar. Finally, the money provided to schools to fund UIFSM is dependent on the average number of meals that the school serves to eligible pupils [(34)]. Those schools with lower UIFSM will receive less money and schools with low take up of school meals may struggle to make their catering service break even. Encouraging children to take the meals will ensure that a school meals service remains available to all children who want or need it.

There are some limitations of the present study and its applicability to other areas of the UK. The study was small and may not be representative of all parents in England. Leicester City is multicultural and school meals must cater for children from a variety of cultural backgrounds. UIFSM take up in Leicester is higher than in other areas of the England and gathering the views of parents whose children do not take the meals is challenging. Parents who did not complete the questionnaires correctly were more likely to have lower socio-economic status, be non-white British and have English as an additional language, meaning some groups were under-represented.

In conclusion, the present study provides new evidence of subsets of parents with varying concerns about school food. This insight may help caterers and marketers of school food to use multiple strategies to target families. Addressing parental anxiety over children's food intake and creating nutritionally-balanced menus that are appealing to children remain key challenges for caterers.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of this work is compliant with STROBE[2] guidelines.

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Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interests.

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GG contributed to the drafting of the paper. JF provided the concept of the study and study design. JA contributed to the statistical analysis and interpretation and the drafting of the paper. JM contributed to the concept of the study and the study design. PJ contributed to the interpretation of data and drafting of the paper. JP designed the study, analysed and interpreted data and drafted the paper. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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CHILDREN AND ADOLESCENTS

Development and validation of a food frequency questionnaire to assess omega-3 long chain polyunsaturated fatty acid intake in Australian children aged 9–13 years

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Abstract

Background: The present study aimed to develop a food frequency questionnaire (FFQ) assessing dietary omega-3 long chain polyunsaturated fatty acid (*n*-3 LCPUFA) intake in Australian children and to validate the FFQ against a 7-day food diary.
Methods: The investigation comprised a cross-sectional and validation study. The study setting was two private primary schools in the in the Illawarra region of New South Wales. Twenty-two Australian children, aged 9–13 years, who were not on a special diet or receiving medical care that limited their food choice in the 3 months prior to recruitment, were recruited into the study.
Results: A total of 131 items, classified according to seven food group categories, was included in the *n*-3 LCPUFA FFQ, as identified from published dietary surveys and a supermarket survey. Good correlations between the FFQ and the 7-day food diary were observed for eicosapentaenoic acid (EPA) [$r = 0.691$, 95% confidence interval (CI) = 0.51–0.83, $P < 0.001$], docosahexaenoic acid (DHA) ($r = 0.684$, 95% CI = 0.45–0.84, $P < 0.001$) and total *n*-3 LCPUFA ($r = 0.687$, 95% CI = 0.48–0.85, $P < 0.001$). Bland–Altman plots showed an acceptable limit of agreement between the FFQ and the average 7-day food diary. However, the mean EPA, DHA and total *n*-3 LCPUFA intakes estimated from the FFQ were significantly higher than those from the average 7-day food diary estimates ($P < 0.001$).
Conclusions: A novel *n*-3 LCPUFA FFQ that has been developed to estimate dietary *n*-3 LCPUFA intakes in Australian children has been shown to have relative validity. The FFQ provides a useful contribution to dietary assessment methodology in this age group; however, reproducibility remains to be demonstrated.

Introduction

Omega-3 long chain polyunsaturated fatty acid (*n*-3 LCPUFA) intakes including eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA) and docosahexaenoic acid (DHA) are essential for optimal health in children, particularly for supporting visual and cognitive development [1,2]. The dietary sources of *n*-3 LCPUFA, however, are limited to a few commonly eaten foods, such as fish and seafood, meat, eggs and foods that have been enriched with *n*-3 LCPUFA [3].

The *n*-3 LCPUFA are insufficiently synthesised *de novo* in the human body [4–7]; therefore, to obtain sufficient fatty acids for optimal health, the consumption of food sources containing preformed *n*-3 LCPUFA is warranted. Previous studies have demonstrated that fish consumption is significantly associated with the concentration of *n*-3 LCPUFA in human tissues such as serum [8–11], plasma [12,13] and erythrocytes [14]; therefore, it can be used as an indicator of *n*-3 LCPUFA status.

Because fish or seafood, the richest food sources of *n*-3 LCPUFA [3], is not regularly consumed by Australian children [15], the use of the 24-h recall (which is the method of choice for national nutrition surveys) to estimate habitual intake of this nutrient may lead to potential reporting bias. If the dietary report takes place on a day that fish or seafood is not consumed, many fish or seafood consumers will report zero intakes on the 24-h recall. Therefore, supplementary information that covers frequency of fish and seafood consumption over a longer reference period of time such as in the case of a food frequency questionnaire (FFQ) might improve estimates of *n*-3 LCPUFA intakes. Food frequency information could be a useful covariate in estimating the probability of consumption and amount of episodically consumed foods (e.g. foods that are not consumed almost every day) [16]. Therefore, it can enhance, and not replace, dietary recalls data obtained in national survey; for example, when estimating usual intake from a few day recalls using statistical modeling by taking into account day-to-day variation [16].

Currently, there is no FFQ specifically designed to assess *n*-3 LCPUFA intake in Australian children. A polyunsaturated fatty acid (PUFA) FFQ for use in Australian adults has been developed previously, and was shown to be a valid and reproducible method for estimating *n*-3 LCPUFA intake compared to biomarkers of *n*-3 LCPUFA (red blood cells and plasma fatty acids) and 3-day weighed food records [17–19]. The present study aimed to develop and validate a FFQ to assess dietary *n*-3 LCPUFA intake in Australian children aged 9–13 years.

Materials and methods

Ethical approval

The recruitment of participants in this study followed protocols approved by the Human Research Ethics Committee at the University of Wollongong (Ethics number: HE11/235; amendment approval: HE11/235; 11 January 2012).

Subjects

Development and pilot testing of the food frequency questionnaire

Australian children aged 9–13 years who were not on a special diet or receiving medical care that limited their food choice in the previous 3 months were recruited between May 2011 and December 2011. The children were recruited through poster advertisements distributed to parents or primary caregivers who participated in a survey aiming to assess fish consumption behaviours [20] along with an enclosed letter. Nine children were recruited this way and completed the pilot testing of the draft FFQ.

Validation of the food frequency questionnaire

Primary school children aged 9–13 years were recruited between January and December 2012. Two schools were randomly selected from a total of 46 private schools in the Illawarra region, New South Wales, Australia (http://privateschoolsguide.com/wollongong-private-schools?search-mode=0). The children were recruited through sealed letters sent to their parents through the school system. A total of 32 children were consented to participate in the study; however, only 22 children completed both the FFQ and 7-day food diary.

Ethics approval was obtained from the Human Research Ethics Committee at the University of Wollongong (Ethics number was HE11/235 and amendment approval HE11/235, 11 January 2012). All subjects and their parents or primary caregivers provided written informed consent for participation in the study.

Development and a pilot study of the food frequency questionnaire

Food items included in the development of the *n*-3 LCPUFA FFQ were selected from the following sources: a PUFA FFQ validated for use in Australian adults using red blood cell biomarkers [17,19]; the 2007 Australian National Children's Nutrition and Physical Activity Survey (Children's Survey) nutrient file [21]; a survey of fish consumption patterns of Australian children and their families (Fish Survey) [3]; and an audit of foods enriched with *n*-3 LCPUFA that were available at major supermarkets in New South Wales in December 2009 (N. Kolanu & S. Rahmawaty, unpublished data) using the following steps:

- Food items that contributed to total *n*-3 LCPUFA were identified from the PUFA FFQ [17], Children's survey [21], Fish survey [20] and supermarket survey were manually aggregated and listed into the following seven food groups based on the richest food sources of the *n*-3 LCPUFA [15]: (i) fish and seafood; (ii) meat products and dishes; (iii) egg products and dishes; (iv) milk products and dishes; (v) cereal products and dishes; (vi) spreads and margarines; and (vii) fish oil supplements. Categories for reporting of frequency of food consumption were based on a semi-quantitative FFQ, the Australian Child and Adolescent Eating Survey' (ACAES) [22].

- Commonly consumed portion sizes of the identified food sources of *n*-3 LCPUFA were identified using dietary data from the 1110 children aged 9–13 years included in the nationally representative Children's survey [21]. A food model booklet was developed as an aid to assist children to quantify their portion sizes. Both the draft FFQ and food model booklet were piloted with input from academic nutrition professionals and registered dieticians and pilot testing in five children; thereafter, a final version was drafted and retested in an additional nine children. The outcomes of the second pilot test were used to remodify the final version of the FFQ. A supplementary questionnaire was completed by parents or care givers and used as a cross-check for brands of foods and/or supplements consumed by the children.

Validation of the omega-3 long chain polyunsaturated fatty acid food frequency questionnaire

The revised final version of the FFQ, referred to as an *n*-3 LCPUFA FFQ, was used in the validation study, and a 7-day food diary was used as a reference method.

7-Day food diary

Each participant received a blank 7-day food diary, with accompanying written instructions on how to record daily food consumption as well as any dietary supplements (e.g. fish oils). Participants were asked to record the names or brands and portion sizes of all food items and drinks consumed over a 7-day consecutive period. Any incomplete information was verified with the participants and their primary caregivers by the researcher.

Master database of omega-3 long chain polyunsaturated fatty acid

Dietary intake of total *n*-3 LCPUFA in Australian children from the 2007 Children's Survey has been reported previously [15]. From the same survey data, values of EPA, DPA and DHA were developed specifically to calculate fatty acids from the children's diet (Judy Cunningham, personal communication) and considered as a master database of *n*-3 LCPUFA for use in estimating *n*-3 LCPUFA intake.

Estimation of omega-3 long chain polyunsaturated fatty acid intake

Food items consumed by each child were translated into a daily equivalent frequency [23]. Food quantities were calculated by multiplying the portion sizes (e.g. small, medium, large) by the daily equivalent frequency. The food frequency data were entered into the dietary analysis package FOODWORKS, version 7.0.2959 (Xyris Software Australia Pty Ltd, Highgate Hill, QLD, USA) to identify food items (food ID) and the amount consumed by each child. Intakes of EPA, DPA and DHA were analysed through merging the Food ID of the consumption data derived from FOODWORKS into the *n*-3 LCPUFA master database. The *n*-3 LCPUFA contents from supplements and foods that were not in the master database were added manually into the merged data. Total *n*-3 LCPUFA intake was calculated by summing the EPA, DPA and DHA values. Similar methods were applied to calculate EPA, DPA, DHA and total *n*-3 LCPUFA intakes from the 7-day food diary, and total *n*-3 LCPUFA values were divided by 7 and expressed as mg day^{-1}.

Statistical analysis

Statistical analysis was carried out using SPSS, version 17.0 (SPSS Inc., Chicago, IL, USA). Intakes of EPA, DPA, DHA and total *n*-3 LCPUFA (mg day^{-1}) are presented as mean $\pm$ SD and median (interquartile range). Dietary intakes of *n*-3 LCPUFA were not normally distributed therefore the data were transformed ($\log_{10}$) for these analysis. The paired sample *t*-test was used to assess differences in *n*-3 LCPUFA intakes between the FFQ and the 7-day food diary (mg day^{-1}). Pearson's correlation coefficient was used to assess the linear proximity relationship [24] between FFQ and the 7-day food diary. The correlation coefficients (r) are interpreted as: $r \leq 0.35$ indicating weak correlation, r = 0.36–0.67 indicating moderate correlation, r = 0.68–1 indicating good correlation and $r \geq 0.9$ indicating very good correlation [25,26]. The bootstrap sampling technique was used to obtain confidence intervals (CI), which are computed as the 5th and 95th percentiles [27]. The total of 1000 bootstrap samples of equal size (n = 22) was obtained from 22 subjects by random sampling with replacement. MATLAB, version R2011b (MathWorks Inc., Natick, MA, USA) was used to construct the bootstrapping sampling.

The Bland–Altman plot, [28,29] expressed as the mean difference and two standard deviations between the *n*-3 LCPUFA intakes obtained by the FFQ and the 7-day food diary, was used to quantify limits of agreement (LA) between the two methods. If 95% of the differences are within $\pm$1.96 SD of the mean of the differences, this indicates good agreement between both measurements [28,29]. The LA is defined such that, in the long run, 95% of future differences between the measurements made on the same subject are expected to lie within these limits [30]. The log-transformed LA values of the Bland–Altman were transformed back by exponentiation, which correspond to the ratio of one method's measurements to the other [30] to provide an easy and reliable practical interpretation. Coefficient reproducibilities, indicating how well the FFQ can predict *n*-3

LCPUFA intakes, were calculated. $P < 0.05$ was considered statistically significant.

Results

The mean (SD) age of total children participated in the present study was 10 (0.93) years, with 55% of the sample comprising girls (n = 17). An n-3 LCPUFA FFQ developed in the present study comprised a seven-item food group consisting of a total of 131 items. The food-items included in the final n-3 LCPUFA FFQ are shown in Table 1.

The mean dietary n-3 LCPUFA estimated using the FFQ and 7-day food diary is shown in Table 2. Mean (SD) (mg day^{-1}) dietary EPA, DHA and n-3 LCPUFA from FFQ were significantly higher (by approximately two-, two- and 1.7-fold, respectively) than estimates using a 7-day food diary, although no difference between methods was found for DPA. Good significant correlations between the FFQ and the 7-day food diary were found for EPA, DHA and total n-3 LCPUFA (Table 2).

Bland–Altman plots showed an acceptable 95% LA in the logged measurement of the two methods. The mean difference between methods falls within the 95% CI for mean of difference (Table 3). There was no systematic variation between the two methods for EPA, DPA, DHA and total n-3 LCPUFA (Figs 1). Exponentiating the LA values gave the mean difference (and 95% LA) for the ratio of the FFQ compared to the 7-day menu diary: 1.31 (i.e. 31% higher) [0.74 (26% lower) to 2.30 (130% higher)] for EPA; 1.11 (0.61–2.0) for DPA; and 1.68 (0.78–3.61) for DHA.

Discussion

We have developed a novel FFQ that is specifically designed to improve n-3 LCPUFA intake in Australian children aged 9–13 years and has been demonstrated to have good relative validity. Any FFQ needs to be sensitive to cultural and dietary practices and is therefore population-specific. In addition, because of the difficulties that children experience in accurately recalling past dietary intakes, validation of a dietary instruments for use in the relevant age group is also required [31].

An accurate dietary instrument to assess n-3 LCPUFA intake in children has a number of uses. These include a reliable method for estimating habitual n-3 LCPUFA intakes, which, in turn, can be used to predict suboptimal n-3 LCPUFA intake-related diseases risks, monitoring trends in intakes of children, and informing the development of nutrition intervention programmes and national policy. Therefore, the selection of an appropriate dietary instrument that can capture the consumption of food sources containing the n-3 LCPUFA is needed.

Ideally, biomarkers may be used as reference methods to validate a FFQ that is designed to assess n-3 LCPUFA intake, as has been reported in validation studies in adults [17,18,32–35]. However, the drawing of blood samples is invasive for children. An alternative option is using multiple days of food recalls, such as in the 7-day food diary [36–38]. Multiple days of observation are needed to estimate habitual intake to improve the reliability of the measurement as a result of day-to-day variation in intake patterns [39]. It has been argued that 7-day food records are an acceptable reference method for validation studies in children [40] as a result of the capability of the method with respect to increasing the precision of the intake data compared to one and three different interview days [40]. In addition, it is a lower burden for respondents compared to weighed food diaries [41].

The mean intake of total n-3 LCPUFA that was calculated using this novel FFQ was approximately one and a half-fold higher than estimates obtained from a 7-day food diary, whereas DHA intake was twice as high using the FFQ data. This discrepancy is explained by the longer reference period of reporting (i.e. 1 month) included in the FFQ, which resulted in fish consumption being captured by the FFQ in some children that had not consumed this food group over the past 7 days. A reference period longer than 1 week may be required to obtain an estimate of habitual n-3 LCPUFA intake, especially from fish or seafood sources. Most children in the present study reported consuming take-away fish and chips and home-made fish products on average between one and three times per month. This is similar to dietary patterns reported in our previous study of Australian families with young children in which almost half of those who consumed fish reported purchasing take-away fish and chips at least once a month [20]. National dietary surveys that commonly use two 24-h recalls may underestimate n-3 LCPUFA intake in children because fish and seafood are not regularly consumed in this age group [15,20,42,43]. For example, in the most recent nationally representative nutrition survey of Australian children (2007 Children's survey) [44], average intakes of EPA (23.5 mg day^{-1}), DHA (40.9 mg day^{-1}) and total n-3 LCPUFA (85.3 mg day^{-1}) were approximately three-fold lower than those reported in our study, whereas DPA intakes, provided mostly from meat, were half the values [44].

In general, it has been reported that FFQs tend to overestimate actual intake, compared to other dietary assessments such as two 24-h food recall [45,46], 2-day food diary [47] and 3-day food record [48], as well as 7-day weighed records [49]. In context of the present study, only

Table 1 Food items assessed in the omega-3 long chain polyunsaturated fatty acid food frequency questionnaire

Group 1: Fish and seafood

Canned fish and seafood
- Tuna
- Salmon
- Herring
- Sardines
- Mackerel
- Anchovies
- Not sure of type

Take-away fish products
- Take-away (e.g. fish & chips)
- Sushi
- Fish burger
- Fish finger
- Prawncracker
- Fishcake
- Seafood stick
- Calamari
- Other (please describe)

Fresh or frozen fish
- Fish finger
- Tuna
- Barramundi
- Blackfish
- Bream
- John Dory
- Snapper
- Swordfish
- Not sure of type

Fresh or frozen seafood
- Prawn
- Squid/Calamari
- Scallop
- Oyster
- Lobster
- Octopus
- Morton Bay Bugs
- Crab/Seafood stick
- Fish roe/fish egg
- Yabbie
- Not sure of type

Group 2: Meat Products & Dishes

Meat
- Sausages, e.g. salami, kabana, devon, saveloy, cabanossi, pepperoni, etc.
- Pork, bacon, ham
- Beef, lamb, mutton
- Turkey, chicken
- Not sure the type

Group 3: Egg products and dishes
- Eco eggs with Omega-3
- Pace Farm Omega-3 Free Range Body eggs
- Farm Pride Free Range Omega-3
- Veggs for Families eggs
- Normal chicken eggs
- (including free range)
- Other Omega-3 enriched eggs
- (please specify brand)
- Duck eggs
- I don't know the type

Group 4: Milk Products & Dishes
- Pura Kids Omega-DHA
- Farmer's Best source of Omega-3
- Other milk added with omega-3, (please specify the brand)
- Whole milk
- Fat reduced/lite milk
- Skim milk
- Soy milk
- None of the above (please specify)

Milk products
- Flavored milk, e.g. hot chocolate, milkshake, smoothie, Milo drink
- Plain milk - glass or with cereal
- Yogurt, frozen yogurt
- Cheese-including on sandwiches, toast or biscuits
- Ice cream
- Yakult
- Cream or sour cream

Group 5: Cereal Products & Dishes

Cereal-based products and dishes
- Sandwich, roll
- Cereal, e.g. breakfast cereal, corn flakes
- Bread, e.g. bread rolls, pita, toast, naan
- Pasta, e.g. lasagna, spaghetti, bolognaise, ravioli, cannelloni
- Pizza
- Rice, e.g. fried rice, risotto
- Noodles
- English muffin, bagel, crumpet
- Wrap
- Kebab
- Oat, e.g. oatmeal, porridge

Omega-3 enriched bread
- Uncle Toby's Plus Omega-3 Lift
- Tip Top UP Sandwich bread with Omega-3 DHA
- Wonder White + Omega-3 DHA bread
- COLES High Top bread with n-3
- Tip Top UP Muffin with Omega-3 DHA
- Diego Wrap Omega-3
- McCain's Healthy Choice Pizza with Omega-3 DHA
- Other cereals/breads/muffins/wraps added withomega-3 (please specify the brand)
- I don't know the type

Cereal-based products and dishes
- Savoury biscuits-crackers
- Sweet biscuits, cookies
- Cakes, pies, pancakes, custard, doughnuts, buns, pikelets, scones, lamington, waffles, tarts
- Pudding

Group 6: Spread or margarine
- Meadow Lea Hi-Omega canola spread
- John West Tuna Fish Spread
- Seachange Omega-3 spread Lite
- Other Omega-3 enriched spread
- (please specify brand)
- Butter
- Olive oil spread or blend
- Dairy spread or blend
- Canola spread or blend
- Polyunsaturated spread or blend (e.g. Meadow Lea)
- I don't know the type

Group 7: Supplement

Fish oil
- Blackmores Kids fruity fishies
- Children's Omega-3 (chewy capsules)
- Haliborange Kids Omega-3
- I.Q. Essentials Children Chewable Omega-3 Capsules
- Kids smart Omega^3 Fish Oil
- Omeguard Kids'
- Swisse Children's Smart Fish Oil 60 Chewable Capsules
- Thompson's Goldfish Junior Omega 3 Capsules
- Triple Omega-3 Gummie Fish
- Other fish oil capsules/omega-3
- (please specify the brand)
- I don't know the type

a single study of Belgian school-aged children (12–15 years) has compared a FFQ with a 7-day food diary [50]. The study reported that the FFQ overestimated mean consumption for most foods (11 of 14 food items), including fruit, vegetables, bread, milk, chips, sweets and soft drink, compared to records from a 7-day food diary.

Table 2 Comparison of eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), docosahexaenoic acid (DHA) and total omega-3 long chain polyunsaturated fatty acid (*n*-3 LCPUFA) obtained from food frequency questionnaire (FFQ) and the 7-day food diary*

	n-3 LCPUFA FFQ			7-day food diary				Validity correlation between *n*-3 LCPUFA FFQ and 7-day food diary		
	Mean	(SD)	Median (IQR)	Mean	(SD)	Median (IQR)	*P* value†	*r*	95% CI‡	*P* value
EPA (mg day^{-1})	67.28	(41.19)	56.52 (31.35–89.80)	45.60	(45.89)	29.44 (14.43–68.70)	<0.001	0.691§	0.51–0.83	<0.001
DPA (mg day^{-1})	40.79	(17.71)	40.58 (28.66–56.74)	33.80	(20.12)	28.99 (18.59–46.08)	0.127	0.204	−0.25–0.62	0.362
DHA (mg day^{-1})	134.53	(109.83)	78.30 (63.76–195.06)	65.22	(87.58)	36.40 (11.48–71.22)	<0.001	0.684	0.45–0.84	<0.001
Total *n*-3 LCUFA (mg day^{-1})	242.60	(153.65)	182.82 (125.79–337.45)	144.62	(143.57)	98.33 (48.89–184.20)	<0.001	0.687	0.48–0.85	<0.001

IQR, interquartile range; *r*, Pearson's correlation coefficient; Total *n*-3 LCPUFA, sum EPA + DPA + DHA.
*Average of 7 days.
†Paired *t*-test after log transformation ($\log_{10}$).
‡CI, confidence interval obtained using bootstrapping with 1000.
§Values after log transformation ($\log_{10}$).

In that relative validity study, Spearman correlation coefficients ranged between 0.10 and 0.65 for various nutrients [50]. A validation study among Australian rural children aged 10–12 years has reported weak correlation for the frequency of fish consumption between a short FFQ (mixed FFQ) and three repeated 24-h recalls (Kendal $\tau \geq 0.1$) [51].

Dietary intake measurements are mostly dependent on individual cognitive aspects, and the intakes values obtained must be considered as values of a latent variable [31]. Capabilities in memorising foods that have been consumed, as well as the interpretation of portion size, differ between individuals, and errors are probable, especially in children [41].

Children's self-reporting of dietary intakes are complex tasks, involving individual cognitive aspects in relation to perception, conception and memory [52]. Children's ability to accurately recall an amount of food eaten can be improved through the use of portion-size aids, such as food drawings, models and photographs [53]. Hence, designing a FFQ for children requires numerous strategies to improve their memory and portion size estimation [54]. It has been reported that children's estimates of portion size using age-appropriate food photographs were significantly more accurate (an underestimation of 1% on average) than estimates using photographs designed for use with adults (which were found to overestimate by 45% on average) [55]. In the present study, a food model booklet was developed to help children to recall the foods they had consumed. A supplementary questionnaire was completed by parents or care givers, and used as a cross-check for brands of foods and/or supplements consumed by the children.

The present study has a number of limitations. Only one measurement per participant per method was made; therefore, reliability or interclass correlation coefficients [30,56] cannot be compared [30]. A limitation of relative validation is that both instruments may have the same source of random error, and therefore both may provide an incorrect assessment of a nutrient intake but still be shown to have close agreement [31,57]. For this reason, the method of triads [58], which includes an appropriate biomarker, is the preferred analysis for validation of a FFQ to assess *n*-3 LCPUFA intakes [19,32–35,59]. Few such studies have been conducted in children because of difficulties in obtaining biomarker variables in this age group. A USA study validated a FFQ completed by parents of children aged 1–11 years against children's erythrocyte membrane concentrations of *n*-3 LCPUFA [59]. Both total omega-3 fatty acids and marine PUFAs that were expressed as percentage of total dietary fat, were associated with a percentage of omega-3 and marine PUFAs in the erythrocyte membranes [59].

Table 3 Log transformed limit of agreement* between food frequency questionnaire and the average 7-day food diary

	Limit of agreement log transformed	Mean of difference	SE of mean of difference	95% CI for mean of difference	Coefficient reproducibility (%)
EPA	−0.29 to 0.83	0.27	0.013	0.24–0.29	68.98
DPA	−0.49 to 0.69	0.10	0.013	0.07–0.13	67.32
DHA	−0.25 to 1.28	0.52	0.018	0.48–0.55	81.00
Total *n*-3 LCPUFA	−0.21 to 0.82	0.30	0.012	0.28–0.33	62.72

CI, confidence interval; EPA, eicosapentaenoic acid; DHA, docosahexaenoic acid; DPA, docosapentaenoic acid; Total n-3 LCPUFA, sum EPA + DPA + DHA.
*Bland–Altman test.

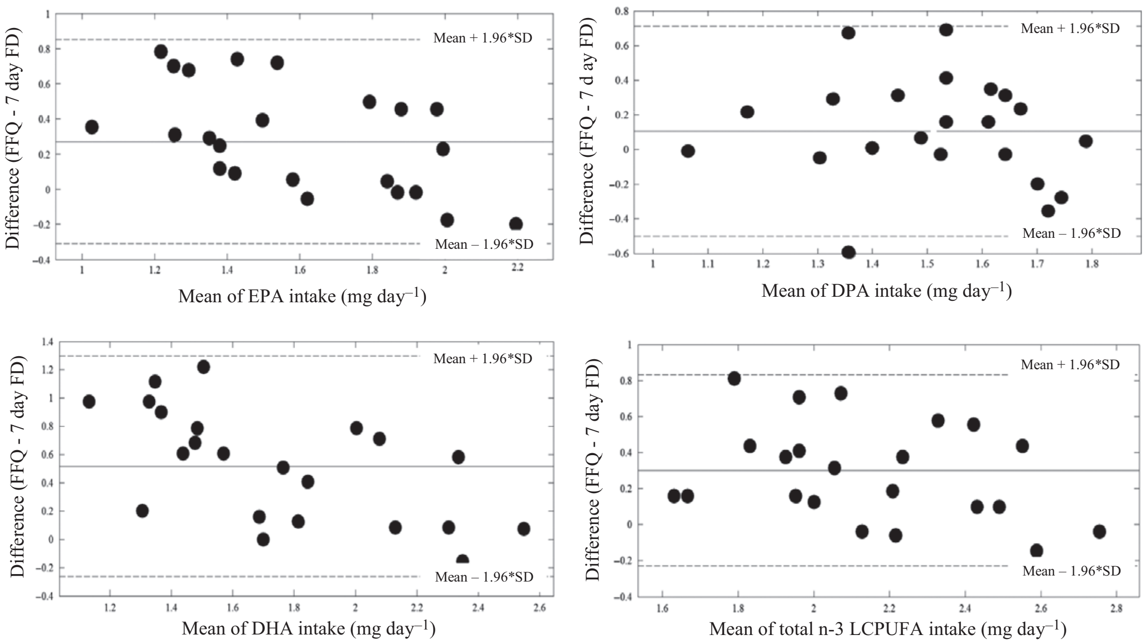

Figure 1 Bland–Altman plot: comparison of the agreement of dietary eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), docosahexaenoic acid (DHA) and total omega-3 long chain polyunsaturated fatty acid (n-3 LCPUFA) intakes determined using food frequency questionnaire and 7-day food diary, after log transformation. FD, Food Diary; FFQ, food frequency questionnaire.

In conclusion, the new FFQ developed in the present study demonstrates relative validity with respect to the assessment of *n*-3 LCPUFA intakes in Australian children. Further research is needed to optimise the FFQ to limit overestimation, as well as to validate the FFQ against biomarkers of *n*-3 LCPUFA status and to assess reproducibility of the method at different time points.

Transparent an accurate reporting of research studies

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained. The reporting of this work is compliant with STROBE guidelines.

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Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

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SR performed the data collection, statistical analysis and interpretation of the data and drafted the manuscript. KC participated in study design and assisted with the first draft of the manuscript. PLW co-authored the manuscript and was involved in conceptualisation of the study. BJM was the originator of the idea of the study, participated in the study design and assisted with the draft of the manuscript. All authors contributed to the manuscript, and read and approved the final manuscript submitted for publication.

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DIETETIC PRACTICE

The use of smartphone health apps and other mobile health (mHealth) technologies in dietetic practice: a three country study

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Keywords
behaviour change, dietetics, education, mHealth, smartphone applications.

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Abstract

Background: Smartphone health applications (apps) and other mobile health (mHealth) technologies may assist dietitians in improving the efficiency of patient care. The present study investigated the use of health apps and text messaging in dietetic practice and formulated intervention recommendations for supporting app uptake by dietitians based on the behavioural 'COM-B' system, where interactions between capability, opportunity and motivation influence behaviour.
Methods: A 52-item online survey tool, taking 20 min to complete, was developed and piloted, with questions exploring the use of health apps and text messaging in dietetic practice, types of apps dietitians recommended and that patients used, and barriers and enablers to app use in dietetic practice. The Australian, New Zealand and British dietetic associations distributed the survey to their members.
Results: A 5% response rate was achieved internationally, with 570 completed responses included for further analysis. Health apps, namely nutrition apps, were used by 62% of dietitians in their practice, primarily as an information resource (74%) and for patient self-monitoring (60%). The top two nutrition apps recommended were MyFitnessPal® (62%) and the Monash University Low FODMAP Diet® (44%). Text messaging was used by 51% of respondents, mainly for appointment-related purposes (84%).
Conclusions: Although the reported use of smartphone health apps in dietetic practice is high, health apps and other mHealth technologies are not currently being used for behaviour change, nor are they an integral part of the nutrition care process. Dietetic associations should provide training, education and advocacy to enable the profession to more effectively engage with and implement apps into their practice.

Introduction

Internationally in 2014, 39% of adults were overweight or obese and 9% had diabetes [(1)]. With escalating social, health and economic costs being incurred from obesity and its associated noncommunicable diseases (NCDs) [(2)], halting the rise of obesity and diabetes is a key target of the World Health Organization's Global Action Plan for the Prevention and Control of NCDs [(3)]. Addressing behavioural risk factors, such as unhealthy diets and physical inactivity, through behavioural counselling and lifestyle modification delivered by registered dietitians, can promote weight loss in individuals who are overweight or obese [(4,5)] and represents one scalable approach for reducing diabetes risk [(6–8)].

It has been calculated that for every NZ$1 (approximately £0.60) spent on dietetic intervention, there could be cost-savings of NZ$5.50 to $99 (£3.30 to

£59.40) to the primary healthcare system [9]. Despite these potential economic benefits, dietetic counselling is time-intensive, and regular face-to-face contact and support of patients is not always possible given the demand for dietetic input outweighs supply. For example, with a prevalence of overweight and obesity at 61.7% in the UK [10] and 8828 registered dietitians [11], there is approximately only one dietitian per 4555 individuals who are overweight or obese, and one dietitian per 7380 head of population.

Smartphones and their associated applications (apps) have become ubiquitous and accessible [12,13], particularly mobile health (mHealth) apps [14,15], leading to opportunities to broaden the reach of dietetic service delivery to those who may be unable to access traditional clinic-based treatments [16,17]. The use of health apps and mHealth technologies may improve the efficiency of patient care [17–19] and help achieve outcomes, such as weight loss and glycaemic control for a larger proportion of the population [20–23]. Health apps may also enable patients to manage their own health as a result of them tracking their behaviours and receiving feedback in real-time [19,24].

Current use and attitudes towards health apps and mHealth technology among the dietetic profession has not been investigated extensively. A small body of research conducted in Canada [25] has revealed enthusiasm and interest from the dietetic profession for using apps in practice, with 57.3% Canadian dietitian respondents reporting current health app use in practice. Another study specifically surveying 180 sports dietitians across five countries, including the UK, Australia and New Zealand [26], found that almost one-third of this niche profession used diet apps to assess and track their patient's dietary intake.

The identification of factors that influence the use of health apps by dietitians and their patients is necessary with respect to the design of interventions that will enable better implementation of apps into the nutrition care process and clinical practice. The COM-B model developed by Michie *et al.* [27], which proposes that behaviours develop from and influence interactions between three key components (i.e. capability, motivation and opportunity), is one framework that can be applied to analyse target behaviours and develop appropriate behaviour change interventions. Therefore, the present study aimed to investigate the nature of health app and other mHealth technology use by dietitians in the UK, Australia and New Zealand. A secondary aim was the formulation of intervention recommendations based on the COM-B system to support and facilitate the ongoing adoption of health apps by the dietetic profession.

Materials and methods

Survey development

The development and piloting of the survey instrument has been documented previously (Chen *et al.*, unpublished) [27]. Survey questions were designed to examine the use of smart devices and health apps by dietitians, recommendations dietitians gave to patients regarding health apps, patient use of health apps, barriers to health app use and continuing education topics of interest. Feedback and comments provided by the pilot respondents informed modifications to the survey design and question flow. Furthermore, questions exploring the use of other mHealth mediums (e.g. text messaging) and how dietitians used health apps as information resources were added, resulting in the final 52-item survey, taking approximately 20 min to complete. The survey was made available online (SurveyMonkey, Palo Alto, CA, USA) from 8 November 2015 to 26 January 2016 in Australia, 10 November 2015 to 28 January 2016 in New Zealand, and 21 January to 10 April 2016 in the UK.

Sample recruitment

Approval for the present study was provided by the Institutional Human Research Ethics Committee (approval number 2015/701). Dietetic associations for each country (Dietitians Association of Australia, Dietitians New Zealand, as well as the British Dietetic Association) were involved in disseminating the survey to its members via paid advertisement. Each dietetic association sent out two advertisements to their members containing a link to the online survey via their weekly member electronic newsletter, social media (Facebook) post, or via emails directly to each member. Eligible participants had to be an Accredited Practising Dietitian (Australia) or Registered Dietitian (UK, New Zealand). Incentives were offered to Australian and New Zealand respondents (i.e. the chance to win one of two Fitbit Flex bands, or a Fitbit Zip, respectively), although no incentive was offered to British respondents because of difficulty in arranging international delivery.

Statistical analysis

All data were collected from the online survey. Univariate analyses were undertaken to calculate frequencies and prevalence according to the use of health apps in practice, based on recommending health apps to patients, personal use of health apps, setting of dietetic practice, country of dietetic membership, length of practice, age and sex. Variables from the univariate analyses significantly associated with use of apps in patient care were modelled with multivariate logistic regression analysis. Differences in proportions were tested using the two proportion *Z*-test. All statistical analyses were conducted using SPSS, version 22.0 [28].

A behavioural analysis was conducted using the COM-B system [27] aiming to identify barriers and enablers to the use of health apps in dietetic practice. Feasible recommendations were formulated to support the use of health apps by the dietetic profession.

Results

An international response rate of 5% was achieved: 7% (418/5852) in Australia, 5% (29/550) in New Zealand and 4% (310/8008) in the UK. In total, 570 completed responses (316, 25 and 229 from Australia, New Zealand and the UK, respectively) were obtained and included for further analysis. The majority of respondents were female (95%) and aged between 26 and 35 years (44%) or 36 and 45 years (24%) (Table 1). Overall, respondents practised in the hospital setting, both inpatient (42%) and outpatient (39%), although, among Australian respondents, private practice was the top practice setting. The most common nutrition management areas were weight management (62%) and diabetes (57%).

Smart devices (e.g. smartphones, tablets, wearable devices and smart watches) were used by 74% of respondents in their dietetic practice, with smartphones being the most popular (69%) (Table 1). Australian respondents reported the greatest use of smartphones in practice (77%) and the British the lowest use (59%).

Other mHealth technologies

Text messaging was used by 51% of respondents in practice, and predominantly for appointment-related purposes (84%) (Table 2). British dietitians were less likely to use text messaging for appointment-related purposes (67%; $Z = -4.3$; $P < 0.0001$) compared to Australian dietitians (91%), although they were significantly more likely to use text messaging for patient reporting of progress (e.g. weight, blood glucose; 30%; $Z = 3.0$, $P = 0.003$).

Use of health apps in patient care

Smartphone health apps were used by 62% of respondents in patient care (Table 1). Length of practice, age and sex were not significantly associated with health app use in patient care within dietetic practice (Table 3). The odds of using health apps in patient care was 7.2 times (95% confidence interval = 4.0–13.0, $P < .0001$) greater among those who recommended apps to patients compared to those who did not, adjusted for personal use of apps, setting of dietetic practice and country of dietetic membership (Table 4).

Health apps were used in patient care within dietetic practice primarily as information resources (74%), followed by patient self-monitoring (60%) and as an extra support for patients (56%) (Fig. 1). Monash University Low FODMAP Diet®, MyFitnessPal® and ControlMyWeight™ by Calorie King were most commonly reported as information resources for providing materials on a specific diet, calorie, carbohydrate or nutrient content information, as well as for self-monitoring of food or weight. For British dietitians, Carbs and Cals comprised the most commonly used app to provide information and assistance to patients in carbohydrate counting and, in New Zealand, FoodSwitch® was used to guide the selection of alternative food choices.

Recommendation of health apps to patients

In total, 84% of respondents had recommended a health app to their patients and all these respondents had recommended nutrition-related apps. Each of these dietitians recommended a mean (SD) of 3.1 (1.9) different nutrition-related apps. MyFitnessPal® was the top recommendation, followed by the Monash University Low FODMAP Diet® app (Table 5). The specific commercial nutrition app recommended by dietitians was significantly related to the setting of dietetic practice ($\chi^2 = 49.0$; $P < 0.0001$). The use of Carbs and Cals was associated with dietitians working with hospital outpatients, whereas the Monash University Low FODMAP Diet® app and Easy Diet Diary® were associated with dietitians working in private practice. Almost half of respondents who recommended health apps in practice did not recommend physical activity or sleep apps to their patients (48%). For those that did, a mean (SD) of 2.4 (1.6) different physical activity and sleep apps were recommended, with Fitbit® (49%), MapMyRun™ (37%) and Couch-to-5K® (30%) being among the most recommended.

When asked to indicate what they recommended their patients use health apps for, the top responses from dietitians were raising awareness (70%), tracking (57%) and as a tool to assist in decision-making (50%). Fewer respondents recommended the use of apps for motivation (44%) or as an extra support for patients (43%). Patients were most commonly advised to use these apps at their own discretion (46%) and with no recommendation made by the dietitian. No significant associations ($P > 0.05$) were found in the frequency with which specific commercial apps were recommended for patient use.

Over half (54%) of the respondents reviewed patient progress with recommended health apps in at least some

Table 1 Participant characteristics and prevalence of smart device and health app use

Country	Australia (*n* = 316)		New Zealand (*n* = 25)		UK (*n* = 229)		Total (*n* = 570)	
	N	%	*N*	%	*N*	%	*N*	%
Sex								
Female	300	95	24	96	219	96	543	95
Male	16	5	1	4	10	4	27	5
Age (years)								
18–25	43	14	4	16	12	5	59	10
26–35	153	48	12	48	86	38	251	44
36–45	68	22	8	32	60	26	136	24
≥46	52	16	1	4	71	31	124	22
Length of practice (years)								
<1	33	10	1	4	10	4	44	8
1–5	108	34	13	52	42	18	163	28
5–10	68	22	6	24	52	23	126	22
10–20	65	21	3	12	62	27	130	23
>20	42	13	2	8	63	28	107	19
Setting of dietetic practice*								
Hospital inpatient	107	34	9	36	123	54	239	42
Hospital outpatient	89	28	14	56	120	52	223	39
Community	72	23	5	20	88	38	165	29
Private practice	133	42	3	12	26	11	162	28
Government and nongovernment organisations for public health	51	16	5	20	23	10	79	14
Other[†]	44	14	5	20	21	9	70	12
Area of nutrition management*								
Weight management	243	77	12	48	99	43	354	62
Diabetes	220	70	13	52	93	41	326	57
Gastroenterology	119	38	7	28	82	36	208	36
Nutrition support	64	20	7	28	109	48	180	32
Allergy and intolerances	89	28	5	20	57	25	151	26
Cardiology	112	35	11	44	17	7	140	25
Geriatrics	83	26	5	20	44	19	132	23
Paediatrics	71	22	4	16	56	24	131	23
Oncology	49	16	3	12	59	26	111	19
Mental health	36	11	6	24	32	14	74	13
Pregnancy/breast feeding	45	14	1	4	13	6	59	10
Other[‡]	68	22	9	36	57	25	134	24
Smart device*								
Smartphone	242	77	17	68	136	59	395	69
Tablet	101	32	8	32	58	25	167	29
Wearable (e.g. Fitbit, Jawbone)	40	13	5	20	14	6	59	10
Smart watch (e.g. Apple watch)	1	0.3	0	0	6	3	7	1
No use of smart device in practice	64	20	5	20	80	35	149	26
Personal use of health apps								
Yes	273	86	18	72	161	70	452	79
No	43	14	7	28	68	30	118	21
Use of health apps in patient care								
Yes	218	69	20	80	115	50	353	62
No	98	31	5	20	114	50	217	38
Recommend apps to patients								
Yes	288	91	22	88	168	73	478	84
No	29	9	3	12	61	27	93	16

*Respondents were able to make multiple selections for this question.

[†]Other categories includes responses with <10%: research/academia 7%, sports nutrition 4%, corporate 4%, food service management 4%, indigenous health 3%, food industry 2%, not currently working in dietetic practice 0.2%.

[‡]Other categories includes responses with <10%: renal 9.6%, sport nutrition 8%, neurology/neurosciences 8%, eating disorder 2%.

Table 2 Uses of text messaging in dietetic practice as reported by users (n = 421)

Country	Australia (n = 140) %	New Zealand (n = 13) %	UK (n = 63) %	Total (n = 421) %
Appointment related (e.g. reminding patients about or booking appointments)	91	92	67*	84
To motivate patients (motivational texts)	20	15	16	19
Patient reporting of progress (e.g. weight, blood glucose)	13	23	30†	19
To remind patients of their goals	9	38‡	17	13
Communication (with patients) (e.g. answer their questions, to sends photos of food eaten)	10	8	11	10
Communication (with staff)	4	8	6	5

*Comparing the UK to Australia, $Z = -4.3$; $P < 0.0001$.
†Comparing the UK to Australia, $Z = 3.0$; $P = 0.003$.
‡Comparing New Zealand to Australia, $Z = 3.1$; $P = 0.002$.

dietetic consultations. Reviewing data collected by apps as part of every follow-up consultation was infrequent (15%) and 30% of respondents rarely or never reviewed their patient's app records. The most common method of reviewing progress made with the app was through verbal means and without looking at the data (60%). A third of dietitians were able to review progress on their patient's smart device, but only 7% of respondents had direct access to the app data, primarily that from Easy Diet Diary® or MyFitnessPal®, which allowed patients to export or share the data with their dietitian.

Patients who use apps

A majority (72%) of dietitians reported that their patients had asked about or were using health apps at their own discretion, and these patients were typically adults under the age of 45 years (64%). Most respondents reported that patients from both sexes had asked them about or self-initiated use of health apps (53%). Weight (76%) was the primary health concern of these patients. Other concerns included general healthy eating (39%), diabetes (38%) and issues related to the FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides And Polyols) diet (35%). Among these patients, calorie counting apps were most asked about or used (71%), such as MyFitnessPal® (89%) (Table 5), followed by physical activity or sleep apps (41%), such as Fitbit® (61%) and MapMyRun™ (36%).

Barriers to using apps in practice

The barriers and reasons for why dietitians were not using health apps in their practice were primarily not having access to a smart device at work (51%) and a lack of infrastructure, such as no WiFi to support the use of apps (42%) (Fig. 2). Respondents also perceived that a lack of awareness about the best apps to recommend (41%) was a barrier to using apps in practice. There were no significant differences between reported barriers of respondents who currently used and those not currently using health apps in practice ($P > 0.05$).

Continuing professional development

Among respondents who recommended apps to patients, knowledge about the apps to recommend was mainly via personal use (77%), advice from another dietitian (56%) and other patients (28%). Although the majority (89%) of dietitians were interested in enhancing their knowledge about apps, only one-quarter (24%) currently indicated continuing professional development as a source of knowledge about what apps to recommend. Topics of particular interest were how to incorporate health apps into dietetic practice (72%) and accuracy or quality (including the credibility, usability, and incorporation of behaviour change techniques) of current health apps (68%). Dietitians also wanted information about the availability and range of current health apps in app stores (65%), as well as being kept informed about current research involving health apps in dietetic practice (61%).

Table 6 presents the results of a behavioural analysis of the use of health apps in dietetic practice conducted using the COM-B model. Capabilities typically related to dietitians' personal experiences with using apps and awareness of what apps to recommend. Opportunities for using apps were limited by an inadequate infrastructure and the availability of smart devices, although dietitians were motivated to use health apps in their practice. Subsequent intervention recommendations are designed to address the limitations identified in the each of the above components of the COM-B model.

Table 3 Factors influencing use of health apps in patient care within dietetic practice (n = 570) determined using univariate logistic regression for unadjusted odds ratios

Factor	Odds ratio	95% CI	*P* value
Recommending health apps to patients			
No	Referent		
Yes	9.8	5.7–17.0	<0.0001
Personal use of health apps			
No	Referent		
Yes	3.3	2.2–5.0	<0.0001
Setting of dietetic practice			
Private practice	Referent		<0.0001
Combination*	0.4	0.3–0.7	0.002
Hospital inpatient	0.2	0.1–0.4	<0.0001
Hospital outpatient	0.8	0.4–1.6	0.5
Nonclinical†	0.4	0.2–0.7	0.001
Country of dietetic membership			
UK	Referent		<0.0001
Australia	2.2	1.5–3.1	<0.0001
New Zealand	3.9	1.4–10.8	0.008
Length of practice (years)			
<1	Referent		0.3
1–5	1.1	0.6–2.2	0.7
5–10	1.3	0.9–3.6	0.1
10–20	1.1	0.6–2.3	0.7
>20	1.2	0.6–2.4	0.7
Age (years)			
18–25	Referent		0.8
26–35	0.8	0.4–1.4	0.4
36–45	0.8	0.4–1.6	0.6
≥46	0.9	0.5–1.7	0.8
Sex			
Male	Referent		
Female	1.5	0.7–3.3	0.3

*Respondents were able to select all the different settings which they worked in, therefore 'combination of settings' is the categorisation of respondents working in a combination of hospital inpatient, outpatient and private practice settings, rather than only in one area.
†Nonclinical settings included: Community, government and non-government organisations for public health, research/academia, sports nutrition, corporate, food service management, indigenous health, food industry, not currently working in dietetic practice.
CI, confidence interval.

Table 4 Factors influencing use of health apps in patient care within dietetic practice (n = 570) determined using multivariate logistic regression for adjusted odds ratios

Factor	Odds ratio*	95% CI	*P* value
Recommending health apps to patients			
No	Referent		
Yes	7.2	4.0–13.0	<0.0001
Personal use of health apps			
No	Referent		
Yes	2.5	1.6–4.1	0.0001
Setting of dietetic practice			
Private practice	Referent		0.01
Combination†	0.6	0.3–1.1	0.12
Hospital inpatient	0.3	0.1–0.6	0.0005
Hospital outpatient	0.8	0.4–1.9	0.6
Nonclinical‡	0.6	0.3–1.1	0.07
Country of dietetic membership			
UK	Referent		0.01
Australia	1.5	1.0–2.3	0.07
New Zealand	4.8	1.5–15.1	0.008

*Each factor was adjusted for all other variables in the table.
†Respondents were able to select all the different settings which they worked in, therefore 'combination of settings' is the categorisation of respondents working in a combination of hospital inpatient, outpatient and private practice settings, rather than only in one area.
‡Nonclinical settings included: Community, government and non-government organisations for public health, research/academia, sports nutrition, corporate, food service management, indigenous health, food industry, not currently working in dietetic practice.
CI, confidence interval.

Discussion

The present study provides valuable insights into the use of smartphone health apps and other mHealth technologies by dietitians in the UK, Australia and New Zealand, and also outlines intervention recommendations formulated against the COM-B system to support the adoption of health apps into dietetic practice. Most dietitians used health apps in patient care within their practice, mainly as information resources, and approximately half used text messaging for appointment-related purposes, although use for behaviour change was less common. Training, education and advocacy were identified as factors to facilitate the incorporation of health apps into dietetic practice and work systems.

Australian and New Zealand responding dietitians (approximately 5% of total membership) reported high rates of using smartphone diet and nutrition apps in their practice and, although a lower rate was observed in the UK, it remained at one in two dietitians. The uptake of health apps by dietitians in this survey is twice that reported by specialist sports dietitians [(26)], and this is possibly explained by the limited availability of specialist sports nutrition-related apps. Variations in smartphone ownership between countries [(12)] or temporal factors affecting the availability and uptake of mHealth apps [(13,14,30)] may also provide explanation of why health app uptake among dietitians in this survey is higher than that of previous surveys [(25)]. Although it is possible that self-selection bias favoured respondents who were app users or had an interest in technology, our respondent characteristics are comparable in age, sex and setting of practice to dietetic demographic data from their country of dietetic membership [(30,31)].

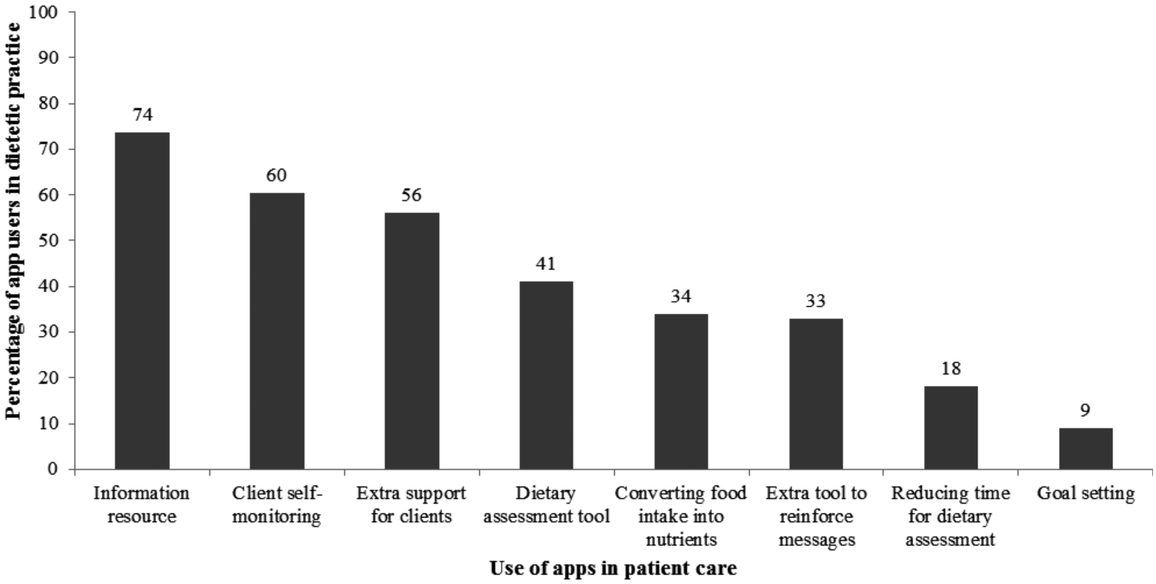

Figure 1 Frequency of distribution of the uses of apps in patient care among app users in dietetic practice (n = 353). Note that respondents were able to make multiple selections for this answer.

Table 5 Top 5 nutrition-related applications by country and combined, as recommended by dietitians and as of interest or self-initiated by patients (as reported by dietitians)

Country	Australia (n = 288*; 242†)		New Zealand (n = 22*; 20†)		UK (n = 168*; 151†)		Countries combined (n = 478*; 413†)	
Rank	App	%	App	%	App	%	App	%
Apps recommended by dietitians								
1	Monash University Low FODMAP Diet® by Monash University (Australia)	63	Foodswitch® New Zealand by The George Institute for Global Health (Australia)	68	Calorie Counter by MyFitnessPal®, Inc. (USA)	67	Calorie Counter by MyFitnessPal®, Inc. (USA)	62
2	Calorie Counter by MyFitnessPal®, Inc. (USA)	59	Calorie Counter by MyFitnessPal®, Inc. (USA)	55	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	56	Monash University Low FODMAP Diet® by Monash University (Australia)	44
3	Easy Diet Diary® by Xyris Software (Australia)	47	Monash University Low FODMAP Diet® by Monash University (Australia)	36	Coeliac UK – Gluten Free app by Coeliac UK (UK)	11	Foodswitch® Australia/ New Zealand (Australia)	31
4	Foodswitch® by Bupa Australia Health Pty Ltd (Australia)	44	Easy Diet Diary® Calorie Counter NZ by Xyris Software (Australia)	32	Monash University Low FODMAP Diet® by Monash University (Australia)	8	Easy Diet Diary® Australia/ New Zealand by Xyris Software (Australia)	30
5	ControlMyWeight by CalorieKing Wellness Solutions (Australia)	34	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	18	Calorie Counter & Diet Tracker by Calorie Count (USA)	8	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	27
Apps which patients were interested in or had self-initiated in use								
1	Calorie Counter by MyFitnessPal®, Inc. (USA)	78	Calorie Counter by MyFitnessPal®, Inc. (USA)	85	Calorie Counter by MyFitnessPal®, Inc. (USA)	81	Calorie Counter by MyFitnessPal®, Inc. (USA)	79
2	Monash University Low FODMAP Diet® by Monash University (Australia)	32	Monash University Low FODMAP Diet® by Monash University (Australia)	30	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	46	Monash University Low FODMAP Diet® by Monash University (Australia)	22

Table 5. Continued

Country Rank	Australia (n = 288*; 242†) App	%	New Zealand (n = 22*; 20†) App	%	UK (n = 168*; 151†) App	%	Countries combined (n = 478*; 413†) App	%
3	ControlMyWeight™ by CalorieKing Wellness Solutions (Australia)	26	Foodswitch® New Zealand by The George Institute for Global Health (Australia)	30	Calorie Counter & Diet Tracker by Calorie Count (USA)	13	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	21
4	Calorie Counter & Diet Tracker by Calorie Count (USA)	22	Carbs and Cals – Diabetes and Diet by Chello Publishing Limited (UK)	20	My Diet Coach by InspiredApps (A.L) Ltd (USA)	12	Calorie Counter & Diet Tracker by Calorie Count (USA)	18
5	Foodswitch® by Bupa Australia Health Pty Ltd (Australia)	21	ControlMyWeight™ by CalorieKing Wellness Solutions (Australia)	10	My Food Diary by My Food Diary (USA)	10	ControlMyWeight™ by CalorieKing Wellness Solutions (Australia)	16

*Number of dietitians recommending apps.
†Number of dietitians reporting on behalf of patients.

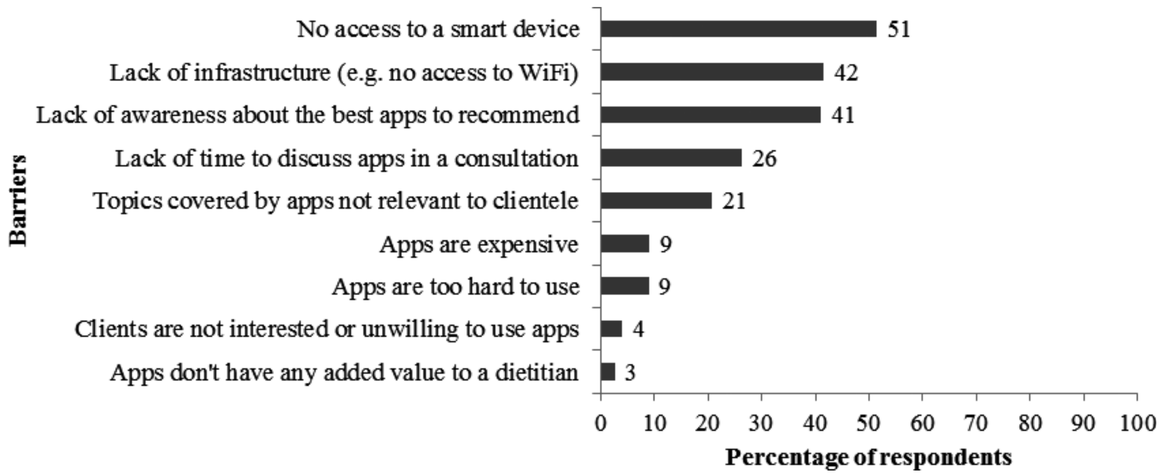

Figure 2 Barriers and reasons for why dietitians do not use health apps in their practice (n = 570). Note that respondents were able to make multiple selections for this answer.

App use in patient care was associated with recommending apps to patients, personal use of health apps and the setting of dietetic practice (with dietitians in private practice being more likely to use apps compared to those in the hospital inpatient setting) but not associated with dietitian age, sex and length of practice. Our findings are consistent with earlier studies investigating the factors that influence entrepreneurial dietitians' use of computers as a professional tool [(32)]. Taken together, the results suggest that familiarity with apps and the presence of supportive environments are enablers of app use. Furthermore, differences in the funding schemes and infrastructural capacities (e.g. access to WiFi and workplace supplied smart devices) between private practice and the National Health Service (NHS) could also account for the higher uptake in private practice.

With 62% of US smartphone owners searching for information about a health condition on their phone [(33)], health apps could provide access to disease-management relevant information. From this survey, health apps were primarily used as an information resource, although the material derived was mainly restricted to specific diets, the calorie or carbohydrate content of foods, and suggestions for alternative food choices. Reviews of nutrition apps have determined their limited functionality beyond a food record [(34)], the limited provision of educational material and recommendations on how to achieve healthy dietary patterns [(35,36)], and inadequate considerations of disease or patient-specific recommendations [(37)]. Similarly, personalised patient education was largely absent from the top functions of diabetes apps from commercial app stores and those documented in the literature [(24,38)].

Although the provision of information may increase knowledge of health behaviours, education alone is insufficient to promote behavioural self-management without more theory-driven behaviour change techniques [(39,40)].

Table 6 A behavioural analysis of the use of health applications (apps) in dietetic practice using the COM-B model, and intervention recommendations for professional associations of dietitians and professional education providers to facilitate uptake of health apps by the dietetic profession

COM-B component	Health applications (app) use in dietetic practice	Intervention recommendations
Physical capability	• Most dietitians have personal experience with using apps. • For those dietitians who have had less exposure to health apps, increasing personal familiarity with apps could increase their physical capabilities with using and recommending apps.	• To increase the skills and knowledge of dietitians: Provide reviews of new release health apps in member newsletters regarding the scientific accuracy and quality (including the credibility, usability, and incorporation of behaviour change techniques) of the app. • Include a regular 'spotlight' section within member newsletters reviewing the quality of popular commercial health apps, and their applications in different nutrition management areas. • Deliver training and education through continuing professional development workshops, seminars and webinars, or short YouTube® video-bites. Content should cover basic features and functions of apps, utility of these different apps in dietetic practice and strategies for engaging patients with health apps. Opportunities to use apps should be included. • Develop a framework guiding dietitians in how to select scientifically accurate nutrition and physical activity apps with high usability features and behaviour change techniques.
Psychological capability	• Dietitians lack knowledge and awareness of the best apps to recommend to their patients.	
Physical opportunity	• It appears that current practice environments do not adequately support opportunities for health app use. Some dietitians reported no access to smart devices at work and a lack of infrastructure, such as Wi-Fi, especially within the hospital setting. • Health apps lack integration into dietetic practice, particularly if apps require switching between different information systems.	• Dietetic association-led advocacy for environmental restructuring within health systems to promote the availability of smart devices in the workplace. • Dietitian-led app design, supported by professional associations, in collaboration with app developers for the development of reputable practice-relevant health apps that are easily incorporated into dietitians' existing work systems, could increase the opportunities to use apps in dietetic practice. • Collaborations with developers of existing health apps, to form partnerships where client app data can be exported into dietitians' record systems for easy access and viewing in consultations.
Social opportunity	• The second most common source of knowledge about apps to recommend was via other dietitians.	• A social context which enables and encourages app use could enhance uptake of apps by dietitians. This may include communication through interest groups and forums to share ideas on app utility for nutrition care. Dietitians may be encouraged to use apps in practice if aware their colleagues also engage with them. • Dietetic associations could partner with other health professionals (such as doctors, nurses, and other allied health members) to promote greater use of apps in the workplace.

Table 6. Continued

COM-B component	Health applications (app) use in dietetic practice	Intervention recommendations
Reflective motivation	• Dietitians are interested in continuing professional development, suggesting they are motivated to learn about and use apps. Current evaluations include the perception that apps are expensive and hard to use.	• Strategies used to increase physical and psychological capabilities could be applied to influence the reflective and automatic motivations of dietitians and increase their confidence with using and recommending apps in their practice.
Automatic motivation	• Most respondents perceive that apps add value to dietetic practice. • Use of apps in practice is associated with dietitians recommending apps to patients. Thus automatic pre-formed assessments of the suitability of an app for patients is linked with use.	• To reshape any pre-existing negative evaluations of apps, dietitians should receive greater education about the potential advantages that apps could offer in supporting practice and enabling patients to more effectively self-manage their health. It is also important that dietitians have an understanding of the disadvantages and limitations of current apps, to minimise potential feelings of threat in relation to apps. • Increasing dietitians' understanding and awareness of the effectiveness of app use through evidence summaries

The only behaviour change strategy present in many health apps is self-monitoring [24,35,41–45]. Yet, it is recognised that self-monitoring is more effective at changing healthy eating and physical activity behaviours when accompanied by at least one additional technique derived from control theory [46]. Specific goal setting is one such technique, although few dietitians have reported using health apps for this purpose. This may reflect how many commercial apps only focus on a limited range of predefined goals (e.g. weight loss targets) but fail to allow users to set other individualised health behavioural goals. One such exception is Dietitians of Canada's eaTracker, which allows users to select from 87 ready-made behaviour based goals or to create their own goals [47]. There is potential for this gap to be bridged if the personalised goals that dietitians negotiate with their patients could be linked into health apps for subsequent self-tracking.

Health apps should not replace behavioural counselling by dietitians but can complement it. Randomised controlled trials have shown that people receiving smartphone apps alone did not experience significant weight loss [48,49]. Instead, significant weight loss was observed when mHealth or technology-based interventions were used in conjunction with counselling [50], irrespective of the intensity of counselling [48], or supported by education [51]. Similarly, in diabetes care, mHealth interventions with patient and health professional interactions were more likely to be effective in improving primary outcomes, such as haemoglobin A1C [52]. The input of human coaches can provide patients with support to sustain engagement and adherence to mHealth interventions [53] and the feedback and tailored advice facilitates behaviour change.

Dietary assessment can often be a time-intensive component of the nutrition care process. With the majority of nutrition apps being calorie counters, they are able to automatically convert food inputs into calorie and nutrient outputs [35]. Studies have shown that dietary assessments conducted through mobile phones and nutrition apps have similar validity and reliability [54], as well as moderate to good correlations for measuring nutrition and energy intakes [55]. In a review of 23 dietary apps that estimated energy intake, the mean energy variation compared to conventional methods was 127 kJ (approximately 30 kCal; 95% confidence interval −45 to 299) [35]. This function of nutrition apps could be utilised to reduce the time spent on dietary assessment and allow dietitians to focus on behavioural counselling [56]. However, this potential is not yet realised because many nutrition apps do not allow data sharing of food diary records with dietitians [35]. Therefore, the limited integration of apps in current dietetic work makes it difficult for dietitians to view and access records when conducting dietary assessments.

Differences in the structure of health systems and practice settings across countries can influence the uptake and use of apps with patients. Notable between-country variations included the popularity of the Monash University Low FODMAP diet® app as the top app recommended by Australian dietitians, which is attributable to the predominance of irritable bowel syndrome cases presenting at private practices [57]. Carbs and Cals was most popular among British dietitians, which may be a result of more diabetic patients being serviced by the dietitians working in the NHS [58]. However, MyFitnessPal® consistently retained its popularity, as also noted in other studies of dietitians [25,26], their patients and the general public [29,59]. Of the free nonsubscription nutrition tracking mobile apps reviewed in one study, MyFitnessPal® was found to be the most beneficial for promoting therapeutic lifestyle change in patients with diabetes because of its extensive food database and ability to integrate with other apps and devices

[37]. However, the use of MyFitnessPal® should be met with caution because the food database is primarily US sourced and not specific to other countries. Furthermore, the cited study failed to account for other aspects of quality [37], such as the incorporation of a limited array of behaviour change techniques [35].

Fitbit® wearable activity trackers and MapMyRun™ were the top physical activity apps recommended, in agreement with findings from previous studies [29,59]. Efforts to increase physical activity are also important in the management of chronic disease [4,7]. Although dietitians were comfortable in recommending nutrition apps, only half of those recommending apps suggested a physical activity app. This may be because of insufficient knowledge about the types of physical activity apps and wearables on the market, or the assumption that physical activity advice is outside the scope of dietetic practice. Unlike nutrition apps, which require manual logging of diet, physical activity apps can passively track activities by linking to wearable devices or smartphone accelerometers. One study found that, for each additional day of physical activity logging, a weight loss of 0.03 kg could be achieved, whereas the number of days food was logged was not significantly associated with weight loss [50]. Dietitians should seek to include physical activity apps in their practice and professional education is indicated to increase dietitians' competency at recommending physical activity apps.

Harnessing mHealth is not only limited to smartphone apps, but also can encompass other functions of smartphones, such as text messaging. A meta-analysis showed that, when text messaging was incorporated into health behaviour change interventions for weight management, intervention participants lost a mean of 2.56 kg compared to 0.37 kg for controls. [60]. With regard to diabetes, individuals receiving support or education via mobile phones using text messaging demonstrated significant improvements in glycaemic control as measured by haemoglobin A1c [61,62]. Yet, despite the evidence, there is an underutilisation of text messaging in dietetic practice to remind patients of their goals, motivate change or monitor progress. Rather, text messaging is widely used for making appointments. Understandably, private practice constraints in time and reimbursement funding may limit a dietitian's ability to send text messages to patients, and the use of automated tailored text messages could provide reminders and motivation for patients.

mHealth technologies and health apps are accepted among patients in their chronic disease management [63] and users perceive them to be effective in promoting healthy eating and exercise [64]. However, a growing number of evaluations describe the need for a greater evidence base for diabetes [23,38,42,65] and nutrition or physical activity apps [35,41,43,45,66–74]. Therefore, to prevent patients from being misguided by false information, dietitians need to be well informed about the quality and effectiveness of apps that can be recommended to their patients. Training through professional organisations is needed to keep dietitians up-to-date with these emerging mHealth technologies. For example, the Academy of Nutrition and Dietetics in the US provides app reviews conducted by registered dietitians, which are included in their *Food & Nutrition* magazine [75]. Furthermore, as highlighted in the key recommendations based on the COM-B system, there is a place for dietetic associations to engage in advocacy regarding the creation of supportive practice environments for the use of health apps.

Although concerted attempts were made to achieve a representative sample across all countries, a low response rate and selection bias are limitations of the present study. Those dietitians who were more technologically aware may have been more likely to respond compared to non-responders; however, as stated previously, the profile of respondents was similar to the demographic characteristics of the broader dietetic profession [30,31]. Additionally, we did not survey patients directly to investigate their use of health apps, and understanding was only extrapolated from dietitian-reported data. In future studies, it would be interesting to compare the prevalence and perception of health app use among patients with obesity and chronic diseases against that of dietitians.

Conclusions

There is a high reported usage of smartphone health apps in dietetic practice. Health apps appear to support clinical practice through the delivery of more patient-centred functions, albeit not yet focusing on behaviour change. Their benefits with respect to improving the efficiency of dietetic service delivery, however, are not yet being realised. Because dietitians will encounter increasing numbers of patients interested in or self-initiating app use, dietitians must develop an understanding of evidenced-based apps with good usability for use in practice. Dietetic associations have a role in providing training, education and advocacy to enable the profession to more effectively engage with and implement apps into their practice.

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Conflict of interests, source of funding and authorship

JC, JL, AB and RH declare that they have no personal or financial conflict of interests. MAF has developed food based apps, although not for weight management. JC (a PhD student at the University of Sydney) is funded by the Australian Postgraduate Award scholarship.

JC, JL, AB, RH and MAF contributed to the conception and design of the study. JC conducted the research, analysed the data and drafted the first version of the manuscript. JL, AB, RH and MAF contributed to writing and editing the manuscript. MAF had primary responsibility for the final content of the manuscript. All authors have critically reviewed the manuscript and approved the final version submitted for publication.

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DIETETIC PRACTICE

Patient-centred care to improve dietetic practice: an integrative review

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Abstract

Background: Patient-centred care (PCC) is associated with significant improvements in patients' health outcomes and healthcare systems. There is an opportunity to better understand PCC in dietetics. Thus, the present integrative review aims to critically synthesise literature relating to PCC in dietetics.
Methods: A systematic literature search was conducted between February and March 2016. Studies were included if they (i) involved dietitians and/or patients who had participated in an individual dietetic consultation; (ii) related to one or more components of PCC; and (iii) were empirical full-text studies in English, involving adult participants, published between 1997 and 2016. Following title and abstract screening, full texts were retrieved and independently assessed for inclusion by two of the investigators. Two independent investigators conducted data extraction and quality assessment using the Mixed Methods Appraisal Tool. Study findings were analysed thematically using meta-synthesis. Twenty-seven studies met the inclusion criteria.
Results: Six themes were discovered inductively: (i) establishing a positive dietitian–patient relationship; (ii) displaying humanistic behaviours; (iii) using effective communication skills; (iv) individualising and adapting care; (v) redistributing power to the patient; and (vi) lacking time for PCC practices. The first three themes were closely related. Studies used a broad range of methodological designs. Limitations of the studies included a lack of reflexivity and a lack of representativeness of the study population.
Conclusions: It is apparent that dietitians require good communication skills and humanistic qualities to build positive relationships with patients. Patients strongly desire individualised nutrition care and greater involvement in care. Ensuring dietitians are able to incorporate patient-centred practises during care requires further research.

Introduction

Patient-centred care (PCC) is a priority for modern healthcare systems [(1,2)]. Patient-centred care increases patient and doctor satisfaction, enhances relationships between clinicians and patients, better engages patients in care, increases patients' quality of life [(3)], and is associated with significant improvements in clinical outcomes [(4–7)]. Benefits to healthcare systems and organisations have also been recognised, including increased healthcare effectiveness [(2)], decreased healthcare costs [(3,6,8)] and reduced length of stay [(6,7)]. Internationally, the importance of PCC has been endorsed by the World Health Organization [(1)], the United Kingdom Health Foundation [(2)] and the United States Institute of Medicine [(9)]. In Australia, implementation of PCC has been supported by the Australian Charter of Healthcare Rights [(8)], the National Safety and Quality Framework [(10)] and the National

Chronic Disease Strategy, as well as being endorsed by the Australian Health Ministers Conference in 2005 [11,12]. Clearly, PCC is emerging as a core component of healthcare systems, warranting further attention.

There are a variety of definitions of PCC. The World Health Organization defines PCC as care that 'meets people's expectations and respects their wishes'[1]. Similarly, the UK Health Foundation defines PCC as coordinated, personalised and enabling care that afford people dignity, respect and compassion [2]. Three systematic [5], integrative [13,14] and narrative [14] reviews have described 15 dimensions of PCC. Examples include: 'essential characteristics of the clinician'; 'clinician–patient relationship' [5,14] or 'therapeutic relationship'[13]; 'patient as a unique person'[5,13,14]; 'clinician–patient communication' [5,14]; and 'patient involvement in care' [5,13,14]. In line with this, an abundance of research now exists to better understand how PCC can be defined, implemented and measured [2,7,15–18]. This research is important to facilitate a shift from the theory of PCC to practice.

Dietitians are health professionals who support patients to improve their dietary behaviours [19]. Dietitians practice in a variety of settings and contexts; usually through individual (also known as one-on-one) consultations [19–21]. Aspects of PCC have been emphasised in international dietetic competency standards since 1997 [19–21]. Currently, the Canadian and European competency standards advocate for the respect of patients' individuality and autonomy and promote enablers of PCC, such as clinician–patient communication [20,21]. Competency standards for dietitians in Europe, Australia, the USA and Canada encourage partnership with patients, involving collaboration between clinicians and patients, patient involvement in decision-making, and formation of relationships based on mutual respect, trust and shared objectives [19–21]. Evidently, the dietetic profession recognises the importance of a patient-centred approach to practice.

Evidence suggests there is opportunity for dietitians to enhance the care they provide by ensuring that it is patient-centred [22,23]. Despite an emerging body of literature on PCC in dietetics, there have been no published reviews on PCC involving dietitians and their patients. One literature review has examined patient-centred outcomes in dietetic research; however, it focused on 'patient participation' [24] and therefore did not encompass the previously mentioned variety of PCC dimensions [1,2,5]. Furthermore, it is more than a decade old and, because the average monthly publication rate of PCC has increased from three to seven between 2000 and 2011[7], research in the area of PCC has clearly progressed [7]. There is need to better understand how PCC can be integrated into dietetic practice and gain evidence of its effectiveness.

One way to gain this understanding is to undertake an integrative review. An integrative review is a type of knowledge synthesis that examines qualitative and quantitative findings to enable a comprehensive overview of the literature [25]. Integrative reviews can provide insight on a phenomenon of interest to inform future research, practice and policy [26]. This type of review is particularly appropriate for the topic of PCC in dietetics because the emerging body of literature includes a diverse range of empirical studies. Therefore, the present integrative review aimed to synthesise existing literature on the topic of PCC in dietetics.

For the purpose of this review, the definition of PCC and its respective dimensions encompasses descriptions provided by the three previous reviews [5,13,14]. Thus, PCC pertains to care that affords patients respect, empathy and compassion; sees the patient as a unique individual who's needs, values, beliefs, and expectations are respected; and views the clinician-patient relationship as a 'partnership' that is collaborative, reciprocal and engaging.

Materials and methods

Overview

By contrast to a systematic review, which addresses a specific clinical question, an integrative review synthesises a diverse range of literature (both qualitative and quantitative), to provide a comprehensive understanding of the phenomenon of interest [25]. Although the diversity and inclusivity of integrative reviews allows for a rich understanding of the topic, it also makes data analysis more complex [25,26]. To maintain a rigorous review process, this integrative review was conducted utilising the five steps outlined by review guidelines [25]: problem identification, literature search, data evaluation, data analysis and presentation.

Sample and inclusion/exclusion criteria

A lack of understanding on how to reorientate dietetic consultations to be more patient-centred is the problem this integrative review addresses. From this, the review question (what is currently known about PCC in dietetic practice?) was developed using the SPIDER tool (Sample, Phenomenon of Interest, Design, Evaluation and Research type) [27]. Studies were included if: (i) an aspect of the study related to one or more dimensions of PCC based on those described in three reviews [5,13,14] (e.g. 'shared decision-making', 'clinician–patient relationship', 'clinician–patient communication'); (ii) the study involved qualified dietitians and/or patients participating in individual consultations where nutrition care was delivered by a dietitian; and (iii) the study was empirical, full-text, in English, involving adult participants, published between 1997 and 2016. This time period was chosen because the first mention of PCC in dietetic care came from the Professional Standards for Dietitians in Canada published in 1997 [(20)].

Studies that involved group-based patient-centred interventions were excluded because the group dynamic is likely to influence the clinician–patient relationship. Furthermore, care provided within this context is not necessarily designed to cater for individual patients' needs and preferences. Studies involving student dietitians were excluded because they are not yet classified as 'competent'. Studies involving dietitians and other healthcare professionals as one group were excluded if data relating specifically to dietetics was unable to be extracted. Paediatric populations were excluded as a result of the focus of 'family-centred care' in this population group [(28)].

Literature search

A systematic literature search was conducted between February and March 2016. Because computerised searches only reveal approximately 50% of eligible studies [(25)], ancestry searching and journal hand-searching were also conducted. With the assistance of a health librarian, a systematic, computer-based literature search was conducted. Databases searched included MEDLINE, PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL) and SCOPUS. Boolean connectors AND, OR and NOT were used to combine search terms. Medical subject headings (MeSH), were used in the execution of PubMed and MEDLINE database searches. Search terms relating to PCC included: 'patient-centred care', 'patient-focused care', 'client-centred care', 'person-centred care', 'professional–patient relationship', 'health professional–patient relationship', 'clinician–patient relationship', 'patient empowerment' or 'patient-participation'. Three search terms for the sample of interest were used: 'dietitian', 'dietician' or 'dietetics'. Google Scholar and PUBMED were used to obtain additional articles identified by journal hand searching. All database search results were imported into EndNote prior to screening.

One investigator (IS) screened the title and abstracts of all 642 studies initially identified through the search using the inclusion and exclusion criteria. Studies that appeared to meet the inclusion criteria based on their titles and abstracts were retrieved for further review. A total of 128 studies were included from the initial screen. Two investigators (IS and CB) independently assessed the 128 full texts using inclusion and exclusion criteria to establish a final number of included studies. Disagreement occurred in the case of two studies; thus, a third assessor (LB) was present to resolve these discrepancies and a final decision was made. Studies excluded were coded based on the exclusion criteria.

Data extraction and evaluation

Data were extracted using a table developed by the research team. Data extracted included: author, year, country, aim, research design, sample, participants (dietitians and/or patients) and key findings that related to PCC with reference to the three reviews [(5,13,14)]. To ensure accuracy, two investigators (IS and CB) extracted the data. Critical appraisal of the data was conducted by two independent investigators (IS and CB) using the Mixed Methods Appraisal Tool (MMAT), version 2011 [(29)]. Agreement was reached on 82.5% of the appraisal items. Where scores differed, discrepancies were resolved with input from all members of the research team during meetings. Because the MMAT allows for simultaneous evaluation of all empirical literature; qualitative, quantitative and mixed methods studies [(29)], it is particularly appropriate for an integrative review. This tool has been shown to be efficient (15 min per study), user-friendly and have high intra-class correlation [(30)].

Data analysis

This integrative review included both qualitative and quantitative studies, which were analysed thematically using meta-synthesis. Meta-synthesis is an integrative interpretation of results to offer a novel finding [(26)]. Data analysis involved iterative comparison of studies to cluster recurrent themes and sub-themes [(25)]. All investigators participated in the data analysis. Findings of all studies were independently read and re-read, coded and organised into categories, which were then compared across studies to identify relationships and themes [(25)]. This process was continued until data saturation was achieved, where no new themes emerged.

Results

Descriptive findings

The (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram (Fig. 1) shows the identification of an initial 642 possible studies; 27 met the inclusion criteria (Table 1). Studies used a broad range of methodological designs, including qualitative focus group and/or interviews (n = 7) [(22,31–36)], descriptive quantitative studies (n = 13) and intervention studies (n = 5). A variety of descriptive quantitative designs were utilised, including Delphi studies (n = 3) [(37–39)], observational studies (n = 2) [(23,40)] and questionnaires/surveys (n = 5) [(41–45)]. Three sequential qualitative–quantitative studies were also

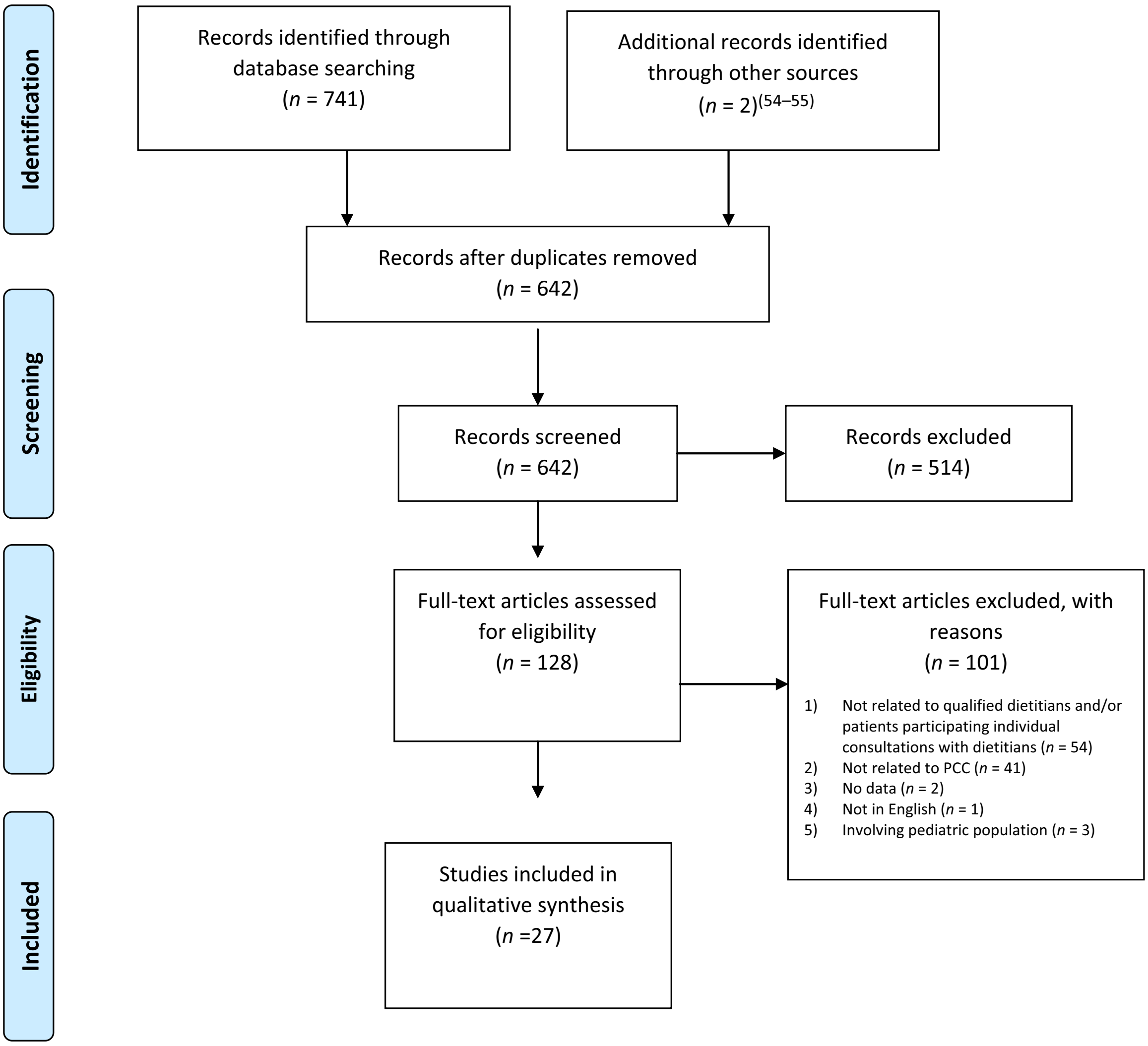

Figure 1 PRISMA flow diagram. PCC, patient-centred care.

included [31,46,47]. Intervention studies included both randomised controlled trials (n = 3) [48–50] and nonrandomised prospective cohort studies (n = 2) [51,52].

Participant numbers for all 27 studies ranged from seven to 1158; most (n = 24) were between nine and 258, with the exception of one larger study (n = 1158) [44]. The majority of studies (n = 22) were published between the years 2009 and 2016 [23,31–34,36–38,40–44,46,48,50–55]. Studies were mostly conducted in Europe (n = 7) [33–35,40,41,44,52], Canada (n = 6) [23,32,38,39,42,43], the USA (n = 6) [22,37,45,49–51] and Australia (n = 6) [31,36,46,47,53,54]. Of the seven European studies, six were from the UK, one was from the Netherlands [52]. One study was conducted in Brazil [48] and another in Israel [55].

Eight studies involved only patients, including all five intervention studies and three qualitative studies [34,35,48–52,54]. Nine quantitative [31,37–39,42,44–47] and three qualitative studies [22,32,36] involved dietitians only. Four quantitative [23,40,41,43] and three qualitative studies [33,53,55] involved both patients and dietitians. Dietitians worked in a variety of settings, including hospital inpatient and outpatient [31–33,46,47,53,55], community and/or private practice [31,36,38,39,44,46,47,53]. Others also worked in research and education [36,44], and some were specialised, such as in the management of diabetes [40] or inflammatory bowel disease [41]. Of the studies that detailed the patients' medical conditions (n = 12), 10 included patients who were suffering from a chronic condition, including diabetes [23,33,40,53–55], obesity [23,33–35,43,49,53,55], cardiovascular disease [23,33,43,55] and cancer [52]. One study included dietitians who also worked with patients with eating disorders and high-risk pregnancy [23].

Only four studies explicitly referred to PCC in their aims [22,36,39,51], four mentioned shared decision-making

Table 1 Description of included studies in order of methodological design

Author (year); Country	Design	Participants/ Sample size ($n = P$)	Aim	MMAT Score†	Findings related to PCC
Almeida, Segurado [48]; Brazil	RCT	Patients (n = 53)	Evaluate impact of nutritional counselling programme on prevention of morphologic and metabolic changes in patients living with HIV/AIDS receiving HAART	**	No significant difference between intervention and control groups
Bowen, Ehret [49]; USA	RCT	Patients (n = 164)	Develop, implement and evaluate IIP based on MI to motivate participants within dietary study of WHI to meet study's nutritional goals	***	Control group significantly reduced percentage of energy from fat between baseline and follow up; difference between groups = 2.6% difference ($P < 0.001$) Intervention group tended to complete more fat scores (monitoring) and more intervention sessions (attendance)
Locher, Bonner [50]; USA	RCT	Patients (n = 43)	Evaluate feasibility/efficacy of multilevel self-management intervention to improve nutritional status in a group of high-risk older adults	****	No main effect of intervention for either caloric intake or weight
Everett, Wolf [51]; USA	Nonrandomised prospective cohort	Patients (n = 71)	To evaluate the effect of patient-centred nutrition counselling methods on clinical outcomes in SLE patients enrolled in a CVD prevention counselling programme	***	Between baseline and 6 months: Percentage calories from fat (P = 0.011) and grams of sodium (P = 0.06) significantly reduced between Percentage of diet rich in fruit and vegetables ($P < 0.001$), high in fibre (P = 0.011), and following low cholesterol diet (P = 0.034) significantly increased Intervention resulted in significant loss of weight (−1.64 kg, P = 0.025)
van den Berg, Rasmussen-Conrad [52]; the Netherlands	Nonrandomised prospective cohort	Patients (n = 38)	Assess the value of individual adjusted counselling by a dietitian compared to standard nutrition care	****	BMI between groups did not differ significantly at any time In early rehabilitation (10–12 weeks) malnutrition prevalence had decreased in intervention (from 4 to 0 of 20 patients) and increased in control (from 3 to 5 of 18 patients) Significantly different between groups ($P < 0.05$)
Cant and Aroni [47]; Australia	Sequential qualitative-quantitative	Dietitians (n = 258)	Examine perceptions of dietitians and patients about dietitians' skills/attributes required for nutrition education of individuals	** ‡	Four main communication competencies identified, agreement among dietitians of importance of these competencies. Results indicate preference for educating or counselling clients using a two-way communication mode rather than information-giving through lecture or instruction

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size (n = P)	Aim	MMAT Score†	Findings related to PCC
Cant and Aroni [46]; Australia	Sequential qualitative-quantitative	Dietitians (n = 258)	Examine dietitians' and clients' perceptions of competence required for the process of nutrition education of individuals and used results to validate performance criteria	*‡	Results indicate a preference for educating/ counselling clients using a two-way communication mode rather than information giving through lecture/instruction Dietitians were of the opinion that 'everything varies according to the client' and selected education topics, strategies and materials they perceived as meeting the needs of an individual client Dietitians aimed to treat their patients with 'encouragement, praise and courtesy so that they are empowered to help themselves'
Cant and Aroni [31]; Australia	Sequential qualitative-quantitative	Dietitians (n = 34)	To examine process evaluation methods used by Australian dietitians in nutrition education of individual clients	* ‡	Most frequently used strategies for process evaluation were: 'observe a client's body language for nonverbal messages about their cooperation with the education process', 'ask clients if they understood the information provided' and 'clarify understanding of diet–disease interaction' Main comments about process evaluation were centred on dietitians' inability to carry out evaluation due to time constraints
Brody, Byham-Gray [37]; USA	Delphi	Dietitians (n = 89)	Gain consensus on the practice activities of advanced-practice RD and NS who provide direct clinical nutrition care	***	Dietitians placed emphasis on communicating with patient and/or family in nonjudgmental manner, understanding patient literacy, barriers, and adjusting education to their needs Employed active listening, choosing appropriate strategies based on the client/patient and situation
Desroches, Lapointe [38]; Canada	Delphi	Dietitians (n = 51)	To assess dietitians' perspectives on the importance and applicability of interventions to enhance adherence to dietary advice for preventing and managing chronic diseases in adults in the Canadian context	**	Four interventions reached strong consensus: (i) feed-back based on self-monitoring; (ii) multiple interventions; (iii) portion size awareness; and (iv) video Patient characteristics and time constraints were identified as barriers for several interventions Dietitians noted that time constraints were a barrier to the implementation of multiple interventions

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size (n = P)	Aim	MMAT Score†	Findings related to PCC
Maclellan and Berenbaum [39]; Canada	Delphi	Dietitians (n = 65)	The concept of client-centeredness was explored within a nutrition counselling relationship	***	Participants strongly or partially agreed with relevance of most approaches to client-centred care Did not agree with: ‘providing clients with only information they want’ and ‘recognising the client as experts when it came to their own nutrition care’ Most frequently cited barriers; unrealistic client expectations, limited time allocated for nutrition counselling
Parkin, de Looy [40]; UK	Observational	Dietitians (n = 4); patients (n = 86)	To examine the relationship between professional expression of empathy and agreement about decisions made in the consultation	***	Dietitians empathetic responses were mainly categorised as 2 (Minimal encourages), 3 (acknowledgement) and 4 (acknowledgement and pursuit) – No dietitians responded with highest level of empathy (6) Significant correlation between empathy and agreement about a decision
Vaillancourt, Légaré [23]; Canada	Observational	Dietitians (n = 19); patients (n = 19)	To assess the extent to which dietitians involve patients in decisions about dietary treatment	***	Overall OPTION score was 29% OPTION positively correlated with duration of consultation. Dietitians scored highest for: (i) exploring patients’ expectations about how to manage problem; (ii) explaining pros/cons of options; (iii) discussing possibility of deferring decision; and (iv) listing dietary options including taking no option. Dietitians scored lowest for: (i) assessing patients preferred approach to receiving info to assist in decision-making; (ii) indicating need for a decision-making stage; (iii) stating there is more than one way to deal with the problem; and (iv) eliciting patients preferred level of involvement in decision-making
Prince, Moosa [41]; UK	Survey/ questionnaire	Dietitians (n = 100); Patients (n = 72)	To assess type and quality of written information on nutrition and diet available to patients with IBD and the opinions of patients and health professionals	***	Only 11% of dietitians considered the extent to which written information ‘considered individual needs’ Open questioning with patients revealed the importance of individualisation and personalisation of information, as IBD was identified as a very personal journey

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size ($n = P$)	Aim	MMAT Score†	Findings related to PCC
Deschênes, Gagnon [42]; Canada	Survey/ questionnaire	Dietitians ($n = 203$)	To identify the factors influencing dietitians' intentions to adopt two SDM behaviours; 1) present dietary treatment options to patients and 2) help patients clarify their values and preferences.	***	Intention for both behaviours quite high, greater intention for behaviour 2 [mean (SD) of 5.68 (0.74)] than 1 (mean (SD) of 5.00 (1.14)] Intention for behaviour 1 predicted by: perceived behavioural control, subjective norm and moral norm Intentions for behaviour 2 predicted by: perceived behavioural control, attitudes and professional norms Salient beliefs that significantly explained intention for both behaviours included lack of time ($P < 0.0001$; $P < 0.0001$) and lack of interviewing skills ($P = 0.05$; $P = 0.06$)
Vaillancourt, Légaré [43]; Canada	Survey/ questionnaire	Dietitians ($n = 13$); Patients ($n = 13$)	To explore both dietitians' and patients' adoption of SDM behaviours in dietetic consultations regarding the nutritional treatment of dyslipidaemia	***	Overall mean (SD) OPTION score was 28% (6%) 62% of DTs preferred to 'share the decision', whereas 54% of patients preferred to 'make the decision' Perceived behavioural control was the only TPB construct significantly associated with intentions 'to discuss nutritional treatment options' and 'discuss patient's values and preferences' for patients and dietitians ($P < 0.05$) Stated reasons for not presenting treatment options; dietitian considering some options not appropriate due to their initial evaluation of patient's health condition and/or lifestyle habits ($n = 4$) or lack of time ($n = 3$)
Whitehead, Langley-Evans [44]; UK	Survey/ questionnaire	Dietitians ($n = 1158$)	Investigated the views of UK dietitians about their training needs and experiences in relation to communication skills in dietetic practice	***	98% rated communication skills as either very or extremely important in client consultation. Highly important communication skills included: greeting appropriately, putting at ease, communication at appropriate level for individual clients, appropriate nonverbal cues, listening attentively, appropriate nonverbal communication, summarising and closing interview (90%) 73% undertook post-registration training, 90% perceived post-registration training had led to improvement in their relationships with patients, confidence in interviews, ability to cope with challenging clients 21.4% felt time keeping in interviews had worsened, 79% experienced greater job satisfaction

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size (n = P)	Aim	MMAT Score†	Findings related to PCC
Williamson, Hunt [45]; USA	Survey/ questionnaire	Dietitians (n = 75)	To identify factors that contribute to the barriers to dietary adherence in individuals with diabetes, and obtain recommendations from dietitians for strategies to overcome these	*	Recommendations for overcoming barriers were similar regardless of cause of barrier and included: more education, better education, simplifying language and tools used in counselling, making referrals to other health professionals, building rapport 69% of respondents indicated need to individualise a plan ahead to overcome time factor Individualised education based on patient readiness to learn was a recommendation to overcome barriers of denial and the perception that diabetes is not serious
Ball, Davmor [54]; Australia	Semi-structured telephone interviews	Patients (n = 10)	To explore the perceptions of patients recently diagnosed with type 2 diabetes regarding nutrition care received from dietitians	****	Participants valued genuine relationships, tailored advice, open communication and sufficient time in consultations The initial interactions with dietitians were often viewed as challenging and overwhelming because of the directive, instructional nature of the consultation Participants desired care and resources individually tailored to their unique nutrition requirements Participants perceived their dietitians as generally supportive; however, many described feeling rushed and not heard
Cant [53]; Australia	In-depth interviews/ focus groups	Dietitians (n = 46); Patients (n = 34)	Explore trust in communication from viewpoint of both client and Dietitian	***	Dietitians aimed to build rapport with clients to gain their trust and respect, patients wanted to be listened to, receive individualised guidance and feel comfortable; dietitians should be 'easy to talk to' for this to be achieved Desirable communication style seen by patients as enabling positive partnership Dietitians wanted to build relationships with patients to gain patients trust; dietitians felt integrity was important for building helping relationships with patients Dietitian–patient relationship depended on openness and trustworthiness Overall patients portrayed collaborative partnerships with dietitian

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size ($n = P$)	Aim	MMAT Score†	Findings related to PCC
Desroches, Lapointe [32]; Canada	Focus groups	Dietitians ($n = 21$)	Identify dietitians' salient beliefs regarding their exercise of two behaviours during the clinical encounter, both deemed essential for SDM to take place: (i) present dietary treatment options to patients and (ii) help patients clarify their values and preferences	***	Participants discussed disadvantages of behaviour (i) making patients feel less secure and increasing dietitians' feelings of incompetence Perceived advantages of adopting behaviour (ii) allow them to target the patient's treatment more precisely, improve the patient's adherence to treatment, and reinforce patients trust in the dietitian Time was a barriers associated with both behaviours
Endevelt and Gesser-Edelsburg [55]; Israel	Focus- groups and in-depth interviews	Dietitians ($n = 17$) Patients (not stated) 12 focus groups	To ascertain the role of the dietitian–patient relationship and the counselling approach in influencing individual patient decisions to adhere to counselling by persisting with nutritional treatment	***	Dietitians explained the degree as mostly clinical and teaching dietitians how to provide patients with information, largely disregarding patients' personality, psychological needs and lifestyle When dietitians took an educational and instructional approach, some patients indicated this discouraged them from returning to the dietitian; for some patients, the informative educational approach is substantial Patients perceived the 'contact' between themselves and the dietitian as long term when dietitians counselled and guided patients Dietitians lack of empathy encouraged some patients to terminate treatment
Hancock, Bonner [33]; UK	Focus groups	Dietitians ($n = 33$); Patients ($n = 17$)	To better understand patients experiences of the dietetic consultation using qualitative analysis	***	Patients appreciated individualised and adapted care, resources and information; some patients felt advice and information did not account for personal situation and was therefore irrelevant Some dietitians were described as nonprescriptive; guiding rather than instructing, most patients liked this approach Patients saw working with the dietitian an important factor in effectiveness of consultation and positive feedback from the dietitian was important motivator for some patients Characteristics and behaviours important for dietitians to possess included listening, rapport, body language, acceptance, support, professionalism and empathy, negative experience expressed when dietitian did not listen properly, unlikable manner of dietitian negatively affected trust, acceptance and nonjudgement equated to openness, patients respected their dietitians' professionalism

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size ($n = P$)	Aim	MMAT Score†	Findings related to PCC
Hardcastle and Hagger [34]; UK	Interviews	Patients ($n = 14$)	To explore the experiences of obese patients following participation in a counselling intervention, to identify influence on behaviour change in relation to physical activity and diet	***	Patients were disappointed when dietitians took an expert-driven approach Interviews highlighted the importance of client-centred approaches, where direct advice giving was rarely the key to change
Jones, Furlanetto [35]; UK	Interviews	Patients ($n = 24$)	Collect patients views on the dietetic service, the treatment outcomes in terms of lifestyle change and impact that attending dietetic services had on lives in order to improve dietetic treatment and assist in selection of appropriate outcome measures in future	***	Many interviewees valued professional support, motivation and encouragement that they received from the dietitian A few patients felt literature provided lacked individualisation 50% reported positive relationship with the dietitian
MacLellan and Berenbaum [22]; USA	Interviews	Dietitians ($n = 25$)	Explore dietitians' understanding of client-centred nutrition counselling	***	When asked how they would define 'client-centred nutrition counselling', most referred to 'meeting patients' needs and wants' Many voiced concerns that clients did not always recognise what they 'need' to know, and may need more information than they 'want' to make an informed decision Many stated they always designed their service to meet clients' needs but not necessarily their wants, some dietitians' felt they were the healthcare experts, not patients Dietitians referred to needs expressed by clients as 'perceived need or want', and when identified by the dietitian, the need was perceived as a 'medical/real' need Several participants talked about the 'meeting of two experts'

Table 1. Continued

Author (year); Country	Design	Participants/ Sample size (*n* = *P*)	Aim	MMAT Score†	Findings related to PCC
McMahon, Tay [36], Australia	Interviews	Dietitians (*n* = 7)	Examine dietitians' perspectives about working with clients in the current client-centred environment	****	The over-riding theme, 'professional identity dilemma', related to the tension dietitians experience in being confident with their own professional identity (experts in nutrition) at the same time as ensuring optimal health outcomes within a supportive nurturing environment One dietitian noted how reflective listening by both parties enabled more appropriate strategies for adherence to dietary plans

BMI, body mass index; CVD, cardiovascular disease; DTs, Dietitians; HAART, highly active antiretroviral therapy; IBD, irritable bowel disease; IIP, intensive intervention programme; MI, motivational interviewing; MMAT, mixed-method appraisal tool; NS, Nutritionist; OPTION, observing patient involvement; PCC, patient-centred care; RCT, randomised controlled trial; RD, Registered Dietitian; SDM, shared decision-making; SLE, systemic lupus erythematosus; TPB, theory of planned behaviour; WHI, women's health initiative.

†Quality Score ranges from meeting one of four criteria (*) to meeting all criteria (****).

‡Mixed-method studies score range from '*' to '***'.

[23,32,42,43] and one mentioned the dietitian–patient relationship [55], both critical components of PCC [5,56]. Several studies explored aspects of PCC indirectly; for example, by gaining consensus on dietitians' perceptions of the importance of practice activities [37], skills and attributes [47], evaluation methods [31] competence and performance criteria [46], quality of information available [41], communication skills [44] and recommendations for overcoming patients' barriers to dietary adherence in patients with diabetes [45]. Qualitative studies indirectly revealed findings relevant to PCC by exploring dietitians' perceptions of delivering nutrition care [53], as well as patients' experiences and perceptions of receiving nutrition care from dietitians [33–35,54].

The methodological quality of studies ranged from low to high. The most frequent limitations of qualitative studies were a lack of reflexivity (i.e. acknowledgement of the effect of the context and researcher) [22,32,53] and unclear explanations of the selection process or reason for some participants not consenting [33,34,55]. Limitations for quantitative descriptive studies included a lack of representativeness of the study population [23,39–42], low response rates [38,43,45] and inappropriate sampling strategies [37,38,45]. Inadequate description of randomisation was a limitation of two [48,49] out of the three randomised controlled trials. All three mixed-methods studies [31,46,47] failed to acknowledge the limitations associated with integration of qualitative and quantitative findings. MMAT scores for qualitative and quantitative studies ranged from meeting one out of the four criteria (*) to meeting all criteria (****). Mixed-method studies scores ranged from meeting one of three criteria (*) to meeting all three criteria (***).

Meta-synthesis

Six themes were discovered inductively: (i) establishing a positive dietitian–patient relationship; (ii) displaying humanistic behaviours; (iii) using effective communication skills; (iv) individualising and adapting care; (v) redistributing power to the patient; and (vi) lacking time for PCC practices. The first three themes were closely related.

Establishing a positive dietitian–patient relationship

The first theme highlighted the importance of positive relationships between dietitians and patients. Positive relationships were viewed as integral to engaging patients in care [53], negotiating action plans, problem solving, and gaining patients' trust and confidence [33]. Dietitians wanted to develop rapport with patients to build relationships that enabled collaborative problem solving [31], and considered that this depended on their empathy, integrity, trustworthiness and respect [31,53].

Only two [33,35] of eight studies representing this theme [31,33,35,44,46,48,53] investigated patients' perspectives. Patients described good rapport as critical [33] and reported that, when dietitians were friendly and encouraging, patients' confidence and trust were increased, and patients explained they were motivated to share information with their dietitian [33]. In one study, half of the patients reported having a positive relationship with their dietitian, and valued the support, motivation and encouragement provided by their dietitian [35]. This theme closely related to the second theme because friendliness [33], supportiveness [35], integrity, and empaththy [53] were humanistic behaviours seen as conducive to positive relationships between dietitians and patients.

Displaying humanistic behaviours

The second theme related to dietitians displaying specific behaviours or characteristics perceived as helpful and motivating to patients. Characteristics included empathy, encouragement, honesty, integrity, trust and respect [33,53,57]. These characteristics appeared to be important because patients were more receptive when dietitians possessed these qualities. Patients responded negatively when dietitians did not demonstrate these qualities.

Dietitians reported that patients' engagement in care depended on the integrity, honesty and 'realness' dietitians brought to the consultation [53]. Furthermore, dietitians considered that they could empower patients through praise and encouragement [46,47]. Patients found it helpful when dietitians were relatable and shared their own personal experience, and viewed 'well-rounded', 'easy going' dietitians positively [53]. Patients reported that dietitians with an encouraging manner helped overcome barriers to behaviour change [33,35]. Patients' trust depended on the friendliness and approachability of dietitians [33]. Empathy was also particularly important to patients but not always demonstrated by dietitians [33,53,55].

Using effective communication

The third theme demonstrated the importance of dietitians using effective communication skills during dietetic consultations. These included verbal communication skills such as active listening, constant questioning and paraphrasing, as well as nonverbal communication skills (i.e. body language, placement of furniture). Good communication skills were important in facilitating collaborative partnerships between patients and dietitians. Patients and dietitians emphasised both the value of and their desire for effective communication. This theme relates to the first theme, 'Establishing a positive dietitian–patient relationship' because dietitians discussed the importance of good communication skills in establishing relationships with patients [33,53].

Patients wanted to be listened to [33] and were appreciative when dietitians were 'easy to talk to' [33,53]. Dietitians valued communication skills [36,37,44,53] and considered that reflective listening skills enabled the formation of a collaborative partnership between dietitians and patients [36]. Dietitians who undertook post-registration training in communication skills reported improvements in their relationships with patients, confidence in interviews, ability to cope with challenging clients and greater job satisfaction [44]. Dietitians had a preference for two-way communication over didactic lecturing and instructing [31].

Individualising and adapting care

The fourth theme emphasised the importance of dietitians providing care that was appropriate to patients' unique needs and wants. When care provided was 'basic' [34], patients experienced disappointment, felt their 'wants' were not considered [34], and reported that the advice was not relevant [33]. Patients valued individualised and adapted care [33,34,41,53,54], when dietitians considered their individual medical, family or economic circumstances and adapted advice accordingly [33].

Dietitians acknowledged the importance of individualising care to meet their patients' needs in four studies [36,37,46,53]. Many dietitians attempted to select education topics, strategies and materials to meet individual patients' needs in a mixed-method study [31,46]. Although some dietitians did not consider individualising care [41] and described this process as challenging [22,36], many still recognised the importance of individualising and adapting care [37,44–46]. Dietitians' suggested two key challenges to adapting and individualising care were: (i) the uniqueness of each patient, making individualising care difficult [36] and (ii) dietitians' professional beliefs hindering the process [22]. Some dietitians considered that patients' 'wants' did not always align with their 'needs' and that, as health experts, dietitians better understood patients' 'real/medical' needs [22].

Redistributing power to the patient

The fifth theme illustrated challenges faced by dietitians in redistributing power to the patient. Possible strategies for power sharing included shared decision-making [42] and adopting a 'nondirective' [33], 'counselling' approach [31], rather than having a superior and expert attitude [22,34]. Some dietitians perceived themselves as the sole experts who were responsible for patients' decisions [22,34]. The investigators from one study concluded that some dietitians considered their 'expert-defined' needs more important than patients' 'perceived' needs [22]. Dietitians perceived a risk in being viewed by patients as 'less expert' [32] or experiencing feelings of incompetence

[42] if they presented all treatment options to patients rather than choosing themselves. This was also referred to as a 'professional identity dilemma'; dietitians struggled with what it means to be the professional in a context where patients too are experts in their care [36].

Some dietitians described themselves as the 'expert' [22] and, similarly, some patients perceived dietitians as being 'expert-driven' [34]. In one study, patients were disappointed when dietitians took this approach and felt direct instruction was not helpful; one patient reported not adopting the dietitian's advice because it did not match their preferences [34]. Some patients described dietitians' directive and instructional approach as 'challenging' and 'overwhelming' [54]. When dietetic consultations were purely 'educational' and 'informative', some patients were discouraged from returning to the dietitian [55]. Alternatively, some patients described dietitians as 'guiding' rather than 'instructing' [34,55]. Patients' frustrations were reduced when information was adequately explained and patients were encouraged to reflect rather than being told what to do [33]. Furthermore, when dietitians adopted a more 'counselling' aligned consultation style, patients were encouraged to engage in ongoing nutrition care with their dietitian [55].

Lacking time for patient-centred practises

The sixth theme illustrated that time was seen by dietitians as a significant barrier to the implementation of PCC practises, identified in seven [38,42–44,54] of the 27 studies included in this review. Dietitians explained that, to adopt shared decision-making, more time was required during consultations to explore patients' thoughts [38], and inadequate time allocation hindered the delivery of nutrition counselling [22]. Lack of time was a significant predictor of dietitians' adoption of shared decision-making [42], and a stated reason for not presenting patients with treatment options [43]. Dietitians who undertook post-registration training to further develop their counselling and communication skills said their time keeping in interviews had declined [44]. Some patients also desired more time during dietetic consultations, and reported feeling 'rushed' and 'not heard' by their dietitian [54].

Discussion

The aim of this integrative review was to critically synthesise existing literature on PCC in dietetics to inform future research, practice and policy. Synthesis of the 27 eligible studies identified six themes. Collectively, this work contributes valuable findings for improving dietetic practice. The findings suggest that: (i) dietitians can establish positive relationships with patients through displaying specific behaviours and using good communication skills; (ii) positive relationships fosters trust and, can increase patients' engagement in care, and are important to patients and dietitians; (iii) considering patients' unique needs and wants to deliver individualised care is important to patients; and (iv) shared decision-making is an important component of PCC, and achieving shared decision-making requires shared power between dietitians and patients. The present study also highlights several significant opportunities for future research.

A multifaceted relationship was observed between the three themes: 'Establishing positive dietitian–patient relationships' 'displaying humanistic behaviours' and 'using effective communication skills'. These themes represent three interrelated dimensions of PCC [5]. Previous studies in other health settings have also identified the relationship between these dimensions [5,58,59]. Specific clinician characteristics or behaviours, including empathy, integrity and honesty, as well as good communication skills, are critical to the establishment of positive clinician–patient relationships. By understanding the importance of these components as a collective, future research can implement PCC more holistically. Thus, the integration of these themes suggests a model for establishing positive relationships with patients, which is fundamental to PCC [5] and should be central in future PCC interventions.

Dietitians and patients perceived positive dietitian–patient relationships as important for enabling problem solving, engaging patients in care [53], and particularly, gaining patients' trust [33]. These findings are consistent with empirical evidence from nursing [58] and occupational therapy [60] practice. As previously discussed, humanistic characteristics [31,33,35,53] and good communication skills were viewed as integral to establishing positive dietitian–patient relationships [33,53,57]. This was also identified in a qualitative study involving occupational therapists and their patients, where successful client-centred relationships depended on therapists' being respectful, trustworthy and having good listening skills [60]. Positive relationships and good communication is essential in providing high-quality healthcare. These practises ensure correct diagnoses are made, appropriate treatment plans are established between patients and clinicians, patients' knowledge is increased, and patients are encouraged to maintain ongoing self-care [58,61]. These studies collectively demonstrate how positive dietitian–patient relationships can be established, which has the potential to improve dietetic practice.

Associations between various PCC dimensions and health outcomes have not been demonstrated in dietetic research but have been shown in other healthcare settings. For example, a systematic review of thirteen studies in the physical rehabilitation setting found that positive clinician–patient relationships were associated with improved symptoms and health status, greater patient attendance and adherence, and greater patient satisfaction with care and treatment [62]. Additionally, effective doctor–patient communication has been positively associated with patient recall, understanding, treatment adherence [63] and psychological well-being [61]. These dimensions may be integral to future patient-centred interventions because they are clearly important to patients and dietitians. Such interventions could also evaluate the effectiveness of these dimensions because this has not yet been achieved in dietetics.

Two studies included in this review suggest that dietitians' adoption of shared decision-making is inadequate [23,43]. Shared decision-making is a critical component of PCC [56]. It involves presenting patients with treatment options and helping patients clarify their values and preferences so they can make informed and appropriate treatment decisions [56]. Shared decision-making has been shown to increased patients' emotional well-being, sense of control over disease, self-management [61] motivation and sense of empowerment [60]. Some dietitians prioritise their expert-defined needs rather than patients' perceived needs [22], and fail to recognise the patient as an expert regarding their own health [39]. For shared decision-making to be embedded in dietetic practice, dietitians need to relinquish their authority as the sole experts and acknowledge patients expertise in understanding their own situation. Dietitians' adoption of shared decision-making is also influenced by their perceived ability to perform these practises [42]; thus, greater confidence may increase dietitians likelihood of implementing shared decision-making. There is opportunity for future research to trial strategies to modify dietitians' attitudes to be conducive to patient-centred shared decision-making practices. Interventions in this area, although particularly challenging, have the potential to increase dietitians' confidence in implementing shared decision-making.

No study included in the present review specifically aimed to examine patients' understandings of PCC; therefore, it is difficult to comment on patients' perspectives on the meaning and importance of PCC. Patients' perspectives should be sought in research that informs the development of patient-centred interventions [58,64]. Gaining a greater understanding of patients' preferences and beliefs regarding PCC would allow interventions to better cater to patients' unique wants and needs and therefore be more appropriate, sustainable, and truly patient-centred.

To date, PCC has not been a focal point in dietetic research despite being emphasised by dietetic competency standards in Australia, UK, USA and Canada [19–21] as early as 1997 [20]. The large number of eligible studies (n = 27) may suggest the contrary; however, only a small number of studies directly referred to PCC in their aims [22,36,39,51]. The diversity in study aims is surprising considering the time span of two decades, as well as the increasing popularity and relevance of PCC in healthcare [7]. Future research in this area should more explicitly focus on investigating PCC to increase the clarity and significance of PCC-related findings relevant to dietetics.

There is a need to develop and evaluate interventions to promote greater PCC practises of dietitians. Only a small number of intervention studies (n = 5) relating to PCC in dietetics have been conducted in the past two decades, and these intervention studies have found inconclusive results. None of these interventions evaluated changes in dietitians' confidence, skills or attitudes regarding PCC. Furthermore, these studies mainly used clinical outcome measures, including anthropometric (weight, body mass index), metabolic (HbA1c, cholesterol) and dietary intake (24-h intake, food frequency questionnaire) measures. As a result, these studies have not examined how factors such as dietitians' confidence in PCC practise, as well as patients' empowerment, satisfaction and self-efficacy, might mediate the relationship between PCC practises and health outcomes. To be patient-centred, future intervention studies should include patient-centred outcomes (i.e. outcomes that are important to patients, such as quality of life). These additions to future interventions might facilitate identifying meaningful associations of potential health outcomes with the patient-centred aspects of the intervention, which is something that no dietetic interventions have achieved so far.

There are both strengths and limitations of the present review. A strength is the inclusion of a wide variety studies; 27 studies comprising a range of methodological designs and objectives provides a broad overview of PCC in dietetics. However, the synthesis of both qualitative and quantitative findings can be complex and can also introduce bias [25]. The quality of this integrative review has been maximised through use of the systematic and rigorous process [25]. To reduce bias, two independent researchers screened 128 full texts against inclusion and exclusion criteria. A third reviewer was available for discussion of any discrepancies. Furthermore, data extraction and quality assessment was performed by two investigators to ensure consistency. Meta-synthesis is an iterative process; therefore, emerging themes were reviewed and revised by all of the investigators. Although the methodological quality of studies did not influence their inclusion or exclusion, the results of the review should be interpreted with caution as a result of the poor quality of some studies.

In conclusion, the findings of the reviewed studies suggest that dietitians can establish trusting relationships with patients by being empathetic, honest, integral and supportive, and also by using effective communication skills. It is clearly important to patients that dietitians ensure care is individualised to meet patients' unique needs and wants. Shared decision-making between patients and dietitians requires power redistribution, which has been challenging for dietitians. The importance of a patient-centred approach is accepted in dietetic competency standards, although the evidence base on how to enact it is sparse.

Conflict of interests, source of funding and authorship

The authors declare they have no conflicts of interest. This review was completed as a component of doctoral research for the first author (IS) and was supported by an Australian Postgraduate Award.
IS, LB and WC contributed to the design of the integrative review and developed the protocol. IS and CB had a lead role in identifying articles for inclusion, extracting data and appraising study methodologies. IS, LB, CB and WB contributed to the data analysis, drafting of the paper, and all agreed to the final version of the manuscript.

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OBESITY AND RELATED DISORDERS

Using data mining to predict success in a weight loss trial

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data mining, weight loss, clinical trial, dietary intervention.

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Abstract

Background: Traditional methods for predicting weight loss success use regression approaches, which make the assumption that the relationships between the independent and dependent (or logit of the dependent) variable are linear. The aim of the present study was to investigate the relationship between common demographic and early weight loss variables to predict weight loss success at 12 months without making this assumption.

Methods: Data mining methods (decision trees, generalised additive models and multivariate adaptive regression splines), in addition to logistic regression, were employed to predict: (i) weight loss success (defined as ≥5%) at the end of a 12-month dietary intervention using demographic variables [body mass index (BMI), sex and age]; percentage weight loss at 1 month; and (iii) the difference between actual and predicted weight loss using an energy balance model. The methods were compared by assessing model parsimony and the area under the curve (AUC).

Results: The decision tree provided the most clinically useful model and had a good accuracy (AUC 0.720 95% confidence interval = 0.600–0.840). Percentage weight loss at 1 month (≥0.75%) was the strongest predictor for successful weight loss. Within those individuals losing ≥0.75%, individuals with a BMI (≥27 kg m^{-2}) were more likely to be successful than those with a BMI between 25 and 27 kg m^{-2}.

Conclusions: Data mining methods can provide a more accurate way of assessing relationships when conventional assumptions are not met. In the present study, a decision tree provided the most parsimonious model. Given that early weight loss cannot be predicted before randomisation, incorporating this information into a post randomisation trial design may give better weight loss results.

Introduction

Greater early weight loss has consistently been shown to predict long-term success in weight loss trials [1–4]. From a clinical practice perspective, there is a lack of an easy to use guideline identifying early success and the measurement values that could be used to trigger a decision-making process to intervene and change therapy for those individuals unlikely to lose a clinically beneficial amount of weight. Recently, a dynamic energy balance model has been developed and used as part of an algorithm [5] to predict whether a subject will lose weight in a weight loss trial [6]. A limitation of this method, as acknowledged by the authors and the accompanying editorial [7], is the complexity of applying such a model quickly in clinical practice because it relies on the input of several variables into a web or locally based algorithm. However, in this initial study, the algorithm was shown to outperform the simple process of examining early weight loss as a predictor of success. Early weight loss was not shown to be significant in predicting weight loss success, which is a finding that is in conflict with previous research [1–3,8].

Most previous research investigating predictors of longer-term weight loss have used linear or logistic regression [1–4,8]. Linear and logistic regression make the assumption that the relationship between the dependent (or logit of the dependent variable for logistic regression) and the independent variable is linear and this may not always be the case. Data mining methods are increasingly being used as an alternative to traditional methods when assumptions are not met [9]. In addition, although coefficients in linear regression and the odds in a logistic regression are relatively easy to understand and communicate, they are not easy to apply in clinical decision-making. Some data mining methods can be used to establish cut-off criteria using different variables to predict an outcome or establish the importance of difference variables in predicting an outcome. For example Batterham *et al.* [10] showed, using a decision tree, that those individuals losing <2% of their initial weight in a weight loss trial were significantly more likely to drop out than those losing more than this amount. The cut-off of 2% was not selected *a priori* but was determined by the data mining procedure and provides a guide for researchers and clinicians to target participants likely to discontinue a programme. If the participant has lost less than 2% at 1 month, additional interventions or follow-ups may be initiated to prevent attrition. The relationship here is not linear in that the response depends on whether the weight loss is less than 2%. Santos *et al.*[11] used recursive partitioning, where the data are repeatedly split into partitions containing similar observations [12] to predict long-term weight loss maintenance; however, only behavioural and psychological factors (self determination, exercise motivation, difference between perceived self and ideal body image, self esteem, social support for exercise, depression, quality of life and dietary restraint) measured using an extensive battery of questionnaires (which are not collected in our research practice) were considered. A better body image and exercise motivation were associated with weight loss maintenance. More readily available demographic and clinical measures such as early weight loss were not used as a predictive variables.

Data mining is broadly defined as 'the study of collecting, cleaning, processing, analysing and gaining useful insights from data' [13] or 'the process of discovering insightful, interesting, and novel patterns as well as descriptive, understandable and predictive models' [14]. There are some examples of the use of data mining in nutrition related research; for example, decision trees have been used to examine the relationship between diet and lifestyle factors associated with oesphageal and gastric cancer [15] and dietary patterns and their association with childhood obesity [16]. However, these methods are not widely used in the nutrition domain and offer an opportunity to gain additional insights from data compared with more traditional methods.

The aim of the present study is to closely examine the relationship between early weight loss and weight loss success [defined as greater than or equal to 5% weight loss [17] to determine a clinical cut-off for use in practice]. Initial weight loss was considered because it has previously been shown to be a predictor of weight loss success using linear [2] and logistic regression. Other variables, such as demographic factors [1,2], weight loss history [1,2], psychological factors [e.g. depression, stress, anxiety [1,11], quality of life [2,11]], eating disorders [1,2], physiological measures (blood pressure, glucose and lipids) [4] and attendance [1] have been investigated for their role in predicting weight loss success; however, initial weight loss is the only variable consistently shown to predict successful weight loss in several studies [1–4]. We investigated whether more sophisticated decision-making processes using data mining methods will have better accuracy than traditional approaches. This analysis will show whether data mining procedures, which do not make the same assumptions of the traditional methods, can be used to develop an easy to use decision process for predicting weight loss success. We further propose that this will outperform a more complicated algorithm [6] previously published in this area.

Materials and methods

Data for the present analysis were made available from a previously published weight loss trial investigating the effectiveness of high vegetable consumption in the context of an energy reduction diet for weight loss where the treatment effect (the difference in weight loss between the prescribed vegetable consumption and control group) was not significant [18]. For the analysis reported in the present study, the demographic variables body mass index (BMI), sex and age were considered in addition to percentage weight loss at 1 month and the difference between actual and predicted weight loss using the energy balance model developed by Thomas *et al.*[5,6]. This algorithm for predicted weight loss includes the weight, height, age, sex and target energy intake of the subject. The variables included were those considered to be easily collected in research or clinical practice. Data for the 93 participants who completed the trial were considered for this analysis. For the generalised additive models (GAM) and multivariate adaptive regression splines (MARS) models, only data on the 76 subjects with complete data for all the considered variables were analysed. Summary statistics of the study sample and weight loss variables are shown in Table 1. Predicting weight loss success is a secondary analysis not considered in the initial study publication. The outcome or response variable in this analysis was a binary variable determining whether or not each participant had been successful in losing weight [defined as greater than or equal to 5% weight loss [17]]. Models were constructed using several data mining methods: decision trees or classification and regression trees, GAM and MARS. The reason for using these methods was that we made no *a priori* assumptions that the relationships were linear. The models chosen are popular data mining methods and all covered in detail in the core texts on these techniques [9,19,20]. Decision trees are based on linear regression and partition significant independent variables in a binary (two-way) split based on a function minimising the sum of squared errors [21]. MARS can be regarded as a modification of the decision (or classification and regression) tree method. MARS uses piecewise functions [functions with a kink in them to model the nonlinearity [22]] instead of step functions that are used in decision tree models to perform an adaptive regression [20] MARS is a nonparametric regression method. GAM is an extension of regression where the linear function (the beta coefficients) are replaced by a more general nonparametric functions [20]. The nonlinear relationships between the response and significant independent variables is usually visualised by using a scatterplot of the partial residuals (where the effect of all the other independent variables is removed) and the independent variable, which is smoothed (the random noise has been reduced) [23,24]. The more traditional methods of logistic regression and a receiver operating characteristic or area under the curve (AUC) analysis were also used. These models were based on predicted weight loss at 1 month or the probability of weight loss success at 1 month. Methods were compared using the AUC, which ranges from 0 to 1, with values closer to 1 indicating a better model and, when the lower CI is >0.5, the model is statistically significant. Model parsimony and use in clinical practice was also considered when deciding on the best model. For this purpose, we aimed to have the least number of significant predictors that would be easy to calculate in a research or clinical context. Prediction model validation [25] was established for the decision tree by using *K*-fold cross validation and the complexity parameter to fine tune the tree based on the cross-validated error to achieve a model that is a balance between complexity and interpretability. Further verification of the variable importance was confirmed by generating 1000 trees using a random forest procedure [19]. In the random forest procedure, bootstrap resampling is used to generate independent trees, which are then combined to determine the variable importance. Data were analysed in R STUDIO, version 0.99.489 (incorporating R, version 3.2.3; The R Foundation for Statistical Computing, Vienna, Austria) [26]. The main packages used were 'rpart' and 'rattle' for the decision tree, 'gam' for the generalised additive model, 'earth' for the binary multivariate additive regression splines, and 'stats' ('glm' for the logistic regression).

Results

The difference between the predicted and actual weight loss at 1 month was statistically significant and the difference between the predicted probability [calculated using the algorithm of Thomas *et al.* [6]] of meeting the 5% criteria and the percentage actually meeting the 5% weight loss criteria showed poor agreement using the kappa statistic (kappa = −0.024, $P = 0.807$); the predicted probability correctly classified 49 of 63 who met the 5% criteria and only six of 30 who did not meet the criteria. The results of the different models are shown in Tables 2–4. The decision tree (Fig. 1) shows that

Table 1 Descriptive statistics of study sample

Variable	Mean (95% CI) and *P* value
BMI at baseline	29.94 kg m^{-2} (29.38–30.50)
Weight loss at 1 year	7.46% (6.29–8.63)
Age	49 years (47–51)
Percentage of women	91% (*n* = 85)
Weight loss at 1 month	2.64% (2.23–3.06%)
Actual weight at 1 month	82.22 kg (79.99–84.44)
Predicted weight at 1 month	80.03 kg (77.89–82.18)
Difference between actual and predicted weight	2.18 kg (1.78–2.59) $P < 0.001$
Percentage meeting ≥5% weight loss criteria	68% (*n* = 63)
Percentage predicted to meet 5% criteria at 1 month	79% (*n* = 73), $K = -0.024$, $P = 0.807$

BMI, body mass index; *K*, kappa statistic.

Table 2 Model summary for the Decision Tree and ROC analysis

Model	AUC
Decision tree (classification and regression tree)	0.720 (0.600,0.840) $P = 0.001$
ROC (probability of success at 1 month)	0.489 (0.363,0.614) $P = 0.863$
ROC (% weight loss at 1 month) (cutpoint −1.68%)	0.740 (0.635,0.845) $P = 0.001$

AUC, area under the curve; ROC, receiver operating characteristic curve.

percentage weight loss is the main predictor of weight loss success. The cut-offs determined by the partitioning algorithm suggested that those individuals losing ≥0.75% in the first month are the most likely to succeed. Within those individuals who have lost more than this amount, those with a BMI ≥ 27 kg m^{-2} are more likely to succeed than those with a BMI < 27 kg m^{-2}. The AUC is above 0.7, which is considered good [27]. The random forest procedure confirmed that the percentage weight loss at 1 month and BMI were the most important predictors. The mean decrease in accuracy related to percentage weight loss at 1 month was 21, and BMI 11, compared with 6, 4 and 3 for the difference between actual and predicted weight, sex and age, respectively; this value reflects the decrease in classification accuracy if the variable is removed, with higher values reflecting more impact. Using percentage weight loss at 1 month alone also gives a good AUC; however, this model only considers one variable and does not consider the relationships with the other predictors. The logistic regression (generalised linear model) has only a moderate AUC identifying only weight loss at 1 month as a predictor. The GAM and MARS models both show nonlinear relationships. The GAM model shows that the relationships with percentage weight loss at 1 month and the actual versus predicted weight are nonlinear. Figure 2 shows the nonlinear spline fit for percentage weight loss at 1 month. The GAM gives the best accuracy for prediction with the highest AUC and the MARS model also has a good AUC. The MARS model selects predicted weight loss at 1 month and BMI as the only predictors, with the former being of more importance than the later. Both the GAM and MARS models can be influenced by collinearity [28]. The correlation between percentage weight loss at 1 month and the difference between the actual and predicted weight loss at 1 month was 0.810 ($P < 0.001$). Generally, correlations >0.9 can be problematic, although it is recommended that correlations >0.8 should be investigated [29,30]. In this analysis, the GAM was affected by this relationship giving inconsistent estimates when both variables were included. When including each separately, the percentage weight loss at 1 month variable was a stronger predictor and so the model containing this predictor was considered (the coefficient and *P* value for the model including difference between actual and predicted weight loss is also included in Tables 3 and 4). When percentage weight loss was removed from the MARS model, only BMI was included, indicating that collinearity was not affecting this model. The MARS model was unaffected by this relationship, giving identical results with and without the difference between actual and predicted variable.

Discussion

Using data mining methods, the present study demonstrates that the relationship of common demographic variables and weight loss success is nonlinear and developing models to predict weight loss success should account for this. A newly developed dynamic energy balance model shown to have good accuracy in a lifestyle based intervention was not able to improve on simple measures for prediction in the present sample of participants in a dietary weight loss trial. A simple decision tree

Table 3 Model summary for the logistic regression

GLM	Coefficient	*Z* value	*P*	
Age	−0.042	−1.464	0.143	0.670 (0.545–0.795) $P = 0.008$
Sex	−0.349	−1.160	0.246	
BMI	0.134	1.378	0.168	
Weight loss at 1 month	−0.974	−2.550	0.011	
Difference between actual and predicted weight	0.578	1.412	0.158	

BMI, body mass index; GLM, generalised linear model (logistic regression).

Table 4 Model summary for the generalised additive model and the multivariate adaptive regression spline

GAM	Coefficient	*F*	*P*	
Age	−0.004	0.014	0.908	0.777 (0.638,0.915) $P < 0.001$
Sex	−1.003	0.823	0.368	
BMI	0.143	1.366	0.246	
Weight loss at 1 month	−0.533	6.744	0.011	
Difference between actual and predicted weight*	−0.503	3.722	0.058	
MARS				
Equation and coefficients: 1.81− (2.46 × bf1) − (17.34 × bf2) + (18.26 × bf3) where bf1 = h (26.82 − BMI), bf2 = h (% weight loss at 1 month − 0.78), bf3 = h (% weight loss at 1 month − 0.58)				0.726 (0.583–0.868) $P = 0.002$

BMI, body mass index; bf, basis function; GAM, generalised additive model; h, hinge; MARS, adaptive regression splines.

*Values from separate GAM model without percentage weight loss at 1 month.

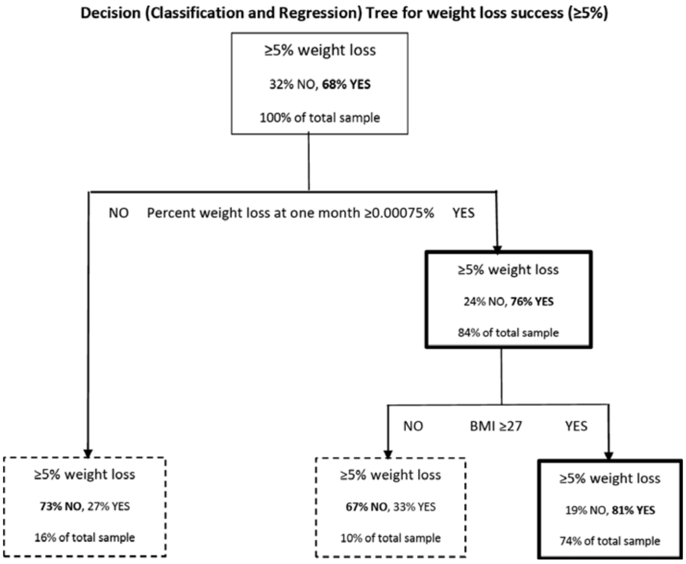

Figure 1 Decision tree.

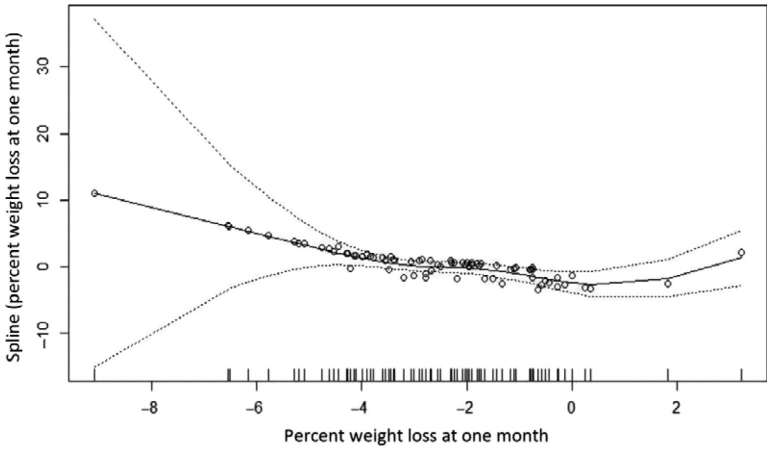

Figure 2 Nonlinear spline scatterplot for the generalised estimating equation fit for percentage weight loss at 1 month.

approach incorporating the percentage weight loss and baseline BMI provided good predictive accuracy in this sample.

Current research investigating predictors of weight loss success [1–4,8] relies heavily on the use of linear or logistic regression, which assume that relationships with continuous predictor variables are linear. If the relationship between the log odds and a continuous predictor variable in a logistic regression or the independent and dependent variable in linear regression is nonlinear, the strength of relationships may be underestimated. Sometimes a polynomial or other power term can be fitted, however, when the relationship does not fit one of these defined terms. GAM can improve the model fit by using splines (or other methods) to more accurately fit the relationship between the independent and dependent variables. Although the logistic regression in this analysis still showed that percentage weight loss at 1 month was a significant predictor and that this is a reasonable representation of the data, the logistic regression does not clearly define the relationship between this variable and BMI in the way that the decision tree does. The use of data mining methods in this analysis clearly shows that these relationships are nonlinear and incorporating this nonlinearity improves the models. Despite their ability to model nonlinear relationships, these models have other considerations and the GAM model in particular was influenced by the correlation of the percentage weight loss at 1 month and the difference between the actual and predicted weight loss. The decision trees are robust to collinearity and, again, with the greater ease of interpretation, this suggests that they are the preferred model in this analysis.

MARS and GAM were included in this analysis because it is increasingly recognised that some relationships in health research are nonlinear and the methods that accommodate this nonlinearity are growing in use in lifestyle and health research [31–36]. These models are also included because they are related to the tree models in the seminal data mining text [20]. Although they can be used to predict weight loss success, the complexity of the algorithms make the decision tree provide a more accurate approach for model parsimony.

Although BMI is easily assessed prior to commencing a weight loss intervention, early weight loss, as well as the strongest predictor of success, percentage weight loss at 1 month, can only be established *after* the trial is commenced. Thus, a rethink of trial design is necessary to incorporate this knowledge even though it cannot be included in the initial randomisation. New trial designs such as adaptive randomisation or sequential multiple assignment can be used to maintain all subjects in the study and, at the same time, target effects [37,38]. From a statistical point of view, this design element could lead to reduced variability in study arm outcomes thus improving the effect size and subsequent power, and reducing the required initial sample size. Most importantly, however, targeting nonresponders and implementing a treatment change may result in better individual outcomes for the participants and more successful therapy for roll out to the general community to treat the obesity epidemic.

Dynamic energy balance models rely on physical laws to predict the amount of weight loss that should occur given the subject characteristics and dietary prescription. Two publically available energy balance calculators are widely reported in the literature [http://www.pbrc.edu/research-and-faculty/calculators/weight-loss-predictor/ [5] and https://supertracker.usda.gov/bwp/index.html [39]]. The former was chosen for this anlaysis as this model has been further developed to predict weight loss success. Both models suffer from the limitation that access to a computer or smart device is required [7], as is input on weight goals and demographic information. The 'Supertracker' can also incorporate information on activity levels, macronutrient intake and input measures of body fat and resting metabolic rate. Both are useful in the research setting and potentially for goal setting in clinical practice. In this case, the use of the predicted probability of success at 1 month gave a prediction accuracy that was not better than chance alone using the AUC. Incorporating the difference between the actual and predicted weight loss [5] (which can be used as a marker of compliance to the dietary prescription) did not come out as a primary predictor in most of the models; however, using a GAM model, it is clear this relationship was not linear and it could be investigated further in other samples.

There are some limitations to this analysis. Many variables have been associated with predicting weight loss [40] and the current analysis was limited to the variables collected for the study considered. Dietary prescription was defined in increments of 500 kJ to make the recommendations on vegetable intake easier to implement. The rate of attrition was moderate (22.5%) in the present study compared to others conducted by our research group and other facilities [41,42]. This may reflect differences in this study population and the results require replication in other populations. Nevertheless, given the ease of calculation of a decision tree in both the free package R STUDIO and commercial packages such as SPSS (IBM Corp., Armonk NY), it is possible that researchers and indeed clinicians with their own unique populations should be investigating the use of these tools. Even without the use of an algorithm, the real clinical message is that, in clients seeking weight reduction, low early weight loss and lower baseline BMI (25–27 kg m^{-2}) should be targeted for more intense approaches or combinatorial approaches (exercise, psychological counselling or potentially pharmacotherapy).

In summary, this analysis demonstrates the potential utility of data mining methods over more traditional analyses to produce better models for prediction of weight loss. It also demonstrates that conventional assumptions such as the linearity of relationships may not be valid. For example, the results of the decision tree show that weight loss success is determined by a cut-off point in weight loss at 1 month of 0.75% and a BMI of 27 kg m^{-2}. The scatterplot for the GAM also shows the nonlinear relationship between weight loss success and percentage weight loss at 1 month. This information is lost if the relationships are considered to be linear. Some of the limitations of these methods (i.e. in this case with respect to collinearity) are also highlighted. When modelling data, there is often a trade off between accuracy and model parsimony. In this analysis, the simpler decision tree approach, although slightly less accurate than the GAM and MARS, is easy to interpret and not susceptible to the collinearity issue observed in the GAM. The models all suggest that percentage weight loss at 1 month is the strongest predictor of weight loss success at the end of the 1 year study and that, within those individuals with greater initial loss, baseline BMI is also important. Alternative trial designs and clinical strategies are recommended where this information is incorporated to improve weight loss outcomes.

Conflict of interests, source of funding, authorship and Transparency declaration

The authors declare that they have no conflicts of interest.

The initial published trial (not the current analysis) was funding by Horticulture Australia Limited using the vegetable levy and matched funding from the Australian Government. The study and secondary analysis was approved by the University of Wollongong Human Research Ethics Committee and registered

with ANZCTR (www.anzctr.org.au) (ACTRN12610000784011).
MB conceived the project, analysed and interpreted the data, and drafted the manuscript. LT, KC, JO and RT assisted with study conception and reviewed and revised the manuscript. All authors critically reviewed the manuscript and approved the final version submitted for review and publication.
The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of the initial trial analysed in this work was compliant with the CONSORT guidelines.

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OBESITY AND RELATED DISORDERS

Trends in dietary intake among adults with type 2 diabetes: NHANES 1988–2012

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Abstract

Background: Dietary recommendations for adults with diabetes are to follow a healthy diet in appropriate portion sizes. We determined recent trends in energy and nutrient intakes among a nationally representative sample of US adults with and without type 2 diabetes.
Methods: Participants were adults aged ≥20 years from the cross-sectional National Health and Nutrition Examination Surveys, 1988–2012 (N = 49 770). Diabetes was determined by self-report of a physician's diagnosis (n = 4885). Intake of energy and nutrients were determined from a 24-h recall by participants of all food consumed. Linear regression was used to test for trends in mean intake over time for all participants and by demographic characteristics.
Results: Among adults with diabetes, overall total energy intake increased between 1988–1994 and 2011–2012 (1689 kcal versus 1895 kcal; $P_{trend} < 0.001$) with evidence of a plateau between 2003–2006 and 2011–2012. In 2007–2012, energy intake was greater for younger than older adults, for men than women, and for non-Hispanic whites versus non-Hispanic blacks. There was no change in the percentage of calories from carbohydrate, total fat or protein. Percentage of calories from saturated fat was similar across study periods but remained above recommendations (11.2% in 2011–2012). Fibre intake significantly decreased and remained below recommendations ($P_{trend} = 0.002$). Sodium, cholesterol and calcium intakes increased. There was no change in energy intake among adults without diabetes and dietary trends were similar to those with diabetes.
Conclusions: Future data are needed to confirm a plateau in energy intake among adults with diabetes, although the opportunity exists to increase fibre and reduce saturated fat.

Introduction

The prevalence of type 2 diabetes has increased substantially over the past several decades, which may lead to future growth in morbidity, mortality and economic costs [1]. Given that the majority of individuals with type 2 diabetes are overweight or obese, weight loss through nutritional therapy is often a first step with respect to controlling diabetes [2]. Modest reductions in weight loss can decrease insulin resistance and improve other health outcomes, such as hypertension [2]. Furthermore, a nutritious diet that aids in weight loss or weight management may reduce the number of pharmacological agents that are needed to control diabetes and may improve psychological health such that the patient is empowered to effectively manage their diabetes. The American Diabetes Association (ADA) advises that individuals with diabetes follow the dietary guidelines for the general population: the Dietary Guidelines for Americans [3]; there is no scientific evidence to support a specific diet for individuals with type 2 diabetes. Thus, the ADA recommends following a healthy, nutrient dense diet in appropriate portion sizes to lose weight or maintain a healthy weight [2].

In the US general population, a significant increase in intake of total calories was found between 1971 and 2000 [4]. Subsequent to the year 2000, calorie intake has remained relatively stable [5]. In a national study of the general population, the percentage of energy from carbohydrate consumption increased, and the percentage of energy from fat and protein decreased between 1971 and 2006; these trends were similar across normal-weight, overweight and obese groups [6]. There are less data available on trends in dietary intake among US adults with type 2 diabetes. In a national study from 1988–2004 among adults with type 2 diabetes, approximately two-thirds consumed more fat and saturated fat than recommended, with older adults eating a lower percentage of calories from fat [7]. In a previous study using the same national data between 1988 and 2004, total energy consumption among adults with diabetes remained stable, except for those aged 45–64 years where consumption increased; for all adults with diabetes, carbohydrate consumption increased [8]. Finally, a national cross-sectional study conducted between 2005 and 2010 assessed whether knowledge of a diagnosis of diabetes made a difference in macronutrient intake; the results indicated that men and women with diagnosed diabetes consumed more protein than their counterparts with undiagnosed diabetes; however, all participants consumed less fibre and more saturated fat than recommended [9].

There are several micronutrients that are known to be important for diabetes management. There is limited evidence to indicate that low vitamin D and calcium levels may negatively affect glycaemic levels [10,11]. Nevertheless, calcium and vitamin D are important for bone health and individuals with diabetes are at an increased risk of fractures [12]. Vitamin C and potassium are found in a variety of fruits and vegetables and potassium may influence insulin secretion [13,14]. In some studies, magnesium deficiency has been associated with type 2 diabetes [15,16]. Despite these associations, the ADA does not have specific micronutrient guidelines for individuals with diabetes because the scientific evidence is insufficient to make any formal recommendations.

The main purpose of the present study was to determine trends in energy and macro- and micronutrient intake among adults with type 2 diabetes using data from the National Health and Nutrition Examination Surveys, 1988–2012. In addition, current dietary intake among adults with type 2 diabetes was assessed by age, sex and race/ethnicity, and comparisons were made to those without diabetes. The results from the present study provide new data on the nutritional status of US adults with type 2 diabetes.

Materials and methods

The National Health and Nutrition Examination Survey (NHANES) is a stratified multistage probability cluster survey conducted in the non-institutionalised US population [17]. Participants are interviewed in their home for basic demographic and health information. Following the in-home interview, participants are scheduled to visit a mobile examination center (MEC) to complete a physical examination and a 24-h dietary recall, and to obtain blood samples for laboratory measurement [18,19]. Between 1988–1994 and 2011–2012, the response rates for the interview ranged from 78.4% to 86.0%; for the examination, response rates ranged from 75.4% to 80.0%. Written informed consent was obtained from all participants and was approved by the National Center for Health Statistics Institutional Review Board.

Study participants

Participants were adults aged ≥20 years (N = 49 770). Diagnosed diabetes was determined if a participant answered ‘yes’ when asked whether a physician had ever told them that they had diabetes, excluding during pregnancy (n = 1193, NHANES III; n = 849, NHANES 1999–2002; n = 910, NHANES 2003–2006; n = 1341, NHANES 2007–2010; n = 592, NHANES 2011–2012). Participants likely to have type 1 diabetes were excluded (n = 265) based on the criteria of diabetes diagnosis at age <30 years, current insulin use, and starting insulin treatment within 1 year of diagnosis [20]. Participants self-reported demographic characteristics, including age, sex and race/ethnicity. The present study reports on non-Hispanic whites, non-Hispanic blacks and Mexican Americans.

Dietary intake

In the MEC, participants were asked to report all foods and beverages that were consumed in the past 24 h. The approaches used to collect dietary data and the databases used to analyse energy and nutrient composition have changed slightly over time; however, estimates are known to be comparable and any effect would be nondifferential [21–23]. In addition, the databases include foods and food products that are traditional to a variety of cultural backgrounds. In NHANES III, the recall was administered using a multiple-pass approach and coding system known as the NHANES III Dietary Data Collection (DDC) System [23]. The DDC system was developed for use in the survey by the University of Minnesota's Nutrition Coordination Center (NCC) and total nutrients were based on the NCC nutrient database. In the continuous NHANES (1999—2012), dietary data were collected using a computer-assisted dietary interview (CADI) system. In NHANES 1999–2000, nutrient intake was based on the University of Texas Food Intake Analysis System (FIAS) database and the USDA 1994–1998 Survey Nutrient Database [21]. Beginning in 2001, the dietary intake data was an integration of two surveys: the USDA's Continuing Survey of Food Intakes by Individuals (CSFII) and the DHHS's National Health and Nutrition Examination Survey (NHANES). The integrated dietary survey was named 'What We Eat in America'[22]. Subsequent to the year 2001, nutrient intake is based on the USDA's Food and Nutrient Database for Dietary Studies (FNDDS).

Statistical analysis

The mean (SE) and percentages were used to describe dietary intake in each survey period using the dietary recall from the MEC; 2-year survey cycles in the continuous 1999–2010 NHANES were combined into 4-year survey cycles as recommended by the National Center for Health Statistics [24]. Data from the 2011–2012 survey were released during the preparation of our paper and we chose to include these data as a 2-year cycle to provide the most recent estimates available; in addition, the 2011–2012 survey cycle was combined with the 2007–2010 survey cycles for significance testing by demographic characteristics. Estimates of dietary intake included mean energy intake (kcal) in each survey period, percentage of calories from consumption of carbohydrates, protein, total fat, saturated fat, polyunsaturated fat, monounsaturated fat; mean fibre intake (g 1000 $kcal^{-1}$); and mean intakes of sodium (mg), alcohol (g), cholesterol (mg), vitamin D (μg), calcium (mg), vitamin C (mg), magnesium (mg) and potassium (mg). Overall estimates were age and sex standardised to the 2007–2010 NHANES diabetic population using age groups 20–44, 45–64, 65–74 and ≥75 years. In addition, dietary intake was stratified by age, sex and race/ethnicity. Linear regression was used to test for a linear trend ($P < 0.01$) in dietary intake with each dietary component as the dependent variable and the midpoint of each survey cycle as the independent variable. Trend testing for estimates that were age and sex standardised also included independent variables for age and sex. Two-sided *t*-tests ($P < 0.01$) were used to determine differences in intake by demographic characteristics in 2007–2012. Finally, to enable a comparison with those with diabetes, overall dietary intake was assessed among those without diagnosed diabetes. Linear regression was used to test for an interaction between diabetes status and study period at the same time as adjusting for age, sex, race/ethnicity, education and body mass index (BMI). All statistical analyses used sample weights and accounted for the cluster sampling design using SUDAAN, release 9.2 (Research Triangle Institute, Research Triangle Park, NC, USA).

Results

Characteristics of participants

There was no significant change in the age or sex distribution over time (Table 1). The proportion who were non-Hispanic white significantly decreased and mean BMI significantly increased over time. The use of insulin was stable and the use of oral agents increased significantly.

Among adults without type 2 diabetes, there was a significant decrease in the proportion of adults aged 20–44 years and an increase in the proportion aged 45–64 years (see Supporting information, Table S1). Similar to those with diabetes, mean BMI increased significantly.

Energy, macronutrient and micronutrient intake

Age and sex-standardised estimates of nutrient intake are presented in Table 2. Estimates stratified by age, sex and race/ethnicity are provided in the Supporting information (Table S2).

Energy intake

Among adults with diabetes, energy intake significantly increased between 1988–1994 and 2011–2012 (1689 kcal versus 1895 kcal, respectively; $P_{trend} < 0.001$) (Table 2). This increase in energy intake was most apparent in those aged 45–64 years and among Mexican Americans (Fig. 1; see also Supporting information, Table S2). There was little change in energy intake between 2003–2006 (1888 kcal) and 2011–2012 (1895 kcal). In 2007–2012, adults 20–44 years consumed more calories than adults age ≥65 years and men consumed more calories than women.

There was no significant increase in total energy intake between 1988–1994 and 2011–2012 among adults without type 2 diabetes ($P_{trend} = 0.975$) (see Supporting information, Table S3). There was a significant interaction between diabetes status and study period after adjusting for sociodemographic characteristics and BMI ($P < 0.001$).

Percentage of calories from macronutrients

For adults with diabetes, the percentage of calories consumed from carbohydrates was stable between 1988–1994 (48.5%) and 2011–2012 (47.4%; $P_{trend} = 0.258$) and there

Table 1 Characteristics of participants age ≥20 years who self-reported type 2 diabetes in the National Health and Nutrition Examination Surveys: 1988–2012

	NHANES III, 1988–1994 (*N* = 1193) % (SE)†	NHANES 1999–2002 (*N* = 849) % (SE)	NHANES 2003–2006 (*N* = 910) % (SE)	NHANES 2007–2010 (*N* = 1341) % (SE)	NHANES 2011–2012 (*N* = 592) % (SE)
Age (years)					
20–44	15.3 (1.93)	17.1 (2.11)	13.2 (2.17)	10.2 (1.17)	10.8 (1.43)
45–64	41.9 (2.25)	45.9 (2.17)	44.4 (2.35)	46.9 (1.81)	47.9 (2.85)
65–74	24.8 (1.92)	23.1 (1.79)	26.7 (2.02)	25.7 (1.35)	22.7 (2.65)
≥75	18.1 (1.44)	13.8 (1.52)	15.8 (1.95)	17.3 (1.13)	18.7 (1.17)
Sex, women	56.0 (2.52)	50.7 (2.29)	53.4 (2.09)	51.7 (2.33)	51.2 (2.55)
Race/ethnicity					
Non-Hispanic white	77.9 (1.61)	72.1 (3.08)	71.7 (3.40)	68.7 (3.45)	69.0 (5.50)*
Non-Hispanic black	15.9 (1.45)	19.5 (3.04)	19.4 (2.40)	20.8 (2.49)	21.6 (4.93)
Mexican American	5.5 (0.47)	8.4 (1.63)	9.0 (2.02)	10.5 (2.37)	9.4 (3.24)
High school education	56.0 (2.79)	63.6 (2.79)	71.3 (1.96)	67.7 (1.46)	73.1 (3.18)
BMI (kg m^{-2}) (mean)	30.4 (0.31)	32.1 (0.45)	32.6 (0.50)	33.2 (0.33)	32.8 (0.51)**
Taking insulin	27.4 (1.42)	25.7 (2.76)	23.3 (1.81)	27.6 (2.00)	26.5 (2.36)
Taking oral agents	47.9 (2.61)	68.9 (2.49)	70.8 (2.52)	74.7 (1.90)	73.2 (3.17)**

*$P < 0.01$ for test of trends.
**$P < 0.001$ for test of trends.
†Percentage (SE), unless otherwise noted in left column.
BMI, body mass index.

Table 2 Intake of energy, macronutrients, and micronutrients from a 24-h dietary recall among adults with self-reported type 2 diabetes in the National Health and Nutrition Examination Surveys: 1988–2012

	NHANES III, 1988–1994 (*N* = 1193) Mean (SE)	NHANES 1999–2002 (*N* = 849) Mean (SE)	NHANES 2003–2006 (*N* = 910) Mean (SE)	NHANES 2007–2010 (*N* = 1341) Mean (SE)	NHANES 2011–2012 (*N* = 592) Mean (SE)
Total calories (kcal)	1689 (26.5)	1753 (35.1)	1888 (37.6)	1827 (31.0)	1895 (44.1)**
Macronutrients (%, SE)					
Carbohydrates	48.5 (0.6)	49.2 (0.8)	47.1 (0.5)	47.5 (0.4)	47.4 (0.7)
Protein	17.8 (0.3)	17.5 (0.3)	16.9 (0.3)	17.2 (0.2)	17.2 (0.4)
Total fat	34.1 (0.5)	34.2 (0.7)	36.1 (0.4)	34.9 (0.4)	35.2 (0.4)
Saturated fat	11.1 (0.2)	10.4 (0.3)	11.8 (0.2)	11.4 (0.2)	11.2 (0.2)
Polyunsaturated fat	7.3 (0.1)	7.6 (0.2)	7.9 (0.3)	7.5 (0.1)	8.5 (0.2)**
Monounsaturated fat	13.0 (0.2)	12.6 (0.3)	13.3 (0.2)	12.8 (0.2)	12.3 (0.3)
Fibre (g 1000 $kcal^{-1}$)	10.3 (0.3)	9.6 (0.3)	8.7 (0.2)	9.0 (0.2)	9.4 (0.4)*
Sodium (mg)	3037 (59.3)	3133 (88.5)	3226 (67.1)	3323 (60.8)	3376 (86.4)*
Alcohol (g)	4.1 (1.0)	3.0 (0.6)	5.1 (0.9)	5.9 (0.9)	3.8 (0.8)
Cholesterol (mg)	258 (10.7)	279 (13.4)	291 (13.1)	282 (8.0)	298 (12.1)
Vitamin D (μg)				4.4 (0.2)	5.2 (0.6)
Calcium (mg)	735 (20.2)	697 (20.5)	829 (23.5)	869 (19.3)	905 (33.1)**
Vitamin C (mg)	102 (4.6)	86 (4.1)	82 (5.2)	76 (3.3)	80 (5.1)**
Magnesium (mg)	281 (6.4)	263 (7.3)	275 (6.9)	273 (4.6)	285 (9.8)
Potassium (mg)	2743 (50.8)	2586 (59.8)	2650 (66.8)	2539 (46.0)	2643 (93.4)

Estimates are age and sex standardised to the 2007–2010 NHANES diabetic population.
*$P < 0.01$ for test of trends.
**$P < 0.001$ for test of trends.

were no changes over time by demographic factors (Table 2; see also Supporting information, Table S2). In 2007–2012, older adults and women consumed a greater percentage of calories from carbohydrates compared to younger adults and men. Overall, there was no change in the percentage of calories from protein, although intake

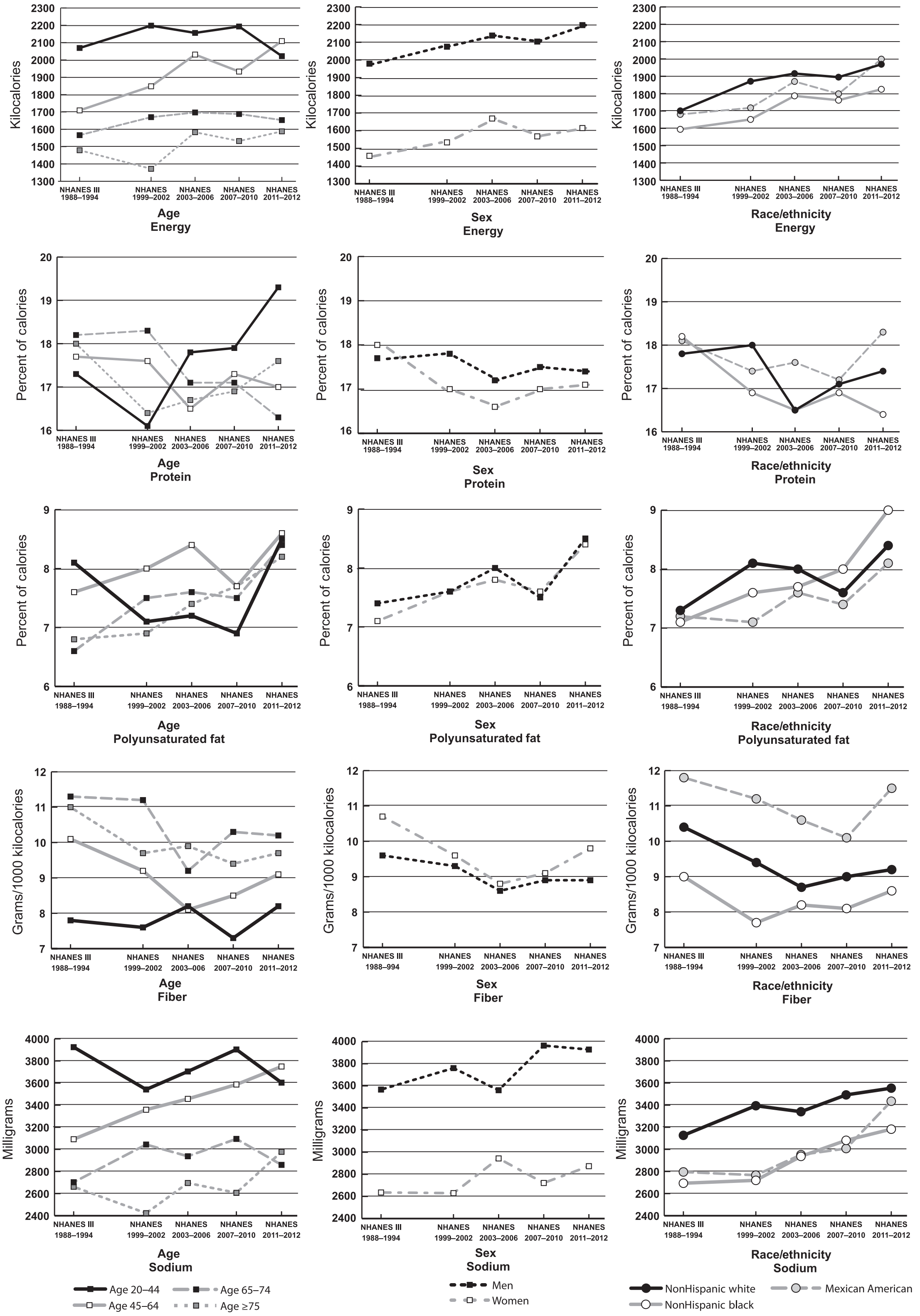

Figure 1 Energy and nutrient intakes among adults with diabetes: NHANES 1988–2012. Trends were significant ($P < 0.01$) for: energy, age 45–64 years and Mexican American; protein, age 65–74 years and non-Hispanic black; fibre, age 45–64 years, ≥75 years, women and non-Hispanic white; polyunsaturated fat, age 65–74 years, ≥75 years, women, non-Hispanic white and non-Hispanic black; fibre, age 45–64 years, ≥75 years, women and non-Hispanic white; sodium, age 45–64 years, men, non-Hispanic white and non-Hispanic black.

decreased for those age 65–74 years and non-Hispanic blacks (Fig. 1; see also Supporting information, Table S2). There was no change in total fat, or saturated fat between 1988–1994 and 2011–2012. In 2007–2012, saturated fat was significantly higher for non-Hispanic whites compared to non-Hispanic blacks and Mexican Americans. The percentage of calories from polyunsaturated fat significantly increased (Fig. 1; see also Supporting information, Table S2) and there was no change in the percentage of calories from monounsaturated fat (see Supporting information, Table S2).

Among those without type 2 diabetes, there was a significant decrease in percentage of calories consumed from saturated fat and monounsaturated fat, which was accompanied by an increase in percentage of calories from polyunsaturated fat ($P_{trend} < 0.001$ for all) (see Supporting information, Table S3). There was no change in percentage of calories from carbohydrates, protein or total fat. After adjusting for sociodemographic characteristics and BMI, there were significant interactions between diabetes status and study period for percentage of calories from protein ($P = 0.007$), total fat ($P = 0.009$) and saturated fat ($P = 0.004$).

Fibre intake (g 1000 kcal^{-1})

Fibre intake significantly decreased between 1988–1994 (10.3 g 1000 kcal^{-1}) and 2011–2012 (9.4 g 1000 kcal^{-1}; $P_{trend} = 0.002$) and this decrease was apparent for those aged 45–64 years, ≥75 years, women and non-Hispanic whites (Fig. 1 and Table 2). In 2007–2012, fibre intake was significantly lower among those age 20–44 years compared to adults ≥65 years (see Supporting information, Table S2). Mexican Americans had the highest intake of fibre and non-Hispanic blacks had the lowest intake compared to non-Hispanic whites.

Fibre intake was stable between 1988–1994 and 2011–2012 (9.2 g 1000 kcal^{-1}) but remained low among adults without type 2 diabetes (see Supporting information, Table S3). There was a significant interaction between diabetes status and study period after adjusting for sociodemographic characteristics and BMI ($P = 0.002$).

Sodium

Overall, sodium intake increased between 1988–1994 (3037 mg) and 2011–2012 (3376 mg; $P_{trend} = 0.002$) (Fig. 1 and Table 2). In 2007–2012, sodium intake was higher for younger adults, men and non-Hispanic whites compared to non-Hispanic blacks and Mexican Americans.

Among adults without type 2 diabetes, sodium intake was stable between 1988–1994 and 2011–2012 (3389 mg) (see Supporting information, Table S3). There was a significant interaction between diabetes status and study period after adjusting for sociodemographic characteristics and BMI ($P = 0.009$).

Alcohol

Alcohol intake remained stable between 1988–1994 (4.1 g) and 2011–2012 (3.8 g; $P_{trend} = 0.392$) (Table 2). Alcohol intake significantly increased for adults age 20–44 years and non-Hispanic blacks (see Supporting information, Table S2). In 2007–2012, alcohol intake was higher in younger adults and men. A standard drink in the US contains 14 g of alcohol; thus, consumption was below the recommendations of ≤2 drinks per day for men and ≤1 drinks per day for women.

There was no change in alcohol intake among adults without type 2 diabetes (see Supporting information, Table S3) and there was no significant interaction between diabetes status and study period.

Cholesterol

Cholesterol intake was stable between 1988–1994 (258 mg) and 2011–2012 (298 mg; $P_{trend} = 0.012$) (Table 2). However, there was a significant increase among those age ≥75 years and women (see Supporting information, Table S2). In 2007–2012, cholesterol intake was lower for older adults age ≥65 years and women.

There was no change in cholesterol intake among adults without type 2 diabetes (see Supporting information, Table S3) and there was no interaction between diabetes status and study period.

Micronutrients

In 2007–2012, vitamin D intake was similar by age but was significantly lower for women than men and for non-Hispanic blacks compared to non-Hispanic whites (see Supporting information, Table S2). Vitamin D intake was not ascertained prior to 2007–2012. Mean calcium intake significantly increased between 1988–1994 and 2011–2012. Vitamin C intake significantly decreased between 1988–1994 and 2011–2012 but was relatively stable between 1999–2002 and 2011–2012 (Table 2). Overall, there was no change in magnesium or potassium intake.

Intake of calcium increased, whereas intakes of vitamin C and potassium decreased, among those without diabetes ($P_{trend} < 0.001$ for all) (see Supporting information, Table S3). There was no interaction between diabetes status and study period.

Discussion

The ADA recommends that adults with diabetes follow a healthy, nutrient-dense and balanced diet to manage their diabetes. In addition, individuals with diabetes should be cognisant of any diabetes-related complications or comorbidities that may require modifications from the general Dietary Guidelines. Among adults with type 2 diabetes, energy intake significantly increased between 1988–1994 and 2011–2012, although there was little change between 2003–2006 and 2011–2012; supplemental analysis revealed that the observed increase in energy intake was not attenuated after controlling for BMI over time. These findings align with previous research in the general US population showing that calorie intake increased between the 1970s and 2000 but remained relatively stable through 2008 [4,5]. In addition, there were few changes in macronutrient composition over the study period for adults with type 2 diabetes. Carbohydrate intake was stable between 1988–1994 and 2011–2012; however, already low fibre intakes in 1988–1994 decreased further over time and were especially low among young adults. The Dietary Guidelines for Americans recommend fibre intale of at least 14 g 1000 $kcal^{-1}$; intake was 7.6 g 1000 $kcal^{-1}$ for adults age 20–44 years and 9.4 g 1000 $kcal^{-1}$ overall in 2011–2012 [3]. Accordingly, it can be assumed that a large proportion of carbohydrate consumption is coming from processed foods rather than whole grains, fruits or vegetables [25]. Protein intake decreased for adults age 65–74 years and non-Hispanic blacks, although the ADA does not have specific recommendations for protein even among those with diabetic kidney disease. The percentage of calories from saturated fat remained stable at 11% despite recommendations that <10% of calories come from saturated fat to reduce the risk of cardiovascular disease (CVD); thus, it appears that adults with type 2 diabetes are not decreasing their consumption of saturated fat and that intake remains at the high end of recommended levels [2,3]. Although saturated fat intake was similar by age in 2007–2012, intake among older adults increased significantly over the study period. Because older adults with diabetes already have a higher risk of diabetes-related complications, high levels of saturated fat intake may exacerbate their CVD risk; indeed, the American Heart Association recommends that dietary intake of saturated fat be <7.0% of total calories [26]. However, there was an increase in the percentage of calories from polyunsaturated fat, which are known to be beneficial for reducing cholesterol when consumed instead of saturated fats, suggesting that adults with diabetes may be trying to improve the types of fat that they consume.

It is important to highlight the suboptimal dietary intake among adults with type 2 diabetes aged 45–64 years, comprising the only age group that showed a significant increase in calorie intake between 1988–1994 and 2001–2012. A previous national study among individuals with diabetes documented a similar trend in increased calorie consumption among this age group between 1988 and 2004 [8]. In addition to the increase in energy consumption, diabetic adults aged 45–64 years continued to consume more saturated fat than recommended (11.5% of calories in 2007–2012), showed a decrease in already low fibre intakes to well below recommendations (8.7 g 1000 $kcal^{-1}$ in 2007–2012) and demonstrated an increase in sodium intake to well above recommendations (3647 mg day^{-1} in 2007–2012). The results in this age group are concerning given that the rate of muscle loss naturally increases around age 50 years and metabolic rate decreases; consequently, the likelihood of weight gain increases if energy consumption is not balanced [27]. For individuals with type 2 diabetes, weight gain and a subpar diet can further increase the risk of common comorbidities that often accompany a diagnosis of diabetes, such as hypertension and high cholesterol [28].

The ADA recommends that individuals with diabetes follow the general population Dietary Guidelines for micronutrient intakes [2,3]. Overall, adults with diabetes were within the recommended range for cholesterol (<300 mg); however, young diabetic adults, men, non-Hispanic blacks and Mexican Americans had intakes just above recommendations. Furthermore, the Dietary Guidelines recommend a daily cholesterol intake of <200 mg for individuals at high risk of cardiovascular disease, which includes many individuals with diabetes. Sodium intake remained stable but was approximately 1000 mg greater than recommended levels (2300 mg); intake was especially high for young diabetic adults and men. The ADA states that, for individuals with diabetes and hypertension, further reduction in sodium should be individualised to help manage blood pressure levels. Much of the sodium in the US diet comes from processed foods; therefore, education on eating whole, unprocessed foods would naturally reduce the amount of sodium consumed in this population at the same time as reducing saturated fat intake [29]. Nevertheless, there is current debate on whether sodium recommendations are too low [30,31]. Although intake of calcium increased over the study period, consumption was below recommended levels (1000–1200 mg). Individuals with diabetes are at a higher risk of bone fractures; thus, calcium is an important nutrient for this population [32,33]. Current vitamin D intake was low for older diabetic adults, which is also important for bone health (15 μg recommended). Intake of vitamin C, which is commonly found in a variety of fruits and vegetables, decreased over the study period but was within recommended dietary allowances (75–90 mg). Magnesium intake did not change over the study period but intakes were below recommended levels (300–400 mg); although magnesium deficiency has been associated with diabetes, levels were also low among those without diabetes [15,16]. Finally, potassium, which is also found in a variety of fruits and vegetables and may influence insulin secretion, decreased over the study period and was below recommended daily intake levels (4700 mg per day) [14]; intake was also low among nondiabetic individuals. It is important to note that the vitamin intakes reported in the present study only account for these nutrients consumed through food, and do not account for intake through supplements or multivitamins.

The prevalence of obesity in the US population increased significantly between 1960 and 2000, with evidence that the epidemic plateaued between 2003 and 2010 [34,35]. This aligns with findings in the general population that have shown an increase in energy consumption between the 1970s and 2000 and a relatively stable energy intake between 2000 and 2008 [4,5,34,36,37]. The results from the present study among individuals with type 2 diabetes were similar in that energy consumption increased between 1988–1994 (1689 kcal) and 2011–2012 (1895 kcal), although the amount of calories consumed between 2003–2006 and 2011–2012 was unchanged (1888 kcal versus 1895 kcal). Interestingly, recent research has suggested a plateau in the prevalence and incidence of diabetes between 2008 and 2012; however, future data are needed to confirm this trend to be able to make any association between changes in calorie intake and the prevalence of diabetes [38]. These findings are encouraging because weight control or loss is a major factor in determining future complications. However, the use of glycaemic medications can make weight management particularly difficult for those with diabetes [28]. Diabetes medications can increase energy intake if patients are over medicated and, consequently, experience hypoglycaemia; in addition, patients may think of their medications as a safety net and an excuse to consume excess energy. Nevertheless, in supplemental analysis, we found no differences in energy intake by insulin use (1871 kcal versus 1810 kcal for no insulin use), use of oral agents (1817 kcal versus 1842 kcal for no oral agents) or BMI (1716 kcal for normal weight versus 1851 kcal in obese) (data not shown). Further investigations with future data will help determine whether energy intake has truly plateaued among individuals with diabetes.

Unlike adults with type 2 diabetes, there was no significant change in energy consumption among adults without type 2 diabetes despite an approximately 100 calorie increase over the study period. Those without diabetes had a lower mean BMI compared to those with diabetes, which may have resulted in smaller change in energy consumption. Energy consumption was higher among adults without diabetes, although this finding is likely a result of the diabetes population being older. Similar to adults with type 2 diabetes, among those without diabetes, the intake of polyunsaturated fat and calcium increased, whereas the intake of vitamin C and potassium decreased; however, saturated fat and monounsaturated fat also decreased among those without diabetes.

A strength of the present study was the nationally representative sample of US adults with type 2 diabetes; thus, the results can be generalised to the US, non-institutionalised population. The relatively consistent methods in the NHANES allowed for the examination of data over several decades and an assessment of trends. Although dietary intake was self-reported, the recall was interviewer-assisted and computer-based to ensure that the most accurate information was collected. In addition, the food databases included a large number of foods and food products; any updates to the food databases over time would be expected to have a nondifferential effect on the assessment of dietary intake by demographic characteristics. Dietary recalls are considered reliable in a healthy normal weight population, although those with diabetes or who are overweight may tend to under-report intake [39]. It is also possible that, regardless of weight status, adults may alter their eating habits if they know they will need to report on what they had eaten the following day [39]. Thus, the energy intake reported may be lower than actual intake. Only one dietary recall was used to estimate nutrient intake because not all NHANES survey years collected two recalls. However, nutrient intake based on one recall can be a reliable measure of usual intake in large population groups [40]. Sodium intakes were adjusted in NHANES 2002–2008 based on the use of salt in home food preparation, although this adjustment was not used in NHANES III, NHANES 1999–2001 or NHANES 2009–2012; thus, estimates in NHANES 2007–2010 and NHANES 2011–2012 cycles may be slightly higher as a result of this change in methods [41]. Finally, diabetes was self-reported and not adjudicated; we focused on the dietary intake of adults with self-reported diabetes who are aware of their diabetes status and should, ideally, be conscientious of their diet. In addition, self-report of diabetes in survey data has been shown to be highly reliable [42].

An optimal diet varies with respect to a variety of factors, including age, current health, medications, activity level and metabolism. As recommended by the Dietary Guidelines, intake should focus on whole foods rich in whole grains, fruits, vegetables, healthy fats and appropriate portion sizes for weight loss or management. The evidence for these recommendations is primarily based on research in the general population related to reducing CVD risk factors, many of which are relevant to those with diabetes; however, there is little scientific research on optimal dietary intake among those with diabetes. Given that there is a lack of evidence to endorse one specific type of diet, dietary intake should be individualised within the parameters of the major guidelines.

Conclusions

The ADA recommends that individuals with type 2 diabetes follow the Dietary Guidelines for Americans and consume a healthy, nutrient dense diet in appropriate portion sizes to lose weight or maintain a healthy weight. Overall, there was a significant increase in energy intake between 1988–1994 and 2011–2012 for adults with diabetes in the US; however, there was evidence that energy intake plateaued between 2003–2006 and 2011–2012. In addition, saturated fat and sodium intakes were high and fibre and calcium intakes were low across all age, sex and race/ethnic groups. Thus, there is substantial opportunity for US adults with type 2 diabetes to improve their dietary intake. Individuals with diabetes, especially older adults who have a higher risk and prevalence of comorbidities, should carefully manage their diet. It is promising that energy intake among adults with diabetes may be plateauing, a finding that has also been found in the general US population, although future data are needed to confirm this trend.

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Conflict of interests, source of funding and authorship

The authors declare they have no conflicts of interest.
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SSC formulated the research question, designed the study, analysed the data and wrote the manuscript. CCC formulated the research question, designed the study, and edited and revised the manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication

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Supporting information

Additional Supporting Information may be found online in the supporting information tab for this article:

Table S1. Characteristics of participants age ≥20 years without a self-reported diagnosis of type 2 diabetes in the National Health and Nutrition Examination Surveys, 1988–2012.

Table S2. Intake of energy, macronutrients and micronutrients from a 24-h dietary recall by age, sex and race/ethnicity among adults who self-reported type 2 diabetes in the National Health and Nutrition Examination Survey, 1988–2012.

Table S3. Intake of energy, macronutrients, and micronutrients from 24-h dietary recalls among adults without a self-reported diagnosis of type 2 diabetes in the National Health and Nutrition Examination Surveys, 1988–2012.

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OBESITY AND RELATED DISORDERS

Lifestyle change reduces cardiometabolic risk factors and glucagon-like peptide-1 levels in obese first-degree relatives of people with diabetes

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Abstract

Background: Preventing type 2 diabetes in a real-world setting remains challenging. The present study aimed to assess the effectiveness of a lifestyle-based programme for individuals at high risk of developing type 2 diabetes as assessed by achieved weight loss, cardiovascular risk factors and glucagon-like peptide-1 (GLP-1).
Methods: Sixty-six obese individuals with history of diabetes in first-degree relatives participated in an 8-month lifestyle programme consisting of 12 × 1.25 h group education sessions led by dietitian and a weekly exercise programme. Before and after comparisons were made of fasting blood glucose, insulin, HbA1c, lipids, GLP-1 and quality of life (QoL).
Results: Fifty-four participants of whom the majority were women [47 females; mean (SD) body mass index 35.3 (2.8) kg m^{-2}; age = 52 (10) years] completed the 8-month programme. Mean (SD) weight loss was 10.1 (6.0) kg ($P < 0.001$). Out of 54 participants, 36 lost more than 7% of their body weight and 47 lost more than 5%, with significant improvements in cardiovascular risk factors, glycaemia and QoL scores. The fall was observed in basal ($P < 0.05$ versus baseline) but not stimulated GLP-1 levels. In the subgroup of participants losing >10 kg, a correlation was found between weight change and change in both basal ($r = 0.61$, $P < 0.05$) and stimulated ($r = 0.49$, $P < 0.05$) GLP-1.
Conclusions: An evidence-based lifestyle programme achieved sustained weight loss in obese first-degree relatives of individuals with type 2 diabetes associated with improvements in cardiometabolic risk factors and QoL without the 'voltage drop' of less benefit commonly seen when moving from the clinical trial experience into the real world.

Introduction

For individuals at high risk of developing type 2 diabetes, interventions based on lifestyle changes are effective in reducing the progression from prediabetes to diabetes [(1–3)]. The challenge for healthcare systems is to translate the evidence from the large and costly randomised trials into routine clinical practice and preferably within community settings [(4)]. In the UK, Public Health England has proposed targeting people with nondiabetic hyperglycaemia (HbA1c between 42 and 47 mmol mol^{-1}) with lifestyle-based interventions which, in practical terms, represents approximately one in 10 of the adult population [(5)]. This population-based approach has been criticised as being unlikely to stem the epidemic of type 2 diabetes and also is likely to be ineffective in reducing cardiovascular risk. One of the main concerns is the 'doubtful' assumption that individuals targeted in the real-world setting will be able to achieve clinical outcomes similar to those of participants in well controlled research studies [(6)].

Being overweight and having family history of diabetes are two important factors used to identify people potentially at high risk of type 2 diabetes [(7)]. Therefore, targeting these individuals would appear to be a more cost-effective approach as opposed to offering HbA1c screening to everyone or offering lifestyle change to 'anyone at risk' [(8)]. Previously, we have reported that, in a pilot study of individuals with very recent onset of type 2 diabetes, a group lifestyle intervention programme comprising an 8-month weight reduction phase followed by an 8-month maintenance phase was associated with sustained weight loss together with favourable improvements in fasting glucose, insulin resistance, blood pressure and HbA1c levels [(9)]. In a second pilot project, we recruited individuals who were at risk of type 2 diabetes from local primary care practices based on criteria from the UK's National Institute of Health and Care Excellence [(10)]. In that study, body weight decreased significantly by an average of 11% after 12 months and was associated with sustained improvements in HbA1c, fasting blood glucose levels, blood pressure, waist circumference and quality of life (QoL), as well as an increase in high-density lipoprotein cholesterol levels.

The present study assessed the effectiveness of a lifestyle-based programme aimed at first-degree obese relatives of people with type 2 diabetes. The impact of lifestyle change was assessed by the achieved weight loss, with changes in glycaemia, cardiovascular risk factors and levels of glucagon like peptide-1 (GLP-1). Previously, in our pilot study of participants with new onset of type 2 diabetes study, despite significant and sustained weight loss and improved glycaemia,we saw no change in either fasting or stimulated GLP-1 levels [(9)]. The GLP-1 response to nutrient intake has been reported as attenuated in type 2 diabetes [(11)] and there has been some debate as to whether this observed abnormality is a cause or consequence of type 2 diabetes [(12)].

Materials and methods

Subjects

Informed written consent was obtained and the study was approved by the Dorset Ethics Committee. Local newspaper articles and poster adverts were used to recruit potential subjects. The criteria for inclusion were age 18–65 years with a body mass index (BMI) of between 30.0 and 39.9 kg m^{-2} and a family history of type 2 diabetes in the first-degree relatives (e.g. parents or siblings). Individuals who have been diagnosed with diabetes, who were not able to attend at least 75% of the sessions or who were prescribed anti-obesity or any other prescription medications that may interfere with the study results were excluded. To eliminate the chance of undiagnosed type 2 diabetes, subjects were screened during the baseline assessment using a 75-g oral glucose tolerance test. If the test confirmed diabetes, the subject was referred to his/her general practitioner.

Procedures

Participants were asked to attend following an overnight 12-h fast. Blood samples were taken for measurement of fasting blood glucose, HbA1c, lipids, insulin and GLP-1. Subjects were given a 75-g glucose load in the form of a glucose polymer and a repeat blood sample for stimulated GLP-1 level taken after 30 min. To eliminate the possibility of undiagnosed diabetes at the baseline assessment, an additional blood test was taken 2 h after a standard 75-g glucose load as per oral glucose tolerance test protocol. Blood for GLP-1 was taken directly into cooled ethylenediaminetetraacetic acid tubes containing DPP-IV inhibitor at a final concentration of 100 μmol L^{-1} (Linco Research, Millipore, St Charles, MO, USA). Samples for insulin and GLP-1 were stored at −40 °C until analysis. Glucose and lipids were measured using a Cobas 8000 automated clinical chemistry analytical system (Roche Diagnostics, Burgess Hill, UK). HbA1c was measured using a Menarini HA-8140 HPLC analyser (Menarini Diagnostics, Wokingham, UK). Insulin was measured by an electrochemiluminescence sandwich immunoassay on an Elecsys E170 Module (Roche Diagnostics). Homeostatic model assessment of insulin resistance (HOMA-IR) was conducted using the HOMA calculator downloaded from the Oxford diabetes clinical trials unit website (https://www.dtu.ox.ac.uk/homacalculator/download.php). Total GLP-1 (7–37 and 9–36), was measured in plasma by a sandwich enzyme-linked immunosorbent assay (Linco Research). Measurements were repeated after 4 and 8 months.

Anthropometry

Height was assessed using standard stadiometer. Weight and percentage body fat were assessed in the fasting state with light clothing and after voiding their bladder using a body composition analyser (BC418-MA; Tanita, Tokyo, Japan). Waist circumference was measured at the level of the ileac crest to the nearest 0.1 cm using standard tape measure, with the subjects in a standing position. Seated blood pressure was measured after a 5-min rest using an automated blood pressure device. Three measurements were obtained, with the average of these measurements being used to represent the blood pressure. Participants brought their repeat prescriptions issued by their doctor to report their medications.

Quality of life assessment

At baseline and after 8 months, participants completed the RAND 36-Item Health Survey Questionnaire [13]. This is validated QoL questionnaire that evaluates eight health concepts: physical functioning, role limitations as a result of physical health, role limitations as a result of emotional problems, energy/fatigue, emotional well-being, social functioning, pain and general health perceptions.

Lifestyle intervention

There was one initial one-to-one session followed by 14 group sessions (group size 6–10) over an 8-month period: an intensive phase of nine sessions in the first 4 months and five sessions during the maintenance follow-up 4 months. Each group session started with a confidential 'weigh in' followed by a 1.25-h education session. Each session covered a topic related to healthy eating, physical activity and behavioural change with an emphasis on reducing the potential risks of type 2 diabetes and heart disease. Participants also received three telephone calls of 0.25 h in duration from the dietitian. The programme was run by a research dietitian with specialist training in behavioural change techniques with support from a research nurse. The programme also offered free of charge weekly exercise sessions at the local health centre.

The programme followed the principles described in the European Evidence-Based Guidelines for the prevention of type 2 diabetes (IMAGE) [14,15] and US DPP publicly available material [16,17]. The change in lifestyle was facilitated using goal-based behavioural change techniques, including self-monitoring, stimulus control, goal setting, slowing rate of eating, ensuring social support, problem solving, relapse prevention, stress managements and cognitive restructuring (modifying thoughts aimed at positive thinking). Participants were encouraged to use food and activity diaries and to weigh themselves weekly. The agreed goal for each participant was to achieve at least 5–7% weight loss during the intensive 4 months phase and then weight maintenance or further weight loss at 8 months, ensuring that the final BMI did not drop below 24 kg m^{-2}.

The dietary advice was based on The UK Balance of Good Health guidelines [18]. Diet and lifestyle histories obtained at the first appointment were used to design participants' individualised diet plans and set their personal short- and long-term goals. Daily recommended energy requirements were estimated based on 7-day food records and Schofield's [19] equation, with a 16.74–41.84 MJ day^{-1} (400–1000 kcal day^{-1}) deficit depending on current body weight and typical dietary intake. The plan was based on the British Heart Foundation material: [20] a food portion plan with a daily energy intake target, description of portion sizes and examples of snacks of different energy intake values.

The exercise component consisted of a weekly 1-h circuit training class of 10 exercise stations alternating between resistance, cardiovascular and respiratory exercises at a local health centre. Prior to starting the fitness programme, fitness of patients was assessed by a qualified fitness instructor and individualised advice was given regarding the type and intensity of the exercise level. Participants were encouraged to increase their activity levels to a minimum of 150 min per week [21] and were advised to monitor their daily number of steps, aiming for 10 000 per day.

Design, sample size and statistical analysis

The present study was designed as a nonrandomised, single arm, intervention with repeated measurements at baseline and after 4 and 8 months of the intervention. The sample size was chosen aiming to detect the changes in GLP-1 concentration and power calculations were based on our earlier pilot study of 22 participants with new onset type 2 diabetes who also followed an 8-month lifestyle intervention, with a weight change of 8% [−7.7 kg (95% confidence interval = 6.6–9.7) kg] after 8 months compared to baseline [9]. The primary aim of the present study was to assess the impact of a change in weight and GLP-1 levels. To detect such a change as being statistically significant at the 5% level, with 80% power, required a sample size of 53. To correct for a 20% drop-out rate, we set a target of 66 participants based on our earlier pilot study data [9].

Data are expressed as the mean (SD). Pre- and post-intervention data were compared with paired *t*-tests using a 5% significance level. Pre- and post-intervention changes were compared using Pearson's or Spearmen's correlation for normally and not normally distributed data, respectively.

Results

During the screening phase, three volunteers were excluded after being found to have undiagnosed type 2 diabetes. Sixty-six participants [57 women; mean (SD) BMI 34.6 (2.6) kg m^{-2}; age = 51 (10) years] were enrolled in the 8-month programme. Eight were found to have impaired glucose tolerance following the oral glucose tolerance test. Fifty-four [47 females; mean (SD) BMI 35.3 (2.8) kg m^{-2}; age = 52 (10) years] completed the programme (18% drop-out rate). Completers were defined as those who attended at least 75% of the group sessions and were present at the 4- and 8-month assessments. Data from baseline to the 4- and 8-month assessments for the 54 completers are shown in Table 1.

At baseline, six participants were taking cholesterol-lowering medications, one was taking blood pressure-lowering medications, six were taking both blood pressure- and cholesterol- lowering medications, and eight were also prescribed anti-depressant medication. During the 8-month study period, blood pressure medications were changed for two patients by their general practitioners.

Weight loss

During the 8-month programme, mean weight loss (SD) was 10.1 (6.0) kg (range 2.2–32.3 kg) compared to baseline. During the initial 4-month phase, the loss for the whole group was 7.8 (3.4) kg, with a further modest loss of 2.3 (3.3) kg between 4 and 8 months (Fig. 1and Table 1). Out of 54 participants, 36 lost more than 7% of their body weight and 47 lost more than 5%.

Glucagon-like peptide-1 concentration

Basal GLP-1 reduced significantly ($P < 0.05$) at 8 months, although there was no change in the stimulated GLP-1 levels compared to baseline. Correlation analyses showed no significant correlation among change in weight with change in basal or stimulated GLP-1 levels. However, for participants ($n = 23$) who lost more than 10 kg [mean (SD) loss −15.3 (5.6) kg], the correlation was significant between the weight change and change in both basal ($r = 0.61$, $P < 0.05$) (Fig. 2) and stimulated GLP-1 ($r = 0.49$, $P < 0.05$) (Fig. 3).

Quality of life and time demands

Based on the RAND 36-Item Questionnaire, at 4 months QoL improved in three domains: 'physical functioning' ($P = 0.04$), 'role limitation as a result of emotional health' ($P = 0.01$) and 'pain' ($P = 0.008$). At 8 months, an improvement was recorded in 'physical functioning' ($P = 0.03$) and 'energy and fatigue' ($P = 0.03$).

Each participant received a total of 19.25 h of intervention time (i.e. 1 h for the initial appointment plus 14 × 1.25 h for the sessions plus 3 × 0.25 h for the phone calls) but, because the sessions were group-based, dietitian's/ nurse's direct time spent per participant was only 5.27 h over 8 months.

Discussion

The present study provides evidence that, by using simple criteria to focus on individuals at high risk of developing type 2 diabetes, meaningful and sustained weight loss is

Table 1 Anthropometric and biochemical data at baseline and change from baseline after 4 and 8 months of lifestyle intervention ($n = 54$)

	Units	Baseline	Mean (SD) change at 4 months	Mean (SD) change at 8 months
Weight	kg	95.8 (11.4)	−7.8 (3.4)**	−10.1 (6.0)**
Weight	%		−8.1 (3.3)**	−10.5 (5.8)**
BMI	kg m^{-2}	34.7 (2.8)	−2.8 (1.2)**	−4.2 (4.3)**
Waist circumference	cm	109.2 (9.1)	−11.9 (6.0)**	−14.3 (7.4)**
% Body fat	%	44.4 (6.3)	−3.0 (2.1)**	−3.6 (3.2)**
kg body fat	kg	42.6 (8.5)	−6.0 (3.1)**	−7.4 (5.2)**
Systolic BP	mmHg	138.3 (15.6)	−8.6 (10.6)**	−12.2 (14.8)**
Diastolic BP	mmHg	82.6 (6.8)	−4.2 (6.5)**	−4.8 (8.8)**
Cholesterol	mmol L^{-1}	5.8 (1.2)	−0.3 (0.6)**	−0.1 (0.5)*
LDL-cholesterol	mmol L^{-1}	3.7 (1)	−0.3 (0.5)**	−0.1 (0.4)
HDL-cholesterol	mmol L^{-1}	1.47 (0.39)	−0.01 (0.20)	0.05 (0.20)
Fasting glucose	mmol L^{-1}	5.1 (0.5)	−0.1 (0.4)*	−0.2 (0.5)*
HbA1c	mmol mol^{-1}	39.5 (4.1)	−0.6 (2.4)*	−1.3 (2.1)**
HbA1c	%	5.8 (0.4)	−0.1 (0.2)*	−0.2 (0.8)**
Triglycerides	mmol L^{-1}	1.4 (0.6)	−0.1 (0.4)*	−0.2 (0.4)**
Ratio cholesterol/HDL- cholesterol		4.2 (1.2)	−0.2 (0.6)*	−0.3 (0.6)**
Fasting insulin	mIU L^{-1}	10.84 (4.72)	−2.59 (3.99)**	−2.61 (4.13)**
HOMA-IR		2.47 (1.15)	−0.61 (0.94)**	−0.62 (1.02)**
Fasting GLP-1	pmol L^{-1}	42.7 (16.2)	Not measured	−4.9 (16.2)*
Stimulated GLP-1 30 min	pmol L^{-1}	59.4 (19.5)	Not measured	2.63 (35.7)

Values are the mean (SD); *$P < 0.05$, **$P < 0.001$ versus baseline (two-tailed paired *t*-test).BMI, body mass index; BP, blood pressure; GLP-1, glucagon-like peptide-1; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

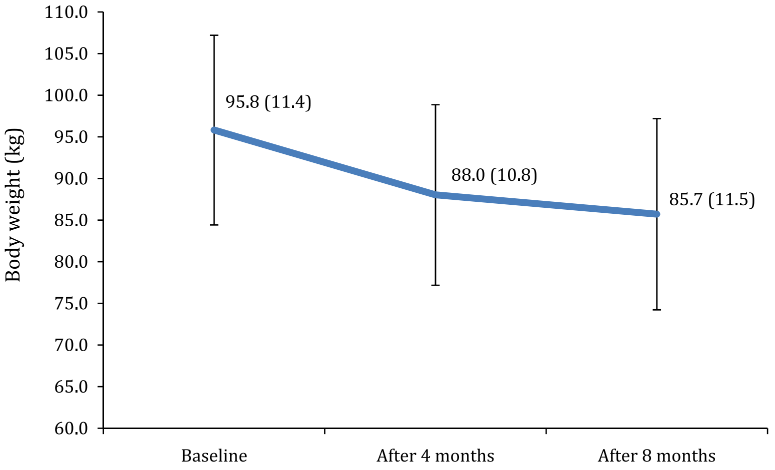

Figure 1 Mean body weight (SD) at baseline and after 4 and 8 months of lifestyle intervention (n = 54).

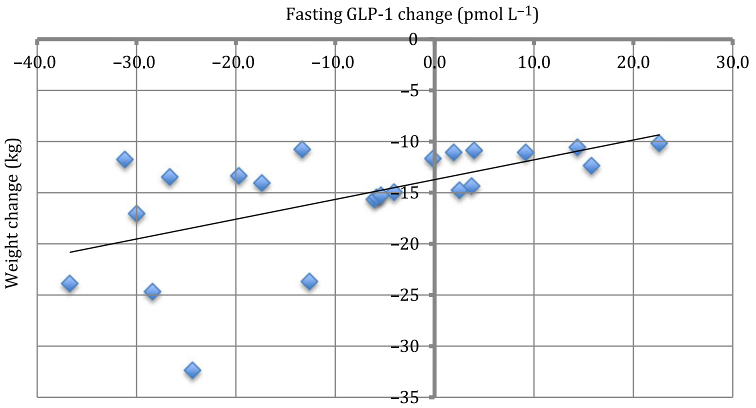

Figure 2 Change in weight and fasting glucagon-like peptide-1 (GLP-1) concentration after 8 months of lifestyle intervention for the group of patients who achieved >10 kg weight loss (n = 23) (r = 0.61, $P < 0.05$).

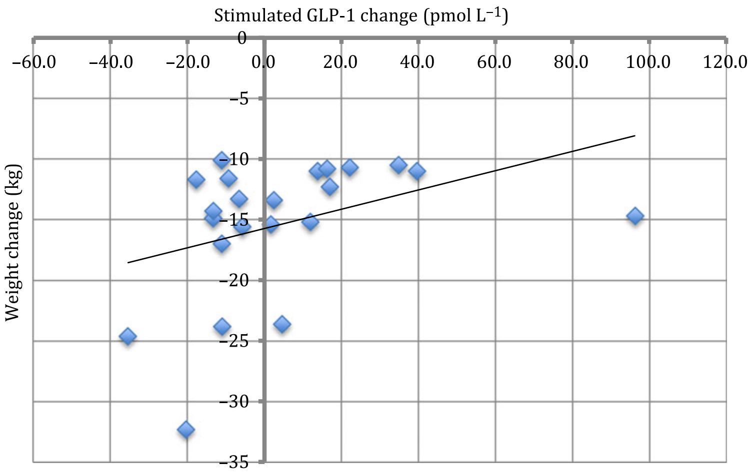

Figure 3 Change in weight and stimulated glucagon-like peptide-1 (GLP-1) (30 min after glucose load) concentration after 8 months of lifestyle intervention for the group of patients who achieved >10 kg weight loss (n = 23) (r = 0.49, $P < 0.05$).

achievable and can be associated with significant improvements in cardiometabolic risk factors. Here, the criteria for inclusion were age 18–65 years with an elevated BMI and a family history of type 2 diabetes in first-degree relatives (e.g. parents or siblings). In the present study, weight loss averaged 10 kg, with almost 90% of participants losing at least 5% of their baseline weight. The majority of participants were female and 82%

completed the 8-month programme. The amount of sustained weight loss and improvement in cardiometabolic factors was very similar to smaller studies that we have performed in individuals with very recent onset of type 2 diabetes [9] and others at risk of type 2 diabetes [10].

Weight loss is established as an appropriate approach for prevention of type 2 diabetes and among at risk individuals where 1 kg of weight loss reduces the risk of type 2 diabetes by 16% [22]. The weight loss achieved in the present study compares well with the Finnish and US Diabetes prevention programmes [1,2] and our earlier pilot projects [9,10]. However, most participants in previous clinical trials focusing on diabetes prevention had impaired glucose tolerance at entry [23]. Outside of a formal clinical trial setting, a recent systematic review of the impact of real-world diabetes prevention programmes (n = 36) reported a much more modest weight loss of around 2.46 kg at 12–18 months [24]. Our intervention was 8 months long, and it is unknown whether the weight loss achieved will be sustained over the long term. However, real-world studies have demonstrated that the weight loss achieved in the first year is maintained at up to the 3-year follow-up point, with data being scarce beyond this [24].

Compared to the present study, in real-world interventions, the greater the number of men, the more likely the incidence of diabetes and weight gain [24]. Unfortunately, difficulty in recruiting male participants is a common problem reported in the majority of real-world programmes [25]. We adopted a group approach rather than one-to-one sessions based on the experience from similar real-world diabetes prevention programmes [25]. Over 12 months, each participant received a total of 19.25 h of intervention time but, because the sessions were group-based, the direct time spent per participant was 5.27 h, which is approximately four-fold less than in US DPP [16]. None of our participants were from ethnic minority populations. It is unclear whether the programme reported in the present study would be applicable to different ethnic groups, some of whom are at substantially greater risk of type 2 diabetes and the complications associated with the condition [26].

In the UK, Public Health England proposes targeting individuals with nondiabetic hyperglycaemia [27]. Similar approaches have been implemented in Finland [28] and Australia [29,30]. In the USA, the Center for Disease Control and Prevention has also established a National Diabetes Prevention Program based on the results of the earlier large-scale evaluative trials [31].

Population-based strategies to improve food quality and physical activity have been advocated as a more cost-effective approach for reducing cardiometabolic risk than targeting individuals [32]. However interventions-based personal risk is widely advocated for cardiovascular disease risk reduction and, in reality, there is a paucity of evidence in support of effective healthy eating and physical activity. For example, in the USA under the Affordable Care Act, all chain restaurants with more than 20 locations are now obligated to show calorie information on their menus based on the concept that more information may lead to positive behaviour change [33]. In reality, although the majority of US consumers appear to want menu labelling [34], current evidence suggests that this does not result in fewer calories being consumed [35]. Therefore, it may be more appropriate to introduce systems that combine both population and individual interventions. Insulin resistance and clustering of cardiovascular risk factors such as hypertension and an unfavourable lipid profile are commonly associated with excess weight gain [36] and even modest weight loss shows an improvement in these risk factors [37–39]. In the present study, improvement was achieved in most cardiovascular risk factors, including blood pressure, lipids and insulin resistance. Compelling evidence demonstrates that the magnitude of risk factor modification is likely to be associated with substantial reductions in both fatal and nonfatal cardiovascular disease events [40–43]. It remains to be determined whether our approach would result in clinically meaningful long-term benefits.

Evidence is emerging that incretin hormone GLP-1 has a major role to play not just in type 2 diabetes, but also in obesity and potentially may contribute to prediabetic hyperglycaemia [44]. Low levels of GLP-1 are seen in some obese subjects and there is negative correlation between BMI and the response of GLP-1 to oral glucose or carbohydrate containing foods [45–49]. In the present study, we saw a very modest lowering of fasting GLP-1 levels without any change in stimulated levels 30 min after an oral glucose load. We did not find a correlation between weight loss and GLP-1 for the whole group. However, there was a positive correlation for the subgroup of subjects who lost more than 10 kg in weight. The significance of this observation needs to be determined. Other studies have reported variable impact on both fasting and stimulated GLP-1 levels in nondiabetic individuals after nonsurgical weight loss [45,50,51].

In conclusion, a group-based lifestyle programme achieved sustained weight loss in obese first-degree relatives of individuals with type 2 diabetes. This was associated with significant improvements in established cardiometabolic risk factors and QoL. Our intervention was based on evidence-based approaches from large-scale clinical trials but required less time and was without the ‘voltage drop’ of less benefit commonly seen when moving from the clinical trial experience into the real-world.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of this work is compliant with CONSORT1/STROBE2/PRISMA3 guidelines.

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Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.
The sponsor of the present study was Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust.
All authors contributed to the study design and helped with recruitment. AB developed and ran the lifestyle programme. JB carried out the biochemical analyses and all authors were involved in the statistical calculations. All authors helped to draft the manuscript and contributed to reviewing, editing and approving the final version of the paper submitted for publication.

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OBESITY AND RELATED DISORDERS

Evaluation of the Alternative Healthy Eating Index as a predictor of 10-year cardiovascular disease risk in a group of Iranian employees

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Keywords
Alternative Healthy Eating Index, cardiovascular disease, Framingham Risk Score, Iranian population.

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Abstract

Background: Noncommunicable diseases, of which almost half are some form of cardiovascular disease (CVD), have overtaken communicable diseases as the world's major disease burden. There is growing evidence that indices of diet quality could have an association with a decreased risk of CVD in several countries. We aimed to examine the association between diet quality, as measured by the Alternative Healthy Eating Index (AHEI), and 10-year predicted CVD risk based on the Framingham Risk Score (FRS) in a group of Iranian employees.
Methods: A cross-sectional descriptive study was conducted on 296 (232 male, 64 female) employees aged ≥30 years selected by nonrandom sampling. AHEI was calculated according to a food frequency questionnaire with complementary questions on intake of cooking fats and oils among households. The 10-year risk of CVD was calculated based on FRS. Total and high-density lipoprotein-cholesterol, fasting blood sugar and blood pressure were measured to help in the calculation of FRS.
Results: AHEI did not have a significant relationship with FRS ($r = -0.02$, $P = 0.67$). However, some of its components, such as the intake of nuts and soy groups ($r = -0.11$, $P = 0.04$) and fruits ($r = -0.14$, $P = 0.01$), had a significant relationship with a reduced risk of CVD. According to stepwise multiple linear regression results, for every single increase in the intake of fruit servings, there would be a 0.14 reduction in the 10-year CVD risk score ($\beta = -0.14$, $P = 0.01$).
Conclusions: The present study showed no significant relationship between AHEI and the 10-year predicted risk of CVD among Iranian employees.

Introduction

Cardiovascular disease (CVD) is one of the most critical causes of mortality and morbidity in the world. Therefore, an early diagnosis of individuals at risk for CVD is the priority of the health system [(1)].

Cardiovascular disease was associated with 17.3 million deaths in 2008 and more than 23.6 million people will die worldwide annually from CVD by 2030 according to the World Health Organization [(2)]. Cardiovascular disease led to 41.3% of all Iranian deaths in 2005; this is estimated to reach 44.8% in 2030 [(3)].

According to the American Heart Association (AHA), factors such as hypertension, high cholesterol and high blood sugar levels, being overweight and obesity resulting from unhealthy diets, smoking and a lack of physical activity are among the modifiable factors that can put a person at risk of CVD [(4)]. According to epidemiological evidence, a high diet quality is associated with a reduced risk of CVD. Studies have revealed that the inclusion of dietary evaluation in a risk prediction model already containing the classical CVD risk factors enhances accuracy and decreases bias with respect to estimating future CVD cases [5]. Adherence to specific dietary guidelines, as identified from either diet scores and indices or factors, has tended to show an inverse association with CVD risk, although the magnitude of protective effects varies across studies [6].

Several indices to assess overall diet quality have been suggested. The US Department of Agriculture (USDA) developed the Healthy Eating Index (HEI) to assess the overall diet quality of Americans. The HEI was based on the Dietary Guidelines for Americans and the Food Guide Pyramid [7]. Some studies have identified a moderate inverse relationship between the HEI score and the risk of CVD [8–10]. To improve the original HEI, McCullough invented a nine-component Alternate Healthy Eating Index (AHEI), which is designed to target food choices and macronutrient sources associated with a reduced risk of chronic diseases [10].

High scores on this index have been shown to be associated with a lower risk of CVD [10] and type 2 diabetes in the US population [11]. Previous findings from the British Whitehall II study also suggest that a higher AHEI is associated with a two-fold higher ratio of setback of the metabolic syndrome, which is known to be a strong forecaster of cardiovascular morbidity and mortality [12]. Nevertheless, despite all of the above, little effort has been made to directly examine the AHEI–mortality relationship and thus ratify its efficacy in informing public health interventions with respect to addressing diet-related chronic diseases [12]. To directly assess the association between AHEI and CVD, as well as to detect those patients who are at risk, a risk estimation tool is required. Among the many available risk-estimation systems, the best recognised (and probably the most globally used) is the Framingham Risk Score (FRS) of which different modified versions have also been developed. Fortunately, a previous study has shown that FRS worked just as well in ranking Iranian individuals and could be used to quantify risk and guide preventive care in Iranian adults [13].

The present study aimed to assess the relationship between the risk of CVD based on FRS and AHEI as a diet quality index in a group of Iranian public sector employees. A further aim was to determine which component of the AHEI contributed most to any decrease in 10-year CVD risk in this population.

Materials and methods

The present cross-sectional study was carried out at two different sites, including the Ministry of Agriculture and the Bureau of Standards in Tehran province, during summer and autumn 2012. The study sample consisted of employees within these organisations who had volunteered to participate. Volunteers were eligible to enter the study if they were aged between 30–74 years, did not have any history of CVD, and did not follow a special diet at the time. Participants with incomplete questionnaires and those who missed the blood test were excluded from the analysis.

Data collection was scheduled for two visits: the first visit for performing interviews and providing instructions for fasting, and second visit for blood pressure measurement and blood sample collection. Data collection tools consisted of a socio-demographic questionnaire including health and medical background, a semi-quantitative food-frequency questionnaire (FFQ) and an oil consumption questionnaire.

The study was approved by the Ethics Committee of the National Nutrition and Food Technology Research Institute (NNFTRI) (ECC: 040412). The purpose and protocol of the study were explained to the participants. Informed written consent was obtained from each participant before the commencement of the study.

Assessment of dietary intake and diet quality score

Trained dietitians collected dietary data using a 168-item FFQ, which has been validated and standardised in several multi-ethnic population-based prospective and cross-sectional studies [14]. This questionnaire was completed by face-to-face interview at the first visit.

Because cooking fats and oils are major contributors of fat intake in the Iranian diet, we designed a separate self-report questionnaire to assess fat and oil intake as precisely as possible. This questionnaire was handed to participants at the first visit and they were asked to take it home and have the person responsible for cooking to complete it. Participants returned the completed questionnaire at the second visit. The amount of each food item reported in FFQ and oil consumption questionnaire was converted to grams using the Directory of Household Measurements [15]. The consumed serving size of each group was calculated based on grams of food item intake, according to the USDA food pyramid [16].

Because the Iranian food composition table is incomplete and provides limited data on many nutrients, we used the food composition table of the USDA [17] to analyse data on food and beverage consumption for energy and nutrients.

The Alternate Healthy Eating Index

The original AHEI consists of nine components. Eight of the nine components [fruit, vegetables, nuts and soy intake, the ratio of white to red meat, cereal fibre, the ratio of polyunsaturated to saturated fatty acids (P : S), trans fats and alcohol] contributed 0–10 points to the total score (where 10 indicates that recommendations were met totally and zero indicates that they were not met at all). Intermediate intakes were scored proportionally between 0 and 10. Scoring of the multivitamin component (the ninth component) was different. Scores of 2.5 and 7.5 points were assigned for use of <5 years and ≥5 years, respectively. The AHEI ranged from 2.5 to 87.5 [10]. In the present study alcohol was excluded from total AHEI scoring because of religious restrictions. Therefore, the calculated score ranged between 2.5 and 77.5.

Blood pressure measurement

On the second visit, a certified MD used a standard mercury sphygmomanometer (Beurer, Ulm, Germany) to assess blood pressures. Participants rested in a seated position for a minimum of 15 min before blood pressure measurement. Two measurements of blood pressure were taken on the right arm with at least 10-min intervals. The mean blood pressure was reported as the final blood pressure.

Blood test

After 12–14 h of overnight fasting, 5 mL of venous blood was collected in a sitting position by a certified phlebotomist. All blood samples were collected between 08.00 and 09.00 h and were kept in vacutainer tubes and centrifuged within 2–3 h of sample collection.

All blood analyses were performed at the Nutrition Research Laboratory of NNFTRI on the day of blood collection. The analyses of samples were performed using Selectra E Auto-Analyzer (Vital Scientific, Spankeren, The Netherlands). Fasting plasma glucose was measured by an enzymatic colorimetric method using glucose oxidase. Total cholesterol was assayed using enzymatic colorimetric tests with cholesterol esterase and cholesterol oxidase. High-density lipoprotein cholesterol (HDL-C) was measured after precipitation of the apolipoprotein B-containing lipoproteins with phosphotungstic acid.

Predicted 10-year cardiovascular disease risk outcome measurements

We used an updated FRS to determine the 10-year CVD risk. The sex-specific risk prediction model formulated by D'Agostino *et al.* [18] included age, total and HDL-C levels, systolic blood pressure (SBP), use of antihypertension medication, smoking and diabetes. Framingham scoring categorises individuals with multiple risk factors into those with a 10-year risk for CVD >20% (high risk), 10–20% (moderate risk) and <10% (low risk).

Statistical analysis

All statistical analyses were performed using SPSS, version 20 (IBM Corp., Armonk, NY, USA). Descriptive statistics were generated for all variables. Pearson's correlation was used to determine the relationship of AHEI score and its components with 10-year CVD risk. Stepwise linear regression models were used to determine whether AHEI could predict 10-year CVD risk. Stepwise linear regression was also used to determine the relationship between AHEI score's components and 10-year CVD risk. Age, sex, total cholesterol, HDL-C, SBP, hypertension medication(s) and smoking were not included as covariates because these were the risk factors used to calculate the 10-year CVD risk score. One-way analysis of variance (ANOVA) was used to determine whether there are any significant differences between the means of three or more groups. $P < 0.05$ was considered statistically significant.

Results

Baseline data were available for 296 participants (78.4% men and 21.6% women) aged 30–60 years. General characteristics of participants and FRS components are shown in Table 1.

The mean of 10-year CVD risk based on FRS was 5.25 ±4.70, with 90%, 6.8% and 2.4% of participants in low (<10%), medium (10–20%) and high (>20%) risk groups, respectively. Distribution of estimated 10-year CVD risk by sex is shown in Fig. 1.

The mean AHEI score was 41.56 ±6.99 and 40.57 ±7.51 in men and women, respectively.

According to one-way ANOVA, the mean intake of AHEI components was significantly different among AHEI tertiles (Table 2).

Table 1 General characteristics and Framingham Risk Score components of participants

Variables	*n* = 296
Age (year), mean (SD)	42.78 (6.65)
Education level *n* (%)	
Under diploma/diploma	79 (26.6)
Associate degree/bachelor	167 (56.4)
Master/doctoral	50 (16.9)
Family history of CVD (yes), *n* (%)	49 (16.6)
Smoking (yes), *n* (%)	31 (8.9)
Hypertension drugs (yes), *n* (%)	15 (5.1)
Diabetes drugs (yes), *n* (%)	12 (4.1)
Cholesterol (mg dL^{-1}), mean (SD)	153.26 (26.03)
HDL-C (mg dL^{-1}), mean (SD)	39.25 (9.58)
FBS (mg dL^{-1}), mean (SD)	92.8 (24.76)

CVD, cardiovascular disease; FBS, fasting blood sugar; HDL-C, high density lipoprotein cholesterol.

The mean AHEI score and its components in the different FRS categories is shown in Table 3. According to one-way ANOVA, the mean AHEI score and the intake of its components was not significantly different among FRS categories, except for the P : S.

Pearson's correlation revealed that AHEI and the 10-year CVD risk based on FRS were not significantly correlated ($r = -0.03$, $P = 0.51$). However, some of AHEI components, such as nuts and soy intake ($r = -0.11$, $P = 0.04$), as well as fruit intake ($r = -0.14$, $P = 0.01$), had a significant inverse relationship with the risk of CVD.

According to stepwise multiple linear regression results, for every single increase in the intake of fruit servings, the risk of CVD decreased by 0.14 units ($\beta = -0.14$, $P = 0.01$). The result of the regression showed that fruit consumption explained 2% ($r^2 = 0.02$) of the variation in the 10-year CVD risk.

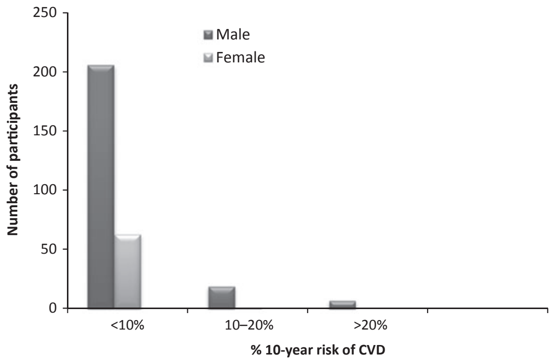

Figure 1 Distribution of participants in the Framingham risk groups. CVD, cardiovascular disease.

Discussion

This cross-sectional study was conducted on a group of employees in the public sector with an mean age of 42.78±6.65 years. According to the FRS, 2.4% of individuals were at high risk and approximately 90% were at low risk of developing CVD in the next 10 years. This score in Malay men with mean (SD) age of 46.6 (6.6) years was 5% and 55%, respectively [19,20]. Despite the similarity in the age of the participants in these two studies, the higher percentage of CVD risk in Malay participants was possibly the

Table 2 Mean (SD) intake of Alternative Healthy Eating Index (AHEI) components based on AHEI tertiles

AHEI components	AHEI T_1 (23.31–37.88) (n = 98)	T_2 (37.93–44.42) (n = 99)	T_3 (44.49–62.20) (n = 99)	P-value
Vegetable (servings day^{-1})	3.02 (1.71)	4.21 (1.98)	5.87 (2.60)	0.000
Fruit (servings day^{-1})	2.06 (1.015)	2.91 (1.36)	4.42 (2.33)	0.000
Nuts and soy (servings day^{-1})	0.15 (0.12)	0.25 (0.21)	0.48 (0.56)	0.000
Cereal fibre (g day^{-1})	9.93 (6.06)	12.63 (6.91)	14.97 (8.00)	0.000
Ratio of white to red meat	0.79 (0.68)	1.22 (1.19)	2.47 (6.56)	0.007
P : S	0.62 (0.29)	0.67 (0.25)	0.81 (0.30)	0.000
Trans fat (% of energy)	1.43 (0.77)	1.23 (0.53)	1.13 (0.51)	0.003
Duration of multivitamin use	0	0	0	0

P : S, polyunsaturated to saturated fatty acids ratio.

Table 3 Mean (SD) Alternative Healthy Eating Index (AHEI) score and mean (SD) intake of its components in Framingham Risk Score categories

Variable	10-year CVD risk Low (<10%) (n = 269)	Moderate (10–20%) (n = 20)	High (>20%) (n = 7)	P-value
AHEI, mean (SD)	41.47 (7.26)	41.10 (5.19)	37.55 (5.21)	0.347
Vegetable (servings day^{-1})	4.34 (2.46)	4.94 (2.23)	3.79 (1.20)	0.466
Fruit (servings day^{-1})	3.20 (1.98)	2.63 (0.98)	1.94 (1.33)	0.112
Nuts and soy (servings day^{-1})	0.31 (0.39)	0.19 (0.16)	0.17 (0.13)	0.298
Ratio of white to red meat	1.54 (4.11)	1.16 (1.02)	0.96 (0.55)	0.859
Cereal fibre (g day^{-1})	12.61 (7.25)	12.99 (8.72)	7.62 (2.79)	0.196
P : S	0.69 (0.28)	0.73 (0.29)	0.98 (0.32)	0.035
Trans fat (% of energy)	1.26 (0.60)	1.29 (0.83)	1.37 (1.00)	0.893
Duration of multivitamin use	0	0	0	0

CVD, cardiovascular disease; P : S, polyunsaturated to saturated fatty acids ratio.

result of a higher percentage of smokers and hypertensive participants compared to the present study (37.6% versus 8.9% and 31.7% versus 5.1% respectively).

The mean (SD) AHEI score was 41.35 (7.11) in the present study. We found no significant correlation between AHEI and the 10-year risk of CVD. This was consistent with findings from previous research that assessed AHEI as a predictor of 10-year CVD risk in Cuban Americans with and without type 2 diabetes [(21)]. In that study, an association between AHEI and 10-year CVD risk was found only for participants with type 2 diabetes. Several studies have reported a significant relationship between AHEI scores and chronic diseases, especially CVD [(10–12)], although most of them were prospective studies with large sample sizes. It appears that the lack of a significant association between the AHEI score and 10-year CVD risk in the present study may be a result of the cross-sectional nature of the study, which makes it difficult to extract causal relationships. Furthermore, this might be a result of the relatively small sample size, which meant that there was a narrower range of AHEI scores. We also examined the contribution of AHEI components to the 10-year CVD risk. Our analysis highlighted the role of fruit intake in reducing the 10-year risk of CVD.

Some AHEI components were not found to be associated with 10-year CVD risk. This was the case for the vegetable group and somewhat also for fibre intake. The high consumption of vegetables, even among participants in the lowest AHEI score tertile, showed a ceiling effect, which may explain why the vegetable component was not associated with CVD risk, despite expectations. The mean ratio of white to red meat was low and the higher rates of polyunsaturated to saturated fatty acids ratio observed in the highest risk group of CVD were in accordance with the findings of the study by Kelishadi *et al.* [(22)], which showed the improper intake of a high amount of hydrogenated fat and the prevalent consumption of fatty lamb meat, as well as the frequency of red meat intake, among Iranian adolescents in the Isfahan Healthy Heart Program–Heart Health Promotion from Childhood study [(22)].

The consumption of nuts and soy was low among the study participants. This may be related to the high price of nuts and also Iranian food habits. The findings from the present study also suggested that the eating indices originally designed for the US population may need to be modified for use in our population. For example, multivitamin use was chosen as an AHEI component on the basis of the results from the Nurses' Health and Men's Health Professional Studies [(21)]. In Iran, multivitamin use is not as common as it is in the US population [(23)] and its role in reducing the risk of chronic diseases has not been investigated in an exclusively Iranian group, although the benefits of its use are still inconclusive in all populations [(21)]. Moreover, the cut-off used for some components (e.g. such as that for trans fat) might not be optimal for assessing the association between trans fat intake and health outcomes in an Iranian population, where the average trans fatty acid content of hydrogenated solid and liquid oil has been 20% [(24)].

In summary, to the best of our knowledge, the present study is the first to examine the relationship between AHEI and 10-year predicted CVD risk using the FRS in Iran. A previous study only determined the association between HEI and cardiometabolic risk factors among the Iranian population [(25).]

One of the limitations of the present study was the relatively small sample size, especially when stratified by sex. Accordingly, we could not examine the observed relationship by sex. Another limitation could be the use of a semi-quantitative FFQ as the only tool for collecting food intake data. The extent to which our findings are generalisable is an important issue that needs to be considered further. Our participants were mainly office-based employees with a middle-rank socio-economic status and more than half of them had high educational levels. Because socio-economic status and educational levels have been shown to be related to healthy behaviours [(12,26)] as related to CVD [(27)], our results may have underestimated the association between AHEI and 10-year CVD risk compared to the general population. Further research needs to be conducted to fully examine the ability of AHEI for use as an assessment tool in predicting the risk of chronic diseases, especially CVD in the Iranian population.

To conclude, the findings of the present study emphasise the importance of high intakes of nuts and soy and fruits in the reduction of 10-year CVD risk. The present study is consistent with previous research showing that the diet quality of many Iranians may need to be improved through nutrition education and other public health interventions, as appropriate [(28)].

Transparency declaration

NH affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

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Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.
The National Nutrition and Food Technology Research Institute of Iran (NNFTRI) provided financial support for the present study.
NH, EN, DB and SD designed the research. EN and DB supervised the data collection. NH and SD collected data. NH, SD and AH-r were responsible for the dietary database. AH-r and FZ performed the statistical analysis. NH and EN wrote the manuscript, and had primary responsibility for the final content. NH, EN, DB, AH-R, SD and FR were involved in revision of the manuscript and production of the final version of the manuscript. All authors read and approved the final manuscript submitted for publication.

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Omega-6 polyunsaturated fatty acids, serum zinc, delta-5- and delta-6-desaturase activities and incident metabolic syndrome

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Abstract

Background: The associations of *n*-6 polyunsaturated fatty acids (PUFA) with metabolic syndrome have been poorly explored. We investigated the associations of the serum *n*-6 PUFA and the activities of enzymes involved in the PUFA metabolism, delta-5-desaturase (D5D) and delta-6-desaturase (D6D) with risk of incident metabolic syndrome. We also investigated whether zinc, a cofactor for these enzymes, modifies these associations.
Methods: A prospective follow-up study was conducted on 661 men who were aged 42–60 years old at baseline in 1984–1989 and who were re-examined in 1998–2001.
Results: Men in the highest versus the lowest serum total omega-6 PUFA tertile had a 70% lower multivariate-adjusted risk of incident metabolic syndrome [odds ratio (OR) = 0.30; 95% confidence interval (CI) = 0.18–0.51, $P_{trend} < 0.001$]. Inverse associations were also observed for linoleic acid, arachidonic acid and D5D activity. By contrast, men in the highest tertile of D6D activity had an 84% higher risk (OR = 1.84; 95% CI = 1.15–2.94, $P_{trend} = 0.008$). Similar associations were observed with many of the metabolic syndrome components at the re-examinations. Most associations were attenuated after adjustment for body mass index. Finally, the associations of D6D and LA were stronger among those with a higher serum zinc concentration.
Conclusions: Higher serum total *n*-6 PUFA, linoleic acid and arachidonic acid concentrations and D5D activity were associated with a lower risk of developing metabolic syndrome and higher D6D activity was associated with a higher risk. The role of zinc also needs to be investigated in other populations.

Introduction

In addition to regular exercise and the prevention of weight gain, specific dietary factors may also have a role in the development of metabolic syndrome. Linoleic acid (LA; 18:2*n*-6) and α-linolenic acid (ALA; 18:3*n*-3) are essential polyunsaturated fatty acids (PUFA) and need to be obtained from diet. In the body, these fatty acids generate longer-chain omega-3 and omega-6 PUFAs and, for these conversions, delta-6-desaturase (D6D) and delta-5-desaturase (D5D) enzymes are required. The potential benefits of the omega-3 (*n*-3) PUFAs in the prevention of metabolic syndrome have been suggested [(1)], but omega-6 (*n*-6) PUFAs could increase the risk of metabolic syndrome through a theoretical increase in inflammation [(2)]. However, studies have failed to detect a link between higher omega-6 PUFA exposure and increased inflammation [(3)], and LA has been inversely associated with low serum high-density lipoprotein (HDL) cholesterol and high triglyceride concentrations and insulin resistance [(4–6)], which are characteristics of metabolic syndrome. Therefore, the omega-6 PUFAs could also be associated with a lower risk of metabolic syndrome.

Only a few population studies have explored the relationship of omega-6 PUFA exposure with the risk of metabolic syndrome, although all have found an inverse association with total omega-6 PUFA or LA [5,7,8]. However, even less is known about the associations of the other omega-6 PUFAs, γ-linolenic acid (GLA; 18:3*n*-6), dihomo-γ-linolenic acid (DGLA; 20:3*n*-6) and arachidonic acid (AA; 20:4*n*-6), which, in serum, mainly reflect endogenous metabolism rather than dietary intakes. Activities of the D5D and D6D enzymes have also been associated with insulin sensitivity and the risk of metabolic syndrome; D6D with a higher risk and lower insulin sensitivity and D5D with a lower risk and higher insulin sensitivity [7].

To better clarify the role of the omega-6 PUFAs and desaturase enzymes in the development of metabolic syndrome, the primary aim of this prospective study was to investigate the associations of the serum omega-6 PUFAs and estimated D5D and D6D activities with the risk of metabolic syndrome after 11 years of follow-up among middle-aged and older men from Eastern Finland. As a secondary analysis, we investigated whether the serum zinc concentration modifies these associations because zinc is a cofactor of the D6D and D5D enzymes [9]. We have shown previously that a higher serum zinc concentration was associated with a higher risk of type 2 diabetes in this study population [10]. Serum zinc concentration also affected the serum *n*-6 PUFA concentrations and the D5D and D6D activities and modified the association between serum GLA and the risk of type 2 diabetes [11]. We also investigated the associations of the serum omega-6 PUFAs and estimated D5D and D6D activities with the components of metabolic syndrome.

Materials and methods

Study population

The Kuopio Ischaemic Heart Disease Risk Factor (KIHD) study was designed to investigate risk factors for cardiovascular disease, atherosclerosis and related outcomes in a population-based, randomly selected sample of men from Eastern Finland. Baseline examinations were carried out in 1984–1989. A total of 2682 men who were aged 42, 48, 54, or 60 years old at baseline (82.9% of those eligible) were recruited in two cohorts. The first cohort consisted of 1166 men who were 54 years old, enrolled in 1984–1986, and the second cohort included 1516 men who were 42, 48, 54 or 60 years old, enrolled in 1986–1989. At the 11-year examination round (1998–2001), all men from the second cohort were invited, and 854 men (95% of the eligible) participated and formed the base population for the current analyses. The KIHD study protocol was approved by the Research Ethics Committee of the University of Kuopio. All subjects provided their written informed consent for participation. Data on metabolic syndrome status at the 11-year examinations were available for 842 men. Of those, 113 had metabolic syndrome diagnosis at baseline and were excluded from the analyses. Of the remaining 729 men, we also excluded those with type 2 diabetes ($n = 12$) or impaired fasting glucose ($n = 23$), or those with missing data on serum fatty acids ($n = 25$) or serum zinc ($n = 8$) at baseline, leaving 661 men for the analyses. Men with an existing condition at the baseline were further excluded from the analyses with metabolic syndrome components.

Measurements

Fasting venous blood samples were collected at 08.00–10.00 h at the baseline examinations. Subjects were instructed to abstain from ingesting alcohol for 3 days and from smoking and eating for 12 h prior to giving the sample. Detailed descriptions of the determination of serum lipids and lipoproteins, assessment of medical history and medications, family history of diseases, smoking, alcohol consumption, and blood pressure have been reported previously [12]. Physical activity was assessed based on the 12-month Leisure-time Physical Activity Questionnaire. The most common leisure-time physical activities, including the frequency, average duration and intensity of each activity, were recorded. The energy expenditure of physical activity was expressed as MJ day^{-1} (kcal day^{-1}). Education was assessed in years by using self-administered questionnaire. The family history of diabetes was defined as positive if a first-degree relative of the subject had diabetes history. The consumption of foods and total energy intake at the study baseline were assessed with a guided 4-day food recording by household measures. Serum zinc concentrations were determined from frozen samples stored at −20 °C for 1–5 years prior to analyses. A Perkin-Elmer 306 atomic absorption spectrophotometer (Perkin-Elmer, Norwalk, CT, USA) was used for measurements. Seronorm (Nycomed, Oslo, Norway) control serum samples were included in all daily batches [12]. Plasma glucose was measured using a glucose dehydrogenase method after precipitation of proteins by trichloroacetic acid. Serum insulin was determined with a Novo Biolabs radioimmunoassay kit (Novo Nordisk, Bagsvaerd, Denmark).

Serum fatty acid measurements

Serum fatty acids were determined in one gas chromatographic run without preseparation. Serum fatty acids were extracted with chloroform–methanol. The chloroform phase was evaporated and treated with sodium methoxide, which methylated esterified fatty acids. Quantification was carried out with reference standards purchased from NU-Check Prep Inc. (Billerica, MA, USA). Each analyte had an individual reference standard, and the internal standard was eicosane. Fatty acids were chromatographed in an NB-351 capillary column (HNU-Nordion, Helsinki, Finland) using a Hewlett-Packard 5890 Series II gas chromatograph (Hewlett-Packard Company, Avondale, PA, USA) with a flame ionisation detector. Results were obtained in μmol L^{-1}. The coefficient of variation was 9.6% for LA, 11.7% for GLA, 8.3% for DGLA and 9.2% for AA. Desaturase enzyme activities were estimated as the ratio of product to precursor and were calculated as the ratio of AA to DGLA for D5D activity and as the ratio of GLA to LA for D6D activity.

Definition of the metabolic syndrome

The metabolic syndrome was defined according to recommendations by the National Cholesterol Education Program (NCEP). The NCEP defines it as the presence of three or more of the following: (i) fasting blood glucose levels ≥5.6 mmol L^{-1} (equivalent to plasma glucose levels ≥6.1 mmol L^{-1}); (ii) serum triglycerides ≥1.7 mmol L^{-1}; (iii) serum HDL <1.0 mmol L^{-1}; (iv) blood pressure ≥130/85 mmHg or the use of blood pressure medication; or (v) waist girth >102 cm.

Statistical analysis

Analysis of variance and chi-squared tests were used to examine the associations between serum omega-6 PUFAs and baseline characteristics. Multivariate-adjusted logistic regression models were used to estimate odds ratios (OR) for incident metabolic syndrome and its individual components at the 11-year examinations in tertiles of baseline serum omega-6 PUFAs and estimated desaturase activities. The model 1 included age (years) and examination year. The multivariable model 2 was further adjusted for potential confounders, including family history of type 2 diabetes (yes/no), smoking (never smoker, previous smoker, current smoker <20 cigarettes day^{-1} and current smoker ≥20 cigarettes day^{-1}), alcohol consumption (g $week^{-1}$), education (years), leisure-time physical activity [MJ day^{-1} (kcal day^{-1})] and total energy intake [MJ day^{-1} (kcal day^{-1})]. All quantitative variables were entered as continuous variables. Cohort mean was used to replace missing values in covariates (<0.5%). Tests of linear trend were conducted by assigning the median values for each category of exposure variable and treating those as a single continuous variable. Statistical significance of the interactions on a multiplicative scale between serum zinc and omega-6 PUFAs or desaturase activities was assessed by likelihood ratio tests using a cross-product term, with both the serum zinc and PUFAs or desaturase activities as medians in the models. Data were analysed using SPSS, version 21.0 (IBM Corp., Armonk, NY, USA).

Results

Table 1 shows the baseline characteristics of the study participants based on the tertiles of serum total omega-6 PUFA concentration. Men with a higher serum total omega-6 PUFA concentration smoked less, drank less alcohol, and had lower waist circumference, systolic and diastolic blood pressure, serum insulin, serum triglycerides, blood glucose, homeostatic model assessment-insulin resistance (HOMA-IR) and HOMA-β. They were also more physically active and had a higher education, HOMA-IS (homeostatic model assessment-insulin sensitivity), and serum HDL cholesterol concentration. They also had a higher intake of energy, total PUFA, LA, monounsaturated fatty acids, trans fatty acids, fibre, and fruits, berries and vegetables, and a lower intake of saturated fatty acids. The correlation coefficient between dietary zinc intake and serum zinc was 0.06.

Between the baseline and the 11-year examinations, 138 men (20.9%) developed metabolic syndrome. After adjustment for age and examination year, serum total omega-6 PUFA were associated with a 70% lower risk of metabolic syndrome (OR in the highest vs. the lowest tertile = 0.30; 95% CI = 0.18–0.51, $P_{\text{trend}} < 0.001$, absolute risk in the lowest tertile 30.5%, absolute risk reduction 21.4%) (Model 1) (Table 2). Further multivariate adjustments did not appreciably change the association (Model 2). When the different omega-6 PUFAs were evaluated individually, serum LA was associated with a 69% lower risk of metabolic syndrome after multivariate adjustments (extreme-tertile OR = 0.31; 95% CI = 0.19–0.52, $P_{\text{trend}} < 0.001$, absolute risk in the lowest tertile 30.9%, absolute risk reduction 21.3%). Similarly, serum AA was associated with a 51% lower risk of metabolic syndrome (extreme-tertile OR = 0.49; 95% CI = 0.29–0.82, $P_{\text{trend}} = 0.006$, absolute risk in the lowest tertile 26.8%, absolute risk reduction 13.7%). Further adjustment for body mass index (BMI) attenuated the associations, especially with total omega-6 PUFA and LA, although they remained statistically significant (Table 2). No statistically significant associations were observed with GLA or DGLA (Table 2). Further adjustments for potential dietary confounders saturated fatty acids, monounsaturated fatty acids, trans fatty acids, fibre, red meat, and fruits, berries and vegetables had no appreciable impact on the associations, either (data not shown).

Higher estimated D6D activity was associated with a higher risk of metabolic syndrome (extreme-tertile

Table 1 Baseline characteristics of the 661 subjects according to the tertiles of total serum omega-6 polyunsaturated fatty acids

	Total omega-6 polyunsaturated fatty acids 1 (n = 220)	2 (n = 221)	3 (n = 220)	P_{trend}
Serum zinc (mg L^{-1})	0.94 (0.12)*	0.93 (0.11)	0.92 (0.09)	0.202
Age (years)	51.6 (6.7)	51.72 (6.7)	50.4 (6.7)	0.073
Education (years)	9.1 (3.2)	9.4 (4.0)	9.9 (3.7)	0.047
Current smokers (%)	39.3	34.8	25.8	0.006
Diabetes in family (%)	31.6	36.9	31.6	0.495
Alcohol (g week^{-1})	85 (109)	66 (85)	58 (91)	<0.001
Leisure-time physical activity (MJ day^{-1}) [kcal day^{-1}]	0.55 (0.59) [132 (142)]	0.61 (0.68) [146 (163)]	0.64 (0.63) [153 (151)]	0.020
Waist circumference (cm)	91.2 (8.2)	88.7 (8.0)	85.6 (7.2)	<0.001
BMI (kg m^{-2})	27.1 (3.0)	26.2 (2.8)	25.3 (2.5)	<0.001
Systolic blood pressure (mmHg)	132 (15)	130 (15)	129 (15)	0.048
Diastolic blood pressure (mmHg)	88 (10)	87 (10)	85 (10)	0.036
Fasting blood glucose (mmol L^{-1})	4.51 (0.36)	4.45 (0.42)	4.40 (0.39)	0.012
Insulin (mU L^{-1})	13.68 (4.80)	9.65 (5.53)	9.19 (3.13)	<0.001
HOMA of insulin resistance	2.42 (1.13)	2.16 (1.05)	1.83 (0.73)	<0.001
HOMA of insulin sensitivity	85.13 (34.99)	93.32 (36.26)	106.93 (42.56)	<0.001
HOMA of beta cell function	115.68 (35.21)	112.49 (36.84)	103.03 (28.04)	<0.001
High-density lipoprotein (mmol L^{-1})	1.29 (0.26)	1.34 (0.28)	1.39 (0.29)	0.001
Low-density lipoprotein (mmol L^{-1})	3.72 (0.95)	3.87 (0.86)	3.86 (1.02)	0.171
Triglycerides (mmol L^{-1})	1.68 (0.82)	1.16 (0.42)	0.92 (0.35)	<0.001
C-reactive protein (mg L^{-1})	2.88 (6.73)	2.00 (2.70)	1.35 (1.97)	<0.001
Linoleic acid (%)	23.01 (2.48)	27.66 (1.39)	32.14 (2.54)	<0.001
γ-Linolenic acid (%)	0.31 (0.12)	0.28 (0.11)	0.27 (0.11)	<0.001
Dihomo-γ-linolenic acid (%)	1.36 (0.25)	1.36 (0.27)	1.30 (0.26)	0.001
Arachidonic acid (%)	4.66 (1.00)	4.92 (0.94)	5.23 (1.04)	0.001
Long-chain omega-3 polyunsaturated fatty acids (%)	4.77 (1.93)	4.67 (1.56)	4.46 (1.26)	0.119
Dietary intakes				
Energy (MJ day^{-1}) [kcal day^{-1}]	10.21 (2.62) [2440 (625)]	10.88 (2.31) [2410 (551)]	10.67 (2.70) [2551 (646)]	0.039
Fruits, berries and vegetables (g day^{-1})†	254 (144)	266 (154)	296 (155)	0.012
Red meat (g day^{-1})	142 (69)	150 (81)	148 (94)	0.557
Zinc (mg day^{-1})	15.6 (3.1)	15.6 (3.9)	15.5 (3.4)	0.974
Polyunsaturated fatty acids (E%)	4.4 (1.4)	4.7 (1.2)	5.2 (1.3)	<0.001
Linoleic acid (E%)	3.2 (1.3)	3.5 (1.1)	4.0 (1.2)	<0.001
Arachidonic acid (E%)	0.07 (0.04)	0.07 (0.03)	0.07 (0.03)	0.677
Saturated fatty acids (E%)	17.7 (3.9)	17.1 (3.6)	16.7 (3.6)	0.013
Monounsaturated fatty acids (E%)	11.3 (2.2)	11.7 (2.1)	12.3 (2.4)	<0.001
Trans fatty acids (E%)	1.0 (0.3)	1.0 (0.4)	1.2 (0.4)	<0.001
Fibre (g day^{-1})	25 (10)	25 (9)	28 (11)	0.001

BMI, body mass index; E%, percent of energy; HOMA, the homeostatic model assessment.
*Values are the mean (SD) or percentages.
†Excluding potatoes.

OR = 1.76; 95% CI = 1.11–2.79, P_{trend} = 0.011, absolute risk in the lowest tertile 17.3%, absolute risk increase 22.5%) (Table 2). The association was attenuated after adjustment for BMI and was no longer statistically significant (Table 2). By contrast, a higher D5D activity was associated with a 55% lower risk of incident metabolic syndrome (extreme-tertile OR = 0.45; 95% CI = 0.28–0.74, P_{rend} = 0.002, absolute risk in the lowest tertile 25.9%, absolute risk reduction = 14.2%) after multivariable adjustment (model 2) (Table 2). Further adjustment for BMI again slightly attenuated the association (Table 2).

The baseline serum total n-6 PUFA and LA concentrations were associated with a lower fasting blood glucose, serum triglycerides and waist circumference, and with a higher HDL cholesterol at the 11-year examinations (see Supporting information, Table 1). AA was associated only with a higher serum HDL cholesterol concentration. D6D

Table 2 Associations of baseline serum omega-6 polyunsaturated fatty acids and desaturase activities with metabolic syndrome at the 11-year examinations

	Tertile of serum omega-6 polyunsaturated fatty acids and desaturase activities			
	1 (n = 220)	2 (n = 221)	3 (n = 220)	P_{trend}
Total omega-6 fatty acids (%)	17.11–30.97	30.98–34.77	34.78–46.18	
Number of events	67	45	26	
Model 1	1	0.58 (0.34–0.90)*	0.30 (0.18–0.50)	<0.001
Model 2	1	0.56 (0.36–0.87)	0.30 (0.18–0.51)	<0.001
Model 2 + BMI	1	0.68 (0.42–1.09)	0.49 (0.27–0.82)	0.007
Linoleic acid (%)	13.35–25.92	25.93–29.50	29.51–41.33	
Number of events	68	42	28	
Model 1	1	0.52 (0.33–0.80)	0.32 (0.19–0.52)	<0.001
Model 2	1	0.50 (0.32–0.79)	0.31 (0.19–0.52)	<0.001
Model 2 + BMI	1	0.62 (0.38–1.00)	0.50 (0.29–0.85)	0.008
γ-Linolenic acid (%)	0.04–0.23	0.24–0.33	0.34–0.87	
Number of events	46	48	44	
Model 1	1	1.04 (0.66–1.65)	0.94 (0.59–1.50)	0.788
Model 2	1	1.06 (0.67–1.69)	0.94 (0.58–1.50)	0.845
Model 2 + BMI	1	1.08 (0.66–1.78)	0.82 (0.50–1.37)	0.426
Dihomo-γ-linolenic acid (%)	0.68–1.23	1.24–1.44	1.45–2.20	
Number of events	39	49	50	
Model 1	1	1.32 (0.82–2.11)	1.36 (0.85–2.18)	0.202
Model 2	1	1.46 (0.90–2.37)	1.44 (0.89–2.33)	0.143
Model 2 + BMI	1	1.54 (0.92–2.60)	1.16 (0.69–1.95)	0.618
Arachidonic acid (%)	2.19–4.50	4.51–5.31	5.32–9.24	
Number of events	59	45	34	
Model 1	1	0.70 (0.45–1.08)	0.50 (0.31–0.80)	0.004
Model 2	1	0.71 (0.45–1.12)	0.49 (0.29–0.82)	0.006
Model 2 + BMI	1	0.74 (0.46–1.19)	0.54 (0.32–0.91)	0.021
Delta-6-desaturase†	0.001–0.008	0.009–0.012	0.013–0.052	
Number of events	38	41	59	
Model 1	1	1.08 (0.66–1.76)	1.76 (1.11–2.79)	0.011
Model 2	1	1.15 (0.69–1.88)	1.84 (1.15–2.94)	0.008
Model 2 + BMI	1	1.14 (0.67–1.92)	1.43 (0.86–2.36)	0.160
Delta-5-desaturase‡	1.56–3.22	3.23–4.10	4.11–11.23	
Number of events	57	49	32	
Model 1	1	0.82 (0.53–1.27)	0.89 (0.30–0.79)	0.003
Model 2	1	0.79 (0.50–1.24)	0.45 (0.28–0.74)	0.002
Model 2 + BMI	1	0.92 (0.57–1.49)	0.58 (0.34–0.98)	0.038

*The values are odds ratio (95% confidence interval), comparing the upper median with the lower median; BMI, body mass index.
†Delta-6-desaturase activity = γ-linolenic acid/linoleic acid.
‡Delta-5-desaturase activity = arachidonic acid/dihomo-γ-linolenic acid.
Model 1 adjusted for age and examination year.
Model 2 adjusted for the model 1+ family history of type 2 diabetes (yes/no), smoking (smoker, previous or current smoker <20 cigarettes day^{-1}, and current smoker ≥20 cigarettes day^{-1}), education (year), leisure-time physical activity [MJ day^{-1} (kcal day^{-1})], alcohol consumption (g week^{-1}) and total energy intake [MJ day^{-1} (kcal day^{-1})].

and D5D activities had opposite associations with fasting blood glucose, serum HDL cholesterol concentration and waist circumference, with D6D activity showing unfavourable associations. Adjustment for BMI attenuated most associations.

In the secondary analysis, a higher D6D activity was associated with a multivariate-adjusted 84% higher risk of metabolic syndrome (OR = 1.84; 95% CI = 1.08–3.16, P_{trend} = 0.026) among those with the serum zinc above the median, whereas no association was observed among those with serum zinc below the median (Table 3). However, the interaction was not statistically significant (P = 0.234). Similarly, the inverse association of LA with incident metabolic syndrome was stronger among those with serum zinc above the median with a borderline statistically significant P for interaction (Model 2,

Table 3 Associations of the baseline omega-6 polyunsaturated fatty acids and delta-5- and delta-6-desaturase activities with incident metabolic syndrome at the 11-year examinations, stratified by the serum zinc median at baseline

	Serum zinc				
	Below median (≤93 mg L^{-1})		Above median (>93 mg L^{-1})		
Events/participants	53/325		85/336		*P* for interaction
Linoleic acid					
Model 1	0.58 (0.31–1.06)*	0.076	0.24 (0.14–0.42)	<0.001	0.049
Model 2	0.59 (0.32–1.10)	0.098	0.25 (0.14–0.44)	<0.001	0.055
Model 2 + BMI	0.81 (0.42–1.57)	0.530	0.33 (0.18–0.60)	<0.001	0.048
γ-Linolenic acid					
Model 1	1.12 (0.62–2.03)	0.702	1.45 (0.88–2.40)	0.145	0.558
Model 2	1.07 (0.59–1.96)	0.825	1.53 (0.91–2.60)	0.112	0.453
Model 2 + BMI	1.04 (0.55–1.96)	0.909	1.32 (0.75–2.32)	0.340	0.810
Dihomo-γ-linolenic acid					
Model 1	1.55 (0.85–2.82)	0.155	1.10 (0.67–1.81)	0.701	0.457
Model 2	1.43 (0.76–2.71)	0.270	1.26 (0.74–2.12)	0.388	0.592
Model 2 + BMI	1.36 (0.70–2.61)	0.368	0.84 (0.48–1.48)	0.540	0.262
Arachidonic acid					
Model 1	0.76 (0.42–1.38)	0.370	0.83 (0.51–1.36)	0.462	0.919
Model 2	0.91 (0.48–1.76)	0.786	0.76 (0.45–1.31)	0.325	0.971
Model 2 + BMI	0.82 (0.42–1.55)	0.536	1.02 (0.58–1.77)	0.954	0.822
Delta-6-desaturase†					
Model 1	1.01 (0.56–1.83)	0.972	1.72 (1.04–2.87)	0.036	0.222
Model 2	1.03 (0.56–1.87)	0.934	1.84 (1.08–3.16)	0.026	0.234
Model 2 + BMI	0.83 (0.44–1.58)	0.573	1.53 (0.85–2.73)	0.154	0.273
Delta-5-desaturase‡					
Model 1	0.56 (0.30–1.01)	0.056	0.60 (0.36–0.99)	0.046	0.964
Model 2	0.53 (0.28–0.97)	0.039	0.61 (0.36–1.04)	0.069	0.855
Model 2 + BMI	0.64 (0.34–1.23)	0.185	0.83 (0.47–1.47)	0.518	0.754

*The values are odds ratio (95% confidence interval), comparing the upper median with the lower median; BMI, body mass index.
†Delta-6-desaturase activity = γ-linolenic acid/linoleic acid.
‡Delta-5-desaturase activity = arachidonic acid/dihomo-γ-linolenic acid.
Model 1 adjusted for age and examination year.
Model 2 adjusted for the model 1 + family history of type 2 diabetes (yes/no), smoking (smoker, previous or current smoker <20 cigarettes day^{-1}, and current smoker ≥20 cigarettes day^{-1}), education (year), leisure-time physical activity [MJ day^{-1} (kcal day^{-1})], alcohol consumption (g week^{-1}) and total energy intake [MJ day^{-1} (kcal day^{-1})].

P = 0.055). Further adjustment for BMI slightly strengthened the interaction (P = 0.048). Also, GLA appeared to be associated with a higher risk of metabolic syndrome only among those with higher serum zinc, although the association and the interaction were not statistically significant. The associations with DGLA or AA or D5D activity were not appreciably affected by the serum zinc concentration (Table 3).

Discussion

In this prospective, population-based cohort study conducted among middle-aged and older men from Eastern Finland, serum total omega-6 PUFA, LA and AA were inversely associated with the risk of developing metabolic syndrome. We also found that higher D5D activity was associated with a lower risk and higher D6D activity with a higher risk of metabolic syndrome. In addition, the associations of D6D and LA were stronger among those with a higher serum zinc concentration. Moreover, total *n*-6 PUFA and LA were inversely associated with fasting blood glucose, triglycerides and waist circumference at the follow-up examinations. These fatty acids and AA were also associated with a higher HDL cholesterol concentration. Higher D6D was found to be associated with a higher fasting blood glucose and waist circumference, and a lower serum HDL cholesterol concentration. Higher D5D activity showed associations opposite to those with the D6D activity. Adjustment for BMI attenuated most of these associations, which suggests that BMI may partly mediate the associations of the omega-6 PUFAs and desaturase enzyme activities with the risk of metabolic syndrome.

Few studies have reported on the associations of the circulating omega-6 PUFAs with the risk of incident metabolic syndrome. One prospective study found an inverse association between serum total omega-6 PUFA concentration and metabolic syndrome over 6 years of follow-up among middle-aged men and women from Finland [5]. Another study among Swedish men, aged 50 years at baseline, observed that GLA and DGLA concentrations were increased and LA concentrations decreased at baseline among those who developed metabolic syndrome during the 20-year follow-up, although no difference in the AA concentrations was detected [7].

The mechanisms explaining the relationship between omega-6 PUFA and metabolic syndrome are still to be determined, although the results may be partly explained by the role of the omega-6 PUFA in the management of the cell membrane and inflammation. Both the omega-3 and omega-6 PUFAs, such as LA, are needed for cell membrane permeability, flexibility and fluidity, and the activity of membrane-bound enzymes [13]. LA has been shown to play an important role in the binding of insulin to its receptors, showing an increase in the number of high-affinity sites with a concomitant decrease of low-affinity sites for insulin [14]. LA has also been shown to be inversely associated with metabolic syndrome components, including low serum HDL cholesterol and high triglyceride concentrations [4–6].

The inverse associations of LA and AA with the risk of metabolic syndrome might be further explained by inflammation. The beneficial effect of the omega-3 PUFA on inflammation has been suggested as a possible mechanism for the inverse relationship between the omega-3 PUFA and metabolic syndrome [15]. On other hand, it is suggested that omega-6 PUFA may increase the risk of metabolic diseases because it has been proposed that omega-6 PUFA could compete with omega-3 PUFA in desaturation enzymes to produce inflammatory eicosanoids [16]. Omega-6 PUFA have multiple roles and all eicosanoids derived from the omega-6 PUFA are not related to increased inflammation. For example, prostaglandin E_2 derived from AA has been shown to exert inflammatory and potential anti-inflammatory responses at the same time [17,18]. In addition, AA has been shown to enhance the antioxidant status and manage production of cytokines and protect β-cells with this mechanism [19,20].

Little is known about the relation between D5D or D6D activities and risk of developing metabolic syndrome. In a previous cross-sectional study, those with metabolic syndrome had a lower D5D activity [21] and, in another study, higher D5D activity was associated with a lower risk and higher D6D activity with a higher risk of developing metabolic syndrome during the follow-up [7]. The association between D5D and D6D activities and metabolic syndrome may be explained by their role in the management of insulin sensitivity [22] and insulin resistance [23], as well as inflammatory markers [24]. A direct association between higher activities of D6D and insulin resistance [25,26], BMI [25,26], fasting blood glucose [27], waist circumference [28], liver fat accumulation [28] and triglyceride concentrations [29] has been observed. By contrast, a higher activity of D5D was inversely associated with insulin resistance [23,26], BMI [25,26,28], blood pressure [27], waist circumference [28], liver fat accumulation [28] and triglyceride concentrations [29], as well as with higher insulin sensitivity [22]. Our findings also support several of these opposing associations with the components of metabolic syndrome.

Higher serum zinc concentrations have been associated with metabolic syndrome [30]. Zinc is also an essential cofactor for D5D and D6D [9]. Therefore, zinc could have an impact on the associations of the omega-6 PUFA and desaturase enzymes with the risk of metabolic syndrome by influencing the activity of these enzymes and the concentrations of their precursor and end-product fatty acids. In the present study, we observed that higher D6D activity and higher concentrations of its precursor, LA, and end-product, GLA, had stronger associations with the risk of metabolic syndrome among those men with higher serum zinc concentration, although the associations with GLA were not statistically significant. This suggest that zinc may have a role in determining the associations of the omega-6 PUFAs with metabolic syndrome, although further studies in other larger study populations are needed to confirm our findings.

The strengths of the present study are the use of serum fatty acids and zinc as objective biomarkers of exposure. Other strengths include the population-based recruitment, extensive examinations for potential confounders and prospectively collected data. A potential limitation is the small number of participants and the use of a single exposure measurement at baseline, which may cause random error as a result of misclassification, and therefore underestimate the true associations.

In conclusion, higher serum total omega-6 PUFA, LA and AA and estimated D5D activity were associated with a lower risk of incident metabolic syndrome and several of its components and higher D6D activity was associated with a higher risk in this population of middle-aged and older men from Eastern Finland.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of this work is compliant with STROBE guidelines.

Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

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TY analysed data and drafted the manuscript. JKV analysed data and had primary responsibility for final content. TY, SV, T-PT, AR, TN and JKV designed the research. SV, T-PT, AR, TN and JKV acquired data. SV, T-PT, AR, TN and JKV critically revised the manuscript for important intellectual content. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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Supporting information

Additional Supporting Information may be found online in the supporting information tab for this article:

Table S1. The associations of baseline serum *n*-6 polyunsaturated fatty acid concentrations and desaturase activities with individual components of metabolic syndrome at the 11-year examinations.

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INBORN ERRORS OF METABOLISM

Glycomacropeptide in children with phenylketonuria: does its phenylalanine content affect blood phenylalanine control?

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[Correction added on 21 February 2017, after first online publication: The article has been edited to correct error in terminology used. 'Plasma phenylalanine' has been changed to 'blood phenylalanine' all throughout the article.]

Abstract

Background: In phenylketonuria (PKU), there are no data available for children with respect to evaluating casein glycomacropeptide (CGMP) as an alternative to phenylalanine-free protein substitutes [Phe-free L-amino acid (AA)]. CGMP contains a residual amount of phenylalanine, which may alter blood phenylalanine control.
Methods: In a prospective 6-month pilot study, we investigated the effect on blood phenylalanine control of CGMP-amino acid (CGMP-AA) protein substitute in 22 PKU subjects (13 boys, nine girls), median age (range) 11 years (6–16 years). Twelve received CGMP-AA and nine received Phe-free L-AA, (1 CGMP-AA withdrawal). Subjects partially or wholly replaced Phe-free L-AA with CGMP-AA. If blood phenylalanine exceeded the target range, the CGMP-AA dose was reduced and replaced with Phe-free L-amino acids. The control group remained on Phe-free L-AAs. Phenylalanine, tyrosine and Phe : Tyr ratio concentrations were compared with the results for the previous year.
Results: In the CGMP-AA group, there was a significant increase in blood phenylalanine concentrations (pre-study, 275 μmol L^{-1}; CGMP-AA, 317 μmol L^{-1}; $P = 0.02$), a decrease in tyrosine concentrations (pre-study, 50 μmol L^{-1}; CGMP-AA, 40 μmol L^{-1}; $P = 0.03$) and an increase in Phe : Tyr ratios (pre-study, Phe : Tyr 4.9:1; CGMP-AA, Phe : Tyr 8:1; $P = 0.02$). In the control group there was a non-significant fall in phenylalanine concentrations (pre-study 325μmol/L: study 280μmol/L [p = 0.9], and no significant changes for tyrosine or phe/tyr ratios [p = 0.9]. Children taking the CGMP-AA found it more acceptable to L-AA.
Conclusions: Blood phenylalanine control declined with CGMP-AA but, by titrating the dose of CGMP-AA, blood phenylalanine control remained within target range. The additional intake of phenylalanine may have contributed to the change in blood phenylalanine concentration. CGMP-AA use requires careful monitoring in children.

Introduction

In phenylketonuria (PKU), a protein substitute free of phenylalanine, but nutritionally complete in all other amino acids, vitamins and minerals, is an essential part of dietary management. The original protein substitutes were based on casein hydrolysates [(1)] and, during the 1970s, they were gradually replaced by L-amino acid supplements (L-amino acids) [(2,3)]. Although considerably improved in palatability and nutritional composition, the amino acid composition (g protein equivalent^{-1}) of protein substitutes has changed little. It is established that their dosage and timing [(4,5)] may have an impact on blood phenylalanine control.

Casein glycomacropeptide (CGMP) is a 64 amino acid phosphorylated glycopeptide released from κ casein by the action of chymosin (rennin) during the cheese-making process; the end product has been adapted for use as a protein substitute in PKU. CGMP was first given to a 29-year-old PKU male after safety studies in PKU mice showed improvement in metabolic control [6–8]. Although its use is not well established within Europe [9], it is clear that CGMP-amino acid (AA) supplements offer several theoretical advantages compared to conventional Phe-free L-amino acid supplements. They have been reported to have a better taste [10,11], increase the efficacy of protein utilisation [12,13], improve nitrogen retention [7,14], potentially improve long-term bone health [15] and have intestinal anti-inflammatory activity that may be important in long term health in PKU [16]. There is a suggestion that they reduce post-prandial phenylalanine concentrations [10].

Unmodified CGMP contains very low levels of arginine, cysteine, histidine, tryptophan, leucine and tyrosine, and the content of the large neutral amino acids, threonine and isoleucine, is two to three times the amount of other protein substitutes based on L-amino acid supplements. Commercial preparations of CGMP-AA, used in the treatment of PKU, require supplementation with limiting amino acids. [17] Although the optimal profile of L-amino acids added to CGMP-AA is yet to be determined, van Calcar (2009) [10] suggested they provide 130% more histidine, methionine, leucine and tryptophan and 150% more tyrosine than the American (2002) dietary reference intakes. Commercial CGMP-AA protein substitutes contain residual phenylalanine (1.5–1.8 mg g^{-1} protein) and there are no published long-term human studies reporting the safety, both in terms of growth and blood phenylalanine control, of CGMP-AA in children. Considering CGMP-AA protein substitutes contain phenylalanine, it is important to establish via longitudinal, long-term studies whether CGMP-AA based protein substitutes have any adverse effect on blood phenylalanine concentrations in children with PKU.

In the first of a series of studies, we investigated the impact on blood phenylalanine control of a CGMP-AA based protein substitute with an amino acid profile that aimed to provide the World Health Organization/Food and Agriculture Organization/United Nations University (WHO/FAO/UNU) (2007) requirements in children aged 5–16 years with PKU.

Materials and methods

Subjects

Twenty-two (13 boys, nine girls) children with PKU were recruited, with a median age (range) of 11 years (6–16 years). Nineteen children were European and three were of Pakistani origin. Inclusion criteria included known adherence with protein substitute and low phenylalanine diet, aged 5–16 years achieving 70% of blood phenylalanine concentrations within the age-related phenylalanine target range (120–360 μmol L^{-1} for children 5–10 years, 120–600 μmol L^{-1} for patients 11–16 years), diagnosed by new-born screening, and not treated with sapropterin dihydrochloride.

The South Birmingham Research Ethics committee granted a favourable ethical opinion. Written consent was obtained for all subjects from at least one caregiver with parental responsibility and written assent was obtained from the subject if appropriate for their age and level of understanding.

Selection into control or CGMP-AA group

Children chose which product they preferred to have as their protein substitute: CGMP-AA or Phe-free L-amino acid (L-AA). To ensure adherence with CGMP-AA at 5 weeks before the start of the study, each child was asked to take 20 g of protein equivalent from CGMP-AA for 7 days. If they preferred the CGMP-AA, they entered the CGMP-AA arm of the study at week 0 (baseline); otherwise, they remained on Phe-free L-amino acids and so entered the control study arm at week 0.

CGMP-AA protein substitute

The CGMP-AA was supplemented with amino acids to meet WHO/FAO/UNU (2007) requirements, with added carbohydrate, fat and a comprehensive range of micronutrients. Each 20 g of protein equivalent from the CGMP-AA based protein substitute contained 30 mg of phenylalanine (Table 1).

Intake of CGMP-AA and conventional phenylalanine-free L-amino acid

The amount of CGMP-AA was individually prescribed for each child, with the dose titrated against blood phenylalanine concentrations. Subjects partially or wholly replaced their conventional L-amino acid supplement with CGMP-AA. If blood phenylalanine concentrations were above target range for 3 consecutive weeks, the dose of CGMP-AA was reduced by 20 g day^{-1} protein equivalent and replaced with 20 g of protein equivalent from Phe-free L-amino acids. Subjects in the control group remained on their usual Phe-free L-amino acid supplement throughout the study period (Table 2).

Anthropometric measurements

At baseline (week 0) and at the end of the study (week 26), weight, height and body mass index were recorded.

Table 1 Nutritional and amino acid profiles for 20 g of protein equivalent of study CGMP product

	Study product CGMP-AA Per 35 g
Energy MJ kJ^{-1} (kcal kJ^{-1})	0.502 (120)
Protein equivalent (g)	20
Total carbohydrate (g)	6.5
Sugars (g)	2.2
Total fat (g)	1.5
Saturates (g)	0.2
Monounsaturated (g)	0.44
Polyunsaturates (g)	0.12
Docosahexaenoic acid (mg)	84
Arachidonic acid (AA) (mg)	0
Eicosapentaenoic acid (mg)	0
Fibre (g)	0.1
Salt (g)	0.53
Vitamin A (μg RE)	283
Vitamin D (μg)	4.5
Vitamin E (mg)	6.5
Vitamin C (mg)	38
Vitamin K (μg)	35
Vitamin B_1 (thiamine) (mg)	0.68
Vitamin B_2 (riboflavin) (mg)	0.78
Vitamin B_3 (niacin) (mg)	8.4
Vitamin B_5 (pantothenic acid) (mg)	2.7
Vitamin B_6 (pyridoxine) (mg)	1.0
Vitamin B_7 (biotin) (μg)	63.9
Vitamin B_9 (folic acid) (μg)	136
Vitamin B_{12} (cyanocobalamin) (μg)	1.6
Choline (mg)	204
Sodium (mmol)	9
Potassium (mmol)	6.8
Chloride (mg)	7
Calcium (mg)	407
Phosphorous (mg)	395
Magnesium (mg)	128
Iron (mg)	7.3
Copper (μg)	748
Zinc (mg)	7.3
Manganese (mg)	1.1
Iodine (μg)	85.7
Molybdenum (μg)	49
Selenium (μg)	29.9
Chromium (μg)	29.9
Amino acids (g 20 g^{-1} PE)	
L-alanine	0.76
L-arginine	1
L-aspartic acid	2.04
L-cysteine	0.01
Glycine	2.77
L-histidine	0.42
L-isoleucine	1.37
L-leucine	1.3
L- lysine	1.07
L-methionine	0.54
L-phenylalanine	**0.03**

Table 1 Continued

	Study product CGMP-AA Per 35 g
L-proline	1.51
L-serine	0.98
L-threonine	2.17
L-tryptophan	0.17
L-tyrosine	1.01
L-valine	1.31
L-glutamine	1.73
Total amino acids	**20.19**
L-carnitine (mg)	1.01
Taurine (mg)	1.13

CGMP-AA, casein glycomacropeptide amino acid; RE, retinol equivalent.

The same investigator measured weight and height. Height was measured on a Harpenden stadiometer (Holtain Ltd, Crymych, UK) and weight was measured on calibrated digital scales. Both were measured to the nearest 0.1 unit decimal point.

Dietary assessments

Each subject/caregiver completed a 3-day weighed food diary. Monthly home visits were conducted to assess adherence with protein substitute and low phenylalanine diet. The 3-day weighed food intake was calculated using the MICRODIET (Microdiet Downlee Systems Ltd, Chapel-en-le-Frith, UK), analysing phenylalanine, protein and energy intake from all natural food sources (e.g. 50 mg of phenylalanine exchange foods, low protein prescribed product, fruit and vegetables).

Blood phenylalanine/tyrosine monitoring

From baseline to study end, weekly overnight fasting morning blood spots were collected by trained caregivers at home. Blood specimens were sent via the postal service to the laboratory at Birmingham Children's Hospital. Blood samples were collected on filter cards [Perkin Elmer 226 (UK Standard NBS); Perkin Elmer, Waltham, MA, USA]. All of the cards had a standard thickness and the blood phenylalanine and tyrosine concentrations were calculated on a 3.2-mm punch by tandem mass spectrometry.

The median of the sum of all the weekly blood phenylalanine, tyrosine and phenylalanine to tyrosine ratios (Phe : Tyr) during the 6-month study period was calculated and compared with median of the sum of all the weekly/fortnightly blood concentrations from the previous 12 months prior to entering the study.

Table 2 Comparison of the median change in blood phenylalanine concentrations (range) from the previous 12 months (before start of study) to week 26 (end of study) for the CGMP-AA and L-AA groups and, for the CGMP-AA group, the percentage contribution of protein equivalent from CGMP-AA from baseline to end of study and median CGMP-AA protein equivalent intake at 6 months

CGMP-AA group							Control group			
		Median phenylalanine µmol L^{-1} (range)		Median % protein equivalent from CGMP-AA					Median phenylalanine µmol L^{-1} (range)	
Subjects	Age (years)	pre- CGMP-AA	6 month CGMP-AA	Baseline	6 month	Median protein equivalent from CGMP-AA at 6 months	Subjects	Age (years)	12 month pre-study	6 month study
1	15	255 (160–440)	345 (290–420)	100	100	60	1	12	360 (100–560)	455 (250–910)
2	11	350 (210–490)	390 (280–510)	100	100	80	2	10	470 (80–570)	245 (110–700)
3	11	550 (240–1120)	610 (320–990)	100	100	60	3	14	350 (180–710)	350 (130–1080)
4	10	315 (70–550)	430 (280–760)	100	30	50	4	9	325 (90–670)	280 (60–450)
5	6	270 (60–510)	420 (160–680)	100	30	20	5	14	540 (100–740)	540 (240–610)
6	6	320 (180–510)	470 (110–710)	100	30	20	6	7	235 (100–500)	180 (80–610)
7	7	220 (90–520)	265 (100–980)	100	70	40	7	12	210 (70–580)	280 (100–520)
8	8	170 (90–660)	250 (110–610)	80	75	60	8	14	240 (70–880)	180 (60–850)
9	7	225 (80–400)	290 (130–700)	75	75	75	9	6	190 (80–480)	270 (110–690)
10	8	225 (100–520)	220 (80–490)	30	30	30				
11	7	280 (80–690)	270 (50–410)	30	30	30				
12	11	290 (80–630)	200 (70–600)	30	30	30				
Median		275	317	100	50	45			325	280
$P = 0.02$							P = ns			

CGMP-AA, casein glycomacropeptide amino acid.

Acceptability

After 7 days of taking CGMP-AA, caregivers and patients completed acceptability questionnaires. They were asked questions about taste, smell, texture, mouthfeel and overall acceptability of the CGMP-AA.

Statistical analysis

Statistical analysis was performed using nonparametric Wilcoxon matched pairs signed rank testing and the Pearson correlation coefficient. $P < 0.05$ was considered statistically significant.

Results

Subjects

Twelve children (aged 6–16 years) were in the CGMP-AA group and nine (aged 6–14 years) were in the L-AA group. At baseline in both the CGMP-AA and L-AA groups, the median protein equivalent from protein substitute was 60 g day^{-1} (60–80 g). Prior to starting the CGMP-AA protein substitute, one subject took a powdered preparation (XP Maxamum; Nutricia Ltd, Trowbridge, UK); 11 liquid pouches [Lophlex PKU, $n = 2$ (Nutricia Ltd) and PKU Cooler, $n = 9$ (Vitaflo Ltd, Liverpool, UK)]. In the L-AA group, the entire protein substitute was from Phe-free L-AA supplements. They either received liquid pouches (LQ Lophlex PKU, $n = 1$; PKU Cooler, $n = 7$) or powdered preparations (PKU gel, $n = 1$; Vitaflo Ltd).

In the CGMP-AA group, CGMP-AA was titrated with their usual L-AA product, the median intake of protein equivalent was 50% from CGMP-AA and 50% from Phe-free L-AA at 6 months. In both groups, the median amount of prescribed natural protein from food sources was 5 g day^{-1} (3–30 g). One 12-year-old boy was excluded from the CGMP-AA group because he failed to adhere to the inclusion criteria of blood phenylalanine control within 70% of target range as a result of poor dietary adherence.

Blood phenylalanine concentrations

At the end of the study period, there was a significant increase in blood phenylalanine concentrations in the CGMP-AA group (pre-CGMP-AA, 275 µmol L^{-1}; with CGMP-AA, 317 µmol L^{-1}; $P = 0.02$), although the median blood phenylalanine control remained within target range. Overall, 75% of the subjects had higher median phenylalanine concentrations compared to the retrospective results for the previous year. In seven subjects, the amount of protein equivalent from CGMP-AA was reduced to avoid median phenylalanine concentrations above target concentrations (Fig. 1 and Table 2). Three subjects remaining on only 20 g of protein equivalent from CGMP-AA had no increase in blood phenylalanine concentrations. However, there was no significant correlation between the dose of CGMP-AA and change in blood phenylalanine concentrations (r = 0.6) (Fig. 1). In the control group, there was a nonsignificant fall in median phenylalanine concentrations (pre-study, 325 μmol L^{-1}; study, 280 μmol L^{-1}; P = 0.9) compared to the previous year's median results.

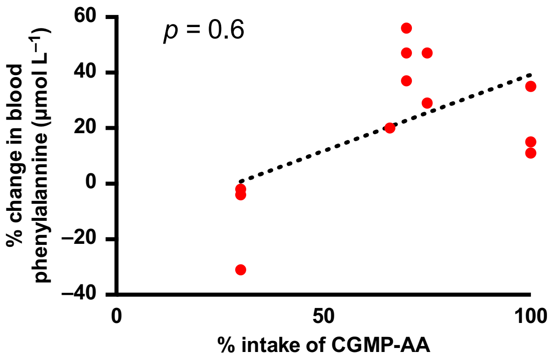

Figure 1 Spearman correlation natural protein intake (g day^{-1}) compared to percentage change in blood phenylalanine concentrations. [Correction added on 21 February 2017, after first online publication: Figure 1 was previously captured with incorrect x-axis and has been corrected in this current version.]

Tyrosine concentrations (table 3)

In the CGMP-AA group, there was a significant decrease in tyrosine concentrations (pre-study, 50 μmol L^{-1}; with CGMP-AA, 40 μmol L^{-1}; P = 0.03), although this was still above the lower reference range. In the control group, tyrosine concentrations remained unchanged (pre and post study 40μmol/L [p = 1]).

Phenylalanine and tyrosine ratio (table 4)

There was a significant difference in the Phe/Tyr ratio in the CGMP-AA group (Phe : Tyr ratio pre-study, 4.9:1, with CGMP-AA, 8:1; P = 0.02). There was no significant difference in the Phe : Tyr ratio in the control group (pre-study phe/tyr 5.8:1, with study 6.7:1).

Three-day weighed food intake (table 5)

The total protein intake from all foods consumed (natural protein from phenylalanine exchanges, low protein prescribed foods, fruits and vegetables) was similar for the CGMP-AA (week 0, 10.8 g day^{-1}; week 26, 9.8 g day^{-1}) and control groups (week 0, 9 g day^{-1}; week 26, 10 g day^{-1}). Both groups consumed 50% more natural protein compared to the prescribed amounts (additional amounts of natural protein: CGMP-AA group, 5 g day^{-1}; control group, 4.5 g day^{-1}). Although there was no

Table 3 Comparison of the median change in blood tyrosine concentrations (range) from the previous 12 months (before start of study) to week 26 (end of study) for CGMP-AA and L-AA groups and, for the CGMP-AA group, the percentage contribution of protein equivalent from CGMP-AA from baseline to end of study

CGMP-AA group						Control group			
		Median tyrosine μmol L^{-1} (range)		Median protein equivalent from CGMP-AA at 6 months				Median tyrosine μmol L^{-1} (range)	
Subjects	Age (years)	pre- CGMP-AA	6 month CGMP-AA	Baseline	6 month	Subjects	Age (years)	12 month pre-study	6 month study
1	15	50 (30–60)	40 (30–60)	100	100	1	12	40 (30–70)	40 (30–50)
2	11	60 (40–140)	50 (40–70)	100	100	2	10	60 (40–250)	70 (40–140)
3	11	50 (40–140)	40 (30–40)	100	100	3	14	75 (40–270)	70 (40–110)
4	10	35 (30–60)	40 (30–90)	100	30	4	9	40 (30–120)	40 (30–50)
5	6	100 (40–240)	45 (30–190)	100	30	5	14	50 (30–90)	60 (30–130)
6	6	80 (40–290)	40 (30–190)	100	30	6	7	40 (30–70)	40 (30–70)
7	7	70 (40–240)	40 (30–80)	100	70	7	12	50 (30–70)	40 (40–60)
8	8	45 (20–170)	30 (20–50)	80	75	8	14	45 (30–80)	40 (20–100)
9	7	40 (30–60)	40 (20–170)	75	75	9	6	40 (30–70)	40 (30–60)
10	8	50 (30–140)	50 (30–130)	30	30				
11	7	60 (30–90)	60 (50–80)	30	30				
12	11	40 (30–130)	50 (30–60)	30	30				
Median		50	40	100	50			40	40
P = 0.03						P = ns			

CGMP-AA, casein glycomacropeptide amino acid.

Table 4 Comparison of median phenylalanine and tyrosine ratios with the previous 12 months (before start of study) with week 26 (end of study) for each subject in the CGMP-AA and control groups

CGMP-AA group				Control group			
		Median phe/tyr ratio				Median phe/tyr ratio	
Subjects	Age Year	12 month pre-study	6 month CGMP-AA	Subjects	Age Year	12 month pre-study	6 month study
1	15	5:1	8.6:1	1	12	8.5:1	11.1:1
2	11	5.8:1	7.8:1	2	10	7.8:1	3.5:1
3	11	11:1	15.5:1	3	14	4.7:1	5:1
4	10	9:1	10.8:1	4	9	8.1:1	7:1
5	6	2.7:1	9.3:1	5	14	10.8:1	9:1
6	6	4:1	11.8:1	6	7	5.8:1	4.5:1
7	7	3.1:1	6.6:1	7	12	4.2:1	7:1
8	8	3.8:1	8.3:1	8	14	5.3:1	4.5:1
9	7	5.6:1	7.3:1	9	6	4.7:1	6.7:1
10	8	4.5:1	4.4:1				
11	7	4.7:1	4.5:1				
12	11	7.3:1	4:1				
Median Phe:try		4.9:1	8:1			5.8:1	6.7:1
$P = 0.02$				$P =$ ns			

CGMP-AA, casein glycomacropeptide amino acid.
[Correction added on 21 February 2017, after first online publication: All ratio listed in this table were previously interchanged and incorrect and have been corrected in this current version.]

Table 5 Comparison of daily dietary intake for energy [MJ day^{-1} (kcal day^{-1})], natural protein, fat and carbohydrate (g day^{-1}) for both CGMP-AA and control groups at the start and end of the study period

	CGMP-AA group				Control group			
	Energy MJ (kcal)	Natural protein g	Fat g	Carbohydrate g	Energy MJ (kcal)	Natural protein g	Fat g	Carbohydrate g
Baseline (week 0)	7.067 (1689)	10.8	52	300	6.795 (1624)	9	53	292
End (week 26)	7.071 (1690)	9.8*	59	300	6.820 (1630)	10	45	300

*includes a median intake of 1.2 g of natural protein from casein glycomacropeptide amino acid (CGMP-AA).
[Correction added on 21 February 2017, after first online publication: The values in column "Energy MJ (kcal)" under the Control group had the wrong decimal place and have been corrected in this current version.]

significant difference in natural protein intake between the two groups, in the CGMP-AA group, an additional median intake of 60 mg of phenylalanine (equal to 12% of the dietary protein) was derived from the CGMP-AA protein substitute. Energy intake was similar in both groups (Table 5).

Anthropometric measurements

No significant changes were recorded for weight, height and BMI both at the start and end of the study between the control and study group (Table 6).

Acceptability

All of the subjects in the CGMP-AA group described the protein substitute as acceptable; with improved taste, mouth feel, texture and smell compared to their conventional Phe-free L-AA substitute.

Discussion

Regarding PKU, this is the first controlled, longitudinal study reporting the impact of CGMP-AA protein substitute compared to traditional Phe-free L-amino acid supplements on blood phenylalanine, tyrosine and Phe/Tyr concentrations in children over a 6-month period. We have identified a significant increase in blood phenylalanine, Phe/Tyr ratios and a significant decrease in tyrosine concentrations over the study period. Overall, median blood phenylalanine control was maintained within the target range, although only with adjustment to the amount of total protein substitute provided by CGMP-AA and the Phe-free L-amino acid supplements. Energy and natural protein intake were similar in both study groups. However, the overall change in blood phenylalanine concentration that we observed was still less than that reported in a 3 week randomised cross-over study in 30 adults with PKU who took all their protein substitute

Table 6 Median (range) of weight and height *Z*-scores for CGMP-AA and control groups from start to end of the study period

	CGMP-AA group		Control group	
	Weight *Z*-score	Height *Z*-score	Weight *Z*-score	Height *Z*-score
Baseline (week 0)	0.660 (−0.610 to 1.130)	0.170 (−0.61 to 1.130)	0.752 (−1.082 to 2.09)	0.465 (−1.164 to 1.842)
End (week 26)	0.910 (−1.0 to 2.460)	0.145 (−0.670 to 1.3)	0.869 (−1.164 to 1.842)	0.4290 (−1.184 to 1.902)

CGMP-AA, casein glycomacropeptide amino acid.

as CGMP-AA, although the differences were not statistically significant in the present study [18].

The impact of CGMP-AA on blood phenylalanine control appeared to vary according to the total amount of protein equivalent the CGMP-AA provided. When 40 g or more of protein equivalent (providing an extra 60–90 mg day^{-1} of phenylalanine) replaced the entire Phe-free L-amino acid supplement, all subjects showed an increase in blood phenylalanine concentrations; when 20 g of protein equivalent from CGMP-AA (providing an extra 30 mg day^{-1} of phenylalanine) replaced Phe-free L-amino acids, blood phenylalanine remained unchanged. Although, overall, we did not find a significant correlation between the intake of CGMP-AA and the change in blood phenylalanine concentrations, we decreased the daily amount of CGMP-AA when blood phenylalanine concentrations increased consistently. Zaki *et al.* [19] in a two phase, nonrandomised study, gave 50% of the protein substitute from unmodified GMP for 9 weeks, followed by conventional amino acid for 9 weeks in a group of 10 children with a median age 6 years. There were no significant differences in blood phenylalanine or Phe/Tyr ratio between the phases, and it was concluded that a 50% replacement of L-AA with GMP was viable. Neither the amount of protein equivalent from protein substitute, nor phenylalanine tolerance was reported.

There are several possible explanations for the significant increase in blood phenylalanine concentrations in the CGMP-AA group. First, the impact of the residual amount of phenylalanine in CGMP-AA is likely to vary according to the phenylalanine tolerance of the individual; a median intake of 60 g of protein equivalent provides an extra 90 mg of phenylalanine. If a child is taking 60 g of protein equivalent from CGMP-AA but is only prescribed 4 g day^{-1} of natural protein, they will receive an extra 45% of phenylalanine from CGMP-AA; in contrast, if a child is taking 30 g day^{-1} natural protein, they would only receive an extra 6% of phenylalanine from CGMP-AA. However, it was interesting to observe in the present study that the same increase in blood phenylalanine concentrations occurred regardless of phenylalanine tolerance.

Secondly, blood phenylalanine and tyrosine concentrations may be influenced by the composition and ratio of amino acids provided in this CGMP-AA product. All CGMP-AA protein substitutes are developed to modify the overall amino acid profile to ensure that no indispensable and conditionally indispensable amino acids are deficient. However, the CGMP-AA product studied had lower amounts of the large neutral amino acids (LNAA) isoleucine, leucine, tyrosine, histidine, and tryptophan than conventional Phe-free L-amino acid supplements, which may have influenced our findings. Both large neutral and the cationic amino acids share a common L-type amino acid transporter enzyme (LAT1) allowing entry of amino acids across the blood–brain barrier. LNAA supplementation in a mouse model reduced blood and brain phenylalanine by 33% and 26%, respectively [20]. Furthermore, leucine is important in stimulating muscle protein synthesis; thus, higher amounts in CGMP-AA may improve blood Phe control. Developing a new formulation of CGMP-AA with increased concentrations of some LNAA (isoleucine, leucine, histidine, tyrosine and tryptophan) should theoretically lower the blood phenylalanine.

In the present study, children taking CGMP-AA had significantly lower tyrosine concentrations with a higher Phe/Tyr ratio. Other studies have described lower tyrosine concentrations with CGMP. van Calcar *et al.* [10] reported tyrosine concentrations below the normal range after a short-term study in 11 subjects taking CGMP; similarly, in one case report when CGMP was given for 10 weeks, an additional 1000 mg of tyrosine was supplemented to achieve normal tyrosine concentrations [8]. Tyrosine is a conditionally essential amino acid in PKU and it appears that is it difficult to increase plasma and even brain concentrations of tyrosine in PKU mouse models [20]. It has been suggested that supplemented tyrosine is used to restore the profound brain norepinephrine deficiency [20].

Other factors that may have influenced phenylalanine concentrations include: failure to complete the prescribed dose of protein substitute, additional natural protein intake in excess of daily allowance, severity of PKU, weight loss, illness or non-adherence to diet, particularly in older children, which can influence blood phenylalanine concentrations. Throughout this pilot study, all of the subjects were visited monthly at home to check adherence and diet histories, as well as to assess stocks of protein substitute used and monitor growth. No differences in dietary patterns or growth were observed. Although, in both groups, blood phenylalanine control remained within target ranges, in the CGMP-AA, it increased significantly. Although the older subjects were less adherent to dietary management, this applied equally to both groups.

There are limitations to the present study. First, completion of a randomised blind study was not possible. The protein substitutes CGMP-AA and Phe-free L-AA have different tastes, textures, smell and appearances, making a randomised blind study difficult. Second, children were resistant to transitioning between protein substitutes, which would be necessary to conduct a long-term randomised controlled trial. A further limitation was the need to reduce the dosage of CGMP-AA once phenylalanine concentrations increased beyond target ranges. This arguably lessened the significance of our findings, although the ethical priority was to maintain phenylalanine concentrations within target guidelines. Finally, gaining adherence in the older age groups in both the CGMP-AA and control group was challenging.

CGMP is associated with taste advantages and potential valuable nutraceutical properties, although caution is warranted and further research is needed before this product can be fully utilised as a replacement for traditional Phe-free L-AA products in children. It does contain residual phenylalanine and its potential destabilising effect on blood phenylalanine concentrations has to be assessed and monitored carefully in children. It is essential that we fully understand the impact of additional phenylalanine intake and the amino acid profile of this protein substitute in children with PKU who are expected to maintain blood phenylalanine within uncompromising and low target ranges.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as lanned (and registered with) have been explained. The reporting of this work is compliant with STROBE guidelines.

Conflict of interests, source of funding and authorship

Professor Anita MacDonald, Anne Daly, Sharon Evans and Satnam Chalal declare that they have undertaken evaluation work for the nutritional companies: Vitaflo Ltd, Nutricia Ltd and Firstplay Dietary Foods. Si Santra has no conflicts of interest to declare in this project.

Funding was received by Vitaflo International to carry out this piece of original work, and we declare that the work is in agreement with the Transparency Declaration. AD was the main researcher for the paper, collected and assimilated data, and wrote the paper. SE, SC, SS and AMcD helped with the collection of data, the interpretation of the results, and made critical reviews and changes to the text as appropriate. All authors critically reviewed the manuscript and approved the final version submitted for publication.

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DIETARY ASSESSMENT AND FOOD BEHAVIOURS

Impact of a targeted direct marketing price promotion intervention (Buywell) on food-purchasing behaviour by low income consumers: a randomised controlled trial

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Keywords
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Abstract

Background: Price promotions are a promising intervention for encouraging healthier food purchasing. We aimed to assess the impact of a targeted direct marketing price promotion combined with healthy eating advice and recipe suggestions on the purchase of selected healthier foods by low income consumers.

Methods: We conducted a randomised controlled trial (n = 53 367) of a direct marketing price promotion (Buywell) combined with healthy eating advice and recipe suggestions for low income consumers identified as 'less healthy' shoppers. Impact was assessed using electronic point of sale data for UK low income shoppers before, during and after the promotion.

Results: The proportion of customers buying promoted products in the intervention month increased by between 1.4% and 2.8% for four of the five products. There was significantly higher uptake in the promotion month ($P < 0.001$) for the intervention group than would have been expected on the basis of average uptake in the other months. When product switching was examined for semi-skimmed/skimmed milk, a modest increase (1%) was found in the intervention month of customers switching from full-fat to low-fat milk. This represented 8% of customers who previously bought only full-fat milk. The effects were generally not sustained after the promotion period.

Conclusions: Short-term direct marketing price promotions combined with healthy eating advice and recipe suggestions targeted at low income consumers are feasible and can have a modest impact on short-term food-purchasing behaviour, although further approaches are needed to help sustain these changes.

Introduction

Diet is a major modifiable risk factor for many cancers [(1)] and circulatory diseases [(2,3)]. Obesity is a significant contributor to cardiovascular disease, diabetes and cancer, and continues to rise both internationally [(4)] and in the UK [(5)]. Of particular concern are persistent inequalities in obesity, diet and health-related outcomes [(6,7)]. Low income consumers in the UK and other European countries tend to have *lower* intakes of fruit, vegetables, wholegrain bread and cereals, fruit juice and oil-rich fish, as well as *higher* intakes of sugar, whole milk and processed meats, compared to higher income consumers [(8–10)].

Increasingly, attention has focussed on system-level interventions that modify the social environment in which food choices are made [(11–13)] and make healthier choices easier [14]. Access and price have been identified as barriers to healthier eating for some low income consumers [15–19], and the World Health Organization and various national governments have called for improved access to affordable healthy food for vulnerable groups [20–22]. If inequalities in diet are to be narrowed, it may be important to target prevention interventions primarily or specifically at these groups [23].

Recent healthy diet strategies [21,24,25] have recommended harnessing marketing levers such as product development, labelling and pricing in support of 'behaviour that builds health', as well as working with retail businesses that have the marketing expertise to engage with customers and encourage specific behaviours. Various studies suggest that interventions using point-of-sale promotions, pricing, in-store signposting and product labelling, singly or in combination, are feasible to implement and have the potential to impact on customer-purchasing behaviour [26–29].

Recent debate has focussed on financial incentives as a motivator to initiate change in health behaviours [11,30–32], although this approach has not yet been demonstrated to produce consistently positive results in diet-related behaviours such as weight loss [33]. Financial incentives comprise food price promotions, subsidies and rewards, and a recent review found that '*retail price promotions can influence purchasing patterns and promote overall greater consumption of the product, but this is highly dependent on the nature of the promotion (e.g. the depth of the discount, the shopper, and the specific food*' (p. 10) [34]. Recent studies in New Zealand and the Netherlands have demonstrated, using randomised controlled trial methods, that price discounts for healthier foods can have a significant and sustained effect on food purchasing [35] and on fruit and vegetable purchases [36]. Although effects tend to be smaller than those obtained in more intensive interventions [37], price promotion interventions potentially have a much wider reach and are relatively cost-effective [38]. This suggests that price promotions can make a useful contribution towards promoting healthy diets, as part of a portfolio of approaches that might also include health education, availability and fiscal measures.

Price promotions have been extensively applied and studied in retailing [39]. Technological developments have given rise to new and more targeted strategies, such as using data linked to loyalty schemes [40,41] and customers' history of purchasing to develop promotions targeted at individual customers [42]. Likewise, technology such as electronic point of sales (EPOS) systems offers a unique opportunity for assessing household food purchases that does not rely on participants' memory or literacy, and also is not subject to recall or social bias and places no direct burden on participants [43,44]. The ability to develop and deliver promotions targeted at groups of customers on the basis of previous purchasing behaviour and other characteristics makes this a particularly promising, although underexplored, route for addressing health inequalities associated with food-purchasing behaviour.

The present study aimed to assess the feasibility and impact of a targeted direct marketing price promotion intervention (Buywell) on food purchases by low income customers who were known not to be purchasing 'healthy' products at the time of the intervention.

Materials and methods

Overview

The intervention comprised a direct marketing (i.e. mailed out to customers' homes) price promotion combined with healthy eating advice and recipe suggestions. Working with a major UK food retailing group, we developed a price-based promotion combined with healthy eating advice and recipe suggestions for selected healthier products, which was mailed to regular low income customers in May 2007. The impact was assessed by examining data on actual food purchases, using EPOS technology, for intervention (37 034) and control group (16 333) customers for 2 months before, 1 month during and 3 months after the intervention. A consumer survey was also conducted post-intervention with 3706 customers to examine their awareness of and reactions to the intervention; a brief summary of findings is reported elsewhere [45]. Ethical approval for the study was provided by University of Stirling Research Ethics Committee.

Identification, selection and randomisation of sample

Information held by the retailer from membership card data and linked EPOS transaction data was used to identify and select the study sample. The first step was to identify consumers who used the retailer for their main food shopping, defined by possession of a loyalty/membership card, proximity to a store in a town with few other major food retailers, and being categorised as in either of the top two customer spending categories, based on the frequency of shopping and the average number of items purchased per month.

The second step was to identify low income customers. Membership data held by the retailing group did not record individual income or socio-economic status. However, based on their postcode and other data, all customers were assigned to a category within MosaicUK, a widely used geo-demographic classification scheme [46]. Three Mosaic categories including primarily disadvantaged customers were identified as the core target for the intervention.

The final step was to identify consumers whose current food purchasing behaviour had the potential to be shifted in a 'healthier' direction. The most practicable strategy was to identify those who could currently be defined as purchasers of 'healthier' foods and exclude them from the sample. All food product categories stocked by the retailing group were examined, and 90 were identified that were low in fat, sugar and sodium according to the UK Food Standards Agency 'traffic lights' scheme [47]. From these, 20 of the most commonly purchased product categories were identified to serve as indicators of 'healthier' shopping. The indicators were based on the 35-item healthy eating indicator shopping basket tool (HEISB) [48]. These included low-fat dairy products (milk, yoghurt, spreading fats) and wholegrain products (brown and wholemeal breads, wholegrain breakfast cereals, wholegrain rice and pasta, beans and peas). Fresh vegetables and fruits (n = 15) included in the HEISB were not used because formative work indicated they were not a reliable indicator of purchasing patterns from the retailing group because these items were occasionally bought elsewhere (e.g. produce markets). 'Healthier' purchasers were arbitrarily defined as those who had bought a wide selection of these items, defined as at least eight (40%), of the healthy eating indicator foods within the last week, and these were removed from the sample.

The retailing group applied the three criteria of regular food shopping, low income Mosaic group and less-healthy purchasing to its customer database for the time period immediately prior to the intervention. This yielded a sample group of 53 367 adults aged 31–65 years, which was then randomised on a 70 : 30 allocation ratio to the intervention (n = 37 034) or control (n = 16 333) groups. The rationale for the 70 : 30 split was to reach as large a customer group as the retailing group could afford (i.e. with the costs of price promotions being borne by the retailer in reduced profits), at the same time as ensuring a sufficiently large control group. The randomisation was carried out by the retailer's own in-house data team, using procedures that were not disclosed to the academic research team.

The intervention

Formative focus group research (six focus groups, n = 34) was conducted with a sample of target group consumers to inform the intervention design. The findings suggested that older and female shoppers were more likely to use price promotions and that, although customers were fairly conservative in their shopping habits, they felt their meals sometimes lacked variety. This suggested the potential for a promotion comprising offers on basic food products that could be combined to make a meal, especially if linked to recipe ideas and if separate coupons were provided to maximise choice and minimise waste. Informed by this research, a direct mail price promotion was developed. This comprised a flyer with two offers. The first was a Healthy Meal Deal, which comprised healthy eating advice, two suggested recipes (one based on mince, vegetables and a sauce, and one based on chicken, vegetables and a sauce) and discount coupons worth £2.50 in total for the ingredients of the two recipes. The recipes were analysed for nutritional content and piloted by nutritionists before being included in the offer. The second offer was a Low-Fat Milk Repeat Purchase offer, which comprised healthy eating advice on the value of calcium to teeth and bone development, and six discount coupons for retailer brand skimmed and semi-skimmed milk in two sizes (Fig. 1). In summary, the five products on which price promotions were offered were low-fat beef mince, skinless chicken, any fresh vegetables, ready-to-eat sauce (two different flavours, both assessed as meeting health criteria) and skimmed/semi-skimmed milk (Fig. 1). The intervention group customers could use the discount by presenting the flyer at the till. The control group did not receive the flyer and would not have been aware of the promotion.

The promotion was mailed from 7 to 28 May 2007. The time of the year was chosen to avoid other key

Healthy meal deal

Aimed to encourage a switch to healthier meals through price reductions on the main ingredients of healthy meals based on low fat beef mince and skinless chicken. Each deal included two attractive simple recipes featuring the promoted ingredients, and three discount coupons worth £2.50 (€2.90) for retailer brand low fat beef mince and skinless chicken breasts, any fresh vegetable, and a retailer brand ready-to-eat sauce which met health criteria (including sodium levels).

Low fat milk repeat purchase offer

Comprised six money-off coupons for retailer brand skimmed and semi-skimmed milk (2 and 4 pint). Usage was restricted to one coupon per visit to encourage repeat purchase. The promotion included messages about the value of calcium to teeth and bone development and guidance regarding young children and milk consumption.

Figure 1 Content of the promotion.

periods of promotional activity, such as Christmas and Easter.

Electronic point of sales data analysis

The outcome measures of interest were uptake of the promotion for each of the promotion products and product switching. Anonymised EPOS data were supplied from March to August (with May as the promotion month) by the retailer by transaction. Recorded purchases of the promoted products were the primary outcome measure. Data were aggregated by customer membership card number to give customer-based data and 'basket' combination data, which were compared from month to month. EPOS data are classified by a sequence of main and sub-categories, with every individual product of a given size having a unique code. There were more than 150 000 products on the retailer's product list, although this included nonfood items and items not currently on sale. Codes were obtained for the promotion products and entered to identify purchase of these products.

Uptake of the promoted products was analysed in terms of the number and proportion of customers buying each of the products, compared with the control group. Chi-squared tests were used to test whether uptake of products by the intervention group in the promotion month could have occurred by chance. Two tests were conducted for all promotion products. First, differences between control and intervention groups were tested. Second, differences were examined between transactions in the promotion month (May) and the average uptake for each product for the months excluding the promotion. This accounts for seasonal variation in uptake of products.

Product switching is an important part of the uptake of any promotion [49] and can have different dimensions: health switching (e.g. from full-fat to semi-skimmed milk), brand switching (e.g. from a branded product to retailer brand) and pack size switching (from the size usually bought to the size included in the offer). In public health terms, only the first form of switching, from a less to more healthy variant, is meaningful [50]. Within the present study, information on switching is presented for milk, where less healthy variants could be clearly identified within the data. Because of the way products were categorised by the retailer in the EPOS data, it was more difficult to identify less healthy variants for the meat products included in the promotion.

Results

Over four million transactions per month were recorded on the retailer-supplied database. Almost all (99.6%) of the study group made purchases from the retailer at the start of the study, falling slightly to 92.6% still making purchases from the retailer by the end of the 6-month study period. The mean number of items purchased per customer over the study period ranged between 83 and 92 (Table 1).

Uptake

Figure 2 illustrates the uptake of the promoted products by both groups over the study period. There was wide variation in the proportions regularly buying each product. Although over 60% bought vegetables, the other four products were less commonly purchased. For example, only approximately 6% regularly bought skinless chicken and fewer than 5% bought ready-to-eat sauce. For four of the five promoted products, there was a small upward spike, ranging from 1.4% to 2.8%, with respect to the proportion of intervention customers purchasing the product in May (i.e. the intervention month) (Fig. 2a): semi-skimmed/skimmed milk (33.2–34.6%), lean steak mince (9.7–12.5%), skinless chicken breasts (6.3–8.2%) and ready-to-eat sauce (1.4–2.8%). Figure 2b shows that the proportion of control customers purchasing each of the five promoted products remained consistent in the month of the intervention, reflecting the constancy of purchasing patterns for most shoppers. Vegetable purchases increased by only 0.2% among intervention customers in May but

Table 1 Number of transactions and customers

Month 2007	Transactions, *n*	Intervention customers, *n*	Control customers, *n*	Total customers, *n*	Total customers as a percentage of original study sample	Items purchased per customer (mean)
March	4 908 066	36 924	16 232	53 156	99.6%	92.33
April	4 397 790	36 464	16 090	52 554	98.4%	83.68
May	4 511 999	35 835	15 783	51 618	96.7%	87.41
June	4 379 735	35 377	15 648	51 025	95.6%	85.84
July	4 255 832	35 077	15 532	50 609	94.8%	84.09
August	4 116 864	34 249	15 178	49 427	92.6%	83.29
Total customer base:		(37 034)	(16 333)	(53 367)	(53 367)	

decreased by 0.8% among control group customers; following the promotion, vegetable purchases decreased in both the intervention and control groups, perhaps reflecting seasonality. For each of the five products, the promotion month showed a significantly higher ($P < 0.001$) value for the intervention group than would have been expected on the basis of average uptake in the other months. Similarly, compared with the control sample, the promotion values for each of the products were significantly higher ($P < 0.001$) than the expected values. The exception was skimmed and semi-skimmed milk (significant at $P < 0.05$). No significant difference was found

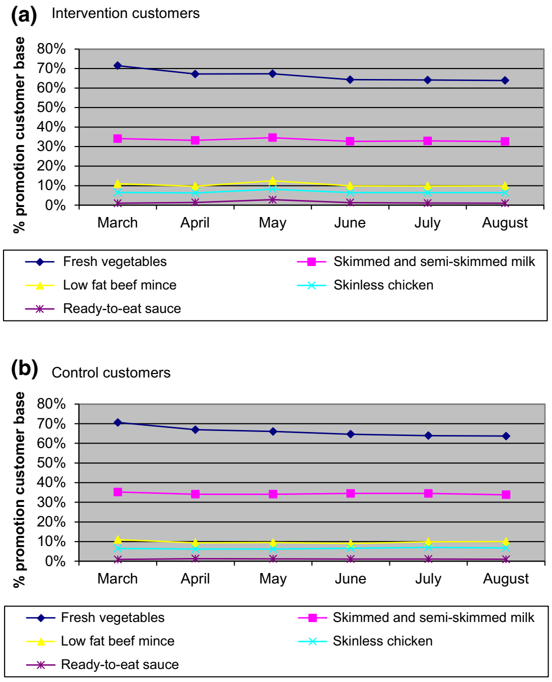

Figure 2 Changes in proportions of (a) intervention customers and (b) control customers buying the promoted products.

between the control and intervention groups for the other months. The increase in the proportion of intervention customers purchasing four of the promoted products was generally not sustained beyond the intervention, with the number of customers purchasing each product reverting to pre-intervention levels or lower from June onwards, again perhaps reflecting seasonal patterns in purchasing.

Further analyses were conducted to explore whether the promotion widened the customer base for the promoted products, as suggested by the data above, or simply encouraged existing customers for the products to buy more than usual. Analysis of the mean number of promoted products purchased per customer each month indicated that this did not tend to vary over the study period (e.g. the mean number of low fat beef mince items bought per customer was between 1.28 and 1.30 per month, including May). This suggests that the increase in uptake was explained primarily by a widening of the customer base (i.e. introducing new customers to the promoted products) rather than by existing customers buying more of a product than they would usually. Overall, the data indicate that the intervention month was associated with an increase in the customer base for most of the promoted products.

Product switching

Table 2 profiles the intervention customers who purchased the promoted milk in May, in terms of continuing customers, new customers and customers who switched brand or switched to lower fat milk. Pack size switching was not relevant because the promotion was not restricted to specific pack sizes. One-third (n = 12 399, 33%) of all intervention customers bought the promoted skimmed/semi-skimmed retailer brand milk during the promotion period. Most of these (n = 10 072; 81%) were continuing customers who had purchased skimmed/semi-skimmed retailer brand milk in the month prior to the

Table 2 Profile of intervention customers who purchased promoted milk in intervention month

Base:	Intervention customers *n*	Percentage of all intervention customers (37 034)	Percentage of all intervention customers who purchased the promoted milk in May (12 399)
Purchased skimmed/semi-skimmed retailer brand milk in May	12 399	33%	100%
Continuing customers – purchased before and during promotion	10 072	27%	81%
Switched from full-fat only:	464	1%	4%
Bought skimmed/semi- skimmed AND full-fat)	367	1%	3%
Bought skimmed/semi-skimmed only	97	0.3%	1%
Switched brand	262	1%	2%
New customers (did not buy any milk from this retail group in April, i.e. pre-intervention)	1601	4%	13%

intervention, whereas almost one-fifth (n = 2327; 19%) were customers who had switched from buying full-fat only, switched from a different brand or were new to purchasing milk from this retailer. As a proportion of all intervention customers, the numbers taking up the promoted milk, either as a result of switching or new purchases, appear to be small, representing 1% (n = 464) switching to healthier milk, 1% (n = 262) switching brand and 4% (n = 1601) being new customers. However, from a health perspective, the key target group for the milk promotion is customers who previously purchased only the full-fat variety of milk. The EPOS analysis showed that 6034 intervention customers purchased only the full-fat milk in April (i.e. before the intervention). Therefore, the 464 customers who switched to a healthier variety of milk during the intervention month represent 8% of the target group.

Table 3 shows that only 36% (n = 169) of those who had switched to a healthier variety of milk continued to purchase the skimmed/semi-skimmed variety in the month immediately after the promotion ended. Retention of the healthier purchase behaviour continued to decline in subsequent months. Only 17% (n = 81) of those who switched to the healthier milk sustained their healthier milk purchasing in each of the 3 months after the promotion completed; these customers represent 1% of the target group of 6034 intervention customers who had purchased only full-fat milk in April prior to the intervention. Retention declined similarly among those who switched brand of milk and among new customers, with 23% (n = 61) of brand switchers and 22% (n = 348) of new customers continuing to purchase the skimmed/semi-skimmed retailer brand milk in each of the 3 months after the promotion.

Discussion

This large randomised trial shows that it is feasible to develop and implement a direct marketing price promotion intervention targeted at low income consumers not currently buying healthy food. Customers who lived in disadvantaged postcode areas and with less 'healthy' current food purchasing patterns were able to be identified by matching EPOS data and customer membership data. These customers were then targeted with price promotion offers, combined with healthy eating advice and recipe suggestions, as informed by consumer research insights into their shopping habits and preferences. If nutrition interventions are to have an impact on dietary inequalities, more intensive and targeted efforts directed at those most in need of support are required. Technological innovations and the development of sophisticated marketing databases provide a means not only of identifying the customers most in need of support, but also of developing, delivering and evaluating interventions specifically for them.

Two key findings emerge from our results. First, there appears to have been a modest and short-lived impact of the intervention on uptake of the promoted products, with the increase in intervention customers buying products in the intervention month ranging from 1.4% to 2.8% for four of the five products. Increased uptake was accounted for primarily by a widening of the customer base rather than by an increased number of purchases by existing customers. If the intervention had only encouraged additional purchasing of the promoted items by customers who already bought them, the contribution to influencing purchasing behaviour in a healthier direction would have been of less significance.

Second, the intervention appears to have been associated with a small increase in health switching for milk. This increase in lower fat milk was modest, comprising 1% of all intervention customers. However, among the key target group for the milk promotion from a health perspective, 8% switched to a healthier variant of milk in the intervention month, suggesting that price promotions can encourage trial of healthy variants. This is an important target food given the higher consumption of full-fat milk by low income groups [51]. Just over one-third of customers who switched to purchasing healthier milk

Table 3 Retention of milk switchers and new customers in the 3 months post-promotion intervention customers

Base	Switchers: Full-fat only to skimmed/semi (464)		Switchers: Brand (262)		New customers (1601)		Total (2327)	
Retained in:								
June	169	(36%)	136	(52%)	778	(49%)	1083	(47%)
June and July	102	(22%)	96	(37%)	502	(31%)	700	(30%)
June, July and August	81	(17%)	61	(23%)	348	(22%)	490	(21%)

Base: intervention.

(36%) continued to do so immediately after the promotion ended, and 17% of switchers continued to purchase healthier milk in each of the 3 months after the promotion completed (1% of the target group). It should be noted that the intervention targeted two different behaviours: the milk promotion targeted switching (from one variant of a regularly-purchased product to a healthier variant of the same product), whereas the Healthy Meal Deal promotion was focused on encouraging the uptake of products that customers had potentially not bought before. The milk switching promotion was potentially simpler than the meal deal promotion both in terms of the communication and the intended behavioural response. The short-lived impact of both promotions, particularly the meal deal uptake promotion, is in line with short-term effects reported in retailing studies [52].

One of the main strengths of the present study was its size, comprising over 50 000 low income customers across the UK. There was a low risk of 'contamination' in the control group because control group customers would not have been aware of the intervention and there were no in-store indicators to suggest that it was taking place. The large sample and geographical spread mean that the results are potentially generalisable to the wider UK low income population, although not necessarily to more affluent UK populations or to low income shoppers in other countries. The commitment and support of the retailing group enabled the research team to access large numbers of customers and to profile them in terms of disadvantage at postcode level and food purchasing behaviour, enabling those most 'at risk' to be identified for participation in the intervention. However, it should be noted that the way in which low income consumers were selected, on the basis of MOSAIC geo-demographic classifications, may have resulted in the inclusion of some higher income customers who were living in lower income areas.

Collaborations between retailers and academic researchers are potentially challenging for both sides because of different working practices and priorities. Working with this retailer involved building and maintaining relationships with key contacts, providing reassurance of the impartiality of the researchers, agreeing an intervention approach that did not require in-store adjustments, and the maintenance of an open working relationship, including the sharing of results. The retailing group allowed the research team direct access to the EPOS data, rather than (as is the case in some studies) having the research team dependent on the retailer or a third party to conduct the analysis. Analysing the EPOS dataset was challenging because of the vast amount of data generated and because products were not necessarily categorised within the database on the basis of nutrition attributes but, instead, according to criteria such as shelf order, making it time-consuming to locate all products of interest for analysis. Another challenge was that the price promotion covered several product categories spread across the retail outlet. Although price promotion effects have been extensively studied in the retail literature, the challenge of a promotion such as the current one, which links products placed at different locations of the store, has been less well researched. Findings from disparate studies suggest that product categorisation is important in shaping the likelihood of healthy food purchasing [53] and that location of the products in their correct categories promotes a greater likelihood of purchase [54].

Subsequent to the survey being carried out, considerable expertise and familiarity with 'Big Data' has been gained and its usefulness is recognised much more widely. Using loyalty card data linked to EPOS transactions requires customers to remember to use their identifier each time that they make an in-store purchase. However, as noted in the Introduction, EPOS analysis has a number of advantages for evaluation purposes in that it is not subject to recall or social bias and places no direct burden on participants [43,44]. This makes it a particularly useful method for evaluating outcomes among obese populations, among whom there is a particular problem of giving socially desirable responses in dietary research [55,56], and among populations with varying levels of literacy [43]. Given the complexity and cost of conducting large-scale dietary and consumer behaviour surveys, EPOS data analysis provides a cost-effective means of evaluating population-level interventions and policies [44].

Purchase behaviour does not necessarily reflect actual dietary intake; we do not know the extent to which individuals in a household consumed the purchased products. However, Eyles *et al.* [43] found that, when electronic sales data were compared with repeated 24-h dietary intake recalls, modest correlations were observed between household purchases and individual intakes for percentage energy from saturated and total fat, carbohydrate, protein and sugar, and that purchase data were a reasonably reliable surrogate measure for certain nutrient intakes. In other words, sales data can serve as a useful proxy for dietary impact. The type of effect found in the Buywell study, if enlarged to a wider product range (e.g. main sources of saturated fat), could make an important contribution to changes in disease risk. Current modelling data at the population level suggest that even modest changes in diet are important. For example, Flores-Mateo *et al.* [57] suggest that reducing salt consumption by 1 g day^{-1}, reducing saturated fat and trans fat by 1% and 0.5% of energy intake, respectively, and increasing fruit and vegetable intake by one portion per day could result in approximately 13 850 fewer UK cardiovascular disease deaths per year, whereas it has been estimated that reducing dietary salt intake by 3 g day^{-1} would prevent 30 000 cardiovascular events, with savings worth at least £40 million a year in the UK [58].

The positive changes in food purchasing behaviour reported in the present study are generally modest in scale. That the impact was restricted to the intervention period was not surprising; it might have been expected that sustained changes in purchasing behaviour could not be achieved with such a short intervention, and reported effects are generally short lived in retailing studies [52]. However, it is encouraging that a short-term and relatively small-scale promotion (i.e. a one-off price promotion combined with healthy eating advice and recipe suggestions) was nonetheless able to trigger changes in purchasing behaviour in a small proportion of the target group. This suggests that a longer-term and more multifaceted intervention may be capable of producing more lasting effects. Hawkes [34] suggests that healthy eating interventions based on financial incentives may be most effective when implemented as part of a wider and integrated package of mutually-reinforcing activities rather than in isolation. A review of financial incentives in the USA noted that financial incentives might be more effective when combined with nutrition education (as the present study has done, although the information/education element was limited to brief messages about the value of calcium to teeth and bone development and guidance regarding young children and milk consumption), and also with components to address access [59].

Overall, the present study demonstrates that it is possible for public health researchers and nutritionists to engage with food retailers to develop and implement healthy eating interventions in real-world settings. We have shown that a direct marketing intervention targeted at individual consumers on the basis of past purchasing behaviour and other characteristics can have a short-term and modest impact on uptake of healthier food products. We have also shown that it is possible to engage with and stimulate change, albeit of short duration, among low-income consumers experiencing dietary inequalities. Future studies could test the acceptability and sustainability of price promotion interventions longer term, and could examine how the effects of price promotion interventions could be reinforced by longer-term and more multi-faceted approaches.

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Transparency declaration

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and registered with) have been explained. The reporting of this work is compliant with CONSORT1/STROBE2/PRISMA3 guidelines.

Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

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MS was the principal investigator and took the lead in writing the paper, which was revised by all authors. AMM contributed to the study design and data analysis, and led the consumer survey. AF and LS conducted the EPOS analysis. ASA and KB developed the intervention recipes and advised on selection of promotion foods and identification of target group. DE conducted the consumer research and contributed to study design. All authors critically reviewed the manuscript and approved the final version submitted for publication

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DIETARY ASSESSMENT AND FOOD BEHAVIOURS

A novel processed food classification system applied to Australian food composition databases

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Abstract

Background: The extent of food processing can affect the nutritional quality of foodstuffs. Categorising foods by the level of processing emphasises the differences in nutritional quality between foods within the same food group and is likely useful for determining dietary processed food consumption. The present study aimed to categorise foods within Australian food composition databases according to the level of food processing using a processed food classification system, as well as assess the variation in the levels of processing within food groups.

Methods: A processed foods classification system was applied to food and beverage items contained within Australian Food and Nutrient (AUSNUT) 2007 (n = 3874) and AUSNUT 2011–13 (n = 5740). The proportion of Minimally Processed (MP), Processed Culinary Ingredients (PCI) Processed (P) and Ultra Processed (ULP) by AUSNUT food group and the overall proportion of the four processed food categories across AUSNUT 2007 and AUSNUT 2011–13 were calculated.

Results: Across the food composition databases, the overall proportions of foods classified as MP, PCI, P and ULP were 27%, 3%, 26% and 44% for AUSNUT 2007 and 38%, 2%, 24% and 36% for AUSNUT 2011–13. Although there was wide variation in the classifications of food processing within the food groups, approximately one-third of foodstuffs were classified as ULP food items across both the 2007 and 2011–13 AUSNUT databases.

Conclusions: This Australian processed food classification system will allow researchers to easily quantify the contribution of processed foods within the Australian food supply to assist in assessing the nutritional quality of the dietary intake of population groups.

Introduction

There is increasing concern from a health perspective that the consumption of large amounts of industrially processed foods is driving the increase in the prevalence of diet-related chronic diseases, in particular obesity [1,2], type 2 diabetes [3] and cardiovascular disease [4]. Food processing can be beneficial in that it aids consumption, improves palatability and taste, increases shelf-life, enhances transportability, and ensures that food quality meets human nutrient needs [5]. However, the advancement of various industrial food processing techniques has also resulted in the production of foodstuffs that are made from extracted foods, formed by chemical synthesis [6,7]. These foodstuffs are often made from cheap ingredients and additives, typically low in nutritional quality, high in energy density, nutritionally deplete, convenient and highly palatable [5,6]. Traditionally, food and beverages have been grouped into either processed or unprocessed food categories where natural, whole or unrefined foods are considered unprocessed, and foodstuffs that have undergone manufacturing methods are often arbitrarily defined as processed foods [6]. However, with the preponderance of processed foods on the market [7], the typical dichotimisation of processed foods is inadequate to evaluate the nutritional quality of these types of foods.

A number of systems for classifying processed foods have been proposed [8–12]. Of these, the NOVA system [13] is the most studied classification system and was developed in response to the increasing dominance of industrially processed foodstuffs in the global food supply [6,7]. The NOVA system distinguishes homemade or freshly prepared dishes from manufactured products and thereby categorises foodstuffs into four groups: minimally processed foods (MP), processed culinary ingredients (PCI), processed foods (P) or ultra-processed foods (ULP), in accordance with the level and type of industrial processing [13]. The NOVA classification system has been used in a number of countries [14–16] and has demonstrated associations between food processing and obesity prevalence [1], as well as levels of food processing and the development of adverse lipid profiles [17]. As a result of the evidence of the adverse health impact of food processing, the 2014 Brazilian Dietary Guidelines have incorporated advice to limit the consumption of processed foods [18].

Despite the growing body of evidence reporting the association of ULP foods with chronic disease, the significance of industrial food processing is often ignored or overlooked when assessing the nutritional quality of individual and population diets. In addition, a classification system to facilitate the identification of the level of processing of individual foods has not been included in food composition databases [12]. This means that, within most existing food group classification systems, foods varying in nutritional quality may be grouped together within the same food category. For example, in the Australian food group classification system, breads, biscuits and breakfast cereal bars are classified within the same major food group (Cereals and Cereal products at the two-digit food grouping classification level) [19,20]. However, categorising foods by their level of processing emphasises the differences in nutritional quality between foods within the same food group; breads classified as either MP or P, whereas biscuits and breakfast cereal bars would fall into either the P or the ULP food categories. This classification system may be useful for monitoring dietary processed food consumption within the population. Using two Australian food composition databases derived from national dietary surveys conducted in 2007 [19] and 2011–13 [20], the present study aimed to: (i) categorise individual foods based on the level of food processing using the NOVA classification system [13] and (ii) calculate and assess the proportion of MP, PCI, P and ULP food products across the Australian Food and Nutrient (AUSNUT) databases. This categorisation will allow for the future assessment of the links between processed food intake and health in Australia.

Materials and methods

The NOVA processed food classification system

The NOVA system classifies foods and ingredients according to the intention of use and degree of industrial food processing rather than in terms of nutrients and food types [13]. Criteria for classifying foods into four groups according to the type and intensity of technological intervention are described Table 1. Briefly, the minimally processed (MP) food category includes both unprocessed foods that are of plant or animal origin and are consumed shortly after harvesting and foods that have been modified by removing parts of the food, without the addition of any other substance. The processed culinary ingredient category (PCI) comprise foodstuffs extracted and refined from constituents of foods, whereas processed foods (P) are derived from whole foods and are manufactured to be consumed as part of meals or dishes. The ultra-processed food (ULP) category involves a reduction in food quality as a result of the removal of beneficial food components, the transformation and degradation of foods and ingredients or the concentration of certain food components [13].

The Australian Food and Nutrient databases

AUSNUT 2007 was the specific nutrient database developed by Food Standards Australia and New Zealand (FSANZ) for estimating nutrient intakes from foods, beverages and dietary supplements consumed as part of the 2007 National Children's Nutrition and Physical Activity Survey (CNPAS) (included children aged 2–16 years) [23]. The AUSNUT 2011–13 version was the FSANZ nutrient database [20] developed to enable food, dietary, supplement and nutrient intake estimates to be made from the 2011–13 Australian Health Survey (AHS) and this included, for the first time, a national dietary survey of National Aboriginal and Torres Strait Islanders [24]. The foods in both databases reflect the foods and beverages reported as being consumed at the time of the survey. Both AUSNUT databases were generated using Australian derived analytical nutrient content data and from data; calculated using a recipe approach; supplied by the food industry; from existing food labels and international food composition tables [19,20]. The NOVA processed food classification system was applied to 3874 food and beverage items in AUSNUT 2007 [19] and 5740 foods and beverages in AUSNUT 2011–13 [20].

Australian Food and Nutrient food group classification system

The AUSNUT classification system groups foods according to a major (two-digit), sub-major (three-digit) or minor (five-digit) food group. The five-digit group then

Table 1 The NOVA processed food classification system (21,22)

Food group and definition	Examples
1 Minimally processed (MP) and unprocessed foods	
Foods of plant origin (leaves, stems, roots, tubers, fruits, nuts, seeds), or animal origin (meat, other flesh, tissue and organs, eggs, milk) distributed shortly after harvesting, gathering, slaughter, or husbanding. Minimally processed foods are unprocessed foods altered in ways that do not add or introduce any substance but may involve removing parts of the food. Minimal processes include cleaning, scrubbing, washing; winnowing, hulling, peeling, grinding, crushing, grating, roasting, boiling, squeezing, flaking; skinning, boning, carving, portioning, scaling, filleting; pressing, drying, skimming, pasteurising, sterilising; chilling, refrigerating, freezing, fractioning, filtering, sealing, bottling, simple wrapping, vacuum- and gas-packing. None of these processes add substances such as salt, sugar, oils or fats to the original foods. Malting, which adds water, is a minimal process, as is fermenting, which adds living organisms, when it does not generate alcohol. Also included are foods made from two or more items in this group, such as granola made from cereals, nuts and dried fruits with no added sugar, as well as foods with added vitamins and mineral such as wheat or corn flour fortified with iron or folic acid	Fresh, squeezed, chilled, frozen or dried fruits, leafy and root vegetables; grains (cereals), brown, parboiled, or white rice; corn cob or kernel, wheat berry or grains; fresh, frozen, and dried beans and other legumes (pulses), including lentils, chickpeas; starchy roots and tubers such as potatoes and cassava; fungi such as fresh or dried mushrooms; freshly prepared or pasteurised nonreconstituted fruit and vegetable juices without added sugars, sweeteners or flavours; grits, flakes or flour made from corn, wheat, oats or cassava unsalted, raw/dry roasted, ground nuts and seeds without added sugars; spices such as pepper, cloves and cinnamon; fresh or dried herbs such as thyme, mint; fresh, chilled, frozen meats, poultry, fish, and seafood whole or in the form of steaks, fillets and other cuts; dried, fresh, pasteurised full fat, low-fat, skimmed milk, and fermented milk such as plain yogurt without added sugar or artificial sweeteners; eggs; pasta, couscous and polenta made from flour and water; teas, coffee, herbal infusions; tap, filtered, spring, mineral water
2 Processed culinary ingredients (PCI)	
Substances extracted and purified by industry from food constituents or obtained from nature. Preservatives, stabilising or 'purifying' agents, and other additives may be used. Processes include pressing, refining, grinding, milling and spray drying. Group 2 products are rarely consumed in the absence of group 1 foods. Also included are: products consisting of two group (i.e. salted butter); group 2 items with added vitamins or minerals (i.e. iodised salt)	Plant oils; animal fats; starches from corn or other plants; sugars and molasses made from cane or beet; maple syrup, honey; butter and lard obtained from milk and pork; salt
3 Processed (P) foods	
Manufactured by adding salt or sugar (or other culinary ingredient such as oil or vinegar) to foods to make them more durable or modify their palatability. Directly derived from foods and recognisable as versions of the original foods. Most processed foods have two or three ingredients. Generally produced to be consumed as part of meals or dishes. Processes include canning and bottling, non-alcoholic fermentation, and methods of preservation such as salting, salt pickling, and curing	Canned or bottled vegetables and legumes (pulses) preserved in brine or pickled; peeled or sliced fruits preserved in syrup; tinned whole or pieces of fish preserved in oil; salted or sugared nuts or seeds; nonreconstituted salted or cured processed meat and fish such as ham, bacon, and dried fish; cheeses made from milk, salt, and ferments; and unpackaged freshly made breads made from flours, water, salt, and ferments; beer, cider, wine
4 Ultra processed (ULP) foods	
Formulated mostly or entirely from substances derived from foods or other organic sources. Typically, they contain little or no whole foods. They are durable, convenient, packaged, branded, accessible, highly or ultra-palatable. Typically not recognisable as versions of foods, although may imitate the appearance, shape, and sensory qualities of foods. Many ingredients are not available in retail outlets. Some ingredients are directly derived from foods, such as oils, fats, starches, sugars, and others are obtained by further processing of food constituents such as hydrogenated oils, hydrolysed proteins, high fructose corn syrup, maltodextrin or synthesised from other organic sources such as casein, lactose, whey and gluten. Numerically the majority of ingredients are preservatives and other additives such as stabilisers, emulsifiers, solvents, binders, bulkers, sweeteners, sensory enhancers, colours and flavours, and processing aids. Bulk may come from added air or water. Micronutrients may 'fortify' the products. Most are designed to be consumed by themselves or in combination as snacks, or to replace freshly prepared dishes and meals based on unprocessed or minimally processed foods. Processes include hydrogenation, hydrolysis, extruding, moulding, reshaping, pre-processing by frying, baking. Included also are products made solely of group 1 or group 3 foods which also contain additives i.e. plain yoghurt with added artificial sweeteners and breads with added emulsifiers	Chips (crisps) and many other types of sweet, fatty, or salty packaged snack products; ice-cream, chocolates, candy (confectionery); French fries (chips), burgers and hot dogs; poultry and fish nuggets or sticks (fingers); mass-produced packaged breads, buns, cookies (biscuits); sweetened breakfast cereals; pastries, cakes, cake mixes; energy bars; preserves (jams), margarines and spreads; packaged desserts; canned, bottled, dehydrated, packaged soups, powdered and packaged 'instant' soups,noodles, sauces and desserts; meat, chicken and yeast extracts; carbonated drinks, energy drinks; sugar-sweetened milk drinks including fruit yogurts; fruit and fruit nectar drinks; no-alcohol wine, beer; pre-prepared meat, fish, vegetable, cheese, pizza, pasta dishes; infant formulas, follow-on milks, other baby products; 'health' and 'slimming' products such as powdered or 'fortified' meal and dish substitutes; whisky, rum, gin, vodka

Table 2 An example of the AUSNUT food group classification [19,20]

Major food category: two-digit food code	Sub-major food category: three-digit food code	Minor food category: five-digit food code	Survey ID: eight-digit food code
12 Cereal and Cereal Products	122 Regular bread and bread rolls	12201 White bread and bread rolls	12201013 Bread roll from white flour

forms the basis of the survey ID (eight-digit) assigned to each food, beverage or ingredient (Table 2) [19,20]. The first two numbers refer to the major food group to which a food belongs, based on a key ingredient (e.g. cereals, fats and oils, fish, vegetables, fruits, meat and poultry). The three-digit sub-major food group falls within the two-digit major food group and includes plant families, different types of breakfast cereals or breads and meat species. The five-digit food code represents the minor food group by which foods are divided based on nutritional or manufacturing factors such as whether they contain saturated fat above or below a nominated value, are fortified, or are produced in a particular way (e.g. canned or dried). The AUSNUT 2007 Food File [25] and the AUSNUT 2011–13 Food Details File [26] provides a complete list of each food group classification system.

For the most part, the foods and beverages included in AUSNUT 2007 and AUSNUT 2011–13 are similar. However, because of changes in the food supply, there have been some modifications to the eight-digit food items across each release. For example, AUSNUT 2011–13 contains a number of new eight-digit food items (n = 76); for example, mixed seafood wild harvested; wild harvested fruit; wild caught dugong (marine mammal); avocado or guacamole dip [20]. Of these new eight-digit food items, a number (n = 31) were included to reflect the foods eaten by indigenous communities that were surveyed for the first time as part of the Australian national dietary survey [24]. In addition, two food groups described as soup prepared, ready to eat, and canned condensed soup unprepared, which were included in AUSNUT 2007 [19], were divided into four food groups (canned soup prepared from dry soup mix; canned condensed soup; soup commercially sterile prepared from condensed or sold ready to eat; soup not commercially sterile purchased ready to eat) and were included in the AUSNUT 2011–13 database [20].

Data coding and analysis

To classify all food and beverage items, two registered nutritionists independently applied the NOVA classification system [13] to each eight-digit food item representing individual food and beverage items contained within AUSNUT 2007 (n = 3874) [19] and AUSNUT 2011–13 (n = 5740) [20] (see Supporting information, Tables S1 and S2). Classification discrepancies on how individual food and beverage items were categorised (n = 10) between the two assessors were discussed and a processed food classification agreed upon (according to the NOVA system) [13] using four steps: (i) the foodstuffs were disaggregated into their ingredients; (ii) each ingredient was classified into one of the four processed food groups; (iii) the level of processing assessed; and (iv) the foodstuff classified as either MP, PCI, P or ULP. In some instances where the classification of a foodstuff was not clear (n = 3; pizza homemade from a commercial pizza base; bread from white flour homemade from bread mix; sausages), the research group (which consisted of dietitians and a registered nutritionist) applied the four steps described and a consensus was agreed by the group. Accordingly, these three food items were classified as processed (P).

Within the AUSNUT databases, items described as 'commercial' (e.g. chocolate chip muffin) were considered as 'mass manufactured' items (as described in NOVA) [13] and were categorised accordingly. Where items were described as either 'homemade' (e.g. crepe or pancake), not described as 'homemade' or 'commercially prepared' (e.g. coffee white from instant coffee powder, made up with cow's milk) or described as 'commercial or homemade' (e.g. sliced bread made from wholemeal, wheaten bread-making flour used to make homemade sandwiches), the foodstuffs were categorised using the four steps described above.

At the eight-digit food item level, the proportion of MP, PCI, P and ULP by AUSNUT food group and the overall proportion of the four processed food categories across AUSNUT 2007 and AUSNUT 2011–13 were calculated. Analysis was performed using EXCEL 2013 (Microsoft Corp., Redmond, WA, USA).

Results

The proportions of foods classified as MP, PCI, P and ULP at the eight-digit food item within AUSNUT 2007 (n = 3874) and AUSNUT 2011–13 (n = 5740) are shown in Fig. 1. The proportions of eight-digit food items classified as ULP were 44% and 36% from AUSNUT 2007 and 2011–13, respectively. Examples of these types of foods include sugar sweetened beverages, biscuits, margarines, processed meats, frozen and flavoured milk and milk substitute products, soups, extruded snack foods, jams and other sweet spreads, and chocolate and confectionery. There appeared to be differences in the proportion of foods classified as ULP in various eight-digit food items

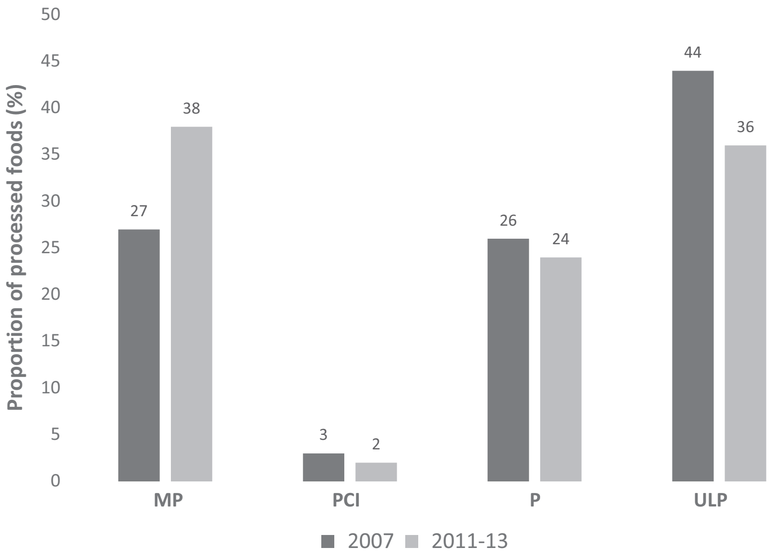

Figure 1 The proportions of foods classified as Minimally Processed (MP), Processed Culinary Ingredients (PCI) Processed (P) and Ultra Processed (ULP) at the eight-digit food code within AUSNUT 2007 (n = 3874) [19] and AUSNUT 2011-13 (n = 5740) [20].

between 2007 and 2011–13. Between AUSNUT 2007 and 2011–13, there appeared to be a difference in the proportion of foods classified as MP (i.e. fruit juices, herbs, fresh milk) in various eight-digit food items. The proportions of eight-digit food items classified as PCI (i.e. honey, butter) and P (i.e. ham, salted nuts, canned fish) remained approximately the same in each food composition database release.

Discussion

Application of the NOVA processed food classification system to the Australian food databases has provided unique insight into the contribution of processed foods in the Australian food supply, as well as information on the variation across the AUSNUT food group classification. Importantly, our results highlight that the overall proportion of ULP food items within the Australian food supply was more than one-third of all foodstuffs across both the AUSNUT 2007 and AUSNUT 2011–13 databases.

Although the proportion of foods classified as MP appeared to have increased overall by 11% from 2007 to 2011–2013, this is likely to have occurred as a result of inclusion of some new food groups consumed by indigenous communities, which were classified as MP (e.g. wild caught fish and seafood, wild harvested fruit). Increases in the number food and beverage items also contributed to the rise in MP included in 2011–13 (e.g. an additional 38 items within the coffee and coffee substitute beverage group, suchas coffee flat white or latte from ground coffee beans, double shot with regular fat cow's milk) and 83% of these foods were classified as MP.

When the overall proportions of ULP foods were compared, there appeared to be an 8% reduction in the proportion of food items classified as ULP between AUSNUT 2011–13 and AUSNUT 2007. This apparent proportional decrease is likely attributable to the increase in the total number of food and beverages included in the AUSNUT 2011–13 database (n = 5740) compared to AUSNUT 2007 (n = 3874) and this variation likely reflects the different purposes of each database. The 2007 database was designed to classify foods consumed by children aged 2–16 years [23], whereas the 2011–13 database was intended for nutrient estimates to be made from foodstuffs consumed by adults, children and indigenous groups during the 2011–13 AHS [24]. As such, it would be expected that there would be a greater number of food items in the 2011–13 database devised for adults and children's diets.

Compared to MP foods, many ULP foods are energy dense, as well as high in refined sugars, sodium, saturated fat and trans fat, and many have a high glycaemic load [12,16]. Epidemiological evidence has described the role of specific ULP foods such as sugar-sweetened beverages in the aetiology of obesity and type 2 diabetes in adults [2,27,28] and children [2,16], as well as a positive association between the consumption of ULP snack foods and cardiovascular risk in young children [17]. In addition, ULP foods such as potato chips, processed meats, refined grains and French fries have been shown to be strongly and positively associated with weight gain in adults in a large American prospective study [29]. Other ULP foods such as white bread, processed meats, margarine and soft drinks have been positively associated with abdominal adiposity in a large European prospective study of adults [30].

The present study provides an important processed food classification system in Australia that will enable researchers to readily evaluate the dietary intake of population groups with respect to food processing. For example, in a previous study, we applied the NOVA system to determine the contribution of the level of processing to daily sodium intake in a sample of Australian pre-school children and found that ULP foods accounted for 48% of total daily sodium intake compared to either P foods (35%) or MP foods (16%) [(31)]. These data provided important information on processed food dietary patterns, particularly the contribution of high sodium ULP foods in young Australian children's diets.

The NOVA system has previously been applied to assess consumption [(14,27,32)] and purchasing [(15,16,33)] of ULP foods. For example, in a large longitudinal Swedish study, the consumption of ULP increased by 142% over a 50-year period [(14)]. In Norway, ULP products accounted for 60% of food purchases compared to 17% of MP products during 2013 [(15)]. Furthermore, in Brazil, a cross-sectional study, showed that ULP foods represented 30% of total energy intake in individuals aged ≥10 years [(32)], whereas retrospective data have shown significant decreases in the energy contribution of MP foods subsequent to the 1980s and during the 2000s [(33)]. More recently, a cross-sectional study utilising the American 2009–2010 National Health and Nutrition Examination Survey (NHANES) revealed that ULP foods comprised approximately 58% of daily energy intake and contributed approximately 90% of all added sugars [(34)].

The Food and Agriculture Organization of the United Nations has included the NOVA system in their guidelines on documenting and classifying food processing from food surveys [(21)]. The NOVA system has also been incorporated into the latest Brazilian Dietary Guidelines, where MP foods are recommended and ULP foods are discouraged, aiming to prevent nutritional deficiencies and reduce the risk of obesity, cardiovascular disease and type 2 diabetes [(18)]. This integration of a processed food classification system into Brazil's national dietary guidelines is unique and recognises the complexity of the food system, as well as the recent changes in population dietary patterns, and also emphasises the importance of food processing within the food supply. Furthermore, based on the NOVA system, a recent World Health Organisation report has described the global shifts in sales of ULP food and drink products over the past decade, and explored the connection between the increase in purchasing of ULP foods and the obesity epidemic in Latin America [(35)].

Given the emerging relationship between the consumption of ULP foods and the risk of chronic disease, our processed food classification will be useful for enabling dietary assessment on the basis of the level of processing to further extend knowledge on the diet quality and dietary patterns amongst Australian adults and children. In addition, rather than defining and categorising food quality in terms of nutrient profiles, primary production and processing could be the foundation for nutrition education campaigns or alternative dietary guidelines. This system could be used to determine Australian household processed food purchases and to examine the availability of the different levels of processed foods across Australian grocery stores and food outlets, providing new opportunities to understand determinants of dietary behaviours [(36,37)].

There are some limitations of the present study to be noted. It is acknowledged that the 2007 and 2011–13 databases may not provide a true representation of the Australian food supply because it is possible that some food items available in Australia were not captured during the dietary surveys and therefore were not represented in the database. Although the NOVA classification system [(13)] provides some guidance, there were instances where the processed food group classification was not clear cut. For example, according to the NOVA system, pizza and mass-manufactured bread were classified as ULP foods. However, we classified a homemade pizza made using a commercially produced pizza base and homemade bread made from a commercial bread mix as P because both items were prepared in the home and had not undergone an intense, industrial level of processing. Because classifications were made on the basis of processing, there were some instances where an ULP classification did not correspond with Australian food based dietary guidelines. For example, margarine is classified as an ULP food and is therefore grouped with foods of the lowest nutritional quality. However, according to the Australian Dietary Guidelines [(38)] and the Australian Heart Foundation [(39)], the consumption of polyunsaturated and monounsaturated based margarines is recommended to reduce the risk of cardiovascular disease [(40)]. Additionally, some breads and pastas, which are recommended as good sources of grains [(38)], were also categorised as ULP. However, we consider these few specific discrepancies with respect to the classification of these foods of high nutritional quality as ULP is minor and unlikely to significantly affect the use and application of this system. If required, researchers could relatively easily classify all of these foods into a further fifth processed food product category and utilise a five-category classification to assess dietary quality of the population.

In conclusion, by applying the NOVA processed food classification system to Australian food databases, we were able to identify the proportion of ULP foods within the Australian food supply. This classification system provides a useful tool for describing dietary patterns, assisting researchers and informing public health policy in the development of dietary guidelines relating to recommended levels of processed food consumption.

Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.

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SO'H was responsible for the study conception, wrote the manuscript and performed the data analysis. CN was responsible for the accuracy of the data analysis and, together with CG, KL, KC and JW, provided significant consultation and critically reviewed the manuscript. Each author has seen and approved the content of the submitted manuscript.

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Supporting information

Additional Supporting Information may be found online in the supporting information tab for this article:
Table S1. NOVA-AUSNUT 2007 classification system.
Table S2. NOVA-AUSNUT 2011-2013 classification system.

